

**Drug funding decision-making
in hospital formulary committees in Germany**

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Abstract

BACKGROUND: Hospital formularies are usually the gatekeepers for pharmaceutical drugs. Typical majority members of hospital formularies are physicians, although most of the time the formulary is chaired by a pharmacist. As German hospitals are struggling with a difficult economic environment the question arises: what kind of decision-making criteria are applied when pharmaceutical drugs should be added to the formulary list? Information regarding this topic is scarce due to the sensitive topic of decision-making.

OBJECTIVES: Build a single decision-making framework which will be created to explain hospital drug funding decision-making and identify underlying mechanisms which explain processes and structures. The results can be used by hospitals to initiate knowledge sharing and provide a basis to analyse local formulary committee decision-making practice. Additionally, they can be used by the pharmaceutical industry to better adapt to the specific needs of the hospital decision-makers.

METHODS: In this study, a mixed-methods approach has been used to confirm and further detail a preliminary hospital formulary decision-making framework derived from literature. An online survey was used to get insights on the structure of German hospital formularies and the relative importance of different decision-criteria. Additional semi-structured expert interviews were used to get in-depth information on the underlying mechanisms which influence decision-making on drug funding.

RESULTS: Decisions for or against a pharmaceutical drug are influenced by a variety of perceived objective and specifically subjective criteria. Despite a consistency in a dominant, high impact role of pharmacists and lead physicians every hospital formulary member has different relative weighting of decision criteria. Drug funding decision-making in German hospital formularies is highly individual but usually starts with a quasi-rational preference influenced by a mixture of analytic and intuitive criteria. The decision to use more analytic or more intuitive criteria is influenced by a variety of factors. The two most important ones are uncertainty and power. The resulting individual preference is then challenged and adapted in a group decision-making process.

Publications

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Declaration

I declare that the work in this thesis was carried out in accordance with the regulations of the University of Gloucestershire and is original except where indicated by specific reference in the text. No part of the thesis has been submitted as part of any other academic award. The thesis has not been presented to any other education institution in the United Kingdom or overseas. Any views expressed in the thesis are those of the author and in no way represent those of the University.

Signed

Date:

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I dedicate this thesis to Sven Filip without whom I probably would have never started writing this. Sadly he left us unexpectedly. Rest in peace my friend!

Table of Contents

1	Introduction.....	12
1.1	Background to healthcare decision-making.....	12
1.1.1	Definition of local, regional and national decision-making	12
1.1.2	Hospital formulary committees	13
1.2	Objectives of this research.....	15
1.3	Structure of this thesis.....	17
2	Literature Review.....	19
2.1	Healthcare and hospital decision-making.....	20
2.1.1	Search strategy.....	20
2.1.2	Number of studies, geographical spread and methodologies	26
2.1.3	Decision-making criteria with perceived objectivity.....	30
2.1.4	Decision-making criteria with perceived subjectivity	32
2.1.5	Differences between the decision levels.....	38
2.1.6	Decision-making supportive methods	41
2.1.7	Conclusions for healthcare decision-making.....	44
2.1.8	Hospital formulary committees – the regional level.....	47
2.2	Construction of a preliminary hospital formulary decision-making framework	61
2.3	Group decision-making models and theories.....	65
2.3.1	Search strategy.....	65
2.3.2	Objective versus subjective decision-making.....	69
2.3.3	Group decision-making.....	72
2.4	Refinement of the hospital formulary decision-making framework.....	79
2.5	Gaps identified in existing literature.....	86
3	Research Strategy.....	88
3.1	Introduction and problem definition.....	88
3.2	Short overview on the overall research design	88
3.3	Research philosophy	90
3.4	Mixed methods.....	95
3.5	Triangulation.....	97
4	Research methods and methodology.....	101
4.1	Literature review (step 1).....	101
4.2	Hospital online survey (step 2)	102
4.3	Survey sampling.....	104
4.4	Expert interviews (step 3).....	106
4.5	Interviewee sampling.....	109
4.6	Market research interviews (step 4).....	111
4.7	Transcript strategy	114
4.8	Validity and reliability	115
4.8.1	Validity and reliability of the (quantitative) online survey.....	116
4.8.2	Trustworthiness, authenticity and credibility for the (qualitative) interviews.....	117
4.9	Time horizon.....	118
4.10	Data analysis	118
4.10.1	Quantitative data analysis (step 5).....	118
4.10.2	Qualitative data analysis (step 6 and 7).....	119

4.11	Discussion and conclusions (step 8)	121
4.12	Ethics	121
4.13	Limitations	124
4.14	Summary	125
5	Hospital survey data analysis	127
5.1	Introduction	127
5.2	Participant structure	128
5.3	Knowledge sharing	129
5.4	Structure of German hospital formularies	130
5.5	Documentation package	132
5.6	Decision-makers and other decision-making aspects	134
5.7	Decision-making criteria for drug funding cases	137
5.8	Summary	144
6	Expert interview data analysis	145
6.1	Introduction	145
6.2	Physicians and pharmacists are the decision-makers, but practical experience has impact on decision-making independent of functional roles	152
6.2.1	Key decision-makers	153
6.2.2	Value of expertise	156
6.2.3	Role of the function	159
6.3	The personality of the individual committee member has strong impact on the group decision-making behaviour	164
6.3.1	Role of the individual	164
6.3.2	Impact of communication	165
6.4	External factors have a significant impact on the formulary committee decision-making	168
6.4.1	Pre-meeting decision-making	169
6.4.2	External impact by the industry	171
6.4.3	Importance of cross-sectional treatment	173
6.4.4	Reputation of the hospital	174
6.5	Subjective criteria impact decision-making but the open use is limited due to perceived difficulties in justification	175
6.5.1	Justification	176
6.5.2	Role of subjective criteria	177
6.5.3	Information sharing	179
6.6	Despite the strong importance of budget impact, economic criteria rarely lead to rejection	181
6.6.1	Budget impact	182
6.6.2	Real costs	183
6.6.3	Importance of economic criteria	184
6.6.4	Type of drugs	186
6.7	Summary	188
7	Company market research data analysis	190
7.1	Introduction	190
7.2	Despite an accepted value of practical experience, the pharmacists have the highest impact on decision-making in the formulary committee	193
7.2.1	Key decision-makers	193

7.2.2	Value of expertise	195
7.3	Pre-meeting alignment leads to decision-making outside of the formulary committee and reduces the committee to a legitimisation role.....	196
7.3.1	Pre-meeting decision-making	196
7.4	Costs are the dominant criterion for specific pharmaceutical drug groups	198
7.4.1	Importance of economic criteria	198
7.5	Summary	199
8	Discussion	201
8.1	Introduction.....	201
8.2	The balance between intuitive and analytic decision-making	203
8.2.1	Economic data and costs.....	204
8.2.2	Type of pharmaceutical drug	206
8.2.3	Emotional criteria and clinical experience.....	207
8.2.4	Administration/ Practical criteria.....	208
8.2.5	Decision-making guidelines and documentation	208
8.2.6	External impact	209
8.3	Decision-makers in the hospital formulary committee.....	212
8.4	Group dynamics and impact on decision-making.....	213
8.4.1	Power relationships.....	213
8.4.2	Centrality and group size	215
8.4.3	Role of the individual and the personality.....	216
8.5	Conclusion	221
8.6	The final hospital formulary decision-making framework	223
9	Implications for stakeholders	225
9.1	Transparency.....	225
9.2	Acceptance of subjective criteria	226
9.3	Economic implications.....	226
9.4	More knowledge sharing and training	227
9.5	Governance and group involvement	228
10	Reflexive view	230
11	Concluding remarks and future research.....	231
12	Personal Reflection	232
13	References	233
14	Appendix.....	244

List of figures

FIGURE 1: KEY INFLUENCING ELEMENTS FOR DRUG FUNDING DECISIONS. (ADAPTED FROM ATIENZA ET AL., 2008).	13
FIGURE 2: STRUCTURE OF THE THESIS.	17
FIGURE 3: THE LITERATURE REVIEW PROCESS.	20
FIGURE 4: FLOWCHART OF THE SYSTEMATIC LITERATURE REVIEW.	21
FIGURE 5: A CONSTANT INTEREST IN HEALTHCARE DECISION-MAKING DURING THE LAST 13 YEARS.....	26
FIGURE 6: COUNTRIES IN FOCUS OF HEALTHCARE DECISION-MAKING RESEARCH.	27
FIGURE 7: TOP THREE RESEARCH METHODS: LITERATURE REVIEW, SURVEY OR INTERVIEW.....	27
FIGURE 8: BALANCED USE OF QUANTITATIVE AND QUALITATIVE RESEARCH METHODS.....	28
FIGURE 9: THREE TOPICS ARE OF GREATER INTEREST COMPARED TO THE OTHER ONES.	30
FIGURE 10: AD HOC PRIORITY SETTING VERSUS RATIONAL PRIORITY SETTING (BALTUSSEN & NIESSEN, 2006).	33
FIGURE 11: EXTENDED HEALTHCARE DECISION-MAKING FRAMEWORK FOR DRUG FUNDING.	46
FIGURE 12: RELATIVE IMPORTANCE OF PHARMACOECONOMIC DATA FOR DIFFERENT THERAPEUTIC DRUG CLASSES.....	53
FIGURE 13: PRELIMINARY HOSPITAL FORMULARY DECISION-MAKING FRAMEWORK.....	62
FIGURE 14: THE SECOND SYSTEMATIC LITERATURE REVIEW.	65
FIGURE 15: LITERATURE REVIEW ON GROUP DECISION-MAKING AND OBJECTIVE VERSUS SUBJECTIVE DECISION-MAKING.....	66
FIGURE 16: HOSPITAL DRUG FUNDING DECISION-MAKING FRAMEWORK.....	82
FIGURE 17: OVERVIEW OF THE CONVERGENT PARALLEL MIXED-METHODS DESIGN.	90
FIGURE 18: DIFFERENT PEOPLE HAVE DIFFERENT PERCEPTIONS OF THE SAME REALITY	92
FIGURE 19: CONVERGENT PARALLEL DATABASE VARIANT MIXED-METHODS DESIGN.	101
FIGURE 20: HOSPITAL SURVEY DATA ANALYSIS.	127
FIGURE 21: PARTICIPANT STRUCTURE.	128
FIGURE 22: GUIDELINES AND DECISION-MAKING CRITERIA.....	129
FIGURE 23: DECISION CRITERIA MENTIONED IN THE GUIDELINES.	130
FIGURE 24: HEAD OF THE FORMULARY.	131
FIGURE 25: THE APPLIED DECISION-MAKING RULE.	132
FIGURE 26: WHO COMPILES THE DOCUMENTATION PACKAGE?	133
FIGURE 27: DECISION CRITERIA IN THE DOCUMENTATION PACKAGE.....	134
FIGURE 28: DECISION-MAKERS WITH HIGHER INFLUENCE.	135
FIGURE 29: TRANSPARENCY REGARDING COMMITTEE MEMBERS AND PHARMACEUTICAL MANUFACTURERS' COOPERATION.	135
FIGURE 30: IS THE FINANCIAL SITUATION A TOPIC IN THE HOSPITAL FORMULARY DISCUSSIONS?.....	136
FIGURE 31: IMPACT OF THE THERAPEUTIC CLASS OF A DRUG ON THE APPLIED DECISION-MAKING CRITERIA.	137
FIGURE 32: DECISION CRITERIA FOR MONOCLONAL ANTIBODIES/ IMMUNOMODULATORS (HOSPITALS WITH < > 800 BEDS)	139
FIGURE 33: RANKING OF DECISION CRITERIA FOR MEDICAL DEVICES (HOSPITALS WITH < > 800 BEDS)	141
FIGURE 34: RANKING OF DECISION CRITERIA FOR ORPHAN DRUGS (HOSPITALS WITH < > 800 BEDS)	143
FIGURE 35: EXPERT INTERVIEW DATA ANALYSIS.	145
FIGURE 36: PROCESS OF BUILDING THEMATIC NETWORKS.	151
FIGURE 37: THEMATIC NETWORK DESCRIBING THE DOMINANCE OF PHYSICIANS AND PHARMACISTS.	152
FIGURE 38: THEMATIC NETWORK DESCRIBING THE IMPACT OF PERSONALITY AND COMMUNICATION.....	164
FIGURE 39: THEMATIC NETWORK DESCRIBING HOW EXTERNAL FACTORS IMPACT DECISION-MAKING.	168
FIGURE 40: THEMATIC NETWORK: THE ROLE OF AND ISSUES WITH SUBJECTIVE DECISION-MAKING CRITERIA.....	175
FIGURE 41: THEMATIC NETWORK DESCRIBING THE IMPORTANCE OF SEVERAL ECONOMIC CRITERIA.	181
FIGURE 42: COMPANY MARKET RESEARCH DATA ANALYSIS.	190
FIGURE 43: THEMATIC NETWORK DESCRIBING THE HIGH IMPACT POSITION OF PHARMACISTS.	193
FIGURE 44: THEMATIC NETWORK DESCRIBING THE INFLUENCE OF PRE-MEETING DISCUSSIONS.	196
FIGURE 45: THEMATIC NETWORK ABOUT THE DOMINANT ROLE OF COSTS.....	198
FIGURE 46: HOSPITAL FORMULARY COMMITTEE DECISION-MAKING FRAMEWORK.	201
FIGURE 47: COMPARISON AND DISCUSSION OF THE COMBINED RESULTS.	202
FIGURE 48: DUAL PROCESSING SYSTEM WITH IMPACT OF UNCERTAINTY AND POWER.	222
FIGURE 49: FINAL HOSPITAL FORMULARY DECISION-MAKING FRAMEWORK.	224

List of tables

TABLE 1: DETAILS OF THE LITERATURE REVIEW DATABASE SEARCH (DB = DATABASE, SUB DBs = SUB DATABASE).	23
TABLE 2: INCLUSION AND EXCLUSION CRITERIA USED IN THE LITERATURE REVIEW.	24
TABLE 3: IDENTIFIED DECISION-MAKING CRITERIA IN HOSPITAL FORMULARY COMMITTEES.....	49
TABLE 4: INCLUSION AND EXCLUSION CRITERIA USED IN THE SECOND LITERATURE REVIEW.....	67
TABLE 5: POTENTIAL STRUCTURES AND PROCESSES IDENTIFIED IN THE LITERATURE REVIEW.....	86
TABLE 6: INCLUSION AND EXCLUSION CRITERIA FOR THE SURVEY SAMPLING.....	104
TABLE 7: HOSPITAL SIZE AND OWNERSHIP STRUCTURE.	104
TABLE 8: EXPERT INTERVIEW SAMPLE.	111
TABLE 9: PARTICIPANT STRUCTURE (MARKET RESEARCH STUDIO INTERVIEWS).....	112
TABLE 10: CODE NAMES FOR COMPANY MARKET RESEARCH INTERVIEWS.	113
TABLE 11: INCLUSION CRITERIA FOR MARKET RESEARCH INTERVIEWS.	114
TABLE 12: SIZE OF THE HOSPITAL FORMULARY COMMITTEE.	130
TABLE 13: THEMES IDENTIFIED FOR THE CODE "SUBJECTIVE INFORMATION".	148
TABLE 14: BASIC THEMES IDENTIFIED FOR THE ORGANISING THEME "VALUE OF EXPERTISE".	149
TABLE 15: THEMATIC NETWORK WITH ALL ORGANISING AND BASIC THEMES.	150
TABLE 16: FIVE THEMATIC NETWORKS WITH ALL 16 ORGANISING THEMES.....	151
TABLE 17: TWELVE DIFFERENT BASIC THEMES.	191
TABLE 18: GLOBAL THEMES TO FORMULATE A PROPOSITION FOR THE ORGANISING AND BASIC THEMES.	192
TABLE 19: FINDINGS FOR THE EMPIRICAL, ACTUAL AND REAL DOMAIN.	218

List of abbreviations

AMNOG	Arzneimittelneuordnungsgesetz (German law on drug pricing)
CEA	Cost Effectiveness Analysis
DCE	Discrete Choice Experiment
DKA	Deutsches Krankenhaus Adressbuch (German hospital list)
DRG	Diagnosis Related Groups
FLIP	Formulary Leveraged Improved Prescribing
G-BA	Gemeinsamer Bundesausschuss (HTA authority in Germany)
HMO	Health Maintenance Organisation
HTA	Health Technology Assessment
MCDA	Multi Criteria Decision Analysis
MCO	Managed Care Organisation
NHS	National Health Service
NICE	National Institute for Clinical Effectiveness
PBAC	Pharmaceutical Benefits Advisory Board
SOJA	Systems of Objectified Judgement Analysis

1 Introduction

1.1 Background to healthcare decision-making

The complexity in healthcare decision-making comes from many external and internal factors which influence the final decision. These factors which have impact on these decisions are a mixture of perceived objective and subjective criteria (Atienza, Merino & Varela, 2008). Objective criteria in the context of this thesis mean criteria which can be measured, such as results of clinical trials or costs for a pharmaceutical drug. Subjective criteria in the context of this thesis mean criteria which cannot be measured, such as personal experience, expert's advice, public pressure or political interests.

They can include the personal experience of decision-makers as well as influence from groups potentially involved in the decision-making process, for instance patient groups, healthcare experts or the pharmaceutical industry (Armstrong et al., 2008; Wirtz et al., 2005). Public pressure on decisions can derive out of patient group activities or comparisons between different country healthcare systems (Gallego et al., 2008; Kapiriri, Norheim & Martin, 2007). Besides perceived objective criteria on drug funding decisions, such as clinical evidence or economic evaluation, also perceived subjective criteria such as personal experience of hospital physicians or pharmacists might be important for the decision-making. All in all this represents the complexity which can be found in drug funding decisions and which is a challenge for decision-makers.

1.1.1 Definition of local, regional and national decision-making

One important differentiation of healthcare decision-making is the level at which healthcare decisions are being taken. In the literature, healthcare decisions are distinguished by three different levels: national, regional or local (Drummond, 2004; van Velden, Severens & Novak, 2005). Regional and local decision-making are sometimes defined differently and therefore the differentiation is not consistent for all studies. Some researchers define the hospital as the local level (Peacock, Mitton, Bate, McCoy, & Donaldson, 2009) and some researchers look into more details and define single people in the hospital, such as physicians, as the local level (Kapiriri, Norheim & Martin, 2009).

Hence, for this thesis the following definitions will be used: Decision-makers at national level include Health Technology Assessment (HTA) authorities, reimbursement agencies or other mostly governmental driven agencies responsible for pharmaceutical drug funding decisions. Decision-makers at regional level include pharmaceutical therapeutic committees, formulary committees which either work on a country's regional level (in case of regional budget responsibility for example) or on a hospital level. Local decision-makers include physicians, pharmacists, nurses who take healthcare decision on a local level in their offices, pharmacies or in hospitals for specific patients. Figure 1 illustrates the different levels of healthcare decision-making.

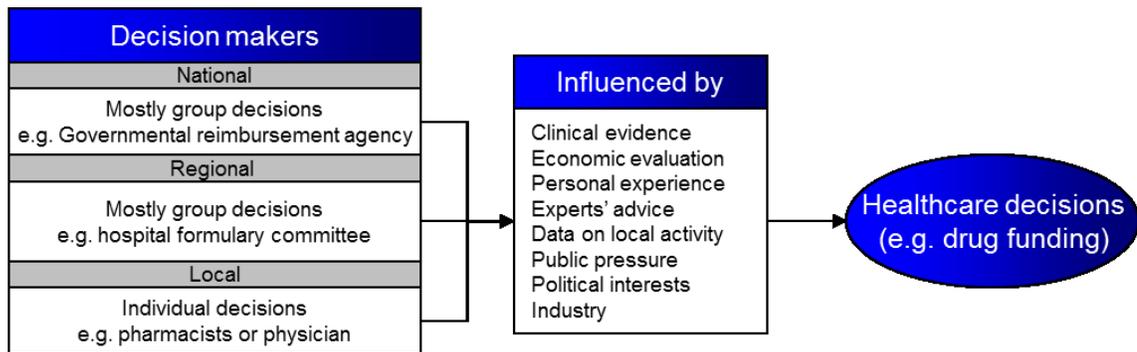


Figure 1: Key influencing elements for drug funding decisions. (Adapted from Atienza et al., 2008).

1.1.2 Hospital formulary committees

The hospital formulary committee is a group of experts who meet regularly to decide on different questions such as the listing of pharmaceutical drugs onto the formulary list. Experts here mean hospital employees with a medical, economic or other special knowledge about the formulary's topics of interest, such as the inclusion of pharmaceutical drugs. Even if reasonable amounts of information exist for decision-making of pharmaceutical drug listing on national or regional health insurance level, the information regarding the specific regional hospital level is scarce. This might be the case owing to the sensitive topic and less pressure for transparency on the hospital level. However, some research on hospital formularies and hospital formulary decision-

making exist for countries like France, Canada, the Netherlands, UK or Germany (Fijn, Brouwers, Knaap & De Jong-Van den Berg, 1999; Gallini, Juillard-Condat, Saux & Taboulet, 2011; Jenkins & Barber, 2004; Martin, Hollenberg, MacRae, Madden & Singer, 2003; Thürmann, Harder & Steioff, 1997). Despite the published research, the decision-making process for pharmaceutical drug listing of formulary committees is “far from clear” (Dean et al., 2013, p.465). Studies about this topic are quite homogenous in terms of hospital formulary structure, activities or members, but there is heterogeneity in terms of the decision-making process and applied decision-making criteria. The majority of the studies agreed in one single, important point: the decision-making process for listing a pharmaceutical drug in hospital formularies is not transparent (Dean et al., 2013; Fijn et al., 1999; Gallego et al., 2009).

The composition of members of a hospital formulary can vary significantly. Basic members of a hospital formulary and mostly similar across all countries are pharmacists and physicians. From formulary to formulary the involvement of nurses, financial administrators, pharmacologists, patients and hospital administration is different. Whereas nurses, pharmacologists and hospital administration are part of some hospital formularies it is very seldom that financial administrators or patients are involved (Plet et al., 2013; Späth, Charavel, Morelle & Carrere, 2003). Typically physicians are in the majority due to representation of all medical departments and the key person in the hospital formulary committee is usually the hospital pharmacist who is often chairing the committee (Fijn et al., 1999). Sometimes additional pharmacists are members of the formulary committee.

Independent of the respective country, hospital formulary committees have between three to 14 committee members not including possible subgroups with additional members (Fijn et al., 1999). For Germany a higher number was reported with a range from four to 40 members and a median of twelve (Thürmann et al., 1997). Fijn et al. (1999) showed in their study that approximately one third of the committees had also nurses as members. However, this is not true for all countries and was also not confirmed for Germany (Thürmann et al., 1997). The composition is not necessarily the

same in every hospital or every country. For example, the French Clinical Pharmacy Association does suggest including also members of the hospital management (besides physicians, pharmacists and nurses) (Späth et al., 2003). The only identified study for Germany by Thürmann et al. (1997) did not consider other stakeholders and concentrated only on the clinical members and the hospital pharmacist.

1.2 Objectives of this research

Hospital formulary decision-makers do not only use objective but also subjective criteria to come to their decisions on drug funding (Barasa et al., 2014; Eddama & Coast, 2008; Koopmanschap et al., 2010; Niezen et al., 2009). Understanding about those applied decision criteria is limited. Especially the understanding of the most important decision criteria for decision-makers and the relative importance of each of the criteria varies (Barasa et al., 2014; Eddama & Coast, 2008; Koopmanschap et al., 2010; Niezen et al., 2009). Additionally, current research revealed gaps in the understanding of the relative importance of the respective stakeholder groups to the final decision-making. Some of the hospital formulary committee members, such as pharmacists or physicians, apparently have important roles and a certain (high) degree of influence on decision-making (Alsultan, 2011; Fijn et al., 1999). Details of the relative importance and the degree of influence remain vague. The existing literature only provides an indistinct picture of the motives or objectives of the different stakeholder groups, even though this seems to be essential for a better understanding of hospital formulary decision-making. Hence, it is not surprising that current research does not show or define any framework describing this process and the relationship between different stakeholders and decision criteria.

Outcomes of the literature review should be used to construct a model framework encompassing the different decision criteria and the different stakeholders in order to provide a theoretical explanation of this relationship as well as the decision-making process. This research aims to assess whether the conceptual framework holds in practice and identifies what changes are required to represent hospital formulary committee decision-making in the specific German context. The descriptive, conceptual framework of the hospital formulary committee decision-making process and the

identification of underlying mechanism which explain processes and structures will help hospitals to better understand their own process, compare it to processes of other hospitals and to identify opportunities for improvement. Additionally, the pharmaceutical industry can better adapt to the specific needs of the hospital decision-makers.

Hence, this research concentrates on the following questions:

- RQ-1. What are the criteria in funding decisions for pharmaceutical drugs in hospital formulary committees?
- RQ-2. What is the relative importance of each of those criteria in funding decisions for pharmaceutical drugs in hospital formulary committees?
- RQ-3. What is the level of influence of each stakeholder group on drug funding decisions of hospital formulary committees?
- RQ-4. What are the motives and objectives of decision-makers when applying quantitative and qualitative criteria for drug funding decisions in hospitals?

Research questions “RQ-1” to “RQ-4” are the guiding questions in order to fulfil the following research objectives:

- RO-1. Identify and assess the criteria used in funding decisions for pharmaceutical drugs in hospital formulary committees.
- RO-2. Identify and assess the relative importance of the different criteria used in funding decisions for pharmaceutical drugs in hospital formulary committees.
- RO-3. Evaluate the influence of each stakeholder group on drug funding decisions of hospital formulary committees.
- RO-4. Identify and evaluate the motives and objectives of decision-makers when making funding decisions for pharmaceutical drugs in hospital formulary committees.
- RO-5. Construct a hospital formulary committee decision-making framework for German hospitals as a basis for future research.
- RO-6. Identify and assess the potential implications for stakeholders.

1.3 Structure of this thesis

The structure of this thesis is shown in Figure 2.

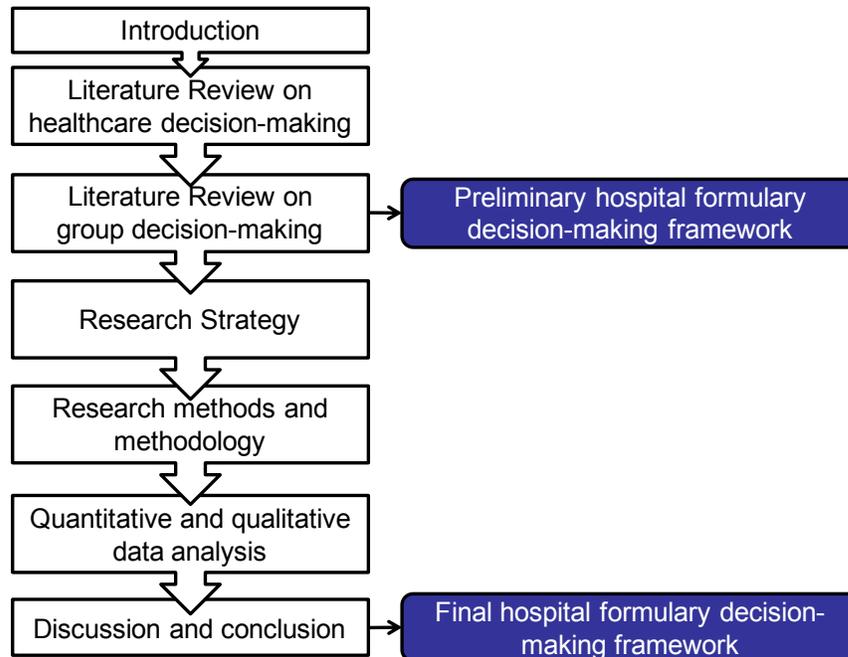


Figure 2: Structure of the thesis.

The first part (chapter 1) is an introduction to the topic of this thesis. Background of healthcare decision-making, research questions and research objectives are introduced.

In the next part (sections 2.1 and 2.2) a literature review on healthcare decision-making and hospital formulary decision-making is conducted. This part discusses the issues around the use of perceived objective and subjective decision-making criteria generally for healthcare decision-making and specifically for hospital formularies. It concludes with the construction of a preliminary hospital formulary decision-making framework.

The following part (sections 2.3 and 2.4) is a second literature review on group decision-making in order to understand the wider question of decision-making. It discusses theories and models on shared preferences, shared knowledge and centrality. Those

concepts are considered for the adaptation of the preliminary hospital formulary decision-making framework.

The next part (chapter 3) refers to the research strategy. The underlying research philosophy and a rationale for the use of a mixed-methods approach are provided. Following this, the next part (chapter 4) describes the research methods and methodologies. This chapter refers to sampling for the survey and the interviews as well as to validity and reliability.

The next part (sections 4.10 to 4.14) provides a description of the data analysis, transcription strategy and ethics. In chapter 5 the results of the survey data analysis are given. Accordingly chapter 6 provides the results of the expert interview data analysis and chapter 7 summarises the results of the company market research interview data analysis.

Chapter 8 merges the outcomes of the literature review, the quantitative and the qualitative analyses and discusses similarities and differences. It refers to the balance between intuitive and analytic decision-making, decision-makers in the hospital formulary committee and the group dynamics and impact on decision-making. This chapter concludes with the construction of the final hospital formulary decision-making framework.

Chapter 9 discusses implications for stakeholders which can be derived from the propositions of the discussion part and the limitations of this research. The thesis closes with a section on limitations, the conclusions and thoughts on potential future research.

2 Literature Review

In order to locate specific healthcare decision-making in hospital formulary committees, the literature review concentrated on healthcare decision-making, particular hospital formulary decision-making and concludes in a preliminary conceptual framework.

The strengths of a systematic literature review are “the narrow focus of the question, the comprehensive search for evidence, [and] the criterion-based selection of relevant evidence” (Collins & Fauser, 2005, p.103). Those strengths are useful in order to understand the very specific question of hospital formulary decision-making but less useful for the wider question of understanding relevant decision-making theories and models. Thus, a second systematic literature review was required to improve the understanding on group decision-making and related theories and models. The topics which were seen as relevant based on the results of the first systematic review on healthcare and hospital formulary decision-making were:

1. **Objective versus subjective decision-making:** Healthcare decisions are based on different criteria which can be perceived as objective, such as data from clinical trials, the price of a pharmaceutical drug, etc. and those criteria that can be perceived as subjective, such as the clinical experience of a physician.
2. **Group decision-making:** Hospital formularies are always a group of experts, who decide on the funding of a pharmaceutical drug together.

The second systematic review should help to identify theories or models which could be used to make the preliminary framework more precise and to broaden the focus of the literature review.

This is the rationale behind the decision to separate the literature review into two constitutive parts: one part which covers the specific topic of healthcare and hospital formulary decision-making and one part which covers a wider understanding of models

and theories about perceived objective and subjective decision-making and group decision-making (Figure 3).

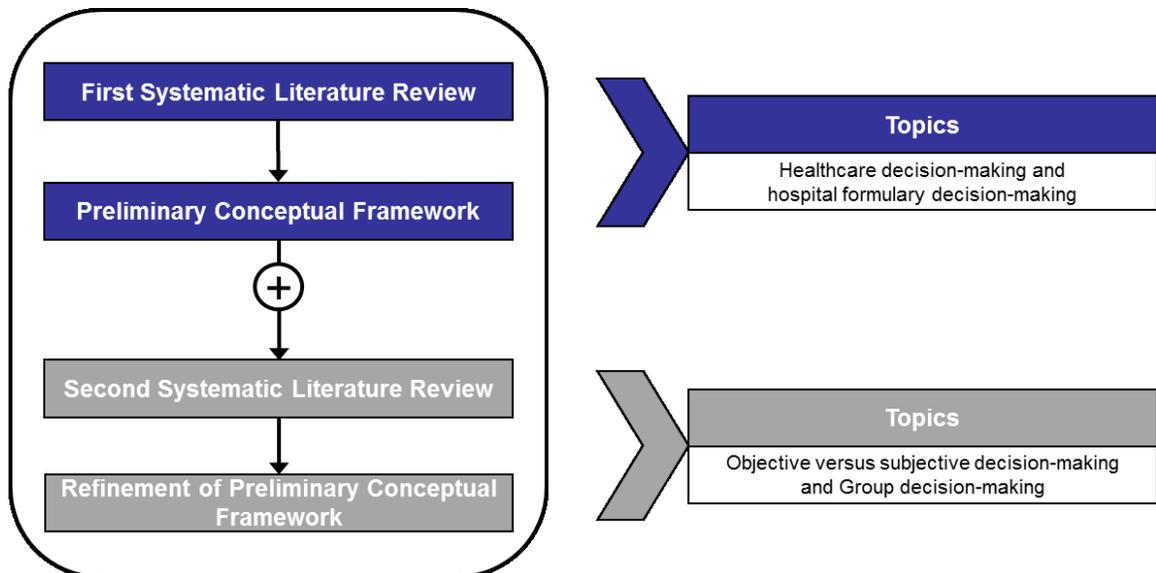


Figure 3: The literature review process.

2.1 Healthcare and hospital decision-making

In this first part of the literature review, research knowledge about hospital formulary structures, applied processes and applied decision-making criteria are analysed and critically evaluated. A specific focus was on the use of perceived objective and perceived subjective criteria in drug funding decision-making and more specifically drug funding decision-making in hospitals. In order to have a comprehensive picture of criteria used in drug funding decisions this review includes quantitative and qualitative research.

2.1.1 Search strategy

The first step in this literature review included a search via *EBSCO* with general search terms (described later) on the following databases: *Business Source Corporate Plus*, *Biomedical Reference Collection Corporate*, *Medline*, *Health Technology Assessments* and a searching via *Science Direct*. From the resulting list of 6,219 papers all abstracts were screened for relevant information on the research questions RQ-1 to RQ-4. The

remaining 612 articles were fully read and assessed in regards to inclusion and exclusion criteria described below. The reference lists of these papers were then used to identify further publications pertinent to the review's objectives which had not been identified through the first procedure. Again, their abstracts were screened, doubles eliminated, resulting in a total of 44 publications for this part of the literature review. Figure 4 is showing this as an overview.

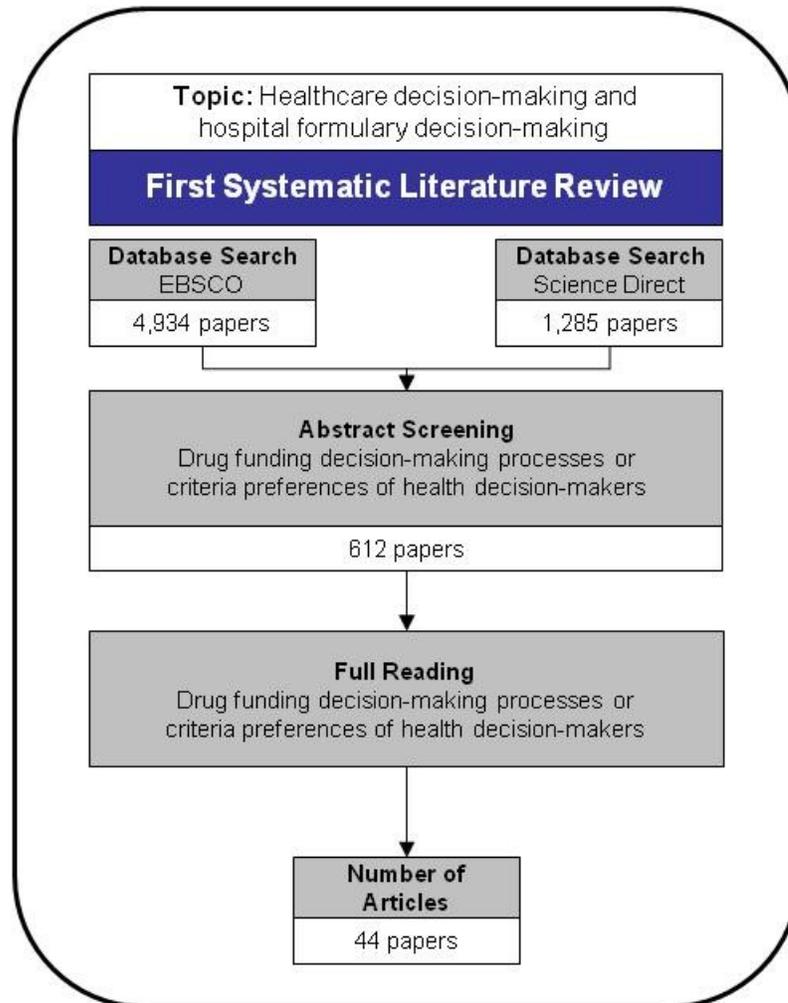


Figure 4: Flowchart of the systematic literature review.

The whole searching process is described in more detail in the following sections.

EBSCO and Science Direct

Within *EBSCO* databases of interest were identified as *Business Source Corporate Plus*, because of its comprehensive coverage of management journals, *Biomedical Reference Collection Corporate* and *Medline*, as both databases are a comprehensive source for medical and pharmaceutical journals. Finally the *Health Technology Assessments* database was included, as it covers health economic related papers.

In a first step the search terms used in *EBSCO* and *Science Direct* on all abstracts were different combinations of “healthcare” and “decision*” and “making*” and the search was restricted to peer-reviewed academic journals in order to utilise a high quality level of literature.

Different additional search terms were discussed with a health economist and those were applied in additional search rounds. The full list of search terms and restrictions regarding the type of literature as well as the single results for each search attempt are summarized in Table 1.

Date	DB	Sub DBs	Search Term	Search Term used on	Restrictions	# results
31.12.2013	ScienceDirect	n/a	hospital* AND formular* AND decision* AND making*	Abstract, Title, Keywords	only journals	24
31.12.2013	ScienceDirect	n/a	krankenhaus*	Abstract, Title, Keywords	only journals	435
31.12.2013	ScienceDirect	n/a	positivliste*	Abstract, Title, Keywords	only journals	30
31.12.2013	ScienceDirect	n/a	arzneimittelkommission*	Abstract, Title, Keywords	only journals	7
31.12.2013	ScienceDirect	n/a	funding AND hospital* AND formular*	Abstract, Title, Keywords	only journals	1
31.12.2013	ScienceDirect	n/a	healthcare AND decision* AND making*	Abstract, Title, Keywords	only journals	651
31.12.2013	ScienceDirect	n/a	Pharmac* AND Therapeutic* AND Committee*	Abstract, Title, Keywords	only journals	137
31.12.2013	Ebsco	Medline, Business Source Corporate Plus, Biomed, Health Technology Assessments	hospital* AND formular* AND decision* AND making*	AB Abstract	all publications	73
31.12.2013	Ebsco	Medline, Business Source Corporate Plus, Biomed, Health Technology Assessments	krankenhaus*	AB Abstract	all publications	433
31.12.2013	Ebsco	Medline, Business Source Corporate Plus, Biomed, Health Technology Assessments	positivliste*	AB Abstract	all publications	0
31.12.2013	Ebsco	Medline, Business Source Corporate Plus, Biomed, Health Technology Assessments	arzneimittelkommission*	AB Abstract	all publications	9
31.12.2013	Ebsco	Medline, Business Source Corporate Plus, Biomed, Health Technology Assessments	funding AND hospital* AND formular*	AB Abstract	all publications	9
31.12.2013	Ebsco	Medline, Business Source Corporate Plus, Biomed, Health Technology Assessments	healthcare AND decision* AND making*	AB Abstract	academic journals	3617
31.12.2013	Ebsco	Medline, Business Source Corporate Plus, Biomed, Health Technology Assessments	Pharmac* AND Therapeutic* AND Committee*	AB Abstract	all publications	793

Table 1: Details of the literature review database search (DB = database, Sub DBs = Sub database).

Inclusion and exclusion criteria

Table 2 shows the inclusion and exclusion criteria, which are explained below.

Topic	Inclusion criteria	Exclusion criteria
Relevant stakeholder groups	groups with direct influence on drug reimbursement or pricing decisions on different decision levels (payers, politicians, HTAs, pharmacists, physicians) and indirect influence, such as pharmaceutical companies or patient organisations.	none
Study topic	research on decision making in health care systems, specifically concentrating on rational or non-rational criteria used by healthcare decision makers	research on construction of new economic models to support decision making or the efficacy of existing economic models
Timeframe	all studies since 1980	studies before 1980
Research type	qualitative and quantitative research in scholarly peer reviewed journals, clearly described study methodology, literature reviews	qualitative and quantitative research in books, grey literature, unclear study methodology, opinion papers
Language scope	English or German	all other languages
Geographical scope	all countries	none

Table 2: Inclusion and exclusion criteria used in the literature review.

Relevant stakeholder groups

One objective of the literature review is to find out the research status for key criteria used by drug funding decision-makers who are directly responsible for drug funding or pricing decisions, such as members of a hospital formulary. For this research, groups with indirect influence (e.g. the pharmaceutical industry or patient groups) were classified as a possible decision criterion. Their activities, such as lobbying activities by patient groups, influence decision-makers who can directly influence drug funding decisions. Hence, literature regarding groups with direct and indirect influence on the decision-making process was considered.

Study topic

Another aim of this literature review is to assess the research which deals with perceived objective and subjective decision criteria beyond the cost-only perspective. Therefore research done on economic models or the effectiveness of existing economic models is not the focus of this review or the thesis and consequently one of the exclusion criteria.

Excluded from the final list were papers with research work that concentrated only on the assessment or optimization of economic methods like cost-benefit-analysis or cost-effectiveness analysis. Even though the results of these analyses might have an impact on drug funding decisions all of these studies did not explain the interaction with other decision criteria nor the relationships between decision-makers.

Time Frame

Originally the time frame for this literature review was limited to studies published later than the year 2000. The rationale behind this decision was the assumption that there was so much development in the last 14 years in the practical field that it does not make sense to include older studies. Finally the researcher decided to broaden the time frame in order to include also studies between the years 1980 and 2000, because of the scarcity of research done specifically with a focus on hospital formularies. Even with the broader scope, the number of research studies with this special focus was low.

Research type

In order to look at the most current research with a high quality standard it was decided to only look at research published in academic journals. For this reason grey literature was excluded. Books were excluded in order to have a very recent view on the discussions around the topic of criteria used in drug funding decisions.

Language scope

Due to the language limitations of the researcher the language scope was limited to research done in English or German.

Geographical scope

There was no limitation regarding the geographical scope of research, because the aim of the literature review was to get the broadest picture possible for healthcare decision-making and hospital formulary decision-making. However, the geographical scope might be “naturally” limited by the language scope. Countries would be excluded due to this limitation, when English or German is not the standard language for research.

Referenced research papers

To complete the picture of relevant research work all abstracts of referenced research papers of the resulting list of papers were also screened for further indication whether the respective paper investigates drug funding decision-making processes or criteria preferences of health decision-makers. If a reference matched these criteria it was fully read and inclusion and exclusion criteria were used to determine the relevance of the paper. After eliminating doubles the end result was 44 relevant papers (Appendix 1) which will be discussed in detail in the next section.

2.1.2 Number of studies, geographical spread and methodologies

One result of the review is that not much research work is done in general on the importance of decision-making criteria used in drug funding decision-making considering the final list of 44 papers. Noticeable was also the lack of research for Germany.

In the last 13 years, except for 2002, 2010 and 2011, research output has been relatively constant with two to five studies each year, demonstrating continued if reduced interest in healthcare decision-making. Between 2003 and 2009 the interest in healthcare decision-making seemed to be higher (Figure 5).

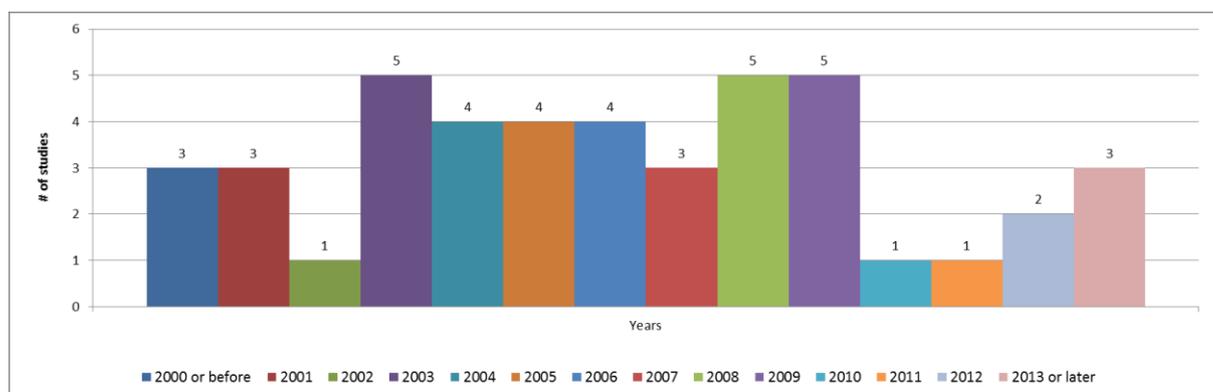


Figure 5: A constant interest in healthcare decision-making during the last 13 years.

Another finding of the review was a geographical research prioritization (Figure 6). The most discussed country in the relevant studies were the USA (17%) followed by UK (16%), the Netherlands (16%), Canada (16%) and Australia (10%). All other countries were discussed in seven or less studies (less than 10% each country).

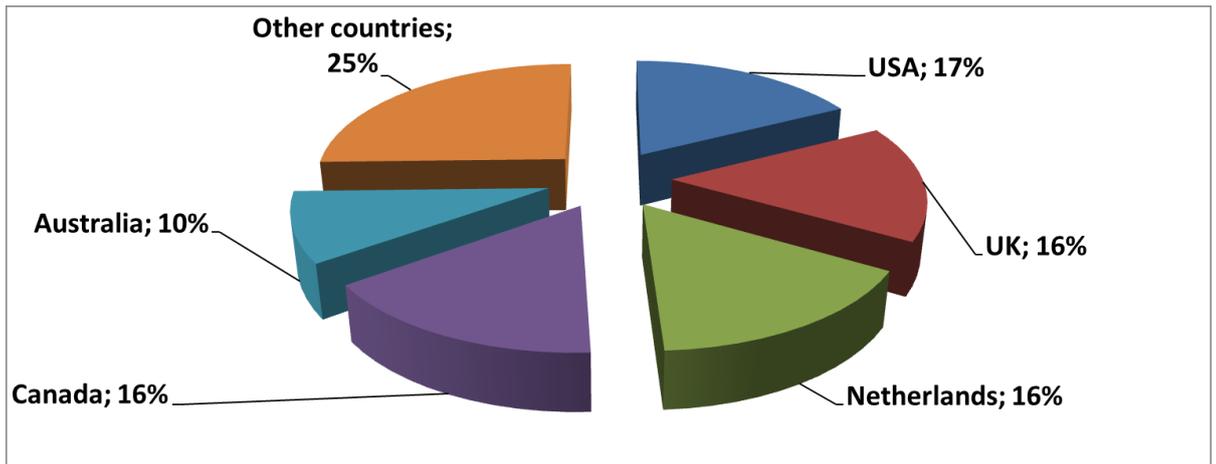


Figure 6: Countries in focus of healthcare decision-making research.

Apart from literature reviews (14 out of the 44 relevant papers), empirical studies were predominantly surveys (ten out of 44 papers) or done via interviews (eight out of 44 papers). Other approaches included mixed-methods approaches, observations or retrospective data analysis (Figure 7).

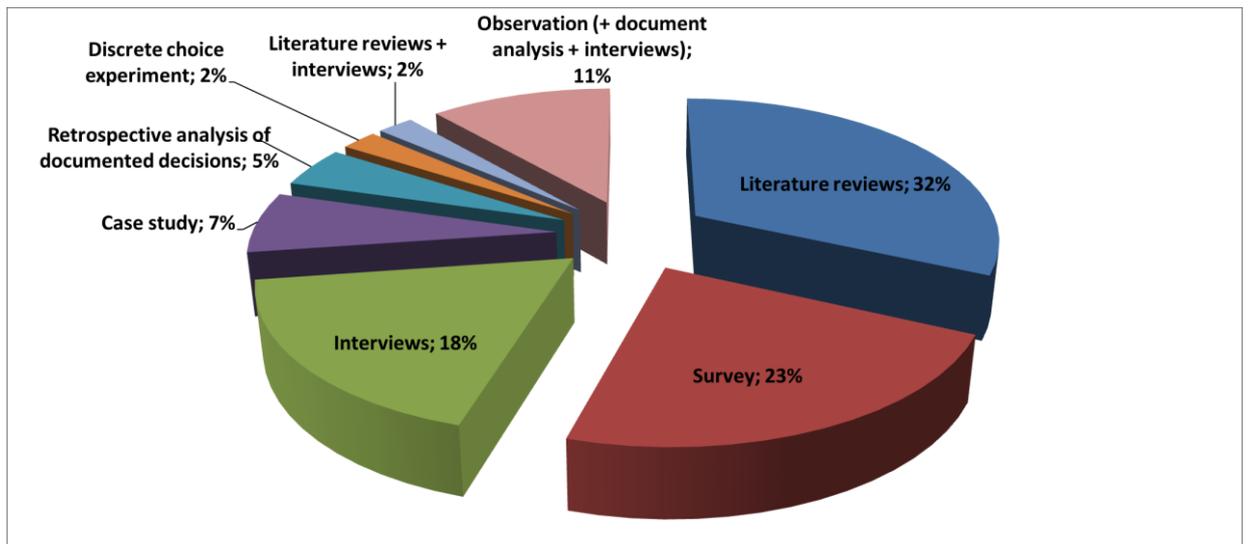


Figure 7: Top three research methods: Literature review, survey or interview.

This becomes more interesting, when looking at the distribution between quantitative and qualitative research methods (Figure 8). Both methods are well-balanced with a small tendency towards qualitative approaches demonstrating that there is not only one correct way to investigate the decision-making phenomenon. This also encourages the use of a mixture of quantitative and qualitative research methods for further empirical work.

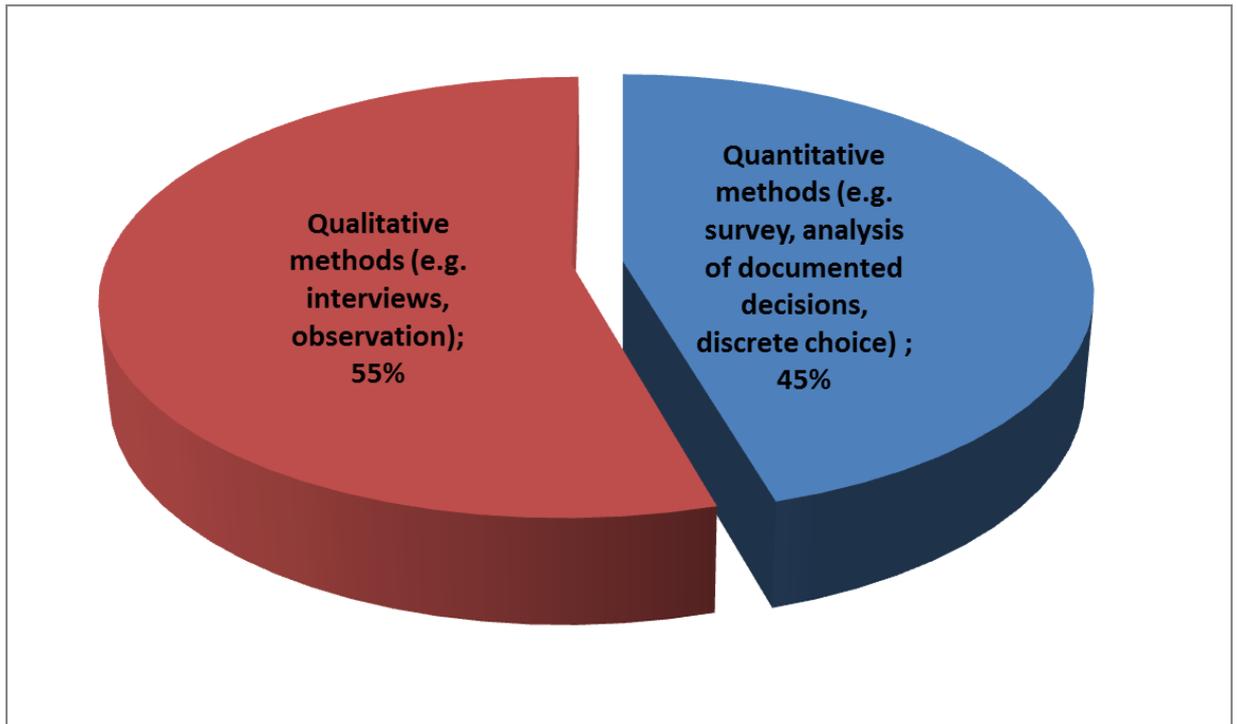


Figure 8: Balanced use of quantitative and qualitative research methods.

Many of the studies which used only quantitative research methods focused on the identification of decision patterns and the importance of single decision-criteria, such as health economic evaluations (Alsultan, 2011; Odedina, Sullivan, Nash & Clemmons, 2002). Additionally one of the main areas of investigation was the structure of hospital formularies (Dranove, Hughes & Shanley, 2013; Fijn, Brouwers, Knaap & De Jong-Van Den Berg, 1999). This is in contrast to the studies which used qualitative research methods and focused on explanations of more complex structures of healthcare decision-making, such as power relationships (Gibson, Martin & Singer, 2005) or priority setting not only limited to one single decision criteria (Martin, Pater & Singer, 2001; Vuorenkoski, Toiviainen & Hemminki, 2003).

The study of Koopmanschap, Stolk and Koolman (2010) in particular is interesting as it was the only study identified which combines quantitative methods with qualitative methods. The authors discussed their quantitative findings with an expert panel. However, the study's relevance is limited because chosen criteria for the discrete choice analysis were potentially biased by the uniform thought process of health technology assessment experts rather than considering alternatives. Even

though they are experts in health economics, they all come from a similar direction of thought which questions whether they were open for a variety of criteria.

Topics of interest

There is no trend in the specific sub topics of drug funding decision-making, but five main areas of interest can be observed (see Figure 9):

1. Importance and use of several criteria (with no specific focus) on drug funding decisions
2. Impact of political and social factors on drug funding decisions
3. Importance and use of economic evaluations or other economic issues
4. Structure of the formulary or the drug funding decision process
5. The use of tools to support decision-making

Research on several decision criteria (with no specific criterion) was focussed on in 14 studies which was the most discussed topic with 32% (Al, Feenstra & Brouwer, 2003; Baltussen & Niessen, 2006; Dakin, Devlin & Odeyemi, 2006). The second and third most frequent topics were the importance and use of economic evaluations in the decision process with 30% (Eddama & Coast, 2008, 2009; PausJenssen, Singer & Detsky, 2003) and the importance of political and social factors for the decision process with 18% (Vuorenkoski, Toiviainen & Hemminki, 2003; Wirtz, Cribb & Barber, 2005). As a single decision criterion, health economic evaluations gained a lot of attention from researchers, which is probably derived from the ethical discussion if cost containment influences the quality of healthcare. Researchers were also interested in finding explanations for healthcare decision-making through identification of political or social factors, such as hierarchical dependencies (Dranove et al., 2003; Gibson et al., 2005).

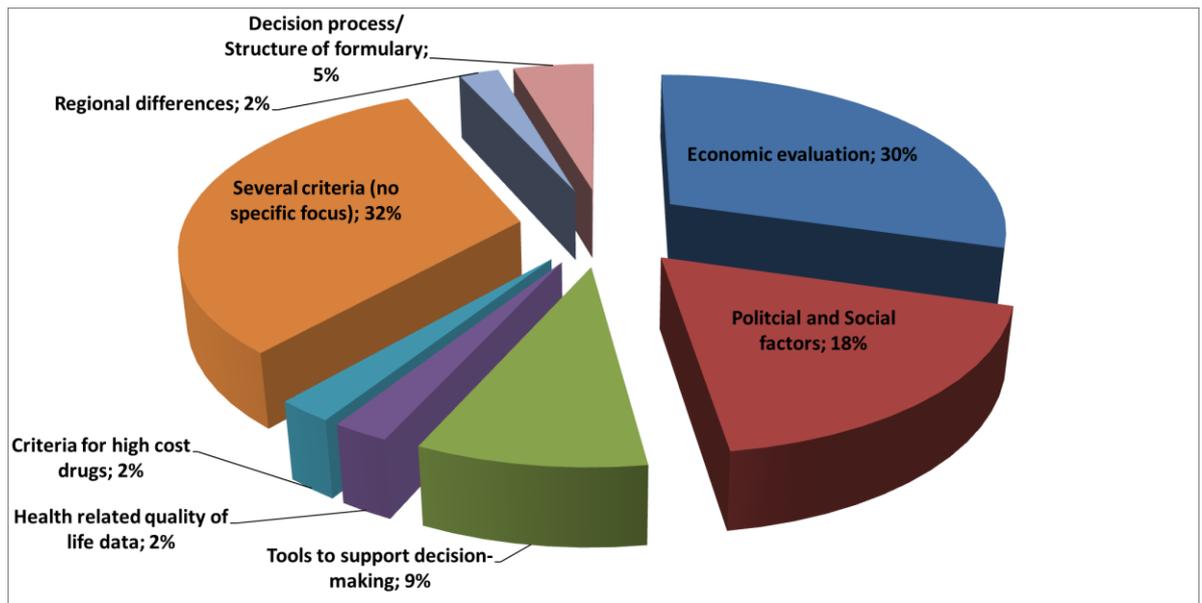


Figure 9: Three topics are of greater interest compared to the other ones.

The following sections will analyse and discuss detailed results of the systematic literature review initially referring to healthcare decision-making in general and finally concluding in decision-making in hospital formularies.

2.1.3 Decision-making criteria with perceived objectivity

Clinical trials data

Probably the most important criterion for drug funding decision-makers is clinical evidence (data from clinical trials) (Jenkins & Barber, 2004; Vuorenkoski, Toivianinen & Hemminki, 2003, 2008; Hutchings, 2009; Walkom, Robertson, Newby & Pillay, 2006). The quality of presented clinical evidence is carefully evaluated by decision-makers and is a key criterion (Vuorenkoski et al., 2008). An explanation for the dominance of clinical evidence is probably the high level of perceived objectivity serving the scientific background of decision-makers. Clinical trials are highly regulated and follow strict rules which should prevent any external influence by involved parties, similar to a laboratory experiment.

The assumption of an objectivity of a clinical trial is only part of the truth. Based on practical experience, this is shown in the demand of decision-making bodies of requesting "real world" data. Decision-making bodies, specifically on the national

level, realised that the efficacy of a pharmaceutical drug which is shown in a clinical trial is probably on a lower evidence level than the efficacy in real life and outside the controlled environment of a clinical trial (Garrison et al., 2007).

Economic evaluations

Much research is focused on the importance and use of economic evaluations for drug funding decisions. A reason for this focus could be either the origin of the researchers, since many are health economists or that economic evaluations have an increasingly important role in regards to drug funding decisions. However, one common result in all studies is that economic evaluations have only low or medium influence on decisions (Eddama & Coast, 2008, 2009; van Velden, Severens & Novak, 2005).

The possible reasons vary. In some cases it appears that economic evaluations lack credibility in relation to their accuracy and objectivity. Therefore, they are seen with caution when it comes to drug funding decision-making (Hoffmann & von der Schulenburg, 2000; Walley, Barton, Cooke & Drummond, 1997). The ability of economic evaluations to provide reliable decision-making support is challenged because of the presumed missing accuracy, as economic evaluations always rely on assumptions (Walkom et al., 2006). Economic evaluations are often conducted by pharmaceutical companies or their consultants. Decision-makers have a certain level of mistrust in studies conducted by industry, who are applying for drug funding (Eddama & Coast, 2008).

In addition to a perceived lack of scientific rigour and mistrust in studies conducted by industry-related service providers, economic evaluations appear to not adequately consider other important perspectives. Respondents of a study conducted in Thailand for example had general doubts in regards to the usefulness of economic evaluations. They believed that economic evaluations do not consider important aspects like ethical considerations, availability of alternative treatments or political pressure (Teerawattananon & Russell, 2008).

Even though the results of one study conducted with key decision-makers in Finland came to the conclusion that decisions are made technically (based mostly on

scientifically and economic criteria) and non-politically from the perspective of decision-makers, the authors of the study suspected other influencing factors like outside stakeholders (pharmaceutical companies, patient groups) to have an impact on final decisions (Vuorenkoski et al., 2003). This influence could be in the form of marketing or lobbying activities as well as through pressure by patient groups.

Budget impact as a decision criterion

Budget impact means to “estimate the financial consequences of adoption and diffusion of a new health-care intervention within a specific health-care setting” (Mauskopf et al., 2007, p. 337). It is another criterion often discussed in recent literature and is perceived to be important for the decision-making process (Cohen, Stolk & Niezen, 2007; Dakin, Devlin & Odeyemi, 2006; Koopmanschap et al., 2010; Niezen, de Bont, Busschbach, Cohen & Stolk, 2009).

Despite being a discussed topic in literature and a possible important criterion, decision-makers refuse to openly admit that budget impact is considered in drug funding decisions. Budget impact as a pure cost calculation is perceived to lack a scientific base in comparison with other economic considerations like cost-effectiveness which consider efficacy of different treatment alternatives in a model (Niezen et al., 2009). Decision-makers often prefer the more scientific tool to justify decisions. Some decision-makers for example are influenced by the budget impact criterion but provide other criteria, such as cost-effectiveness or clinical evidence as the rationale for their decisions in order to have a solid base for justification towards the public and to avoid criticism (Niezen et al., 2009).

To conclude, clinical evidence seems to be very important but often it is not sufficient to decide only on this information (Garrison et al., 2007). Economic evaluations appear to be controversial as a decision criterion (Eddama & Coast, 2008). Budget impact is perceived to be less objective and decision-makers believe that it lacks scientific rigor (Niezen et al., 2009).

2.1.4 Decision-making criteria with perceived subjectivity

Drug funding decisions are decided not only by perceived objective, technical or economic evidence, but also decided by perceived subjective criteria, such as

feelings, political driven pressure, personal experience or the severity of disease (Armstrong, Mitton, Carleton & Shoveller, 2008; Barasa, Molyneux, English & Cleary, 2014; Cohen et al., 2007; Dakin et al., 2006; Eddama & Coast, 2008; Gallego, Fowler & van Gool, 2008; Jenkins & Barber, 2004; Koopmanschap et al., 2010; Niezen et al., 2009; Teerawattananon & Russell, 2008; van Velden et al., 2005; Vuorenkoski et al., 2003, 2008; Wirtz, Cribb & Barber, 2005; Walkom et al., 2006). The importance of perceived subjective criteria increases if other data is limited or if the perceived objective data is of low quality in terms of scientific rigor (Leung, Halpern & West, 2012).

Baltussen and Niessen (2006) describe the priority setting in drug funding decision-making as an ad-hoc decision derived out of the different multidisciplinary factors and the inability of decision-makers to cover all of these. Ad-hoc in this respect refers to a decision where all decision criteria are evaluated without any structure or ranking. Baltussen and Niessen (2006) see a risk of cognitive overload for the decision-maker who is required to handle and assess the information flood. On the other hand they describe a “rational priority setting” process in which all the different decision criteria have different but specific relative importance weights resulting in a rank order (Figure 10).

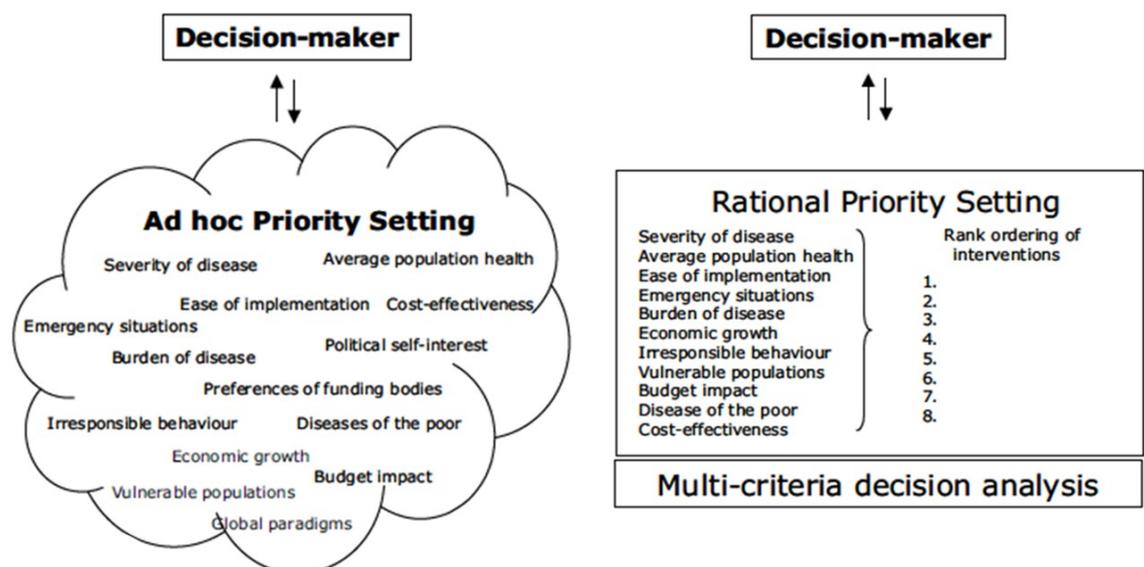


Figure 10: Ad hoc priority setting versus rational priority setting (Baltussen & Niessen, 2006).

Personal or local experience as a decision criterion

A study by Wirtz et al. (2005) on decision-making by the National Health Service (NHS) in the UK verifies the existence of perceived subjective and intangible criteria. This study identified two dimensions having significant impact on drug funding decisions. The first dimension relates to personal aspects, like subjectivity and is described with the personal experience of patients or doctors. The second dimension relates to political aspects described in the next section.

Decision-makers stated that positive personal experience of the drug, either from patients themselves or from physicians, has the potential to change an assessment positively. Adding to that, policy makers also mentioned the potential influence of excitement about the novelty of a new health technology (e.g. drug) (Wirtz et al., 2005). This is confirmed by another study by Armstrong et al. (2008) where non-scientific criteria such as clinical experience derived from clinical practice showed a significant weight in drug funding decisions. The decision-makers even considered the clinical practice as a fully legitimate reason to overcome the uncertainty of limited scientific data. In addition, this also confirms the doubts about the infallibility of clinical trials data and challenges the perceived objectivity. Decision-makers want to hear about perceived subjective information, such as personal experiences with the pharmaceutical drug. Some research (Armstrong et al., 2008; Wirtz et al., 2005) allows the conclusion that this criterion has significant weight in decision-making. This is emphasized by the research method Armstrong et al. (2008) applied. They used several information sources, such as meeting documentation, interview data and information taken during meeting observations for their conclusions. With this approach, several perspectives were considered and allowed a broad perspective on the subject. Wirtz et al. (2005) also used a research method which allowed the researchers to consider many perspectives for their outcomes. They conducted twenty in-depth interviews with different decision-makers.

Political aspects as decision criteria

In one study objections were raised against long discussions with stakeholders to avoid jeopardizing long-term relationships (Wirtz et al., 2005). Decision-makers also have to navigate the active pressure from clinicians on drug funding decisions with the maintenance of these relationships. In this case, it is pressure from influential

clinicians who would like to see a drug being approved for the formulary or to prioritise specific requests (Armstrong et al., 2008). This has been confirmed by other studies from Australia, Norway, Canada and Uganda which revealed pressure from clinicians, patient groups or politicians as influential criteria (Gallego et al., 2008; Kafiriri, Norheim & Martin, 2007). Protection of long-term relationships and avoiding discussions with influential members of the formulary committee assumes some kind of “hidden agenda” for the committee members. This needs to be considered for the outcomes of the thesis.

The importance of pressure from patient groups is not specifically analysed in the relevant studies but still relevant from a practitioner's experience. One prominent case is the “trastuzumab case”¹ where patient and political pressure finally led to funding of trastuzumab without prior approval from the appraisal agencies responsible for assessment of economic evaluations of drugs (e.g. NICE for the UK) (Simoens, 2007).

Gibson et al. (2005) focused in their research on the impact of power differences in a hospital operational planning committee. The strong influence of senior members of the committee was apparent, with more junior members referring to the hurdle for them to vote openly against proposals from senior members whom they directly report to. The study also mentions a potentially disproportionate impact of committee members who are rhetorically strong and the general feeling that disagreement or discussion is not welcome.

The studies focusing on political aspects differentiate between two criteria which influence decision-making (Armstrong et al., 2008; Gibson et al., 2005; Wirtz et al., 2005):

- Relationships with external stakeholders or key people, such as politicians, patient groups or the pharmaceutical industry.

¹ Trastuzumab is a monoclonal antibody for the treatment of early-stage breast cancer. The funding was heavily discussed in the UK in 1999-2002 due to the high cost of this treatment.

- Relationships with internal stakeholders, such as important and politically strong people in the decision-making group.

Other criteria discussed in the relevant literature

Depending on the respective country and the healthcare system, the severity of disease or burden of disease also appears to be a criterion used in decision-making, although this criterion is not mentioned very often. Hutchings (2009) found this to be relevant especially in France, while this aspect is less recognized in the UK due to the assessment methodology of the national health technology assessment authority (NICE). Even more distinct was the result in a study conducted by Koopmanschap et al. (2010) which clearly showed a high level of severity of disease changed the willingness to reimburse a drug significantly. The study used a discrete choice experiment (DCE), a quantitative research method, to elicit preferences of healthcare decision-makers on the national level but did not challenge the outcomes. The DCE is a very artificial decision situation inherent to the method, especially if conducted on its own without any further discussions on the results. In addition, severity of disease might be of less importance if a decision-maker has direct budget responsibility and the consequence of a positive decision is a budget impact, as usually is the case in a hospital (Koopmanschap et al., 2010; Niezen et al., 2009).

Health related quality of life is a subjective measure of the health status of individuals and it is reported as a decision criterion of importance (Wu, Sause & Zacker, 2005). The study of Wu, Sause and Zacker (2005) showed that parts of the interviewed formulary committee members (33.9%) endorsed their willingness to pay a premium, in contrast to 37.5% who were not willing to pay any additional money. Even though some decision-makers are convinced of the importance of health related quality of life, the study also revealed that in total, efficacy, safety and costs are preferred and more important as already shown in other studies (Hutchings, 2009; Jenkins & Barber, 2004; Vuorenkoski et al., 2003, 2008; Walkom et al., 2006).

Besides the already mentioned criteria the relevant literature shows some evidence of additional criteria. For example, ethical reasons (with reference to life-saving

treatments or equity of access) or the availability of alternative treatments seemed to be also utilized by decision-makers (Teerawattananon & Russell, 2008) but were mentioned only in one study of the relevant literature.

It is also possible that decision-makers were unaware or not willing to comment on additional decision factors like influence through indirect lobbying methods as also assumed by the authors of one study (Vuorenkoski et al., 2003).

Open use of perceived subjective criteria: a question of accountability and justification

One reason why it is difficult to get information on other criteria than perceived objective criteria is the reluctance of decision-makers on all levels to openly acknowledge the use of perceived subjective criteria. Behind this is the issue for decision-makers that they are accountable for many difficult allocation decisions and accountability needs to be defensible against legal and public challenges (Wirtz et al., 2005). It is much easier to defend a decision if the decision-maker can explain how the process has led to the specific decision. In practice this means that decision-makers try to defend their decisions with a robust decision process (Wirtz et al., 2005) and with the use of rigorous and objective scientific data (Jenkins & Barber, 2004; Walkom et al., 2006). As a result, written decisions as part of drug funding decision documentation are mostly justified with scientific or economic reasons independent of how many other subjective, intangible criteria have been adopted (Dean et al., 2013). This has also been a result of a literature review on the use of pharmacoeconomics in decision-making which included 31 studies (Walkom et al., 2006). A study in Finland where the outcome suspects a very objective driven decision process assumed that decision-makers tend to be very technical and scientific in order to avoid blame because of unpopular decisions (Vuorenkoski et al., 2003).

This previous section discussed the findings in regards to the different criteria that decision-makers balance in making a drug funding decision. However there are a variety of decision-makers dependent on the national healthcare system and place of operation (national, regional or local).

Besides the use of perceived objective and subjective criteria in decision-making, the different levels (national, regional or local) also appear to have differences in applying decision criteria. In the following sections, the literature was analysed with a focus on the difference in importance and use of criteria by national and regional decision-makers. Because this thesis focused on group decision-making in hospital formularies, only the decision-making process on the national and the regional level is relevant. As described above, local decision-making refers to decision-making of individual people, such as a physician who decides on a treatment of a patient. Hence, local decision-making is not group decision-making.

2.1.5 Differences between the decision levels

Some of the studies only concentrated their research on one decision level like the regional level (Jenkins & Barber, 2004) and others focused on more than one level (Vuorenkoski et al., 2003). The result of these studies let assume that all decision levels have different objectives which can differ slightly or significantly, depending on the individual structure of the respective healthcare systems. Hence, the role of the decision-maker varies and healthcare decision-making is not only done with different criteria but also on different levels of a healthcare system with a respective focus depending on each level. Al, Feenstra and Brouwer (2003) expressed this variety and differences in healthcare decision-making with one sentence: “THE decision maker does not exist” (p. 35). As a consequence these studies also show that each decision level might have different importance weightings for the decision criteria and also might have adopted a different subset of criteria.

2.1.5.1 National Level

On a national level, national agencies should have a focus on the societal impact of their decisions and criteria will be viewed at a broader level. The decision-makers on the national level have a greater focus on politics and legal issues where this differs to objectives on a local or regional level (van Velden et al., 2005). From a practitioner's view it is surprising that there appears to be consensus in the literature of a very small influence of economic evaluations on the national level (Eddama & Coast, 2008; van Velden et al., 2005). In practice, economic evaluations are mostly required for drug funding applications and commonly used on the national level (Drummond et al., 1999).

In contrast to the low or moderate importance of economic evaluations, the identified literature (Dakin et al., 2006) sees an increase in importance of national budget impact as a criterion for drug funding decisions. More and more countries require inclusion of budget impact calculations in their reimbursement dossiers before approving market access and funding. It is becoming increasingly important because a drug can be cost-effective, but still funding might be rejected out of an unfavourable budget impact situation (Cohen et al., 2007).

Even if evidence is rare, also on the national level there seems to be more decision criteria which are relevant for healthcare decision-making besides the pure economic focus. George, Harris and Mitchell (2001) reviewed reimbursement decisions from 1991 to 1996 submitted to the Australian Pharmaceutical Benefits Advisory Board (PBAC), which is the national reimbursement agency. The main outcome of this analysis was the confirmation of consequent use of health economic measures. However, they also found hints which endorse the use of additional decision criteria. They emphasized the fact that the PBAC has guidelines which clearly define additional criteria, such as the "community need or benefit" or treatment of "significant medical conditions" (PBAC Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee, Version 4.4, p.5).

Justification of a decision is another important point that decision-makers on a national level bear in mind during the process of decision-making. The importance of public pressure as an influential criterion decreased with a more regional level of decision-making. On the regional level the importance of public opinion is less influential as compared to the national level. This could be explained with the dependency of national policy makers to the public regarding their re-election (Teerawattananon & Russell, 2008). This suggests that national decision-makers have the perceived expectations from the public in mind and consider these in their decision-making scheme. Unfortunately an indication on the level of impact of public pressure on drug funding decision cannot be clearly seen in the relevant literature.

2.1.5.2 Regional Level

The regional level has different challenges. At this level the decision-makers think very clearly about the local situation (of a region or a hospital) (Jenkins & Barber, 2004). This means that every decision focuses on the direct impact on the regional level. This can lead to different decisions as the regional level is not significantly impacted by public pressure because decision-makers are not dependent on public re-election (Teerawattananon & Russell, 2008). In contrast, local pressure exists from influential individuals. From the observations on the regional level, it is valid to assume that pressure from physicians play an important role at the regional level. Three studies (Armstrong et al., 2008; Gallego et al., 2008, Martin et al., 2001) confirmed these assumptions. Pressure is not necessarily always direct pressure, but it can also mean that decision-makers try to avoid arguments with colleagues because they are afraid to harm their relationships with them (Wirtz et al., 2005).

The impact of economic evaluations and budget impact could be expected to be high due to the nature of the decision-making process being under budget constraints. Despite this assumption there is only little evidence that speaks for a moderate influence of economic evaluations on the regional level (van Velden et al., 2005). In a study by PausJenssen, Singer and Detsky (2003) conducted in a formulary committee in Ontario, Canada, formal economic evaluations had only a minor impact, but economic considerations in general became of greater importance if higher costs were expected. It is easy to assume that decision-makers in a hospital have local issues (of the hospital) in mind and might consider a broader impact only in a second step after evaluating every argument that is locally relevant. A UK based study with regional decision-makers even speaks of a “disconnect” between economic evaluations and the decisions which are essential for regional decision-makers (Eddama & Coast, 2009, p.269) and explains a low impact on decision-making.

In regards to budget impact, the expectation of a moderate to high influence on the decision-making is being confirmed by research. Since budget impact calculations are aimed for a specific healthcare context (Mauskopf et al., 2007) it is applicable for the hospital situation. Even though in many cases decision-makers (on a regional

level) refuse to openly admit the use of budget impact, the importance and influence appears to be evident (Gallego et al., 2008; Niezen et al., 2009).

2.1.6 Decision-making supportive methods

The last sections have shown that healthcare decisions are complex multi-criteria decisions usually taken by a group (on the national and regional level). Presumably due to the complexity, decision-making lacks a certain level of transparency, which is criticized by researchers (Armstrong et al., 2008; Dean et al., 2013; Fijn et al., 1999; Plet, Hallas, Nielsen & Kjeldsen, 2013).

Hence, one of the main goals of theory development in the context of healthcare decision-making on drug funding is to increase transparency of the decision-making process to improve the understanding of formulary decisions. Very often this is tied to the goal of reducing the influence of perceived subjective decision criteria (Walkom et al, 2006) which can be seen in some methods developed with the aim to assign relative weighting to decision criteria.

Systems of Objectified Judgment Analysis (SOJA) is a methodological framework which assumes a standard set of decision criteria including relative weighting done by an expert panel which ensures the adaptation to the local situation (Janknegt & Steenhoek, 1997; Walkom et al, 2006). Another very recent framework to support hospital formulary decision-making on drug funding is part of a project called *Formulary Leveraged Improved Prescribing (FLIP)* conducted in the USA and described in the paper of Schiff et al. (2012). This framework is structured in six domains where each domain consists of detailed questions which should support committee members in evaluating pharmaceutical drugs. None of the domains or the connected questions possesses a relative importance and the framework does not consider adding importance weights.

The important decision-making criteria from other studies can also be recognized in the domains of Schiff et al. (2012), such as efficacy, safety or cost issues. But they are only used as a check-list for decision-makers and suggest transparency.

Another decision-making supportive method is *Multi Criteria Decision Analysis* (*MCD*A) which is increasingly utilized in healthcare decisions (Baltussen & Niessen, 2006; Baltussen, Youngkong, Paolucci & Niessen, 2010).

Devlin and Sussex (2011) defined *MCD*A as “a set of methods and approaches to aid decision-making, where decisions are based on more than one criterion, which make explicit the impact on the decision of all the criteria applied and the relative importance attached to them”(p. 4). There are several different *MCD*A approaches but most of them make use of a *value measurement model* or *weighted sum approach* (Thokala & Duenas, 2012). This comprises of creating a value $V(1) \dots V(n)$ for n decision alternatives where the alternative 1 is preferred if $V(1) > V(i)$ with (i) representing any other possible alternative. $V(i)$ is considering all criteria for the respective alternative. The equation for this function is:

$$V(a) = \sum_{i=1}^n w_i v_i(a)$$

w_i represents the relative importance and $v_i(a)$ represents the score of the alternative a for criterion (i) (Thokala & Duenas, 2012). This equation has a pre-requisite that for every criterion a relative importance has been set as well as a score for each criterion on the respective alternative. If pre-requisites are fulfilled the result is an overall score for each decision alternative which makes it then easy for the decision-maker to choose. The pre-requisites already show the weakness of *MCD*A. It is not only necessary to determine scores for each criterion on the respective alternative but it is also compulsory to define a relative importance compared to other criteria, which requires a good understanding of the relationships between the different criteria. Thokala and Duenas (2012) summarize all main issues regarding *MCD*A: The decision-makers need to find consensus on the selection of criteria, the relative importance and the score for each criterion.

A general issue with the decision-making support methods is the motivation of such tools to reduce decision-making only to perceived objectivity. For example, Janknegt and Steenhoek (1997) stipulate in their *SOJA* methodology to exclude “these factors [such as emotions] as much as possible in the decision-making process” (p.550). Moreover, they believe that *SOJA*’s main advantage is that “all emotional, financial

and other non-rational selection criteria are excluded and that drug decision making is based solely on rational criteria” (p. 559). This might be an explanation why the use of such methods is limited in hospital formulary decision-making, since literature (Dranove et al., 2003; Gallego, Taylor & Brien, 2009; Gibson et al., 2005; Martin et al., 2001; Wirtz et al., 2005) shows evidence that hospital formulary decision-making is not only based on perceived objective criteria.

An implementation issue with most of these methods as well as with *SOJA* or *FLIP* is the consensus on relative weighting of decision criteria (Janknegt, 2001). Therefore *SOJA* for example is often supported by software packages where all formulary committee members provide their individual weight for each decision criteria with the purpose of receiving an individual preference list. This individual preference list can then be compared with the other member’s preference lists and should finally lead to a consensus. Hence, although *SOJA* focuses only on perceived objective decision criteria, it is basically a subjective method (Janknegt et al., 2007). This decreases transparency again, since the decision-making is done in a second step by discussion between the formulary committee members and theoretically involves new (hidden) criteria or at least refined criteria assessment which leads to the consensus.

Additional issues around those decision-making support methods are complexity, required time for development, maintenance and analysis and the possible manipulation as stated in a Dutch study by Fijn et al. (1999). The interest of hospital formulary committees is reflected in the awareness and knowledge about those methods. Most of the hospital formulary committees (97%) which participated in the study of Fijn et al. (1999) were familiar with supportive methods such as *SOJA*. On the other hand, the actual usage of only 16% of all study participants also reflects the low acceptance of those methods.

In spite of these issues, all methods or frameworks (e.g. *SOJA*, *MCD*) which try to provide a standard set of decision criteria are similar in the key criteria applied. This suggests a possibility of designing a general pharmaceutical drug funding decision-making framework. And it is a motivation and justification to define a framework

which describes not only the perceived objective part of hospital formulary decision-making, but also considers other important criteria.

There is no evidence that these frameworks are used by German hospital formularies and the identified literature does not provide any hint on the reasons why these kind of decision-making supportive methods are not used.

2.1.7 Conclusions for healthcare decision-making

Use of perceived objective and subjective criteria

Current research shows the existence of perceived subjective criteria being considered in addition to perceived objective criteria in drug funding decision-making.

Identified major criteria have been:

- Efficacy and safety of a pharmaceutical drug, proven by data from clinical trials.
- Health economic evaluations
- Personal or local experience, which refers to feedback on the drug value from trusted individuals such as physicians, pharmacists or patients.
- Budget impact calculations, which show a possible monetary impact on a given, constraint budget based on the population likely to take the drug and estimated drug costs.
- Political aspects which consider pressure from external forces like influential clinicians or patient groups on the decision-making process or on specific decision-makers. This also includes the objective of decision-makers to secure important relationships.
- Severity of disease which tries to explain the impact of the disease on the patient.

The most discussed criteria are health economic evaluations. Although many healthcare systems require this as formal criteria for reimbursement applications, research implies only a low to moderate impact of economic evaluations, specifically on the regional level (e.g. hospital).

Each decision level is different

The general use of perceived subjective criteria seems to be independent of the decision level, because the widespread use of such criteria on a national and regional level has been shown in the relevant literature. Although both levels use such criteria, the relative importance of specific criteria varies and is often highly dependent on the respective decision level and healthcare system.

Political aspects seem to be relevant on both levels although from different perspectives. On the national level this could be pressure from patient groups whereas influential clinicians can be the main factor on the regional level, as this level is confronted less often with patient groups.

From a research perspective, budget impact appears to be moderately important on the national level. Practitioner's experience and new healthcare system changes (shift of budget responsibility towards the regional level) lead to the conclusion that the importance of budget impact as a decision criterion on the national level will even further decrease. On the contrary the importance of budget impact should increase on the regional level.

In contrast to the national level there is a high influence of reported local and personal experience on the regional level. Physician's life experiences with drug efficacy or hospital staff experience with handling drugs appear to have impact on drug funding decisions.

Economic evaluations are perceived to be of low impact on the national level and with only moderate impact on the regional level. Practitioners have a different opinion on this; especially on the national level they see economic evaluation as a major criterion for drug funding decisions (Heitzman, Shapurji, Poulin & Lesser, 2009; Janus, Natanek, Evers & Dewhurst, 2007).

Each decision level has its own subset of important criteria

Figure 1 illustrated the complexity of funding decisions for drugs. If the results of the literature review are added to this basic model of drug funding decision-making this leads to an extended version of the displayed funding for drugs decision process. In

this framework, shown in Figure 11, it is considered that every decision level has its own subset of decision criteria and that also the structure of the country healthcare system has impact on decision-making. The relative importance of each criterion as well as the general importance needs to be considered separately because it can differ significantly for each level. There might be also the possibility that some criteria which are important for one level are not taking into consideration on a different level.

Nonetheless, not only every decision level has its own subset of criteria but also on each single level, individual decision-makers have their own subset of decision-criteria which they apply to the decision-making process.

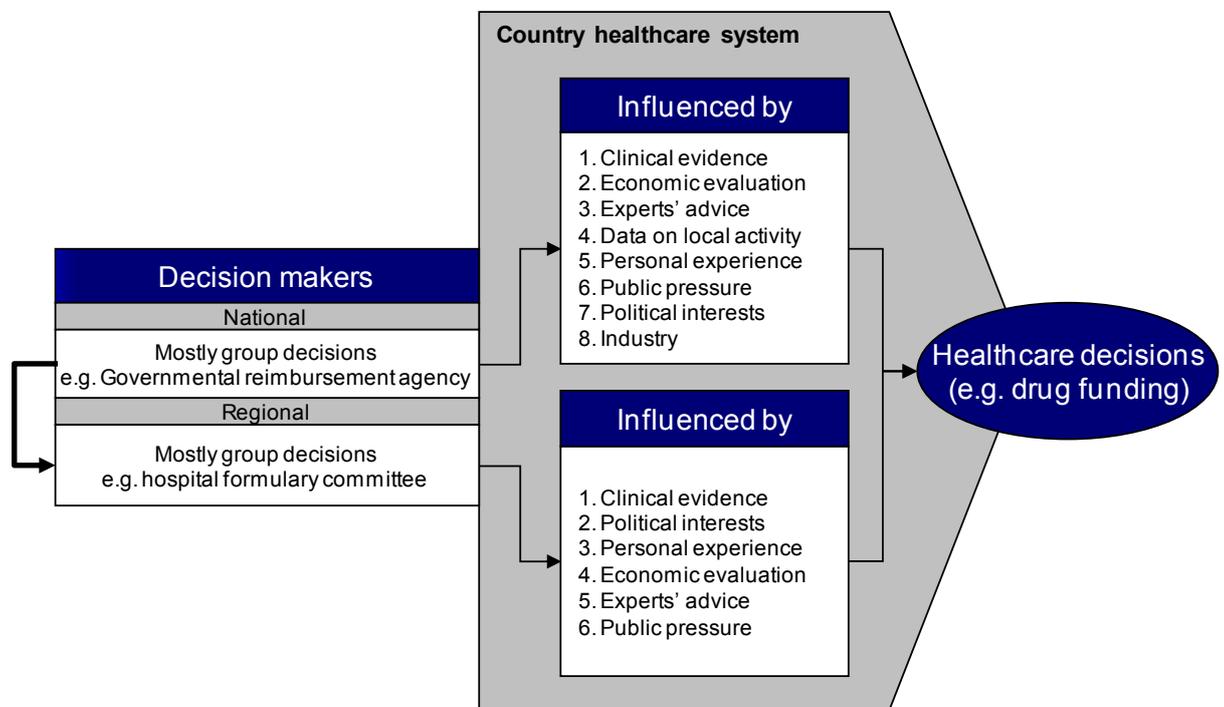


Figure 11: Extended healthcare decision-making framework for drug funding. (adapted from Atienza et al., 2008).

The past sections of this literature review showed the complexity of healthcare decision-making. The next sections will focus on the main topic of this research: decision-making in hospital formulary committees. The extended healthcare decision-making framework for drug funding (Figure 11) will be adapted to the results of the specific situation of hospital formularies.

2.1.8 Hospital formulary committees – the regional level

2.1.8.1 Complexity of formulary decisions

Formulary committees are challenged with complex decision situations characterized by uncertainties in available information and the assumptions which are basis for some of the evidence as well as the varying amounts of available evidence. Clinical uncertainties around the efficacy of pharmaceutical drugs and connected financial implications for the hospital are two of the main considerations for committees (Williams & Bryan, 2007). All hospital formulary committees need to balance different criteria to be able to make reasonable decisions on whether or not to accept a pharmaceutical drug on to their hospital formulary list. Due to the nature of such funding decisions, formulary committees have to assess the trade-off between the benefits, risks and costs.

Formulary committee members face even more complexity when considering exceptionally expensive pharmaceutical drugs for orphan diseases. Usually the trade-off here involves a balance between a major benefit for a small group of patients and a smaller benefit for a large group of patients as hospital budgets often are restricted (Gallego et al., 2009). In the same study physicians also reported the dilemma of focusing on the patient's needs on the one hand but considering a restricted hospital budget on the other hand. This concern is supported by the general importance of budget impact for healthcare decision-making reported by other studies (Cohen et al., 2007; Dakin et al., 2006; Koopmanschap et al., 2010; Niezen et al., 2009).

2.1.8.2 Criteria used in hospital formulary decisions

The above sections about healthcare decision-making represent the variety of criteria used by decision-makers. They use perceived objective criteria, such as data from clinical trials or health economic evaluations, but they also make use of perceived subjective criteria, such as recommendations from physicians or experience in other hospitals. This is not only true on the national level, but also on the regional level, which refers to hospital decision-making (Armstrong et al., 2008; Gallego et al., 2008; Gibson et al., 2005; Jenkins & Barber, 2004). And these subsets of decision criteria are highly individual, which is one of the outcomes of a study by PausJensen

et al. (2003) where members of a formulary committee in Canada acknowledged that decision-making is also dependent on the individual "set of values"(p.290) of each formulary committee member. This individuality challenges many of the conducted studies with a pure positivistic background since every prediction of a decision outcome is fallible. The use of individual subsets of decision criteria makes decision-making in hospital formularies a complex phenomenon with a high level of unpredictability. For people, who like to apply a math formula to those kinds of decisions, this might be a disadvantage. But it can be an advantage considering that different views and opinions have a chance to influence decision-making.

Table 3 shows a summary of all decision criteria identified by studies of the above literature review with a focus on hospital formulary committee decision-making. This demonstrates that most of the studies only identified the main criteria: efficacy, safety and costs. Depending on the study, additional criteria were identified but not consistently for all studies. One explanation for this is the focus of some research studies on specific topics, such as health economic evaluations. Another explanation might be the applied research methodology. If a study used a survey as the stand-alone research method, it was more difficult to get in-depth information on any underlying structures, such as the impact of influential formulary members. For example, in the study of Fijn et al. (1999), pharmacists were named by 42% of the participants of a survey as the most influential members of the hospital formulary committee. However, the study did not provide any in-depth information on the reasons for this strong influence.

Author	Efficacy	Safety	Economic data and costs	Type of pharmaceutical drug	Administration/ Practical criteria	Emotional criteria and clinical experience	Patient's quality of life	Relationships to the pharma industry	Decision-making guidelines	Knowledge sharing	Advocates and power relationships	Other
Alsultan (2011)	x	x	x								x	
Fijn et al. (1999)	x	x	x						x		x	
Gallego et al. (2009)	x	x	x	x		x	x				x	
Janknegt (2001)	x	x	x			x					x	
Jenkings and Barber (2004)	x	x	x			x		x		x	x	- Patient demand
Martin et al. (2003)	x	x	x	x	x	x			x			
Mittmann and Knowles (2009)	x	x	x	x		x			x			- value added services - bundling of services
Motheral et al. (2000)	x	x	x				x				x	- Patient demand
Odedina et al. (2002)	x	x	x	x	x					x		
Späth et al. (2003)	x	x	x				x	x				
Williams and Bryan (2007)	x	x	x							x		
Haslé-Pham et al. (2005)	x		x				x			x		
Plet et al. (2012)		x	x		x	x			x			- treatment guidelines
Dranove et al. (2003)			x					x			x	
Gibson et al. (2005)										x	x	- tight timelines

Table 3: Identified decision-making criteria in hospital formulary committees.

The following sections will reflect in more detail on the main decision criteria identified by research on hospital formulary decision-making and thus evaluate the importance of those criteria for the decision-making process on the regional level. As already mentioned in the healthcare decision-making part of this literature review, there is no doubt about the importance of clinical trials data. Hence, this was not further explored.

Economic data and costs

Health economic evaluations, and specifically cost-effectiveness analyses (CEA), are used seldom in decision-making at the hospital level (Gallego et al., 2009; Williams & Bryan, 2007). Although a literature review by Walkom et al. (2006) showed considerable variance in the regular use of economic evaluations in hospital formulary decision-making, varying from 23% (Kulsomboon et al, 2001) to 86% (Odedina et al., 2002) the general impact of such data is limited.

One of the issues around the data provided to hospital formulary committees is the lack of local adaptation. Very often the data used is in a general way instead of adapting to the local hospital situation which makes it very difficult for the decision-makers of a formulary committee (Späth et al., 2003; Walkom et al., 2006; Williams & Bryan, 2007). This in particular is valid for health economic studies where cost assumptions are mostly general and not adapted to the hospital situation (Haslé-Pham et al., 2005).

One result from a study by Odedina et al. (2002) is notable as it showed a (slight) positive correlation between the use of health economic data in decision-making and the perceived ease of making a decision by the formulary committee members. The explanation by the authors of the study is the perceived objective nature of quantitative data from health economic analyses which seem to simplify the decision-making due to a potential easier justification. Odedina et al. (2002) only asked pharmacists in their study. This could be the reason for this outcome since pharmacists could use economic arguments against a potential medical argumentation of a physician. Additionally, the objective nature of health economic evaluations can also be challenged. In different studies, (Späth et al., 2003; Walkom et al., 2006) formulary committee members raised concerns about the amount and possible bias of assumptions accompanying health

economic evaluations. Odedina et al. (2002) might be wrong in the assumption of the objective nature from health economic evaluations due to the fact that those evaluations are often designed in cooperation with industry and thus can be biased (Bell et al., 2006). Likewise, if a hospital formulary member does not have the required expertise to fully assess such a model, which is another main obstacle identified by literature (Haslé-Pham et al., 2005; Späth et al., 2003), the meaning to the hospital context of health economic models is difficult to understand.

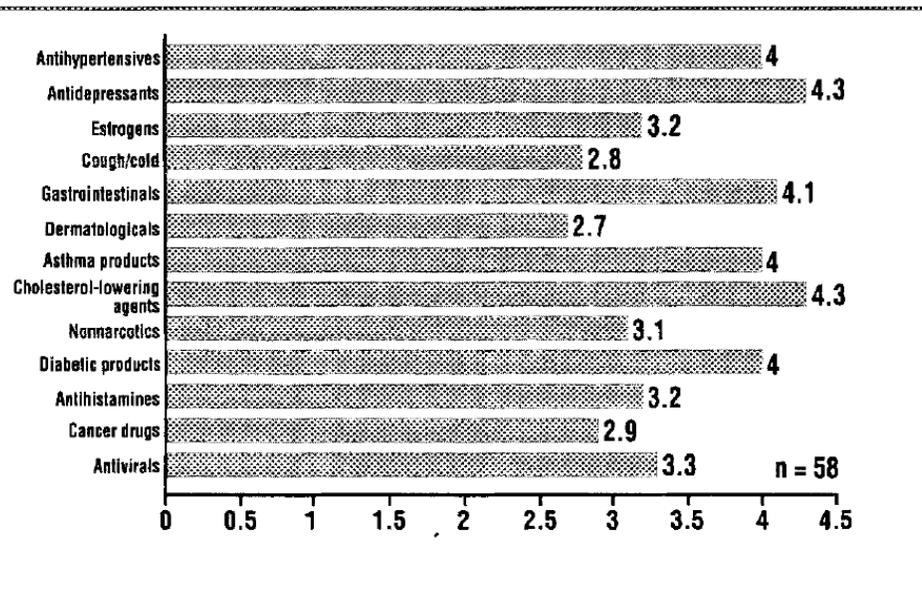
An explanation for the positive correlation between the use of health economic evaluations and the ease of decision-making in the Odedina et al. (2002) study could therefore be that external groups (e.g. politicians, patients) have the perception of objectivity of health economic evaluations and that decision-makers make use of that. If this is the case, a health economic evaluation would serve as justification for a decision and makes it easier for hospital formulary committee members to find an official reason for their decisions. This is supported by the fact that decisions by hospital formulary committees are seldom published or properly documented.

The decision-making documentation is often not available outside of the committee and often only the decision is provided in the documentation, but not the reasons nor the process of decision-making (Martin et al., 2003). In most cases, only the perceived objective evidence, such as clinical study outcomes or costs but not the perceived subjective data, such as assumptions or recommendations of colleagues are mentioned (Dean et al., 2013). This is critical as it does not reflect the full picture of the decision-making process and an external person gets a completely different and incomplete idea of the rationale behind a decision. As shown before, decision-makers use perceived subjective criteria, such as feelings, political driven pressure, personal experience or the severity of disease as basis for their decision-making (Armstrong et al., 2008; Eddama & Coast, 2008; Gallego et al., 2008; Vuorenkoski et al., 2003, 2008; Wirtz et al., 2005). Those decision criteria are not visible if they are not mentioned in the decision documentation and thus the true rationale behind a decision is hidden.

Type of pharmaceutical drug

The type of a pharmaceutical drug is one criterion which influences the decision-making process in hospitals. Formulary committee members consider different aspects in the decision-making process if the drug is used for treatment of a severe disease and no comparable alternatives are available. Very often, those drugs are very expensive due to a limited number of potential patients. A study conducted by Gallego et al. (2009) in public hospitals in Australia focused on such pharmaceutical drugs. The participants in this study generally felt that besides clinical data, costs were sometimes the most influential decision criterion. Still, in cases where formulary committee members had to decide on treatments for severe diseases with no alternatives, lack of clinical data or issues related to treatment costs decreased in importance.

To further support the possible importance of the drug type for the relative criteria weighting another study considered different therapeutic classes. Motheral et al. (2000) asked hospital formulary committee members to rate the importance of pharmacoeconomic information by therapeutic drug class.



Mean rating of importance of pharmacoeconomic information by therapeutic drug class. Ratings range from 1 (pharmacoeconomic information is not important for decision-making in this therapeutic class) to 5 (pharmacoeconomic information is extremely important for decision-making in this therapeutic class).

Figure 12: Relative importance of pharmacoeconomic data for different therapeutic drug classes (Motheral et al., 2000).

The result shows a different relative importance between the different classes (Figure 12). Here the question arises if the type of pharmaceutical drug determines the choice or relative importance of decision criteria.

Administration/ Practical criteria

Administration of a pharmaceutical drug and practical criteria, such as ease of preparation or application, is only mentioned in a few research papers (Martin et al., 2003; Odedina et al., 2002; Plet et al., 2013). The relative importance of this criterion was medium ranked compared to other criteria or not considered. In the latter cases, the study participants revealed administrative or practical considerations during decision-making but did not provide details on the importance. This leads to the assumption that administrative or practical criteria have a minor impact in hospital formulary decision-making. Nonetheless, the reason for this underrepresentation in the identified studies might also derive from the selection of study participants as well as the number of the

concerned group of users in hospital formulary committees. In studies where those decision criteria were mentioned, usually one representative of the concerned user group, such as a nurse, was part of the respondent group (Martin et al., 2003; Plet et al., 2013).

Emotional criteria and clinical experience

Current research confirms the use of perceived subjective criteria such as ethics or clinical experience in decision-making of hospital formulary committees (Wirtz et al., 2005). Janknegt (2001) names some of the decision criteria more precisely and talks about "emotional factors"(p.50), "unconscious factors"(p.50) or "other factors"(p.50) instead of subjective criteria.

Especially the incompleteness of available data, lack of local adaptation and the uncertainties around presented evidence lead to decisions which are achieved by discussion and consensus instead of simply applying a math formula (Wirtz et al., 2005). This finding suggests a general critique towards supportive decision-making methods, such as *SOJA*, *FLIP* or *MCDA*. All of these methods, which were described in detail above, try to quantify the decision-making process with application of a proposed math formula. In contrast to this, many studies (for example: Armstrong et al., 2008; Eddama & Coast, 2008; Gallego et al., 2008; Vuorenkoski et al., 2003, 2008; Wirtz et al., 2005) confirm that the decision-making process involves also perceived subjective criteria and a high individuality in regards to the relative importance of such criteria. This questions the sense of the supportive decision-making methods which is presumably reflected in the limited acceptance and practical use.

In addition, this finding confirms the assumption that lack of perceived objective criteria and uncertainty about the presented information leads to the usage of other criteria. It is also important that pharmaceutical drug funding decisions have impact on patients, physicians and clinical staff which adds an emotional component to the complex decision situation enticing committee members to consider perceived subjective criteria (Janknegt, 2001).

Authors like Janknegt (2001) argue that decision-making should be made on a rational level and they are critical on the use of perceived subjective criteria in decision-making.

Perceived objective criteria are appreciated more due to the educational background of hospital formulary committee members, most of them coming from a scientific background. In fact, Walkom et al. (2006) remark that due to the sensitive nature of drug funding, studies with such a research focus tend to present a picture of rational decision-making (using only perceived objective criteria) since the respondents who are involved in the decision-making might want to present the process in good light.

But even these authors recognize that decisions usually involve "emotional factors"(Janknegt, 2001, p.50) not necessarily assuming that committee members are fully aware of the impact of such factors on their decision-making. This actually shows the issue around the question how decision-making should be conducted. On the one hand, if Janknegt (2001) speaks about a "rational level"(p.50), he stipulates a "transparent process"(p.50) without perceived subjective criteria and with a clear criteria definition. On the other hand he agrees that perceived subjective criteria are applied in the decision-making process. So why should it be wrong to use them and what makes the perceived objective criteria more valuable for a good decision? An example for this can be found in an Australian study by Gallego et al. (2009). Members of Drug Therapeutic Committees who decide on drug funding of high cost medicines in public hospitals refer to case reports for pharmaceuticals with little evidence and thus showing only marginal benefits. This means that the perceived objective criteria only show weak evidence of efficacy. In spite of this weak perceived objective evidence, the committee members describe an impact on their decision-making behaviour in terms of being more tolerant due to the "serious potential outcome of doing nothing" (Gallego et al., 2009, p.30). This shows that in situations of lack of perceived objective information, hospital formulary members use alternative decision criteria which also can be of perceived subjectivity. Additionally, none of the identified studies, either in favour of or against using perceived subjective criteria, studied the quality of decision-making. Hence, decision-making comprising the use of perceived subjective criteria is not inferior to decision-making limited to the use of perceived objective criteria. Conversely it can theoretically be superior, but this is also not shown by the identified studies.

Patient's quality of life

The patient's quality of life is another criterion which is mentioned in some studies (Haslé-Pham et al., 2005; Späth et al., 2003; Walkom et al., 2006). Späth et al. (2003) hypothesized that the importance of patient's quality of life is derived from a potential positive effect on the hospital's external "image". This means, that they assumed that an increase of patient's quality of life leads to a positive external opinion about the hospital and in consequence to a higher attractiveness for new patients.

However, they did not further challenge or question the importance of this criterion. In fact, the importance of patient's quality of life is not challenged by any of the identified studies. Haslé-Pham et al. (2005) concentrated in their study on two specific criteria: medico-economic studies and patient reported outcome studies, covering patient's quality of life information. Hospital formulary committee members were very interested in both criteria but the influence on decision-making was only moderate. The authors of this study explained the high interest but low impact scenario with the lack of methodological knowledge by the hospital formulary committee members which is needed to make the right interpretations. Except for the potential positive impact on the hospital's reputation, none of the studies explained a rationale why patient's quality of life information could be of importance for decision-making. Thus, the importance of this criterion is not clear.

Relationships to the pharmaceutical industry

The influence of the pharmaceutical industry on the decision-making process cannot be a direct one, since representatives of the industry are not members of the hospital formulary committees. Still, there is an indirect influence due to relationships between the industry and the hospital or single members of the formulary committee, such as sponsorships or clinical studies. The impact on decision-making of such relationships and the relative importance of this criterion is vaguely described in the literature. Only three of the studies (Dranove et al., 2003; Jenkins & Barber, 2004; Späth et al., 2003) picked this topic as a theme and two out of three studies used qualitative research methods with the possibility to get more in-depth information on a topic with high sensitivity. The study by Dranove et al. (2003) which used a survey as the research

method, counted the number of sales force visits and identified a positive correlation between this and the possibility of making a positive adoption decision for a pharmaceutical drug. The research method did not provide any chance to analyse this phenomenon more thoroughly and to find an explanation for the impact of sales force visits on decision-making.

Späth et al. (2003) recognized that relations between the pharmaceutical industry and the decision-makers influence the decision of those committees. An explanation provided by the authors of the study is the applied study method. Späth et al. (2003) used qualitative interviews and content topic analysis which appears to be a better research method for this sensitive topic of drug funding decision-making compared to pure quantitative approaches. Unfortunately, they neither explained the level of influence on decision-making nor the reason why decision-makers are influenced by those relationships.

More insights on the possible influence of relationships between the industry and hospital formulary committees provided a third study by Jenkins and Barber (2004), which showed that hospital formulary committees seem to adapt their discussion behaviour dependent on the relationship between the industry and the hospital. This does not mean that such a relationship impacts a decision always positively. Pressure from the industry's sales force or potential bribing was seen critically and usually led to a more rigid evaluation of the pharmaceutical drug.

Decision-making guidelines

The hospital formulary committee decision-making process to list pharmaceutical drugs is sometimes regulated by hospital guidelines. Decision-making guidelines exist in order to inform members of a hospital formulary. They are supposed to make the decision-making process transparent, which can be challenged due to the fact that most of the guidelines are not very precise in their regulations and leave a lot of space for interpretation (Fijn et al., 1999; Plet et al., 2013). Those guidelines can include a description of the decision-making process, roles, responsibilities and decision-making criteria as well as the relative importance of such criteria. The existence of decision-making guidelines varies from country to country and hospital to hospital. Most of the

time there is no guideline and in cases where a guideline is available, the criteria which should be used in the decision-making process are often not explicitly mentioned or there is no information on relative importance (Martin et al., 2003; Mittmann & Knowles, 2008; Plet et al., 2013).

Knowledge sharing

The majority of drug funding requests to a hospital formulary committee are accompanied by a documentation package, which is supposed to provide information for each case to the members of the committee. This documentation package is compiled and then distributed to all members of the formulary committee to inform decision-making (Haslé-Pham et al., 2005; Jenkins & Barber, 2004). It includes clinical trial results, additional medical publications, relevant guidelines and the application form of the pharmaceutical company although the concrete content varies. The information sources for evidence in the documentation package varied depending on the country. Frequently official health technology assessment agency (such as NICE in the UK or G-BA in Germany) reports, published literature and published literature sponsored by industry were brought up as primary information sources (Williams & Bryan, 2007). Odedina et al. (2002) also showed that hospital data was considered as an important source for pharmacoeconomic analysis.

Two studies confirm the leading role of a pharmacist to compile this documentation package (Haslé-Pham et al., 2005; Jenkins & Barber, 2004), whereas the other studies do not mention the responsible person for the documentation. The studies usually did not further investigate the importance of the provided documentation package and the impact on the decision-making process. This is relevant due to the possible dominance of pharmacists regarding the influence on the content of the documentation package shown in the two studies mentioned. If the documentation package had a strong influence on decision-making, the pharmacists automatically would have a strong influence on decision-making, too. Decision-makers seem to have concerns with the level of available information in advance of a committee meeting (Gibson et al., 2005). They criticized the short timeframe between availability of information and the decision-making as well as the completeness of information. Again, both factors are mainly

influenced by the person who is in charge of compiling the information. If some decision-makers have less information on a case, this leads to uncertainty and in consequence decreased involvement of the affected decision-makers in the discussions (Gibson et al., 2005). Hence, knowledge sharing has strong impact on the outcomes of the decision-making process, although this phenomenon is only rarely investigated.

Advocates and power relationships

Several studies (Alsultan, 2011; Fijn et al., 1999; Gallego et al., 2009; Gibson et al., 2005; Janknegt; 2001; Jenkins & Barber, 2004; Motheral et al., 2000; Wirtz et al., 2005) revealed the existence of an advocate as an important decision criterion. In this context an advocate is meant to be the person who supports the drug addition to the formulary. This can be a physician who is then taking over the role as a patient advocate or some committees even invite external representatives to present their case. Partly this is endorsed by a study by Fijn et al. (1999) which highlighted the strong influence of hospital pharmacists on decision-making, confirmed by 42% of the committees who participated. Alsultan (2011) also confirmed the impact of single members of a hospital formulary committee such as influential physicians or pharmacists on the decision-making process. Considering these studies it seems that influential hospital formulary committee members (Gallego et al., 2009) can have significant impact on decision-making.

One study does not fully support the influence of such criteria (Motheral et al., 2000). Here the individual demand for a pharmaceutical drug by a physician or patient only came up with a medium importance score. However, Motheral et al. (2000) primarily surveyed formulary committee members of health maintenance organizations (HMO) which usually deal with more than one hospital. Additionally the respondents were mainly pharmacists (three-fourths) and the results were not discussed afterwards which only led to the results of the quantitative survey. These study characteristics and the focus only on the USA might be the explanation for a different outcome compared to other studies many of them conducted in Europe.

Except for two studies (Dranove et al., 2003; Gibson et al., 2005), no other study explicitly looked at the motivation of decision-makers, interpersonal factors as well as power relationships between different hospital formulary decision-makers. One main outcome of the Dranove et al. (2003) study, which concentrated on Pharmaceutical & Therapeutics Committees of Managed Care Organizations (MCO), has been the insight on the importance of working relationships in the respective organizations. The study revealed different objectives by decision-makers in the committee depending on whom they report to and how their yearly performance goals have been determined. This outcome was confirmed by Gibson et al. (2005). Participants in their study doubted a true representation of member's opinions due to the fact that some formulary committee members reported directly to other more senior members. Formulary committee members were reluctant to discuss against the opinion of their bosses.

Power relationships between individuals are not the only factors driving the motivation of hospital formulary committee members. Another result of the Dranove et al. (2003) study is the impact of the Pharmaceutical & Therapeutics Committees' size which can negatively affect an adoption decision if the committee is larger. The issue here is presumably the difficulty to reach a consensus in a bigger group or in a group with more diversity in terms of the represented functions. In contrary, participants in the study by Gibson et al. (2005) described a "feeling pressured to conform and reluctant to vote in opposition [...] or to express dissent [...]" (p. 2359). This indicates that groups as such do influence decision-making and that once the majority of the group seems to go into one direction, it becomes harder for other group members to go into a different direction. This dynamic even increase if some group members are more dominant in their roles, for example, in terms of their rhetoric capabilities (Gibson et al., 2005) or due to the power relationships as mentioned before. A further exploration of these aspects will be done in section 2.3.3.

Despite the interesting outcomes of the Dranove et al. (2003) study, the results were not further discussed with the respondents, which is derived from the use of a survey research method and the targeted survey respondents. It was limited in providing

detailed information which is also remarked by the authors of the study. However, due to the named reasons the results of the study might only show a small representation of the decision-making reality, but they still provide the perspective of the pharmacy directors.

In contrast, the research approach by Gibson et al. (2005) was completely different. The use of a qualitative case study and interviews as the research method enabled the authors to gather in-depth information on the relevance of power relationships in the decision-making process. Additionally, the mixture of job functions in the conducted interviews was much broader and did not only focus on pharmacy directors, but included representatives from administration and medical functions. This approach made it possible to gather a heterogeneous picture of the different hospital formulary committee perspectives on the decision-making process.

2.2 Construction of a preliminary hospital formulary decision-making framework

The first part of the literature review has shown that hospital formulary decision-making starts with the individual preferences of the formulary committee members. Those preferences are based on the decision criteria sets which differ individually and which are the basis for the subsequent group decision-making process. In this process the individual preferences of each member are discussed with the other members of the formulary committee. Depending on group decision-making mechanisms discussed in detail in the next section, members align their individual preferences which finally lead into a consensus group decision (Figure 13).

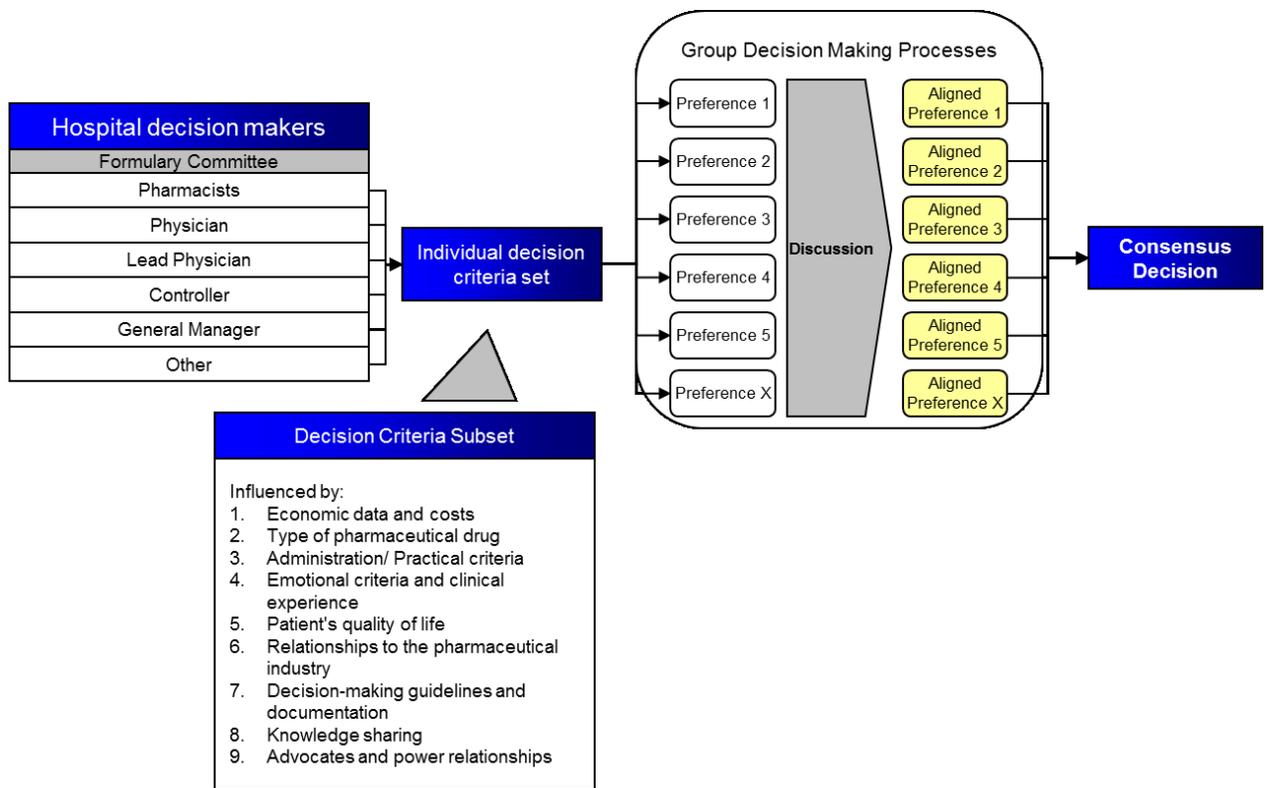


Figure 13: Preliminary hospital formulary decision-making framework.

Different aspects of this preliminary hospital formulary decision-making framework need to be looked at in detail. For example, there is no clarity on the importance of individual formulary committee members for the decision-making process in Germany. It has been shown in the literature review that pharmacists most likely have a central role, but there is no evidence for Germany. In addition, the impact of other groups, such as physicians, general managers or financial administrators is not apparent. There are hints that physicians play a bigger role in formulary committees decision-making and that there is less impact by general managers or financial administrators, but this has also not been shown for the German context.

Current research also lacks information on the transition from the individual decision criteria sets to the aligned preferences and the final group decision. Besides efficacy and safety of a pharmaceutical drug, the following thematic clusters were identified during the systematic review in the previous sections:

1. **Economic data and costs:** this includes health economic evaluations, budget impact calculations and acquisition costs.
2. **Type of pharmaceutical drug:** differences in the decision criteria subsets in dependency of the type of pharmaceutical drug, such as generics or orphan drugs.
3. **Administration / Practical criteria:** advantages or disadvantages in the practical application of a certain drug, considering the local circumstances of the hospital.
4. **Emotional criteria and clinical experience:** including treatment experience from colleagues or other hospitals, decisions taken by other formulary committees or anecdotal stories from other hospital formulary committee members.
5. **Patient's quality of life:** impact of a treatment for the patient's life and the respective meaning for the decision-making process.
6. **Relationships to the pharmaceutical industry:** indirect impact of relationships between members of the formulary committee and the industry.
7. **Decision-making guidelines:** influence of guidelines which provide rules and recommendations for the decision-making process.
8. **Knowledge sharing:** impact of the compiled "evidence" and facts about the discussed product and the influence of the pharmacist who usually compiles this evidence.
9. **Advocates and power relationships:** individuals with a higher impact on the decision-making process due to several reasons, such as hierarchical dependencies, role of the formulary chair, responsibility for the creation of case documentation.

The literature review showed that current research partly identified the applied decision criteria but did not assess the relative importance of those. Hence, the preliminary hospital formulary decision-making framework also lacks information on the relative importance for the different decision criteria.

Additionally, decision-making theories or models were not considered and research focused only on the practical part of hospital formulary committee decision-making. It was necessary to conduct a second systematic literature review on theories and models for objective versus subjective decision-making as well as group decision-making. The results of this second literature review were used to adapt the preliminary hospital formulary decision-making framework.

2.3 Group decision-making models and theories

Figure 14 shows that the first systematic literature review was conducted on healthcare and hospital formulary decision-making and that the results were used to design a preliminary conceptual framework. The following sections will focus on theories and models to improve the conceptual framework.

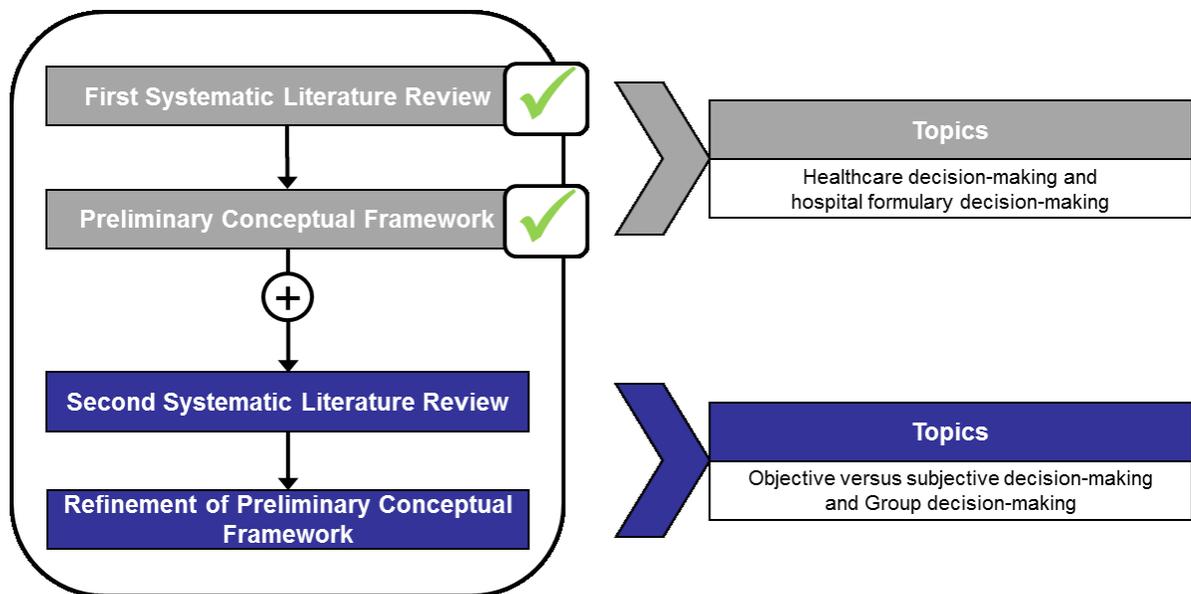


Figure 14: The second systematic literature review.

2.3.1 Search strategy

The second literature review was conducted similarly to the systematic review done in the first step. A search via *EBSCO* with general search terms (described later) was conducted on the following databases: *Business Source Corporate Plus*, *Medline* and a searching via *Science Direct* with limitation to the following sources: *Business*, *Management and Accounting*, *Decision Sciences*, *Nursing and Health Professions*, *Psychology*, *Social Sciences*. For the resulting list of 6,879 papers all abstracts were then screened for relevance concerning the review's goals. This resulted in a list of 536 papers which were partly read and assessed in regards to inclusion and exclusion criteria described later. The reference lists of these papers were then used to identify further publications pertinent to the review's goals which had not been identified through the

first procedure. Again, their abstracts were screened, doubles eliminated, resulting in a total of 67 publications for this part of the literature review. Figure 15 is showing this as an overview.

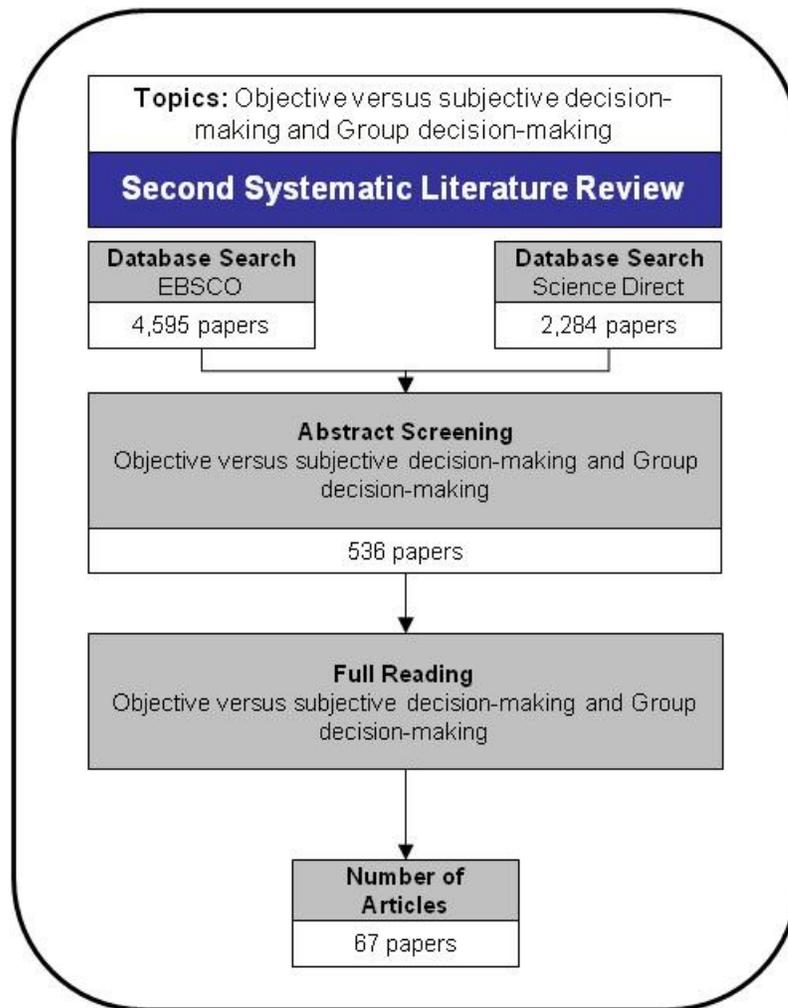


Figure 15: Literature review on group decision-making and objective versus subjective decision-making.

EBSCO and Science Direct

In a first step the search terms used in EBSCO and Science Direct on all abstracts were different combinations on "group decision-making" or "objective" and "subjective" and "decision-making"

Inclusion and exclusion criteria

Table 4 shows the inclusion and exclusion criteria, which are explained below.

Topic	Inclusion criteria	Exclusion criteria
Study topic	decision-making of groups including a research focus on power relationships, group dynamics, role of individuals, knowledge sharing and multi-criteria decision-making, rational decision-making	medical research on decision-making, mathematical models of decision-making, research on individual decision-making without focus on objective/subjective criteria
Timeframe	all research since 1990	research before 1990 (exception for seminal texts)
Research type	qualitative and quantitative research in scholarly peer reviewed journals, theses, clearly described research methodology, literature reviews, books	qualitative and quantitative research in grey literature (except theses), unclear study methodology, opinion papers
Language scope	English or German	all other languages

Table 4: Inclusion and exclusion criteria used in the second literature review.

Study topic

This second literature review considered research on decision-making of groups including a research focus on power relationships, group dynamics, role of individuals, knowledge sharing and multi-criteria decision-making. The first systematic review showed that hospital formulary decision-making is always a group activity, in which individuals need to find a consensus on a complex decision scenario. The complexity of these scenarios is derived from questions which consist of a variety of different criteria. Hence, research on multi-criteria decision-making should be in focus of this review. The first systematic review also showed that some individuals in the hospital formularies have more influence than others and that available information plays an important role in formulary decision-making. In contrast, individual decision-making was mostly excluded from the review due to the fact that in hospital drug funding decision-making always more than one individual is involved.

Time Frame

All studies since 1990 were considered in order to have a more recent picture of research in this field. The researcher was aware that research on group decision-making has been conducted long before 1990. However, the researcher also assumed, if decision-making theories or models are still of relevance, they would be referenced in research published in the last 24 years.

Research type

In order to look at research with a high quality standard it was decided to only consider research published in academic journals and seminal texts. For this reason grey literature and pure opinion papers were excluded. If the study methodology did not seem to be clear, the research was also not considered for the review.

Language scope

Due to the language limitations of the researcher the language scope was limited to research done in English or German language.

Referenced research papers

In order to complete the picture of relevant research work, all abstracts of referenced research papers of the resulting list of papers were also screened for further indication that the respective paper is looking into decision-making of groups including a research focus on power relationships, group dynamics, individual roles, knowledge sharing and multi-criteria decision-making. If a reference matched these criteria it was fully read and inclusion and exclusion criteria were used to determine the relevance of the paper. Due to the long history of general decision-making research, the researcher decided to allow seminal texts to be included on the review even if they were published before 1990. Research was considered to be seminal if it was cited in two or more of the papers included in the review. Additionally all citation “branches” and sub-branches of all relevant papers have been assessed in the same way.

Appendix 2 shows the final list of papers from this second literature review.

2.3.2 Objective versus subjective decision-making

In traditional behavioural decision-making research, emotions and other subjective factors are often seen as additional, external factors which influence an objective decision-making process, which is often equalized with rational decision-making (Loewenstein & Lerner, 2003; Peters, 2006; von Neumann & Morgenstern, 1947). Those studies argue that the influence by subjective factors can be indirect, for example, by changing the perception of probabilities of decision alternatives. This means, the decision-maker (unconsciously) uses subjective factors to change the probability that a perceived objective criterion is true. Or it can be direct with increasing emotional intensity which results in an increasing impact on the objective decision-making (Loewenstein & Lerner, 2003). One example for high emotional intensity would be the case when a doctor treats a relative.

That research is based on the assumption that the cognitive process of decision-making does not necessarily need subjective factors, such as emotions, but emotions do exist and can influence this process. Likewise, emotion is even seen by some traditional behavioural researchers as a factor which potentially falsifies an objective decision-making process (Sloman, 1996; Kahneman, 2003). This would only be true, if real objectivity did exist. More likely is that perceived objectivity is an attempt to provide an accurate representation of reality. In this case, all factors, either perceived objective or subjective, should be taken into consideration for decision-making. In the author's view, this is the only way to safeguard that all possible representations have been evaluated and to prevent the exclusion of potential valuable information on reality.

Most of the traditional models of objective or rational decision-making require a comprehensive knowledge of all possible alternatives and assume a world which can be fully predicted (Simon, 1978). As shown in the first systematic literature review, hospital formulary decision-makers almost always have to deal with lack of information on a new pharmaceutical drug, even for perceived objective information, such as clinical trial data. And they cannot perfectly predict the consequences in case the hospital uses the drug. Hence, cases where the decision-maker in the hospital has comprehensive

knowledge hardly exist and consequently the traditional models of objective or rational decision-making do not apply. Even in an ideal case where comprehensive knowledge about a decision task exists, decision-makers might be cognitively limited to process all the information leading to an approximation but often not perfect solution. This concept is called *bounded rationality* and is based on seminal work of Herbert Simon (1965).

Further research concentrated on the assumption that the concept of *bounded rationality* is an accurate description of human decision-making processes. Kahnemann and Tversky (1974) showed in their research that biases in uncertain decision-making situations exist which people try to solve using *heuristics*. However, in their opinion the use of *heuristics* often leads to suboptimal outcomes, inferior to logical analysis. This view was criticized by other researchers and led to an alternative concept called *fast and frugal heuristics* (Gigerenzer & Todd, 1999) where heuristics are defined as "a strategy that ignores part of the information, with the goal of making decisions more quickly, frugally and/or accurately..." (Gigerenzer & Gaissmaier, 2011, p.454).

Besides the concepts on the use of heuristics, the unrealistic assumption about complete knowledge and perfect predictability has also led to another main research stream with a different opinion on the quality of subjective factors (Fehr & Gächtner, 2002; Han, Lerner & Keltner, 2007; Lerner & Keltner, 2000; Lerner & Tiedens, 2006; Pfister & Böhm, 2008; Pillutla & Murnighan; 1996; Zeelenberg, Nelissen, Breugelmans & Pieters, 2008). Here, subjective factors are not categorized as a distortion to the cognitive and objective process, but as an essential part of decision-making.

Research has been conducted in healthcare, especially for physicians or nurses, which confirm that subjective criteria such as intuition are a basic and important component of decision-making processes (Benner, 1984; Benner, Hooper-Kyriakadis & Stannard, 2011; King & Appleton, 1997). Intuition is particularly used when the time for decision-making is short and the task is difficult. In contrast, if the decision-maker has enough time and the task is simpler, the use of an analytical process is preferred (Hammond, 1996, 2000; Pixley, 2004; Zinn, 2008). This is due to the use of assumptions and varying

quality of data. Subjective factors help people to reduce uncertainty by reducing a decision from a highly complex task to a task with less complexity. This simplification can even lead to better outcomes than pure objective decision-making. Research in the financial sector concluded that the stock market experts seem to be overwhelmed by the quantity of available information which they used for their financial analysis and therefore did not perform better than the lay people group (Gigerenzer, 2007). However, other recent qualitative studies from the financial sector, such as Fenton-O’Creevy, Soane, Nicholson and Willman (2011), confirm that experts use a mixture of perceived objective and subjective factors. Most of the studies in the first systematic literature review, either quantitative or qualitative research, also showed evidence of this mixture of decision-making criteria.

This constant switch between subjective factors and perceived objective factors has been formulated into a framework by Hammond (1996, 2000) which he referred to as *cognitive continuum*. He argues that decision-making can oscillate on a continuum ranging between intuition and analysis. The *cognitive continuum* model is one main example for a series of models and theories from different behavioural researchers with the common idea of human information processing (which includes decision-making) based on a dual processing system. *System 1* works intuitively and is fast, automatic and unconscious, whereas *System 2* works analytic and is slower, deliberate and conscious (Epstein, 2008; Evans, 2006; Gilovich, Griffin & Kahneman, 2002; Lieberman, 2003; Nisbett, Peng, Choi & Norenzayan, 2001; Stanovich & West, 2000; Strack & Deutsch, Sun, Slusarz & Terry, 2005; Toates, 2006; 2004; Wilson, 2002). In contrast to Hammond and his *cognitive continuum* model, other dual-processes researchers see the two systems in a competitive situation (Dhmi & Thomson, 2012). For example, Evans & Stanovich (2013) constructed a model where initially all decisions are processed by *System 1* and *System 2* verifies the outcome of the *System 1* intuition. If the assessment is not satisfactory, *System 2* might intervene and change the initial decision-making. This view implies an either intuitive or analytic decision-making process which is in contrast to the *cognitive continuum* model and the understanding of how healthcare decision-

making works with a mixture of objective and perceived subjective criteria (Croskerry, 2009; Custers, 2013; Norman, Monteiro & Sherbino, 2013).

In addition, Baltussen and Niessen (2006) mentioned a risk of cognitive overload for the decision-maker who is required to handle and assess a flood of information about a new pharmaceutical drug. Thus, the *cognitive continuum* model fits well for healthcare decision-makers and also provides a rationale for the use of subjective criteria. Due to the complexity of healthcare decisions, the *analysis* side of the *cognitive continuum* is only used in a limited way and many of the decisions are located more on the *intuitive* side. With increasing complexity, for example with high uncertainty of clinical data or a high severity of the disease, healthcare decision-makers supposedly increase the use of their gut feeling (or intuition) and decrease the use of analysis of perceived objective information.

Hammond's *cognitive continuum* model support of a quasi-rationality using a mixture of objective and subjective assessment is positively evaluated in the medical (physicians and nurses decision-making) context in recent publications (Cader, Campbell & Watson, 2004; Croskerry, 2009; Custers, 2013; Norman, Monteiro & Sherbino, 2013; Standing, 2008). In this context Hammond's model is also preferred to other dual-process theories.

2.3.3 Group decision-making

Decision-making in a group is a complex process as many individuals collectively form a decision in a group environment. This adds additional variables which impact the process of decision-making.

Different early studies on group decision-making, much of them conducted in social psychology research, have been done focused on the question how individuals come to decision preferences and how those individual decision preferences conclude in an aggregated group preference (Arrow, 1963; Black, 1958; Lorge & Solomon, 1955; Smoke & Zajonc, 1962; Steiner, 1972). Preference in this context means that one option is preferred over a set of alternative options. In later stages of group decision-making

research, groups were considered as information processing systems and therefore looked at how groups use information for their decision-making (Hinsz, Tindale & Vollrath, 1997). The key concept behind information processing is *social sharedness*. This means the level of information that is being shared between group members. Even more it describes the level of things, such as information, motivations, attitudes, preferences, ideas, cognitions or cognitive processes, being shared between members of a group (Hinsz et al., 1997). *Social sharedness* is not only the central concept behind information processing in groups, but also a central idea for group decision-making.

Social Decision Scheme Theory, and its successor *Social Judgment Scheme Theory*, belong to the most popular models trying to represent how individual decision preferences aggregate into a group preference (Davis, 1973; Stasser, Kerr & Davis, 1989). This concept will be described in more detail in the next section.

Other theories focus on the explanation of variables which could influence either the individual decision preferences or directly the group decision preferences. Much research has focused on the level of information sharing and how this affects group decision-making (Gigone & Hastie, 1993, 2013; Hinsz, 1990; Stasser & Titus, 1985, 1987; Tindale & Sheffey, 2002; Vollrath, Sheppard, Hinsz & Davis, 1989). A related topic with a focus on influential power of individuals in group decision-making is *cognitive centrality* (Kameda, Ohtsubo & Takezawa, 1997). Kameda et al. (1997) defined “members in terms of the degree of centrality in the sociocognitive network. The greater the degree of overlap between the information held by a given member and the information held by other members on average, the greater the degree of centrality for that member” (Tindale & Kameda, 2000, p. 128). They describe the phenomenon that cognitively more central members of a group have a bigger level of influence on decision-making.

2.3.3.1 Shared preferences and Social Decision Scheme Theory

The basic idea of *Social Decision Scheme Theory* is saying that a group decision is the aggregation or combination of the different individual decision preferences of each

group member. The result is a single consensus group decision (Davis, 1973; Stasser, Kerr & Davis, 1989).

Davis (1973) formally describes a set of mutually exclusive and discrete decision alternatives, $a = \{a_1, a_2, a_3, \dots, a_n\}$ and n showing the total number of decision alternatives. He defines two vectors. One is used to describe the probability p that a group member will prefer alternative a , with $p = \{p_1, p_2, p_3, \dots, p_n\}$ and n again showing the total number of alternatives. For example, p_1 is the probability that a group member will prefer a_1 . The second vector describes the distribution of group member's preferences, with a group size of r and with $r = \{r_1, r_2, r_3, \dots, r_m\}$. For example, r_1 describes the number of group members who prefer alternative a_1 . A recent study by Ambrus, Greiner and Pathak (2013) based their research on the seminal work of Davis (1973). The main result of their study shows that group members with a median opinion have the strongest influence on decision-making. This result also confirms the concept of *cognitive centrality* (Kameda et al., 1997) described in more detail later in section 2.3.3.3.

In order to illustrate this more clearly and to put this into the hospital formulary decision-making context, one needs to consider a formulary committee of eight members, that is $r = 8$. In addition the number of decision alternatives is two. a_1 is for the inclusion of a specific pharmaceutical drug and a_2 is against the inclusion of the pharmaceutical drug. For example, in case of $r = \{2, 6\}$, two members are for the inclusion and six members are against the inclusion. In addition, $p = \{0.3, 0.7\}$ denotes that the probabilities are higher for not including the pharmaceutical drug on the formulary list.

One general limitation of the *Social Decision Scheme Theory* is the prerequisite that the decision alternatives need to be discrete. For example, decisions between alternative A or alternative B or yes or no decisions. Davis (1996) therefore reformulated the *Social Decision Scheme* model to a *Social Judgment Scheme* approach which also considers continuous decision-making, such as budget decisions. This will not be referred to in

detail, because hospital formulary decision-making usually consists of discrete decision alternatives (for example, to decide for or against the listing of a pharmaceutical drug – yes or no).

Social Decision Scheme Theory is not a model to fully explain all decision processes. Davis (1973) already mentions in his paper that his model does not consider “personal factors” or “social context”, which is a strong limitation in regards to hospital formulary decision-making. As shown in the first part of the literature review, specifically the personal factors do play an important role during the decision-making process in formulary committees (Dranove et al., 2003; Gibson et al., 2005). It is also questionable if a mathematical model, such as the *Social Decision Scheme Theory*, is an appropriate basis for a framework which should explain hospital decision-making. In contrast, *Social Decision Scheme Theory* was meant to predict outcomes of group decision-making. According to Wirtz et al. (2005), hospital formulary decisions are often accomplished by discussions and consensus and not a math formula which speaks against the applicability of this theory. Likewise, the aim of this research is exploratory and aspires to explain the decision-making process in hospital formulary committees and thus following a different direction. In spite of these limitations, the basic idea of *Social Decision Scheme Theory* can be used for a hospital formulary decision-making framework as it formally explains the aggregation of individual preferences which finally form a single consensus group decision.

2.3.3.2 Shared knowledge

In spite of group decision-making research focusing on preferences, like the *Social Decision Scheme Theory*, other research tried to explain group decision-making from a different angle. Vinokur and Burnstein (1974) assumed in their *Persuasive Arguments Theory* that for a given issue, always a set of arguments exists. A group decision-making process will then be influenced by a sample of this set of arguments. One central assumption they made "was the importance of unshared and unique arguments"(Tindale, Kameda & Hinsz, 2003, p.15). In their view, shared arguments or information had little impact on the decision-making outcomes due to the fact that everyone had that

information already. In their opinion unshared arguments or information influence group member's preferences more strongly.

Other seminal research by Stasser and Titus (1985) led to different conclusions. They showed that the probability that a group recalls certain information increases with the number of group members who know the information. Unshared information is often not brought up during group discussions and shared with other group members, whereas shared information is more often discussed (Hinsz, 1990; Tindale & Sheffey, 2002; Stasser, Taylor & Hanna, 1989; Vollrath et al., 1989). It has also been shown, that group members have a tendency of recalling information better if they have not heard this information the first time (Larson & Harmon, 2007). This can have the effect that members of a group do not have all relevant information to make a comprehensive and informed decision (Brodbeck, Kerschreiter, Mojzisch & Schulz-Hardt, 2007; Mesmer-Magnus & DeChurch, 2009; Stasser & Titus, 1985).

Other factors, such as the individual motivation, also play a substantial role for the question if information is shared between group members or not. Toma, Vasiljevic, Oberlé and Butera (2013) showed in their study that group members who were assigned experts share unique information with others only if the expert's thinking was cooperative. In a competitive situation there is a higher chance that those assigned experts withhold information. Assuming that the different members of a hospital formulary committee have different motivations and that pharmacists have a focus on economic goals whereas physicians have a focus on medical goals, information sharing in hospital formulary committees could be suboptimal.

Parks and Cowlin (1996) showed in a study with small groups that a (mock) proof of a fact's existence during discussions increases the acceptance of these facts compared to other presented information. Hence, the documentation usually prepared and provided by the pharmacist (Haslé-Pham et al., 2005; Jenkins & Barber, 2004) could potentially have a significant impact on decision-making.

Larson, Foster-Fishman and Keys (1994) showed that an increase of group discussion time also increased the chances of unshared information to be shared within the discussion. On the other hand, less time or time pressure can even emphasize the importance of shared information and reduces the willingness of group members to look at more decision options (Janis, 1972; Kelly & Karau, 1999). No research on the importance of time for the hospital formulary decision-makers has been conducted.

2.3.3.3 Centrality

Information sharing has been studied well as shown in the last section. Kameda et al. (1997) followed the idea that a high level of knowledge sharing from one individual group member with other group members lead to more power in the decision-making process. They identified two reasons to believe in this idea. First, Stasser, Stewart and Wittenbaum (1995) learned in their research that expert individuals in a group have a bigger impact on decision-making if their expert role is known to all other group members. Secondly, they suggested that a group member will be rather recognized as an expert in the group if the perception of the other group members about his or her expertise is more established. This is again associated with the presented knowledge about information sharing in the above section. Even if an individual has a lot of unique information, he or she is not necessarily recognised as the expert of the group. Research by Festinger (1964) and Park and Crowlin (1996) have shown that validation of information leads to easier acceptance by the group and in consequence to improve the individual's status as the expert. For example, if (mock) fact sheets are provided to the group members during the discussion which support a specific argument. Conversely, shared information is socially validated through the group. For an individual group member with a high level of shared information this facilitates to be perceived as an expert and thus have more impact on decision-making. Kameda et al. (1997) called this *cognitive centrality* and defined this as the “number of arguments that Member *i* shares with other members” (p. 298). The higher this number is for member *i*, the higher the level of *cognitive centrality* is for member *i*. This finding has also been confirmed by later research where Wittenbaum and Bowman (2004) found that people rate the task capability of others more positively the more shared information they discuss. Kameda

et al. (1997) confirmed in their research that cognitive central group members have a higher influence on the decision-making process compared to group members who are perceived as cognitive peripheral. Cognitive central group members proved to be more dominant in the group discussions and resistant to counter-arguments. Even in minority situations, when the individual group member represented a minority preference, cognitive central group members showed higher influence to the group decision. It was easier for them to steer the decision towards their preference compared to cognitive peripheral group members.

The explanation of cognitive centrality can be applied to the hospital formulary committee context. In the first literature review, Gibson et al. (2005) showed that some individuals in formulary committees have a higher influence on decision-making than others. In some cases this is due to a hierarchical dependence between different members of the committee, but other important factors were also mentioned, such as seniority or a good rhetorical capability. Seniority or a higher level in the hospital hierarchy automatically means an expert distinction and for cognitive central members it is easier to steer decisions (Kameda et al., 1997) which can be suggestive of members having a higher rhetorical capability.

2.3.3.4 Subset of arguments

It was mentioned before that for every decision task, Vinokur and Burnstein (1974) assumed that always a set of arguments exists. Kalven, Zeisel, Callahan and Ennis (1966) also confirmed in their research on juries that members of the jury already have an initial opinion when they hear about the evidence and clearly before they start the jury discussion. Group members preliminary build their individual decision preference which has a dominant function in all subsequent discussions (Greitemeyer & Schulz-Hardt, 2003; Faulmüller, Kerschreiter, Mojzisch & Schulz-Hardt, 2010; Stasser & Titus, 1985). Thus, the subset of arguments of each group member impacts the discussion in two ways: First, it aligns the preliminary decision preference of each group member with all the additional arguments which are brought up during discussion by other group members. Second, the discussion is built upon the subset of arguments and the balance

of arguments determines finally which decision preferences will be chosen or changed (Stasser & Titus, 1985). In addition, Stasser and Titus (1985) concluded that the preliminary decision preferences lead to a selection bias in regards to the information which is used in the discussion and shared with the other group members. People with specific decision preferences advocate their preference by means of using information to defend it.

The last section of this literature review summarized the main concepts and theories of decision-making and more specific group decision-making. Knowledge about fundamental concepts such as intuition, shared preferences, shared knowledge or centrality as well as the importance of objective and subjective decision-making was discussed. Much of the research about general objective and subjective decision-making or group decision-making was done in laboratory-like experiments (Ambrus et al., 2013; Faulmüller et al., 2010; Greitemeyer & Schulz-Hardt, 2003; Larson & Harmon, 2007; Toma et al., 2013; Wittenbaum & Bowman, 2004). Despite this methodological limitation, much of the research conducted in healthcare and hospital formulary decision-making revealed phenomena which can at least partly be explained by the general theories and models discussed in the second literature review.

2.4 Refinement of the hospital formulary decision-making framework

Figure 13 showed a preliminary hospital decision-making framework which incorporated the results of the first literature review. It has been shown that research in the specific area of hospital decision-making is focused on practical issues and lacks theoretical background. The results of the second literature review complete the hospital decision-making framework and add the theoretical component considering ideas and theoretical models from behavioural decision-science and psychology research.

One main result from the first literature review showed, that besides perceived objective criteria, subjective criteria have a strong impact on decision-making, specifically in

cases where the perceived objective criteria is subject to uncertainty. *Dual processing systems*, such as Hammond's *cognitive continuum* model (1996, 2000), represent a good theoretical basis for decision-making in hospital formularies and help to understand the different use of analytic or intuitive decision-making.

According to the *Social Decision Scheme Theory* (Davis, 1973, 1996), group decision-making processes function as a combination of all group members' preferences which are aggregated to form a group response. This mechanism can be observed where healthcare decision-makers face the challenge of making complex funding decisions, often in a group environment. Thus, the general mechanisms of this aggregated function should also be applicable for hospital formulary decision-making. However, Davis' (1973, 1996) model aimed to predict group decision-making outcomes, but this study wants to further explore the group decision-making phenomenon itself. Wrtz et al. (2005) showed that decision-making is not only bound to a fixed relative importance of decision criteria but is mainly impacted by group discussions and other group decision-making phenomena, such as influential individuals or information sharing. This is also indirectly confirmed by the failure of multi-criteria decision-making tools which are not adopted in hospital formulary committees.

Two main theoretical models from behavioural decision-science and psychology research will be added to the preliminary hospital decision-making framework:

1. *Dual processing systems*: Healthcare decision-makers face the challenge of making multi-criteria funding decisions and they use a mixture of analytic and intuitive decision-making. *Dual processing systems* build the basis for a better understanding of the interaction of these two different ways of making decisions (Epstein, 2008; Evans, 2006; Gilovich et al., 2002; Hammond, 1996, 2000; Lieberman, 2003; Nisbett et al., 2001; Strack & Deutsch, 2004; Stanovich & West, 2000; Sun et al., 2005; Toates, 2006; Wilson, 2002).
2. Group decision-making: Most of the time these decisions need to be taken in a group environment including the complexity derived from intra-group dynamics. For example, this constitutes an increased influence on decision-making due to

hierarchical dependencies between group members, dominant acting group members or uneven knowledge sharing between group members (Armstrong et al., 2008; Kameda et al., 1997).

Those two concepts can help to understand hospital formulary decision making (Figure 16). In a first step (Figure 16 “step 1”) every decision-maker (usually a member of a hospital formulary committee) tries to establish their own preference by using a *dual processing system*. In a second step (Figure 16 “step 2”) this preference will be discussed and potentially aligned considering the other members’ preferences to conclude in a final decision. Key theoretical group decision-making concepts, such as centrality (Kameda et al., 1997) or asymmetric information sharing (Stasser & Titus, 1985), have influence on the final decision in step two.

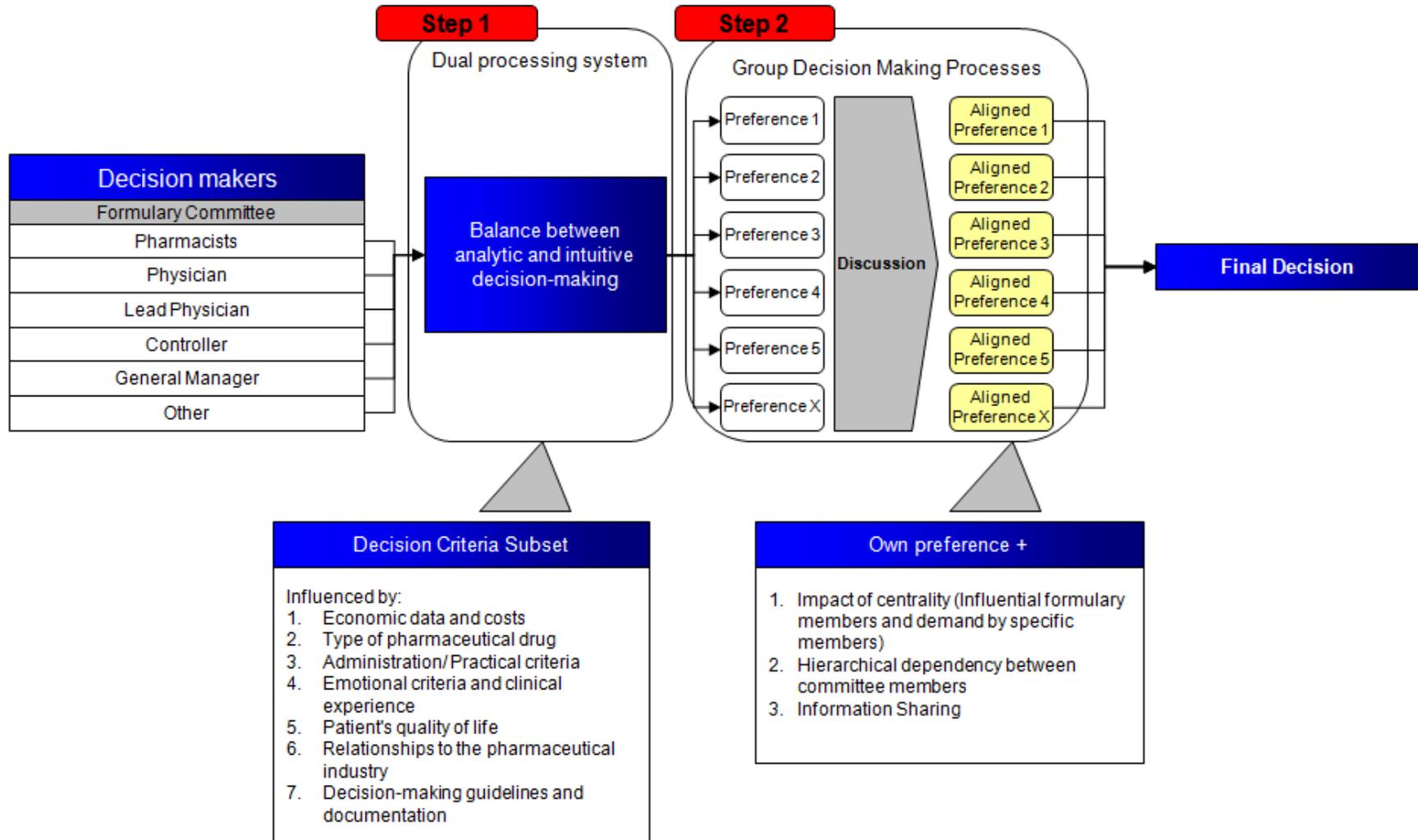


Figure 16: Hospital drug funding decision-making framework.

In order to fulfil research objectives RO-1 to RO-6 this research needs to find some explanations for the decision-making process in German hospital formularies and the applied decision-making criteria. Hence, it is not sufficient to just present and describe research outcomes. The analysis must identify the processes and structures which finally lead to the empirically visible results.

This approach is in-line with a Critical Realist research philosophy which is explained in detail in section 3.3.

The literature review revealed a lack of use of health economic evaluations although hospital formularies seem to have a strong focus on economic measures. Potential explanations are a level of mistrust in complex analyses derived from lack of expert knowledge of the formulary committee members and mistrust in analyses conducted by the industry. In addition, health economic analyses probably do not consider the local situation of the hospital.

It was also shown that decisions seem to be made only based on medical or economic criteria at least officially. Considering the outcomes of this literature review, it can be assumed that hospital formulary committee members also use other criteria than just the technical (medical, economic) ones. In cases where ethical arguments are used, such as saving the life of a patient, the impact of such other criteria can be significant. Presumably members take their decisions “flowing” from an analytical to a more intuitive thinking depending on the complexity of the decision-making process. If it comes to a cognitive overload due to a considerable amount of information, formulary committee members make more use of the intuitive thinking and decision-taking. However, formal documentation or guidelines only mention technical criteria as justification for decision-making. Formulary committee members are reluctant to make the use of perceived subjective criteria official, as they probably think that the use of objective criteria is easier to justify. Despite the use of subjective decision criteria, any criteria related to the administration of pharmaceutical drugs have a low impact on decision-making. Nurses are the concerned group for those criteria and physicians and pharmacists do not seem to take their concerns serious as a consequence of a superiority thinking (Robinson et al., 2010; Thomas, Sexton & Helmreich, 2003; Vazirani, et al., 2005). This is also

being reflected in the small number of nurses as members of the hospital formulary committee.

Ad-hoc priority setting, without a clear prioritization of decision-making criteria, is the normal way of decision-making processes in hospital formularies. Maybe the reason for this is the difficulty to quantify the importance of subjective decision-making criteria and the individuality of decisions. Determination of the relative importance of criteria does not make sense in this case as every decision has individual and different importance levels. Hospital formulary committee members try to identify perceived objective criteria for their decision-making as they might feel a simplification of the decision process.

Some individuals in the hospital formulary committee have a certain level of power for different reasons and they can influence decision-making. One reason could be the fear of some members to jeopardise their relationships with powerful people or another reason might be the “blind” acceptance of an expert role. It was also shown that external groups, such as patient groups or politicians, can have certain levels of power with impact on how decisions are made. This originates from dependencies of formulary committee members to be re-elected or due to ethical pressure (in case of patient groups). Power derived from hierarchical levels seemed to influence decision-making in some formulary committees, because members are afraid of the consequences in case they do not follow their boss.

The literature review showed that relations between the pharmaceutical industry and the committee members influence decision-making. Members appreciate that most of the knowledge on pharmaceutical drugs, especially new treatments, comes from the manufacturer. On the other hand, members are afraid of being accused of bias in their decision-making or bribery or they are just afraid of being misled by statements of the manufacturer. Thus relationships with the industry are a very sensitive topic and most of the formulary committee members accept, but distrust the influence of this relationship on their decision-making (Jenkins & Barber, 2004).

Formulary committee members are not satisfied with the preparation time for the formulary committee meetings and the amount of provided information. This can lead to uncertainty and as a consequence to a decreased active involvement in the decision-making process. Maybe the applicants (physicians or pharmacists) do not realise this as they are the responsible members to provide the information on a pharmaceutical drug. Or they do not want other members to reflect too much on a case.

The following table shows potential processes and structures which were identified in the literature review:

Empirical	Potential structures and processes
Lack of use for health economic evaluations although hospital formularies seem to have a strong focus on economic measures.	Mistrust in complex analyses derived from lack of expert knowledge of the formulary committee member and mistrust in analyses conducted by the industry.
	Health economic analyses probably do not consider the local situation of the hospital.
Officially, decisions seem to be made only based on medical or economic criteria. But formulary committee members admit to use other criteria.	Presumably members take their decisions “flowing” from an analytical to a more intuitive thinking depending on the complexity of the decision-making process. If it comes to a cognitive overload due to a big amount of information, formulary committee members make more use of the intuitive thinking and decision-taking.
Formal documentation or guidelines only mention technical criteria as justification for decision-making.	Formulary committee members are reluctant to make the use of perceived subjective criteria official, as they probably think that the use of objective criteria is easier to justify.
Small number of nurses as members of the hospital formulary committee and administrative criteria have low impact on decision-making.	Physicians and pharmacists do not seem to take concerns of the nurses serious as a consequence of a superiority thinking.
Ad-hoc priority setting, without a clear prioritization of decision-making criteria is the normal way of decision-making processes in hospital formularies.	Determination of the relative importance of criteria does not make sense as every decision has individual and different importance levels.
Some individuals in the hospital formulary committee have a certain level of power for different reasons and they can influence decision-making.	Some members are afraid to jeopardise their relationships with powerful people or they probably accept an expert role without questioning it.
External groups, such as patient groups or politicians, can have certain levels of power.	Dependencies due to a re-election goal or ethical pressure in case of patient groups might lead to power of external groups.
Power derived from hierarchical levels seemed to influence decision-making in some formulary committees.	Members are afraid of the consequences in case they do not follow.
Relations between the pharmaceutical industry and the committee members influence decision-making. Formulary committee members deny an influence of this relationship on their decision-making.	Members appreciate the industry's knowledge on pharmaceutical drugs, but members are also afraid of being accused of bias in their decision-making or bribery or they are just afraid of being cheated by statements of the manufacturer
Formulary committee members are not satisfied with the preparation time for the formulary committee meetings and the amount of provided information.	This can lead to uncertainty and as a consequence to a decreased active involvement in the decision-making process.

Table 5: Potential structures and processes identified in the literature review.

2.5 Gaps identified in existing literature

Different aspects of hospital formulary decision-making were not discussed in existing literature. For example, there is no clarity on the importance of individual formulary committee members for the decision-making process in Germany. It has been shown in the literature review that pharmacists most likely have a central role,

but there is no evidence for Germany. In addition, the impact of other groups, such as physicians, general managers or financial administrators is not apparent. There are hints that physicians play a bigger role in formulary committees decision-making and that there is less impact by general managers or financial administrators, but this has also not been shown for the German context. Current research also lacks information on the transition from the individual decision criteria sets to the aligned preferences and the final group decision.

The literature review showed that current research partly identified the applied decision criteria but did not assess the relative importance of those. Hence, the preliminary hospital formulary decision-making framework also lacks information on the relative importance for the different decision criteria.

Additionally, decision-making theories or models were not considered and research focused only on the practical part of hospital formulary committee decision-making. This is why a second literature review was conducted. However, the conclusions derived from this second review and preliminary incorporated into the hospital drug funding decision-making framework need to be challenged by this research.

3 Research Strategy

3.1 Introduction and problem definition

The literature review identified research gaps and showed that hospital formulary decision-making is not well understood. This research needs to investigate more specifically the role of different functional groups and their impact on decision-making. Additionally, more insights are required on the importance of different objective and subjective decision criteria as well as to understand the theoretical fit of *Dual processing systems* and the mechanisms of group decision-making in the context of German hospitals. Owing to the fact that the topic is very sensitive it seems to be difficult to get access to involved stakeholders (e.g. physicians, pharmacists) and to collect suitable data for research.

Every decision taken in favour of one pharmaceutical drug automatically means a limitation to fund another pharmaceutical drug due to limited healthcare budgets. In essence the decision-maker also decides to limit treatment to patients of the rejected drug, thus bringing the decision-maker into a situation of justifying his decision (Niezen et al., 2009; Wirtz et al., 2005). The influential and political nature of this has an impact on the willingness of drug funding decision-makers to reveal (all of) their real influences. A “hidden agenda” of decision-makers needs to be considered when choosing the right research methodology.

This research fills some of the identified research gaps. In the next sections, the philosophical position and the basic methodological concepts used for this research will be elucidated. Then each activity of the applied research methods will be explained and this will also cover topics such as sampling, validity and methods of analysis. The final section of the methodology and methods chapter will close with comments on ethics.

3.2 Short overview on the overall research design

The following will provide a short overview and rationale for the overall research strategy in order to facilitate a better understanding of the more detailed explanations to follow in chapter 4.

Based on the results of the literature review, a convergent parallel mixed-methods design with a combination of quantitative (survey) and qualitative (expert and market research interviews) research methods was chosen. One of the strengths of a convergent parallel mixed-methods design is the possibility to combine complementary results from quantitative and qualitative research methods (Creswell, 2003).

According to Creswell (2003), the convergent parallel mixed-methods design has four main steps:

1. Concurrent quantitative and qualitative data collection: Independent from each other, the research questions and methods for both parts, quantitative and qualitative, are defined.
2. Separated analysis of the two data strands: Both parts, quantitative and qualitative, are analysed separately and results are presented.
3. Merge the two data sets: Results from both parts, quantitative and qualitative, are merged in a combined analysis. Identify, compare and contrast similar or different themes and synthesize the results. If required, additional analyses are conducted.
4. Interpret the merged data sets: The outcomes of the merged data sets analysis are used to form a better understanding of the research phenomena. It is also important to consider and discuss differences or contradictions between the two analyses of data sets.

In the parallel-databases variant of the convergent parallel mixed-methods design all data sets are analysed separately and only the results of the different analyses are then compared. Hence, step three of the above standard process is skipped. Instead, both data sets are analysed separately (step two) and the independent quantitative and qualitative results are synthesised in the final discussion. This variant is specifically useful if both data strands are used in a complementary manner to achieve a better understanding of a phenomenon (Creswell, 2003).

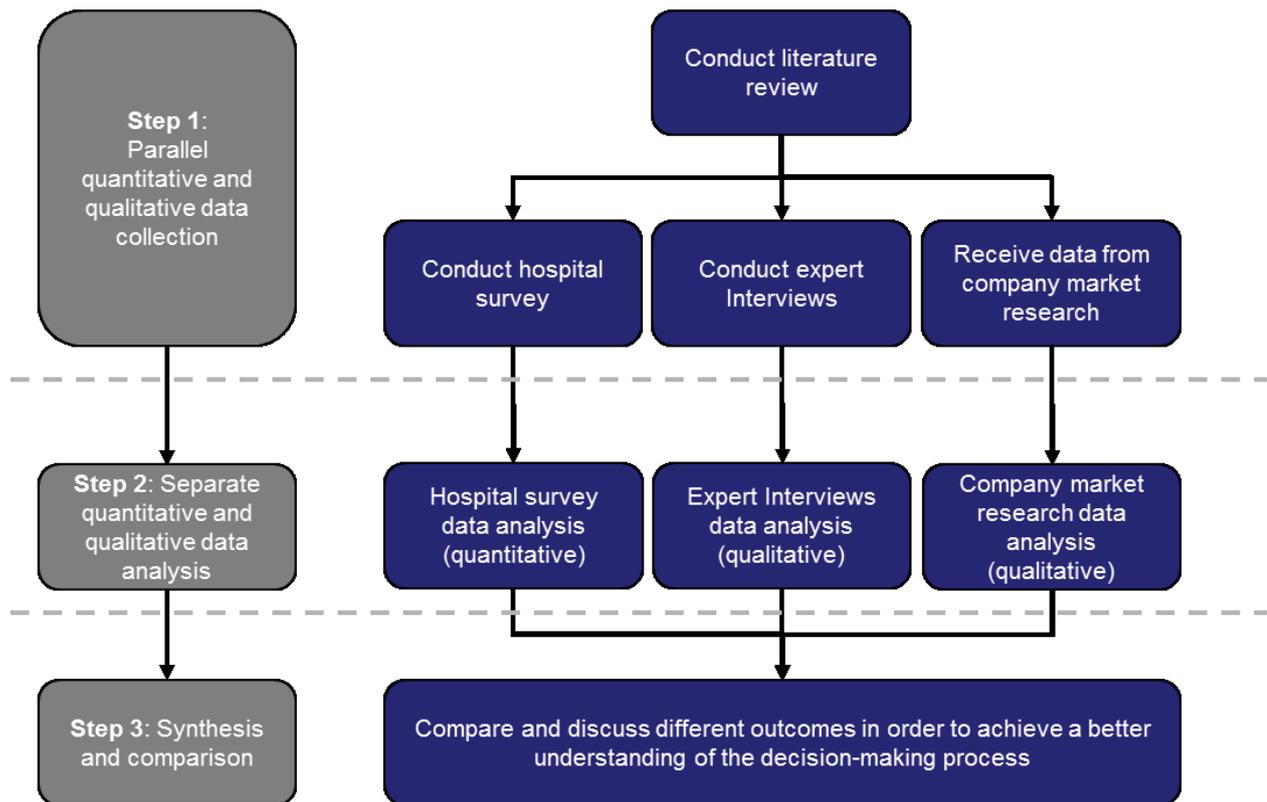


Figure 17: Overview of the convergent parallel mixed-methods design.

The parallel database variant of the convergent parallel mixed-methods design was used for this research and is shown in Figure 17.

3.3 Research philosophy

This section explains the choice of the research philosophy for this thesis. This is important since the research philosophy impacts the whole research project, such as the applied research methods or the way the data analysis is conducted (Collis & Hussey, 2003).

There are two basic philosophical positions: positivism and constructivism. A positivist assumes that an objective reality exists and that a researcher can observe this reality. A constructivist believes that the world consists of (subjective) individual constructed realities (Guba & Lincoln, 1994). Both basic positions have different beliefs in regards to ontology, i.e. the questions of existence and epistemology, i.e. the questions of knowledge. In addition, much research work is based on research

philosophies somewhere in between the two basic philosophical positions, such as post-positivism, critical realism or critical theory.

This research is based on the research philosophy of critical realism. Critical realism was developed by Bhaskar (1978) as an alternative to the existing and established research philosophies. Bhaskar (1978) criticized the strict separation of positivism and constructivism and the resulting difficulties in applying appropriate research methods for business management research.

One of the main differences to other research philosophies is a positivist ontology in connection with a constructivist epistemology. Critical realism knows three levels of reality: the *real*, the *actual* and the *empirical* (McEvoy & Richards, 2006). The *real* describes the underlying structures, objects and mechanisms which generate phenomena. This is the “deepest” level of reality and those underlying structures, objects and mechanisms are not directly observable. The *actual* describes the part of reality which occurs in the background and might be experienced or not. It is a subset of the *real* and consists of the events which are generated by the (non-observable) objects and mechanisms of the *real* (Zachariadis, Scott & Barrett, 2013). The *empirical* is the subset of the *actual* which can be experienced and is therefore primary target of critical realist’s research. It is the goal of a critical realist to experience as much as possible of the *empirical* domain in order to better understand the underlying structures and mechanisms of the *real* domain.

For this research it is assumed that the hospital formulary decision-making process, objectives of decision-makers and power relationships between formulary committee members are part of the *real* domain as they are not directly observable. The decision-making behaviour and applied decision-making criteria are part of the *actual* domain because they are generated or derived from the directly non-observable objects and mechanisms in the *real*. Every specific behaviour and decision criterion which has been observed by this research is part of the *empirical* domain. The *real* domain is perceived by different people with different perceptions and to identify as many of these perceptions as possible leads to a better view onto reality (Perry, Riege & Brown, 1998) as shown in Figure 18. Perry et al. (1998) also

describe a perception as “...a window on to reality from which a picture of reality can be triangulated with other perceptions” (p.554).

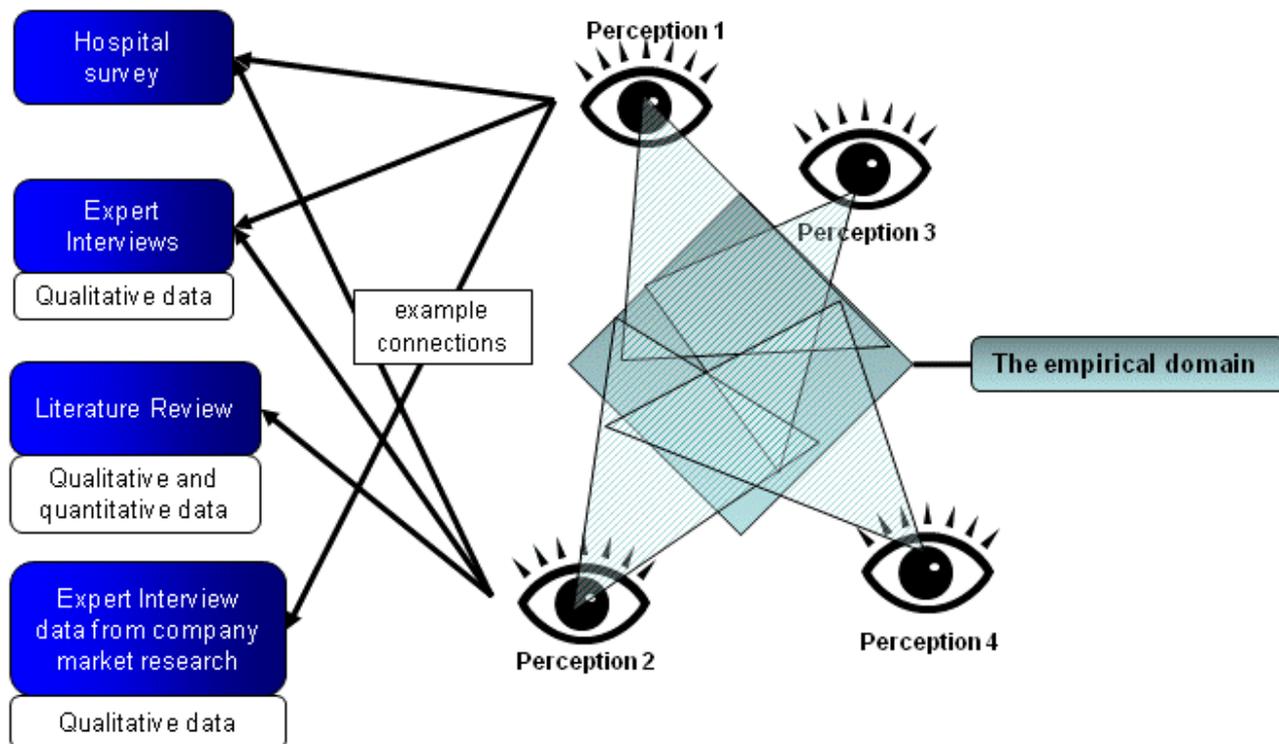


Figure 18: Different people have different perceptions of the same reality (Adapted from Perry et al., 1998).

Consequently, observing and analysing individual decision-maker behaviour and decision-making criteria preferences will lead to a better understanding of what is happening in the *real* domain.

Another characteristic of critical realist research philosophy is *retroduction*, which describes the way of interpreting and analysing information. As indicated above, critical realists assume that the structures and mechanisms of the *real* domain can never be experienced directly, but rather rely on what can be observed in the *empirical* domain. Thus, the information gathered by research can only be a hint of how the underlying structures and mechanisms in the *real* domain function. This shift from interpretation of the observable information to a postulate or model of the underlying structures and mechanisms of the *real* domain, which have caused the observable information, is called *retroduction*. A critical realist therefore always asks

why something has happened in the *empirical* domain and what can be the mechanism behind that (Olson & Morgan, 2004).

The separation of the three levels of reality also means that interpretations, derived from observable information of the *empirical* domain, are never perfect. This is due to the fact that the underlying structures or mechanisms can never be observed directly. Only certain events in the *actual* domain which are caused by such structures or mechanisms can be observed in the *empirical* domain. This also means that the *empirical* domain does not even allow observing all events generated by those mechanisms in the *actual* domain. As a result, these interpretations are always good as long as there are no better interpretations. Better interpretations can potentially come from additional information gathered in the *empirical* domain and then lead to a correction of the latest interpretation. The idea behind this process is an ongoing improved understanding of the *real* domain and its underlying structures and mechanism. Accordingly, this research did not want to show the perfect model of a drug funding decision-making process in a hospital formulary, but the goal was to enhance the understanding of this process. A better understanding of the process provides greater transparency on the complexity of decision making for drug funding decisions. This allows stakeholders to reflect on their process and this enables potential improvements.

Critical realists support the use of mixed-methods research and for many cases the most useful research methods approach is a mixed-methods approach with a combination of quantitative and qualitative methods (Olsen, 2002). This is because quantitative and qualitative research methods have different strengths and weaknesses which can be differently utilized during a research project. Quantitative research methods can be used “to develop reliable descriptions and provide accurate comparisons” (McEvoy & Richards, 2006, p. 71) whereas qualitative research methods have their strength in “illuminating complex concepts and relationships that are unlikely to be captured by predetermined response categories or standardised quantitative measures” (McEvoy & Richards, 2006, p. 71). Thus, a mixed-methods research approach helps to uncover and better understand the objects and mechanisms (here: the decision-making, the objectives of decision-makers and power relationships between formulary committee members) which lead to decision-

making. Independent of the applied research method(s), a researcher needs to consider that the outcome of any research is subject to fallibility due to the incapability of observing the *real* domain (Zachariadis et al., 2013).

This made a convergent parallel mixed-methods design with a combination of quantitative and qualitative research methods the optimal approach for this research project. Strengths of the quantitative research methods were utilized to improve the understanding of structures of hospital formularies in German hospitals, to collect information on the hospital formulary committee members and to achieve a first understanding of their potential relationship towards each other. In addition, different applied decision-making criteria filtered out of the literature review results were tested on their relevance and importance for drug funding decision-making in German hospitals. In a parallel step, the strengths of qualitative research methods were utilized to deepen the achieved knowledge of the literature review as well as to broaden the understanding of specific parts of the overall drug funding decision-making process. For example, in the quantitative survey part a few questions generally tried to clarify the power level of specific hospital formulary committee members and the potential impact of this on the final decision-making. Due to the limitation of surveys to gather deep knowledge on this complex relationship structure, the qualitative interview part was used to improve the understanding on this specific subject. Here it was possible to ask *why* and *how* questions and to challenge answers taken out of the survey part or given directly by interview partners.

Before, it was mentioned that using a mixed-methods approach does not only need justification in terms of the methodological sense but it also needs support by the applied research philosophy. In this case, it was clearly outlined that a mixed-methods approach makes sense due to the different strengths and weaknesses of quantitative and qualitative research methods which were utilized to best address the research questions. The overall research goal, to improve the understanding of the drug funding decision-making process in German hospital formularies, can best be achieved by trying to interpret the observable events in the *empirical* domain and then to design a framework which shows as best as possible the underlying structures and mechanisms in the *real* domain. The aim is not to predict decision outcomes

(positivism) or just to understand the individual beliefs of decision-makers (constructivism), but the goal was to enhance the understanding of the decision-making process in order to allow stakeholders to better understand their own process, compare it to processes of other hospitals and to identify opportunities for improvement.

Despite the advantages of critical realism as the underlying philosophy of this research it is important to reflect on potential disadvantages. For example, retrodution can lead to different results since underlying structures or mechanisms can never be observed directly and the interpretation is dependent on the researcher. Hence, it is crucial to be as transparent as possible in the way retrodution is conducted. Additionally, if two different generative mechanisms in the *real* domain create a similar event in the (observable) *empirical* domain, the interpretation of such results can lead to false conclusions (Zachariadis et al., 2013). This context dependency of events and the potential fallibility in the interpretation of events is always part of critical realism. Another example is the use of quantitative and qualitative research methods which is generally supported by critical realism. If the different methods lead to divergent outcomes, the interpretation of the results can be different (Creswell, 2003; Easterby-Smith, et al., 2008).

The last sections have explained in detail why critical realism as the underlying research philosophy is appropriate and that the preliminary framework derived from the literature review is part of the critical realist approach. This framework allows a tentative examination of the *actual* and *real* domains, which is then adjusted according to additional or contradictory data from this research. Furthermore, it has been shown that a mixed-methods approach in combination with triangulation methods had the greatest potential to be a valuable addition to existing research. Following a more detailed explanation on mixed-methods design and triangulation, the next sections will define the implementation of the research design.

3.4 Mixed methods

The literature review has shown that healthcare decision-making is dependent on a variety of criteria and that it can be very subjective, depending on the individual set of decision criteria (Barasa et al., 2014; Eddama & Coast, 2008; Koopmanschap et

al., 2010; Niezen et al., 2009). It is likely to be different for the different decision levels in a healthcare system. For example, a national decision-maker in a governmental health technology assessment (HTA) institution might look very closely on health economic cost-effectiveness whereas a hospital pharmacist on a local hospital level is likely to primarily consider the impact of the pharmaceutical drug on his budget. This research is focusing only on decision-making in hospital formularies. Conversely, based on the literature review results it is also reasonable to assume that there is a variance of applied decision-making criteria, individual sets of decision criteria and individual power dynamics dependent on the respective hospital formulary.

The individual sets of decision criteria and the variety of involved stakeholders favour a flexible research approach. In order to better understand the decision-making process it is crucial to look at it from different perspectives because of the different decision criteria applied and the different stakeholders involved in the process. From the author's perspective and philosophical point of view (see section 3.3), only this approach makes it possible to get closer to the underlying objects and generative mechanisms which explain the decision-making process. This implicitly recommends a convergent parallel mixed-methods design, which enables the researcher to gather more than just one perspective on the same phenomena (Creswell, 2003; Easterby-Smith, Thorpe & Jackson, 2008). In spite of the advantages of a mixed-methods approach, the use of mixed methods is also considered controversial due to the risk of contradictory results making it difficult to reach a conclusion (Easterby-Smith et al., 2008). The author disagrees regarding the negative connotation with contradictory results. In contrary, contradictory results make it possible to identify new topics or themes which might have been unseen when using only one research method. Additionally, the use of a mixed-methods approach enables possibilities to increase validity through data triangulation or methodological triangulation (see section 3.5)

A mixed-methods approach can also be a challenge from a research philosophy point of view.

Bryman and Bell (2007) stated that qualitative and quantitative methods are based on different epistemological positions, meaning different perspectives on how to acquire

knowledge about the phenomena being researched. Therefore the research philosophy must fit to the concept of a mixed-methods approach (see section 3.3).

Mixed-methods research is not necessarily the better research approach leading to better outcomes and it is subject to the same limitations as mono-method research. If it is appropriate to use and done properly, it has the potential for the researcher to enable access to difficult research areas, to provide a better understanding of phenomena compared to mono-method research and might improve validity when triangulation is used (Bryman & Bell, 2007; Creswell, 2003).

This research uses a mixed-methods design for the following reasons:

1. **Complementarity:** Mixed-methods can be used to get complimentary information on the phenomenon under observation (Creswell, 2003; Zachariadis et al., 2013). Different perceptions of the *real* domain improve the understanding of the underlying objects and generative mechanisms.
2. **Compensation:** A weakness of one research method can be compensated by other research methods (Zachariadis et al., 2013). Critical realists recognize the difference in strengths and weaknesses of quantitative and qualitative research methods. The use of different methods to compensate this is accepted (Zachariadis et al., 2013).
3. **Diversity:** Divergent views of one phenomenon can improve the research outcomes. Again, different views of the *real* domain improve the understanding of the underlying objects and generative mechanisms (Zachariadis et al., 2013).

For this research, especially considering the varying results of former research on this topic, a convergent parallel mixed-methods design is appropriate and a valuable addition to the mono-methods approaches done in the past as it is a new approach to understand hospital formulary decision-making.

3.5 Triangulation

The decision to use a convergent parallel mixed-methods research design was based on two main reasons: the chances of getting better access to the research area and the

belief that a combination of different research methods lead to a better understanding of the phenomena. For example, it was very difficult to find hospital formulary committee members who were willing to participate in an interview. Hence, the use of the online survey made it possible to gather more perceptions of the phenomena from different people. A third important reason was to take advantage of triangulation and hence the possibility of improving validity of the gathered data.

Triangulation means "...using more than one method or source of data in the study of social phenomena" (Bryman & Bell, 2007, p.412). Two different types of triangulation were important for this research: data triangulation and methodological triangulation. Looking for different perspectives of different decision-makers can be referred to as data triangulation and using different research methods can be referred to as methodological triangulation according to Denzin (1970).

Data triangulation helped to strengthen the validity of data. This was done by asking different decision-makers in the hospital formulary (decision-makers with different functions and from different hospitals) to provide information on the research topic. Thus, different perspectives about the same phenomena were collected. In cases of diverse information from different decision-makers, it was possible to identify areas of interest which were not covered by the literature review. Those areas were considered in more detail in the further process.

Three main goals are formulated for methodological triangulation:

1. **Confirmation:** Different methods will be applied to improve the reliability of the findings, thus limiting individual bias of each method (McEvoy & Richards, 2006). In this research some questions in the quantitative part were validated (confirmed) by questions in the qualitative part (e.g. questions on the influence level of different formulary committee members).
2. **Completeness:** Using different methods will result in a higher level of detail as different methods have slightly different perspectives (McEvoy & Richards, 2006). Some information on the drug funding decision-making process is hardly measurable by quantitative research methods whereas some information can be easily collected. This is for example the case with relationships between the different hospital formulary members, which could

be easier explored by using qualitative research methods, such as expert interviews. In contrast, the importance of different decision-making criteria could be well captured by quantitative research methods.

3. **Abductive inspiration or retroduction:** Using different methods also gains a much deeper understanding of the phenomenon and the underlying causal mechanisms (McEvoy & Richards, 2006).

Retroduction is the logical key concept for critical realism (McEvoy & Richards, 2006) as it fits perfectly well to the idea of interpreting observable experience to explain the underlying structures and mechanisms of the *real* domain. In this research, a survey and interviews were used to let hospital formulary committee members describe parts of their decision behaviour. Those descriptions represent events triggered by the generative mechanisms of the *real* domain. And they can only be captured in the *empirical* domain, which is the observable subset of the *actual* domain (Zachariadis et al., 2013). Using *retroduction*, those descriptions were used to conduct an interpretation of the underlying mechanisms of the *real* domain (here: the decision process, the objectives of decision-makers, the power relationships between decision-makers and the decision criteria).

Retroduction is also compatible with the explanatory focus of critical realist research work. The confirmation goal of triangulation makes also sense for critical realists as they assume one social reality which exists independent of the mind. Therefore different observations can be used to challenge each other in regards to the best explanation of the structures and mechanisms of the *real* domain which have caused them. Finally, the completeness goal of triangulation is compatible with a critical realist research philosophy. Different research methods (quantitative or qualitative) can result in different insights on the same reality which can be utilized to improve the interpretations of the *real* domain. Thus, the use of triangulation methods is generally supported by critical realism as the underlying philosophy for this research.

This research used quantitative methods (expert survey) and qualitative methods (expert interviews, company market research data) to collect information on the same phenomena but with a different focus to gain complementary perspectives.

Quantitative methods were used to collect:

- General information on the hospital formulary decision-making process
- General information on the structure of the formulary committee
- The different members of the formulary committee
- Influence of the different committee members on decision-making
- Applied decision criteria.

In order to deepen those insights and to get in-depth information on formulary committee member's roles, influence and motives as well as the relative importance of decision criteria, additional qualitative research methods were used. According to the convergent parallel mixed-methods design, both research methods were used in parallel (Creswell, 2003).

4 Research methods and methodology

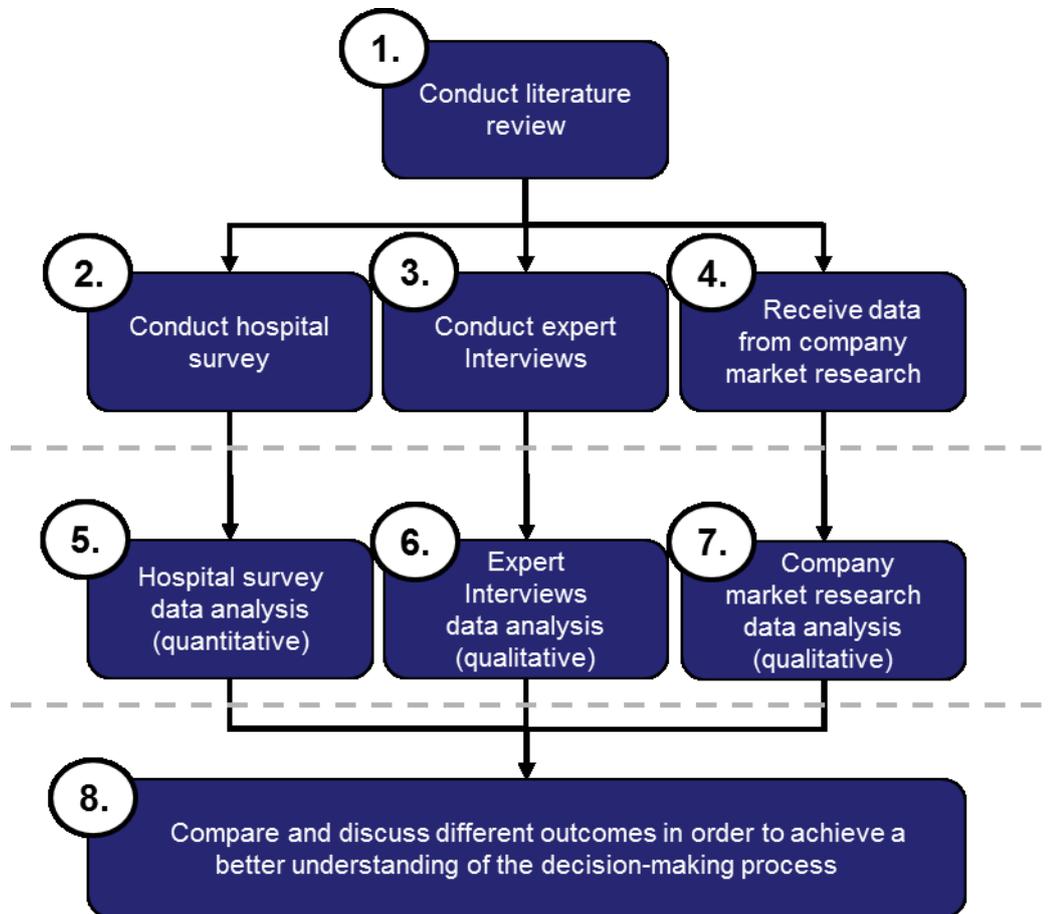


Figure 19: Convergent parallel database variant mixed-methods design.

Figure 19 shows the overall research process which consists of eight main activities with step 2, 3 and 4 being conducted partly in parallel and independent from each other. These activities are described in detail in the following:

4.1 Literature review (step 1)

The literature review consisted of a three-step systematic review. As a first step, hospital formulary decision-making was investigated, followed by a review of healthcare decision making. The latter offered a broader view as it included other decision making levels. Finally, general decision making was addressed to identify basic theories and models relevant for the specific questions of the thesis.

In total the results of the literature review built the basis for creating a research framework, combining some of the general decision-making models with the specific results of hospital formulary committee decision-making (see Figure 16).

4.2 Hospital online survey (step 2)

The second step was a web-based survey (see full survey in Appendix 3) using the service provider SurveyMonkey (<http://de.surveymonkey.com>). This survey was created to identify the basic structures of hospital formularies (e.g. number of participants, frequency of meetings) and to elicit which functions are represented in the committee (e.g. physicians, pharmacists, nurses). In addition the survey asked respondents to rate the importance of different decision criteria (identified in step 1 in the literature review) on a Likert scale and to add and rate additional applicable criteria. The survey also included questions in regards to the perceived influence of different members of the group on the decision process. All questions were formulated based on the literature review results with the intention to answer research questions RQ-1 to RQ-4, but primarily RQ-1 and RQ-2. This means that the survey aimed to add knowledge to the structures of decision-making, such as the importance of each group of the hospital formulary committee. Furthermore, the survey addressed the use and the importance of decision criteria applied in step one of the dual processing system of the hospital formulary decision-making framework (Figure 16).

A cover letter (see Appendix 4) introduced the research project and provided the required hyperlink to the SurveyMonkey project website. The research rationales as well as the research questions were described. This was sent via email to the hospitals in the sample addressing the Head of the Hospital Formulary or other members of the hospital formulary. In order to improve the response rate, all hospitals in the sample were reminded twice to complete the survey. The reminder was sent by email after eight and twelve weeks. In many cases the hospitals responded by refusing participation due to three main reasons (in the order of most received):

1. Participation not possible because of limited time

2. Participation not possible because the hospital generally does not participate in surveys
3. Participation not possible because the area of interest is a confidential, hospital internal area

In those cases, hospitals were marked in the overall sampling and no reminders were sent.

Before the survey was fielded, it was piloted with two hospital formulary committee members. Those committee members were first asked to fill out the online survey and then to have a follow-up discussion. During this follow-up discussion the committee members were asked to provide general feedback on different aspects of the online survey. For example, they were asked if the wording used in the survey was understandable, if questions seem to be relevant to them, if answer alternatives were missing, how long they needed to complete the survey and if the required time was appropriate and feasible in a normal working environment of a hospital formulary committee member. The feedback was mostly positive and only some minor adjustments were done. The most significant change was adding the group of financial administrators (=accountants in other countries) to the answering options of some questions. The required time indicated was around 30 minutes and just at the maximum of what seemed to be acceptable for the two committee members.

Online surveys have advantages, such as faster response, attractive formats and fewer unanswered questions (Bryman & Bell, 2007, Easterby-Smith et al., 2008). But they also can have disadvantages, such as anonymity issues, multiple replies or they are restricted to an online population (Bryman & Bell, 2007). By using SurveyMonkey, possible anonymity issues were not a problem, because respondents were only identified by a unique numerical identifier. This identifier ensured that only one questionnaire was submitted from this address, but at the same time the numerical identifier did not allow a direct identification of the real name or address. In this way, the risk of multiple replies was also reduced. The restriction to an online population was not seen as an issue for this research, since (mostly) all hospitals have access to the internet. At least, all hospitals of the sampling frame had an email address.

4.3 Survey sampling

As said before, the survey had the primary goal to identify basic structures of hospital formularies in Germany. Hence, the inclusion criteria for the survey were very broad. In 2013, Germany had 1,996 hospitals (Statistisches Bundesamt, 2013).

Based on the results of the literature review, pre-discussions with the two hospital formulary committee members and the professional experience of the author, the following inclusion and exclusion criteria for the survey sampling were determined:

Criteria	Inclusion	Exclusion
Number of beds	≥ 300 beds	< 300 beds
Type of institution	Private, public, ecclesial	none

Table 6: Inclusion and exclusion criteria for the survey sampling.

Number of beds

In Germany, the average hospital had 181 beds (Statistisches Bundesamt, 2013), with big university hospitals often having more than 1,000 beds. Table 7 shows a detailed breakdown of number of hospital beds in Germany.

Number of beds	
Hospitals with < 50 beds.....	377
Hospitals with < 100 beds	256
Hospitals with < 150 beds	250
Hospitals with < 200 beds	182
Hospitals with < 300 beds	273
Hospitals with < 400 beds.....	200
Hospitals with < 500 beds.....	137
Hospitals with < 600 beds.....	92
Hospitals with < 800 beds	75
Hospitals with > 800 beds.....	94
Ownership	
Public hospitals.....	596
Free/Ecclesial hospitals.....	706
Private hospitals.....	694
Total	1,996

Table 7: Hospital size and ownership structure.

For the purpose of this research, the minimum number of hospital beds was 300. If hospitals have less than 300 beds the two pilot formulary committee members felt a risk of analysing hospitals which are too specialised. Bigger hospitals include these specialist functions, but provide a broader basis of additional functions. Having this in mind, there would have been a risk of a big variance of different drug funding decision-making processes derived only from this special group of very small hospitals, which are usually organised differently. For example, one major consideration is that small hospitals often do not have a formulary committee. On the other hand, the survey should include also very big hospitals. They usually all have a hospital formulary committee and the size of a hospital was a potential variable with impact on the drug funding decision-making which should be tested.

Type of institution

The sample was not limited in regards to the type of institution. Three main types of institutional ownership exist in Germany: public, private, ecclesial. A hospital can be either owned by a city or state, which is called a public hospital or by a company, a company group or a financial institution, which is called a private hospital. Finally, the church can be owner of a hospital, which is called an ecclesial hospital. Usually unrestricted access to all hospital types exists as long as patients are insured by one of the many health insurance companies. Such insurance is compulsory. For this research, there was no limitation in terms of these different ownership structures. To the contrary, there was a potential value in including these different types of institutions, since they could be a variable impacting the decision-making. It was reasonable to assume that, in regards to drug funding, a hospital with private ownership might have different goals compared to a hospital with an ecclesial ownership. Privately owned hospitals are owned by private investors with the profitability goals. Additionally they are often listed at the stock exchange which increases the pressure on their return on investment. Hence, those hospitals potentially have a strong economic focus due to their ownership status.

The sample was created through self-selected non-probability sampling as the main purpose was exploration (Saunders, Lewis & Thornhill, 2009). This means that hospitals were selected from a complete list of all German hospitals (Rombach Druck- und Verlagshaus GmbH & Co. KG: Deutsches Krankenhaus Adressbuch

(DKA) 2012) who fulfilled the inclusion criteria for the study. The DKA is a publicly available, paid address book of all hospitals including information on the number of beds and the type of institution. It is updated every year. For the survey the DKA 2012 was used. The sampling frame for the survey included 598 hospitals which were contacted and asked via email to participate in the survey.

4.4 Expert interviews (step 3)

The expert interviews were semi-structured and based on the outcomes of the literature review. They followed three main goals of which the first and second ones were more explanatory and the third was more exploratory:

1. To gain a deeper understanding of the use of decision criteria and their relative importance.
2. To gain a deeper understanding of the influence of different formulary committee members and the respective impact on the final decision-making. This addressed the group decision-making process in step two of the hospital decision-making framework (Figure 16).
3. To identify additional topics or issues which have not been considered as a result of the literature review and which are relevant for the research objectives RO-1 to RO-6.

Depending on the specific research goals a structured, semi-structured or unstructured interview type is favourable. Because of the mix of explanatory and exploratory goals the semi-structured interview was considered to be the most appropriate (Saunders et al., 2009). In contrast to pure quantitative research methods, such as a survey, semi-structured interviews are also capable of describing and explaining complex, social phenomena (Sayer, 2000). Thus, they have a central role for critical realist research on decision-making, because of their ability to describe and explain the multifaceted generative mechanisms of the *real* domain (Zachariadis et al., 2013).

All questions were put into an interview guide, which was used to steer the interview but provided enough flexibility in terms of the more explorative information (Bryman & Bell, 2007). Especially in cases, where new themes or topics which were

relevant for the research objectives occurred, the interviewer tried to explore those specific issues.

The interview guide was then tested in two pilot interviews and the respondents of these two pilot interviews were asked questions about:

- the structure of the interview,
- the comprehensibility of the questions,
- the detail level of the questions and
- the length of the interview.

According to the pilot interviewees, only physicians and pharmacists really have the power to influence drug funding decisions. In contrast, the literature review showed that other groups, such as general managers of hospitals or financial administrators can influence decision-making. Thus, challenging questions to verify this expert opinion were added to the expert interview guide. Except for this change the feedback was positive and no additional adaptations to the interview guide were recommended. There were only concerns about the length of the interview. The original interview length was something between 45 minutes and one hour. Both pilot interviewees raised the concern that this will be too long and that it would be difficult to get respondents for the interviews without payment. Based on this feedback the interview guide was streamlined and some questions regarding the structure of the formulary committee, which were also part of the online survey, were removed. The final interview length was then estimated to be between 30 and 40 minutes. This change was seen as acceptable from the two pilot interviewees.

The general interview structure and the content of the separate sections are shown in following (the complete interview guide can be found in Appendix 5):

Introduction

The research project was shortly described as well as the general process of the expert interviews.

Decision-making process

This part included questions and discussions on the decision-making process, the type of decision-making, time related issues around decision-making and the transparency of the process.

Decision-making criteria

The following part included questions and discussions on the applied decision-making criteria. The focus on this part was the use of subjective decision criteria, such as experience or gut feeling. Other questions were related to difficult decision situations or the reason why different decision criteria are used.

Group decision-making

Following this, questions and discussions primarily focused on the topic of decision-making in interaction with other formulary committee members. The influence of formulary committee member's opinions on the decision-making behaviour of the interviewee as well as the level of influence and power of specific hospital formulary committee members were discussed here.

External influence and closing

The interview closed with questions on possible external factors which influence the decision-making behaviour of the formulary committee.

As discussed earlier, this interview guide had the aim of providing a framework for each interview and did not limit the possibilities of the interviewer to freely explore interesting themes or topics. Usually some questions of the interview guide were used to open the discussion. Following this, the interview often developed into a discussion where the interviewer followed up on answers or asked specific questions which investigated the answer of the interviewee. If the specific discussion seemed to be finished, the interviewer returned to the interview guide and used another of the interview guide questions.

The initial contact with all interview participants was done by email. For this purpose a cover letter was developed which shortly introduced the author and the research project. The research goals were explained and a bigger section referred to confidentiality in order to reassure confidence in the project. If there was a positive answer on the participation, one telephone call was conducted in advance to enable the potential participant to clarify questions which were not addressed by the cover letter. For example, some interviewees wanted a verbal confirmation about the anonymity of the interviews. This pre-call was also used by the author to talk shortly about the way the interviewee was selected, as this was in all cases someone from the professional network of the author. Specifically in cases where the author did not know the interview partner personally, this pre-call discussion about the referring

contact was helpful to build up trust (Polit & Beck, 2004). Besides the possibility of asking organisational questions, the main purpose of this pre-call was the arrangement of a potential date and time for the interview.

Most of the interviews were conducted by telephone. One pilot interview was done in person at the hospital. Since literature generally recommends conducting non-standardised interviews face-to-face (Bryman & Bell, 2007; Saunders et al., 2009), the reasons for doing this by telephone are explained in the following. The main reason why telephone interviews were chosen was based on the recommendation of both pilot interviewees. They argued that a physician or a hospital pharmacist has limited time and as such a telephone interview would be easier to conduct than face-to-face interviews.

Another point was the perceived anonymity of a telephone call. They felt more comfortable answering questions about a sensitive topic like decision-making if asked on the telephone.

Considerable planning flexibility was requested by the respondents. Both pharmacists and physicians had challenges to determine a fixed interview time due to their hospital duties and patient emergency cases which of course had priority. For example, four interviews were cancelled on one day and rescheduled. One interview was postponed three times on short-notice due to emergency cases. Having in mind that the interviewees were spread across Germany, this made it operationally impossible to conduct most of the interviews face-to-face.

4.5 Interviewee sampling

The sampling was a non-probability, heterogeneous approach, done by screening of existing professional networks, followed by the use of the snowball-technique to find additional experts. Experts here mean hospital employees with medical, economic or other special knowledge about the topic of listing of drugs to the hospital formulary. In addition they should be active or former members of a hospital formulary committee. This sampling approach is appropriate to use if access to the area of interest is difficult to achieve or the identification of the right cases is difficult (Babbie, 2008; Saunders et al., 2009). Experts from public professional networks,

such as Xing (<http://www.xing.de>) or LinkedIn (<http://www.linkedin.com>), were asked for their interest in participation or if they knew someone else who potentially could be interested. Considering the low level of response to this request, it was clear that access to those experts is challenging. Thus, the professional network of the author was used to identify interested interview partners. If interview partners were identified, they were asked if they knew additional experts who could be interested. After discussions with the two pilot interviewees, three main groups of respondents were identified, who seemed to have the greatest potential of providing valuable input to this research:

1. Medium non-private (public or ecclesial) hospitals with 300-800 beds, due to their potential variety of functional departments and thus their variety of members in the hospital formulary.
2. Large non-private (public or ecclesial) hospitals with more than 800 beds, including university hospitals and their potential focus on scientific goals.
3. Private hospitals with more than 300 beds, due to a potential stronger focus on economic measures.

According to studies about hospital formulary committees (Armstrong et al., 2008; Späth et al., 2003) two sub-groups with potentially different interests are important to answer the research questions: pharmacists and physicians. This was also confirmed by the preliminary analysis of the online survey, where pharmacists and physicians were the only groups with impact on decision-making and the feedback from the pilot interviewees. The minimum requirements were that all participants should be involved in drug funding decision-making in formulary committees. This concluded in a sample of six experts, two different functions in each of the three main groups of hospitals (medium non-private, large non-private, private).

Owing to the central role of pharmacists in the hospital formulary and that physicians have the highest representation in the hospital formulary, the initial sample was extended to one additional expert per main group, either pharmacist or physician. Thus, the final sample for the expert interviews consisted of nine experts which are shown in the following table:

Interview	Respondent Code	Function	Chair	Hospital size (approx. number of beds)	Type of institution (ownership)	Main group
1	B1	Physician	No	580	Ecclesial	Medium non-private
2	B2	Pharmacist	Yes	1,700	Public	Large non-private
3	B3	Pharmacist	Yes	570	Private	Private
4	B4	Pharmacist	Yes	1,100	Public	Large non-private
5	B5	Pharmacist	Yes	1,400	Public	Large non-private
6	B6	Pharmacist	Yes	380	Ecclesial	Medium non-private
7	B7	Pharmacist	No	1,100	Public	Large non-private
8	B8	Physician	No	1,400	Public	Large non-private
9	B9	Pharmacist	Yes	990	Ecclesial	Large non-private

Table 8: Expert interview sample.

The table also shows that one physician for a private hospital is missing and it was not possible to get one additional interviewee from a private hospital (neither physician, nor pharmacist). The researcher then decided to add another interviewee from a public hospital who is not the chair of the hospital formulary committee.

4.6 Market research interviews (step 4)

In addition to the expert interviews, the researcher was able to achieve access to an additional source of information. Market research interviews on a company drug product, conducted with 32 pharmacists, physicians and nurses for a pharmaceutical company during two months in 2013, covered the hospital formulary decision-making process.

The researcher was allowed to use the interview raw data and to extract the specific information on the researcher's questions regarding hospital formulary decision-making.

This fitted well into the mixed methods approach and added additional perspectives to the difficult-to-gather information on hospital formulary decision-making.

Physicians and nurses were separately interviewed in small groups in a studio of the market research company. Every physician and every nurse worked in a different hospital. Two group interviews with nurses and four group interviews with physicians were conducted. Pharmacists, often chairs of a hospital formulary committee and therefore in an exposed position, were interviewed in single interviews. Two interviews were done by telephone and six in a studio of the market research company. Every pharmacist worked in a different hospital.

The following table summarizes the participant structure of the market research interviews conducted in a studio and by telephone. Information on the size or the ownership of the hospital was not given:

Role	City 1	City 2	City 3	City 4	Sum	Type
Physicians	4	4	4	4	16	Group
Nurses	4	-	4	-	8	Group
Pharmacists	-	2	2	2	6	Single
Pharmacists	1	1	-	-	2	Single/Tel.
Sum	9	7	10	6	32	

Table 9: Participant structure (Market research studio interviews).

The transcribed data did not include code names and respondent's answers were just indented. Hence, the researcher assigned code names to allow identification of the different functional groups in the analysis. The following code names were used (Table 10):

Interview	Respondent Code	Type of interview
1	PG1	Physician Group Interview 1
2	PG2	Physician Group Interview 2
3	PG3	Physician Group Interview 3
4	PG4	Physician Group Interview 4
5	NG1	Nurse Group Interview 1
6	NG2	Nurse Group Interview 2
7	P1	Pharmacist Interview 1
8	P2	Pharmacist Interview 2
9	P3	Pharmacist Interview 3
10	P4	Pharmacist Interview 4
11	P5	Pharmacist Interview 5
12	P6	Pharmacist Interview 6
13	P7	Pharmacist Interview 7
14	P8	Pharmacist Interview 8

Table 10: Code names for company market research interviews.

The market research interviews were conducted with the aim to gain information on the procurement process of a specific pharmaceutical product and the general process of decision-making in hospital formulary committees. Thus, the market research inclusion criteria were determined to consider those two aims and the participants were selected narrower than the inclusion criteria envisioned for the expert interviews of this research. However, the researcher considered that this limitation does not reduce the value of the given information but with the objective of being transparent, all inclusion criteria will be shown in Table 11.

Physicians	Nurses	Pharmacists
Head physician, in total 30% should be members of the formulary committee		Head pharmacist and member of the hospital formulary committee for at least two years
Balanced mix of operating theatre, intensive care and emergency care	Balanced mix of operating theatre, anaesthesia and intensive care	
Decision-maker for product x	Experienced users of product x	Procurement and supply of product x
> ten applications of product x per year	> ten applications of product x per year	> five supplies of product x in the last six months
Six anaesthetists with focus on heart surgeries		

Table 11: Inclusion criteria for market research interviews.

There are limitations with this data. The market research interviews had broad objectives and hospital formulary decision-making was a specific topic for part of the interviews. Hence, the data is less detailed compared to the expert interview data. The market research interviewer wanted to better understand the decision-making process, but did not try to identify the underlying mechanisms. Hence, the data is not as rich in regards to information as the expert interview data, but provides supportive information.

In addition, it is not clear which type of hospitals (size or ownership) the respondents were located at.

4.7 Transcript strategy

In order to analyse the expert interviews, the interviews were recorded on a digital recording device and then all data was transcribed. The following main transcript rules of Kuckartz, Dresing, Rädiker and Stefer (2010) were applied:

1. The interviews were transcribed literally and were not summarized.
2. Language and punctuation was slightly flattened to adapt to written German. For example, “This won’t help” would be transcribed as “This will not help” or in German: “Er hatte noch so’n Buch genannt“ would be transcribed as “Er hatte noch so ein Buch genannt“.

3. Longer breaks (approximately breaks longer than 3 seconds) were marked with (...).
4. Vocalisations like „mhm“ or „aha“ were not transcribed. Vocalisations like laughing or sighing were noted down in brackets.
5. The input of the interviewer was displayed as “I” whereas the input of the interview respondent was displayed as “B”. The number of the interview was added behind the “B”. For example, for interview number 5, the input of the interview respondent was displayed as “B5”.
6. Each change between interviewer and interview respondent was shown in a new paragraph.

As indicated before, the interview data from the market research project was already transcribed when the author received it.

A sample transcript of the expert interviews can be found in Appendix 6.

4.8 Validity and reliability

Validity deals with the question if the data which is captured and used for analysis is representative of what one wants to look at (Bryman & Bell, 2007; Collis & Hussey, 2003).

Quantitative researchers use different definitions for validity than qualitative researchers. In quantitative research, validity has three main categories: design validity, measurement validity and inferential validity (Zachariadis et al., 2013).

Reliability describes the possibility of someone else being able to repeat this research and getting similar results (Bryman & Bell, 2007; Collis & Hussey, 2003). Validity and reliability are the main concepts for quantitative research. Qualitative researchers use different aspects for validity and reliability, such as trustworthiness, authenticity and credibility in order to increase the quality of a research study (Creswell & Miller, 2000; Golafshani, 2003; Porter, 2007).

In a convergent parallel mixed-methods design, which is the applied method for this thesis, validity should be considered separately for the quantitative data and the qualitative data (Creswell, 2003).

4.8.1 Validity and reliability of the (quantitative) online survey

Face validity is the minimum level of measurement validity for a quantitative research project. It can be achieved if experts with experience in a specific topic confirm the appropriateness of the research approach and the data sources (Bryman & Bell, 2007). As described in chapter 4, the online survey was tested with two experienced hospital formulary committee members in order to achieve face validity. In addition, a healthcare professional with more than 20 years of experience, who is a Sales Director at a pharmaceutical company and who is responsible for drug funding negotiations with hospitals had been asked to assess the online survey (and also the interview guide for the expert interviews). He reviewed both and confirmed that those measures are appropriate to answer research questions RQ1-RQ4 and research objectives RO1-RO6. Therefore face validity has been achieved.

Pure quantitative research often tries to achieve generalisability or design validity (Bryman & Bell, 2006; Zachariadis et al., 2013). In critical realist research this is problematic (Johnston & Smith, 2010; Zachariadis et al., 2013). Empirical events are observable traces of events in the *actual* domain which are derived from mechanisms in a specific context. External validity then assumes that similar relationships between events in the *empirical* domain can appear under completely different circumstances. From a critical realist view this is not impossible, but cannot be concluded from the observed empirical events. Similar events in the *empirical* domain can occur with similar or completely different generative mechanisms in the *real* domain. Hence, there is no causal relation between two similar events in the *empirical* domain and two similar generative mechanisms in the *real* domain (Zachariadis et al., 2013)

Reliability is a concept which is not applicable from a critical realist perspective. Owing to the critical realist assumption that every perception is fallible, different research could come up with different results. However, also these results are fallible and thus it is desirable from a critical realist perspective to collect as many perceptions as possible in order to continuously improve the understanding of the generative mechanisms of a phenomenon.

4.8.2 Trustworthiness, authenticity and credibility for the (qualitative) interviews

Qualitative researchers have also measurements to prove credibility of their findings. Trustworthiness, authenticity and credibility should help to determine if findings of a qualitative study are “accurate from the standpoint of the researcher, the participant, or the readers of an account” (Creswell, 2003). Multiple methods can be used to ensure the quality of findings and it is recommended to use multiple approaches (Creswell, 2003). In this thesis the following methods were applied: triangulation, rich description, reflexivity and comprehensive data presentation:

Triangulation

The main concept applied is data triangulation as described in detail in the sections before. Using different sources of data, helped to increase the validity of this research. Thus, the sample selection for the expert interviews was crucial. Hospital formulary committee members with different perspectives and goals, such as pharmacists and physicians, were selected for the interviews. In addition, representatives from a variety of different hospital types (private, public, ecclesial) and sizes (380 beds –1,700 beds) were asked during the expert interviews to gain perspectives from as many different sources as possible. The data from the market research project additionally added different perspectives to allow triangulation. As a result, using these different sources to create the themes, led to an increased validity (Creswell, 2003).

Rich description

Results from the thematic analysis were presented with a rich description of the setting and the circumstances. Additionally, different perspectives were provided which created a more realistic picture of the findings (Creswell, 2003).

Reflexivity (researcher’s bias)

During the data analysis, the researcher provided additional explanations, how the interpretation of findings was influenced by the researcher’s background. Due to the fact that the author is a healthcare professional, reflexivity is crucial for credible research (Creswell, 2003).

Comprehensive data presentation

Data was presented in a comprehensive way. This means that besides the regular themes, also discrepant information, which ran contrary to the regular themes, was exposed and discussed. For the reason that all perceptions are fallible, it is essential for the discussion to provide all evidence without any filters. Presenting more than just one perspective makes the findings more valid (Creswell, 2003).

4.9 Time horizon

This research is a cross-sectional study, as it is showing the process for drug funding decision-making (in Germany) at a specific time (Babbie, 2013). The research phase was conducted over a twelve months period. Hence, a cross-sectional analysis is a valid assessment for a point in time. This research does not focus on showing changes over time, which would be a longitudinal study design (Babbie, 2013). Practical experience also shows that changes in drug decision-making are not changing greatly in short time periods and often changes are over a longer term driven slowly by large changes in governmental policy.

The expert interviews showed a variety of perceptions about the same phenomena. This is not only in line with the critical realist research design and data triangulation, but also one primary goal of cross-sectional research (Bryman & Bell, 2007).

4.10 Data analysis

4.10.1 Quantitative data analysis (step 5)

An applied convergent parallel mixed methods design requires the separate analysis of the quantitative and qualitative data (Creswell, 2003). The researcher decided to focus on descriptive statistics for the analysis of the quantitative survey data for two reasons:

Firstly, in critical realism, quantitative methods can be viewed as mainly descriptive due to their methodological inability to uncover the generative mechanisms of the *real* domain and to sufficiently explain complex social mechanisms, such as the decision-making process or the power relationships between formulary committee members (Sayer, 2000; Zachariadis et al., 2013).

Secondly, low willingness to participate in research on this sensible topic and to share insights on the internal process of hospital formulary decision-making reduced the statistical power of the survey data. Hence, the quantitative survey data is a limited, but still a valuable source of information to support the explanation of the underlying mechanisms in the *real* domain. It can help to identify structures (e.g. the structure of hospital formularies in German hospitals) and indicate the importance of applied decision-making criteria (Zachariadis et al., 2013). However, as standalone data it only becomes valuable in combination with other data sources, such as the qualitative expert interview data and the qualitative data from the market research study.

4.10.2 Qualitative data analysis (step 6 and 7)

For the reason that the expert interviews and the market research data derived from different data gathering steps, both data sets were first analysed separately. After that and according to the convergent parallel database variant of a mixed-methods design, both qualitative data sets, as well as the quantitative data set, were compared and discussed in the final discussion chapter.

One qualitative data set was transcribed and the company market research data was already transcribed at the time of reception. Both were (separately) analysed with thematic network analysis (Attride-Stirling, 2001), a specific approach to conduct and structure a thematic analysis (Braun & Clarke, 2006; Miles & Huberman, 1994). The goals were to identify relevant topics or issues according to the research questions RQ1-RQ4 and the research objectives RO1-RO6. It was necessary to decide between an inductive thematic analysis which develops the themes purely from the interview data or a theoretical thematic analysis which works more deductively and uses questions and themes derived from the literature review for the coding procedure (Braun & Clarke, 2006). Because of the inability to observe objects and generative mechanisms in the *real* domain and the resulting risk of fallibility it did not make sense to use a pure inductive or a pure deductive approach. Hence, this research deductively used pre-developed themes from the literature review and the specific research questions, but during the coding procedure additional (new) themes

were allowed. Using this approach, the conclusions on the *real* domain from other research were considered and added to the perceptions from this research.

Thematic network analysis consists of six main steps (Attride-Stirling, 2001) which were followed during the analysis:

1. Code material: Codes represent the basic content of selected data, which are interesting for the phenomenon under research and which show potential themes (Attride-Stirling, 2001; Braun & Clarke, 2006). In this step, all transcripts were read and data clusters were built. First codes were generated to describe those data clusters. Eleven codes were derived from the literature review and the preliminary decision-making framework and two additional ones were identified during the coding process.
2. Identify themes: In the next step, codes which described an overarching theme were cumulated into one group. Following this, the themes were refined to achieve a balance between being specific to avoid repetitions and being broad enough to compile different text segments which share a similar idea. For example, the coding procedure of the expert interviews led to 134 different themes.
3. Construct thematic networks: The themes defined in step two were re-named as basic themes and those which shared larger issues were clustered into organizing themes. Following this, different organizing themes which share a “claim, proposition, argument or assumption” (Attride-Stirling, 2001, p.393) were again clustered into global themes. The claim, proposition, argument or assumption was used as the name of the global theme which represents the “ideas mentioned at the lower level” (Attride-Stirling, 2001, p.393) orientated on the basic themes. This step was finished with the graphical “web-like” (Attride-Stirling, 2001, p.393) representation of the global, organizing and basic themes.
4. Describe and explore thematic networks: This is a first step of the analysis and it includes the description of the thematic network as well as an exploration to identify patterns. The network was used as a guide to go through the original transcripts and to analyse the underlying ideas supported by the respective text segments.

5. Summarize thematic networks: Once the description and exploration of a thematic network was finished, the underlying patterns and ideas were summarized.
6. Interpret patterns: This step combines the outcomes of the thematic network analysis with the research questions. Underlying pattern and ideas which were identified during step four and five were discussed in relation to the research questions RQ-1 to RQ-4.

4.11 Discussion and conclusions (step 8)

The final step of this research incorporated all data (literature review, the online survey, the expert interviews and the market research interviews) into a concluding analysis using data triangulation and methodological triangulation. This helped to confirm, adapt and extend the hospital formulary decision-making framework which was introduced in the literature review chapter. *Retroduction* was used to interpret the observable information from the *empirical* domain, captured with quantitative and qualitative research methods, with the aim to create propositions about the underlying structures and mechanisms of the *real* domain, such as the way step 1 and step 2 in the hospital drug funding decision-making framework (Figure 16) function.

4.12 Ethics

This section refers to the ethical considerations which accompanied this research. It follows the rules of the ethical code book of the University of Gloucestershire (University of Gloucestershire, 2008). Research ethics describe the way the researcher should behave in relation to the rights of the subjects of the research project or other people affected by the research (Saunders et al., 2009). Ethical issues can arise throughout the whole research process (Creswell, 2003). Accordingly, the researcher needs to address and discuss them. Four main areas of ethical principles are important to consider (Diener & Crandall, 1978):

1. **Harm to participants and privacy:** It is the researcher's responsibility to ensure that the collected data and the research does not harm or jeopardize the participants (Bryman & Bell, 2007, Creswell, 2003). A research project in a sensitive context like drug funding requires a high level of confidentiality.

Many hospital formulary committee members would not like to talk openly about their choice of decision criteria (Wirtz et al., 2005). Hence, it is the researcher's responsibility to protect and respect participant's privacy (Creswell, 2003). For example, the data presented in this thesis does not mention any hospital names to make it impossible for external people to trace back the information sources.

All collected raw data from the expert interviews was safely stored on a password protected hard drive. Only the author had access to this hard drive. For the analysis, the data was only used in an anonymous way from the beginning. The different participants were coded without real names. For example, participant number one was coded with "B1". This code was then used throughout the thesis.

All raw data from the online survey was stored on the same hard drive. The online survey was already made anonymous during the data collection. Therefore it was not possible to connect one answer from the online survey to a specific person or hospital. As mentioned before, there was a possibility for the participants to receive a preliminary analysis of the online survey data as a reward for participation. In this case the participants needed to provide an email address. Although this email address could be any email address, this basically connects the answers of the online survey to one specific person. Thus, it was required to also save this raw data on a password protected drive.

All raw data from the market research project was stored on the same hard drive. This data was already made anonymous when the author received the electronic files. Participants were coded without real names, similar to what has been done for the expert interviews. In addition, the author signed an agreement with the market research company, declaring that the author will only use the interview data for analysis connected to this thesis and that he will not try to decode the raw data to identify any of the participants.

With this process, the author is the only one who could connect answers, either from the expert interviews or the online survey, with a concrete person.

All raw data will be deleted with a software tool which makes it impossible to recover, as soon as the thesis is fully accepted by the University.

2. **Informed consent:** It is the researcher's responsibility to be fully transparent towards the participants in terms of the purpose of the research, the participant's role and its possible consequences (Sarantakos, 2005) and to allow participants to refuse participation (Creswell, 2003). The participants should not be deceived and they should be aware about their participation in a research study (Creswell, 2003). Participants were always informed about the research purpose in advance of data collection.

The expert interviews which were part of this research involved participation of adult human experts. In advance of every expert interview, a cover letter with a description of the research project including a section on confidentiality has been sent to the participants. In addition, the author had a telephone call in advance of every expert interview to give the participant the possibility to ask additional questions. Lastly, right before every interview was conducted, the author again explained the purpose of this research, that the interview data will be transcribed and analysed for this purpose and asked the participant to confirm his consent with doing this interview. The interviews were only started if the participant clearly confirmed his/her consent which happened in all interviews. The author knows one of the participants personally. He has no relationships with any of the other interview partners. None of the interview partners were paid for doing the interviews, but there was an offer to all participants to receive some exclusive preliminary analysis from the online survey. Participants were required to provide an email address if they wanted to receive this data.

Regarding the data from the market research project, the participants were already aware that their answers would be transcribed and analysed by the pharmaceutical company for market research purposes. The participants were also paid for their interviews and the interview transcript data was provided without any names to the author. Two written agreements were set up to clarify the use of the market research data for this thesis: one, between the

author and the market research company, which allows the author to use the interview transcripts for analysis in the context of this thesis and another one, between the author and the pharmaceutical company, which also allows the author to use the interview transcripts for analysis in the context of this thesis. Both agreements also regulated the appropriate use of the data and the anonymity of all participants.

Regarding the data of the online survey, the email which was sent out to all hospitals in the sample, also described the research project and the use of the data for this thesis. With the participation in the online survey, people automatically agreed with the use of the data for this research. Participants of the online survey were not paid.

4.13 Limitations

It was already mentioned that face-to-face interviews were operationally less viable due to the geographic spread of the interviewees and also not recommended by the pilot interviewees due to concerns of losing interviewee's willingness to provide in-depth information on the decision-making process. Telephone interviews facilitate the collection of such sensitive data because they allow the interviewees to feel more comfortable because of the perceived anonymity (Hopper, 1992). In addition, there is little evidence that telephone interviews produce a lower quality data than face-to-face interviews (Novick, 2008). However, the focus on the pure interview wording without the consideration of any non-verbal factors, such as gesture and facial expression, can be seen as a limitation for this research (Fontana & Frey, 2005). Hence, for this research this can be seen as limitation although it is a minor issue. Generative mechanisms are identified by the researcher's ability to link the data from the *empirical* domain to structures in the *real* domain which is independent of non-verbal clues (Zachariadis et al., 2013). Another limiting aspect is the general interviewer bias (Saunders et al., 2009). An interviewer has an impact on the interview process, for example, the interviewer can ask questions using different accentuation, tone, gesture and mimic which could have an impact on interviewees and their responses. By using semi-structured interviews and an interview guide to minimize the bias, this risk was limited (Saunders et al., 2009).

Interviews were conducted in German language because this was the mother-tongue of all participants, but for the analysis, the (German) transcripts were translated into English. This resulted in quotes which were sometimes a bit convoluted. It was decided to translate as close as possible to the original German wording in order not to lose any language specific information.

One potential limitation of this study is based on a result of this research. As described more in detail in section 6.4.1, some discussions happen already outside of the hospital formulary committee meeting which potentially impacts the decision-making process. For example, this happens when a small group of people come to an agreement in advance based on these pre-meeting discussions. However, this is not always the case and the impact of these pre-discussions is also not fully clear.

Lastly, all collected data is based on the different perceptions of people involved in the decision-making process and basically fallible. Triangulation should help to increase the chances of getting a more accurate representation of the generative mechanisms of the *real*, but also triangulation itself is fallible because it is based on assumptions and finally relies on the individual interpretation of the researcher.

4.14 Summary

This chapter presented the research strategy and research methodology utilized for this thesis.

In the beginning, the main outcomes of the literature review were repeated and the knowledge gaps in existing literature were discussed in order to conclude with the research questions and research objectives. General concepts, such as mixed-methods research and triangulation were explained since they are basis for the applied research design. The research philosophy needs to match with the applied methods and methodologies. Critical realism fits with mixed-methods research as well as with triangulation and was elucidated before the concrete research design was discussed in detail. The different steps of this research, such as the online-survey, expert interviews or the market research interviews were described including the utilized

sampling approach. This chapter finished with some remarks on ethics and possible limitations of the adopted research design.

The next chapter will describe the data analysis and discuss the results of the analysis.

5 Hospital survey data analysis

5.1 Introduction

The hospital survey data analysis represents step five in the research design (Figure 20). According to the convergent parallel database mixed-methods design (Creswell, 2003), the survey data is analysed separately in the first step and is then combined with the qualitative data in a second step to identify the mechanisms of the *actual* and the *real* domain.

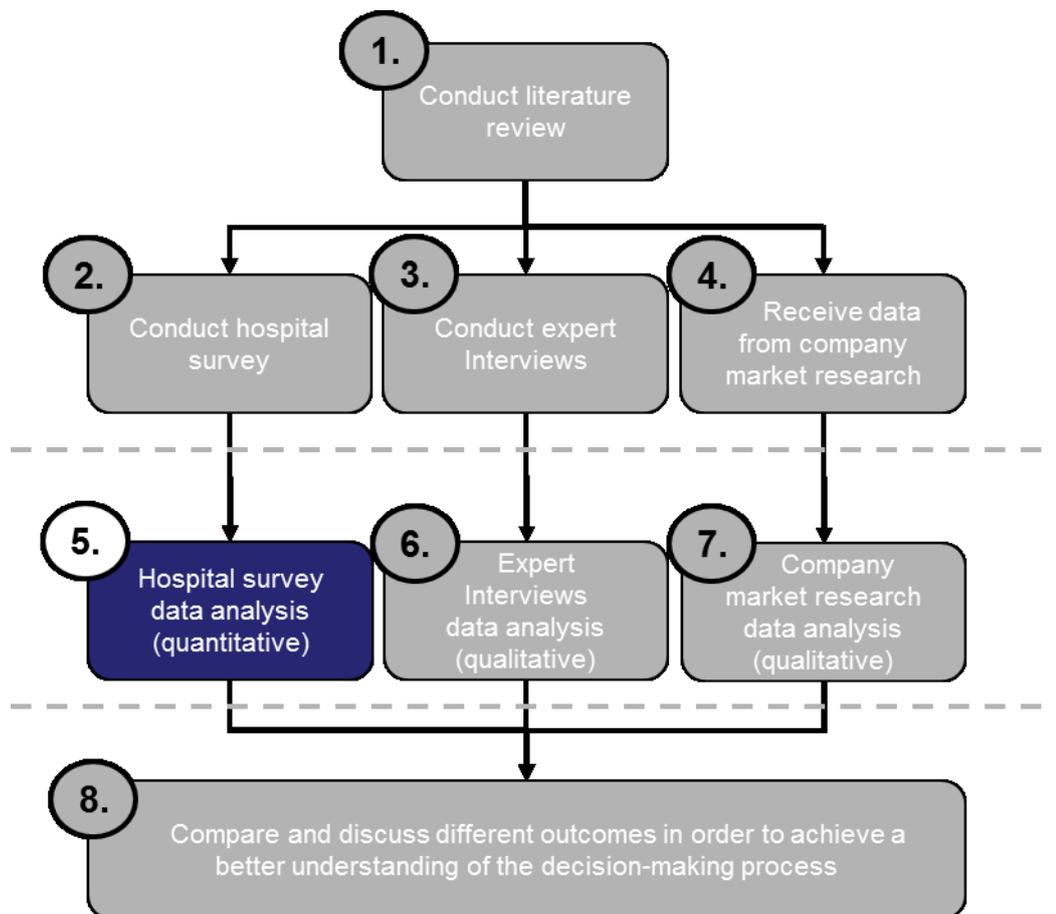


Figure 20: Hospital survey data analysis.

The hospital survey was conducted to answer primarily RQ-1 and RQ-2 but also to provide explanatory ideas on RQ-3 and RQ-4.

In total, 584 hospitals which fulfilled the inclusion criterion of more than 300 beds were asked to participate in the online survey. Out of these 584 hospitals, 47 filled out the online survey corresponding to an 8% response rate. Twelve surveys were

only partially filled out. Thus, they were not considered for the final analysis which included 35 completed questionnaires (response rate of 6%). The explanation for the low response rate of the online survey can most likely be found in the *actual* or *real* domain and thus will be topic of later chapters. However, one assumption is that formulary committee members are reluctant to share insights into the processes and structures of the committee because they do not want this to be assessed or changed.

5.2 Participant structure

Two-thirds (66%) of the hospitals have more than 800 beds. One-third (33%) have 300-800 beds. Hence, the participant structure is balanced, but the topic seems to be more interesting for bigger hospitals especially considering the higher number of smaller hospitals (94 hospitals with > 800 beds versus 504 hospitals with 300-800 beds, see Table 7). A different explanation could be the limited resources of smaller hospitals and therefore less time to participate in an online survey. The survey request was sent by email to the head of the hospital formulary or alternatively to an active member of the hospital formulary. 83% of the valid responses came from pharmacists, 14% from physicians and 3% from the general manager of the hospital (Figure 21). This distribution is not surprising since a pharmacist is most of the time the head of the hospital formulary (see results later).

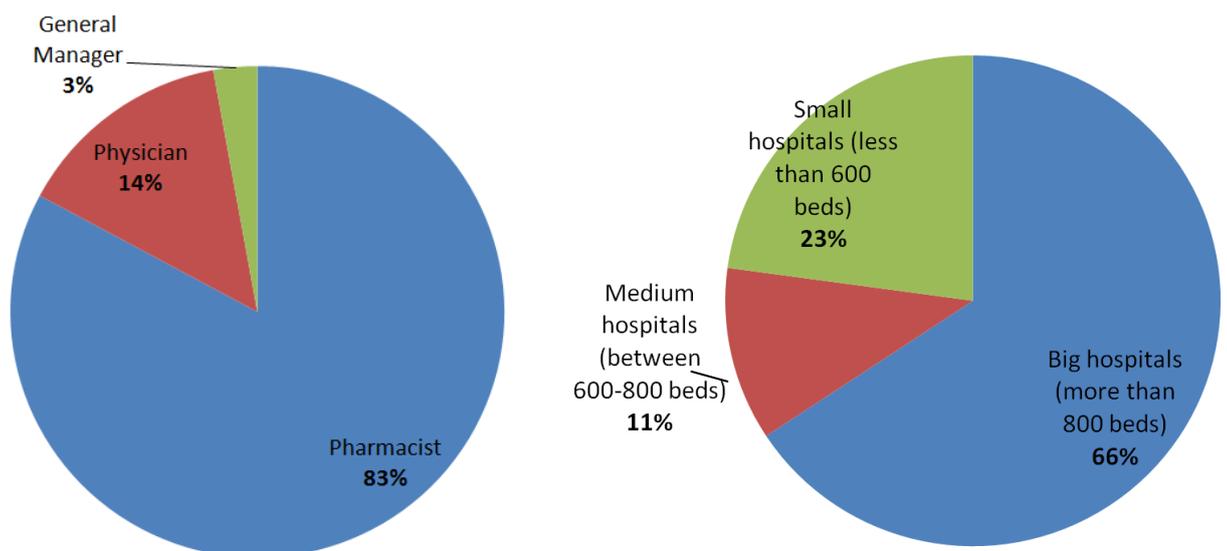


Figure 21: Participant structure.

5.3 Knowledge sharing

According to the survey results, only 49% of the hospitals have written guidelines for the decision-making process of the hospital formulary (Figure 22). 34% of the hospitals do not have any, neither written nor verbal, guidelines which regulate this process.

Considering the content of existing guidelines, 80% of the written guidelines name criteria which should be applied in the formulary listing decision-making process. However, only half of these guidelines define the relative importance of decision-making criteria.

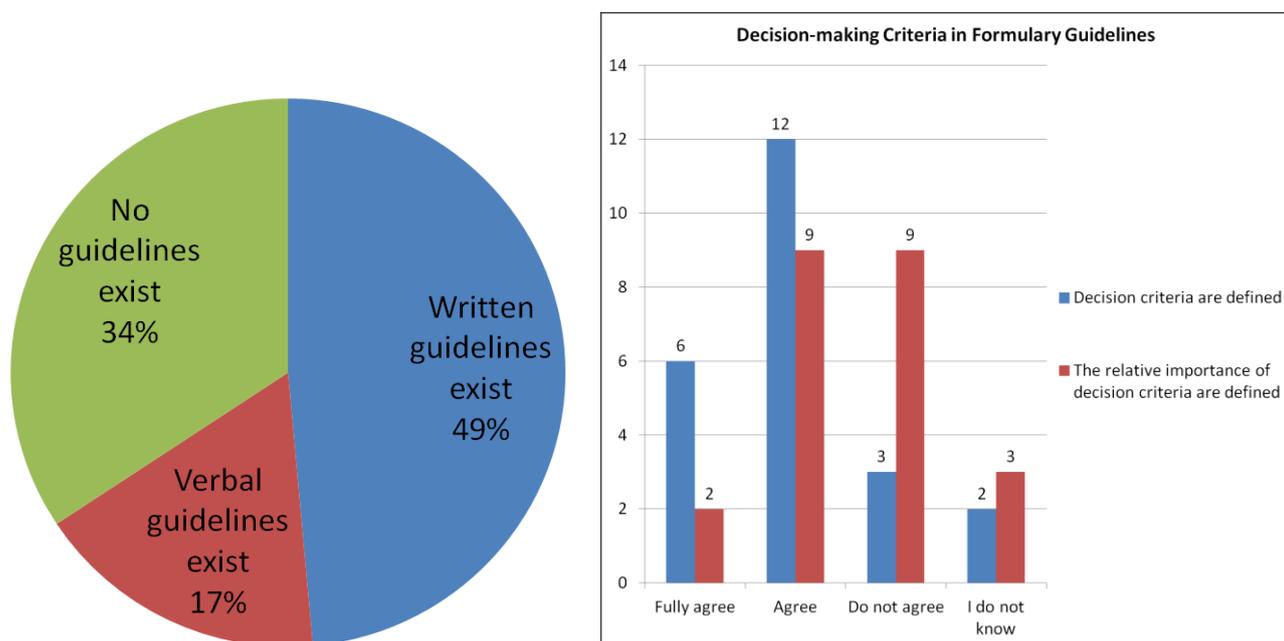


Figure 22: Guidelines and decision-making criteria.

In most of the cases (54%), budget impact is mentioned as the most important criterion (Figure 23). Other important criteria mentioned are: clinical study data, price of the pharmaceutical drug and existing alternatives. In addition to those objective criteria, also subjective decision criteria are mentioned, such as recommendation by pharmacists or physicians or the experience in the hospital with the specific pharmaceutical drug.

The existence of written guidelines which name decision-making criteria does not necessarily mean that hospital formulary members also make use of these criteria.

However, this result shows that hospital formulary decision-making is complex and uses a variety of criteria, objective as well as subjective criteria.

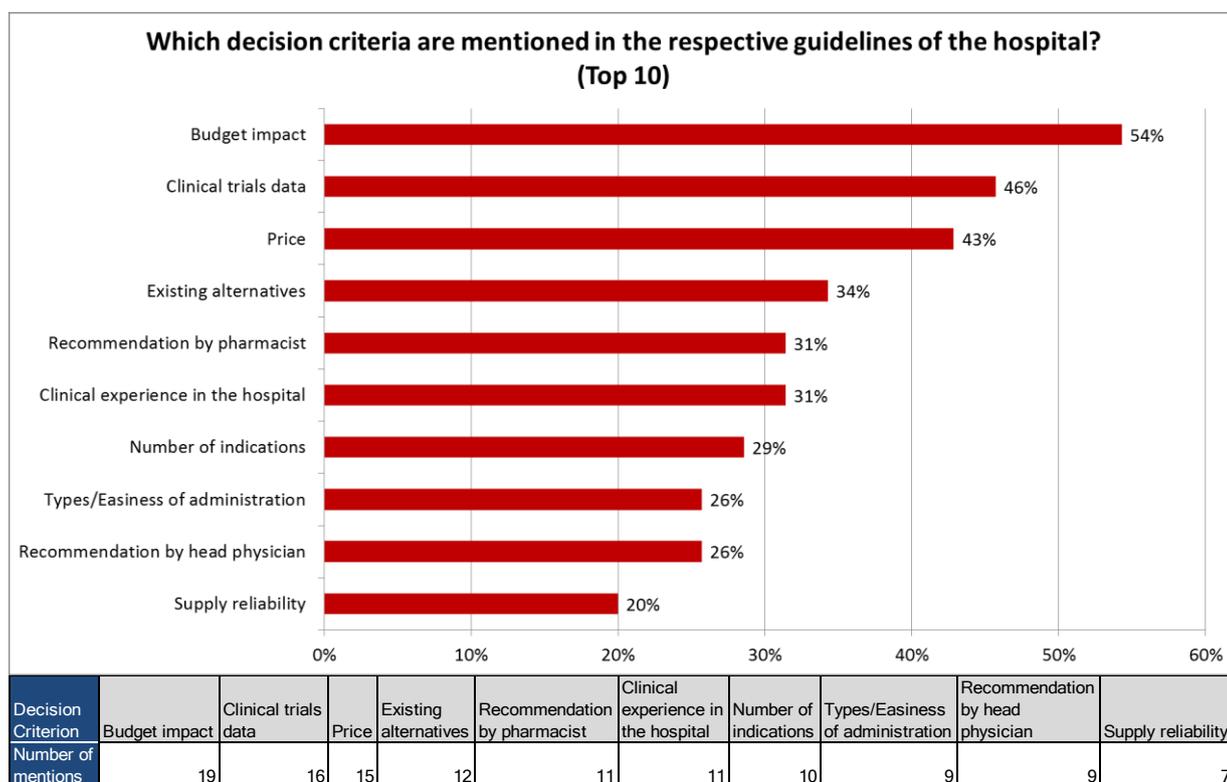


Figure 23: Decision criteria mentioned in the guidelines.

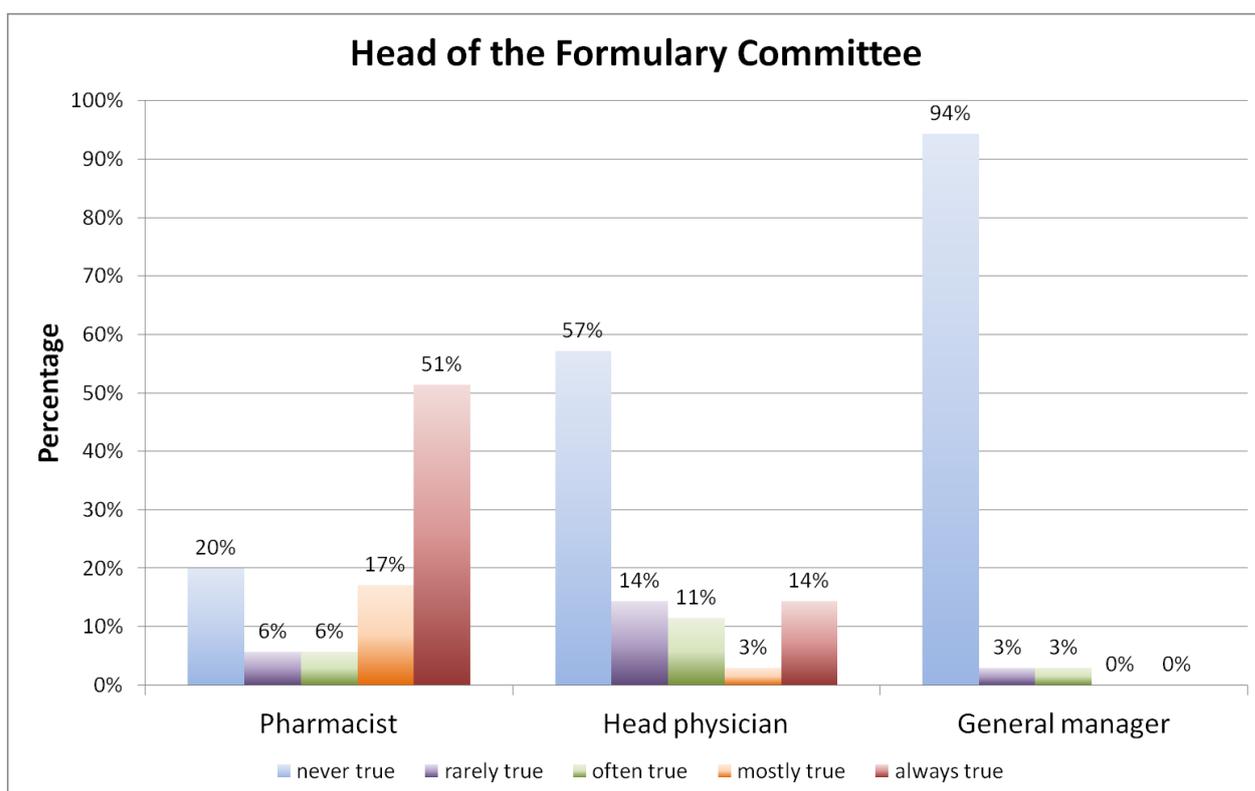
5.4 Structure of German hospital formularies

Information about hospital formulary committees in Germany is scarce and the only study which was identified in the literature review was published in 1997 (Thürmann et al., 1997) and revealed a median number of twelve members of a hospital formulary committee. This research showed that most of the committees consist of more than twelve members (for 28.57% of the respondents this was always true). Very seldom hospital formulary committees have three to five members. This result might be influenced by the higher participation of the group of bigger hospitals (>800 beds) who make up about 66% of all participants. It also showed that the number of participants fluctuates (Table 12).

	Never true	Rarely true	Often true	Mostly true	Always true
3-5 members	77,14%	8,57%	14,29%	0,00%	0,00%
6-8 members	42,86%	20,00%	14,29%	8,57%	14,29%
9-12 members	31,43%	28,57%	11,43%	17,14%	11,43%
more than 12 members	25,71%	17,14%	8,57%	20,00%	28,57%

Table 12: Size of the hospital formulary committee.

The survey showed that in most of the cases hospital formulary committees are led by a pharmacist. This is often, mostly or always true for 74% of the respondents (Figure 24). Often, the head physician is taking the lead for the hospital formulary committee. This is often, mostly or always true for 28% of the respondents. The results show clearly that the General Manager is usually not in the lead of the formulary committee (94%).



Number of mentions	never true	rarely true	often true	mostly true	always true
Pharmacist	7	2	2	6	18
Head physician	20	5	4	1	5
General manager	33	1	1	0	0

Figure 24: Head of the formulary.

The preferred way of coming to decisions is, according to the survey data, on a consensus basis (Figure 25). Hospital formulary committees also use a simple majority for decision-making.

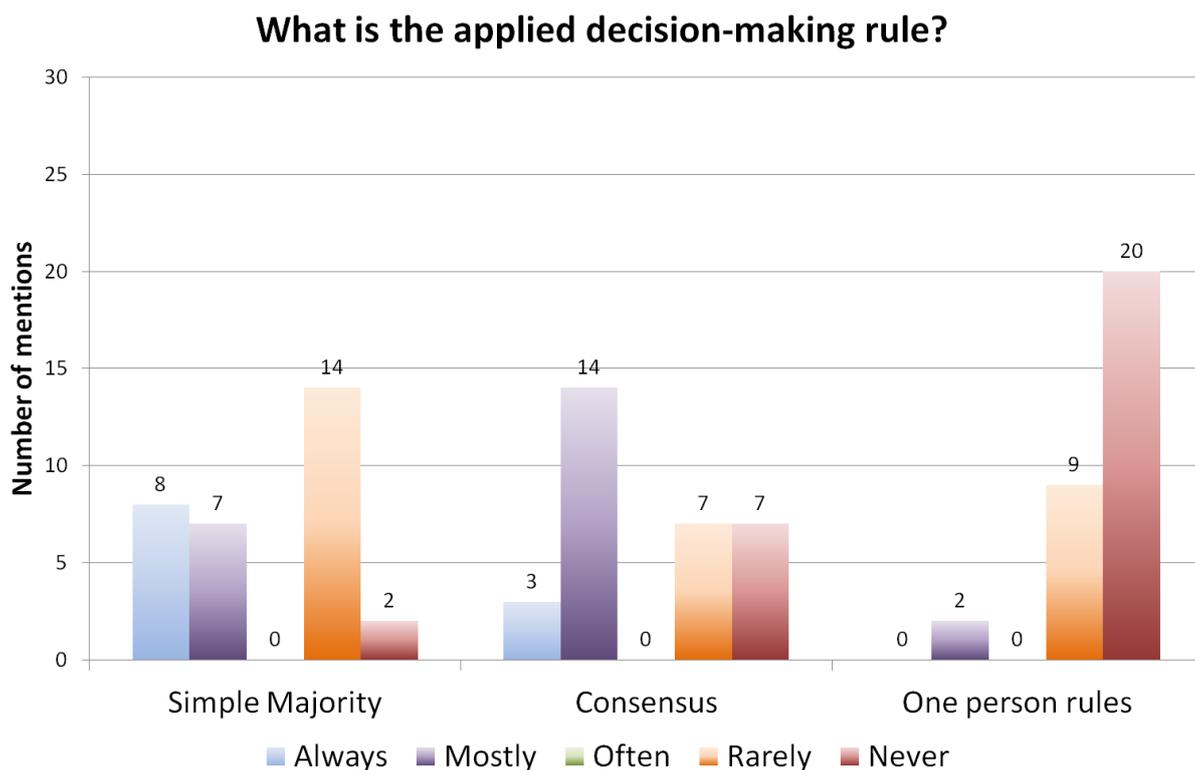


Figure 25: The applied decision-making rule.

5.5 Documentation package

Members of the hospital formulary committee usually receive a documentation package before the meetings which contains information about the respective pharmaceutical drugs. According to the survey, only 11% of the hospital formularies do not provide such a package. In addition, the provided information is used by most of the participants for their decision-making. Only 13% of the respondents said that they rarely use the information. The content of the documentation package varies between hospital formularies. Mostly basic data, such as clinical trials data or the price of existing alternatives, is given to inform the member's decision-making.

The survey showed that the documentation package is compiled by the pharmacist and in rare cases also by a physician (Figure 26).

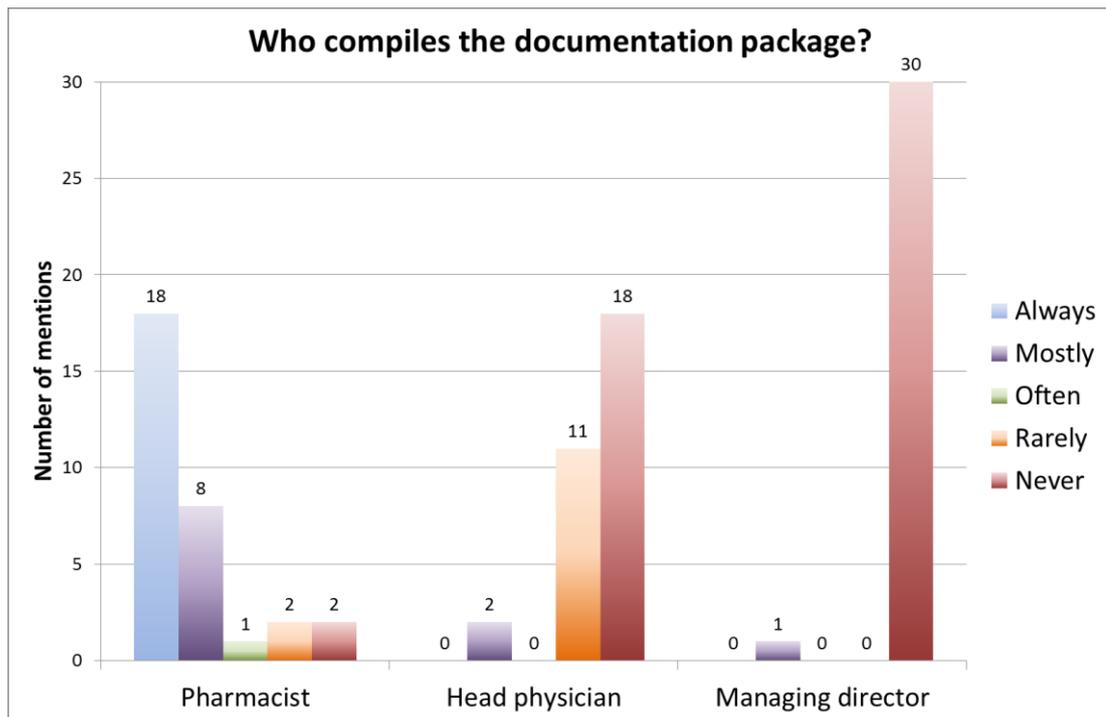


Figure 26: Who compiles the documentation package?

61% of the respondents stated that information material of the pharmaceutical manufacturer is considered for the documentation package. In 84% of the cases, clinical trials data is mentioned in the documentation package which confirms the importance of such data and the results of the literature review. Economic data is also top-ranked with price (71%), budget impact (55%) and health economic evaluations (52%). The high number of mentions for health economic evaluations is unexpected due to the results of the literature review showing a low acceptance of those evaluations. Overall the results show the high priority for economic data in the documentation package (Figure 27).

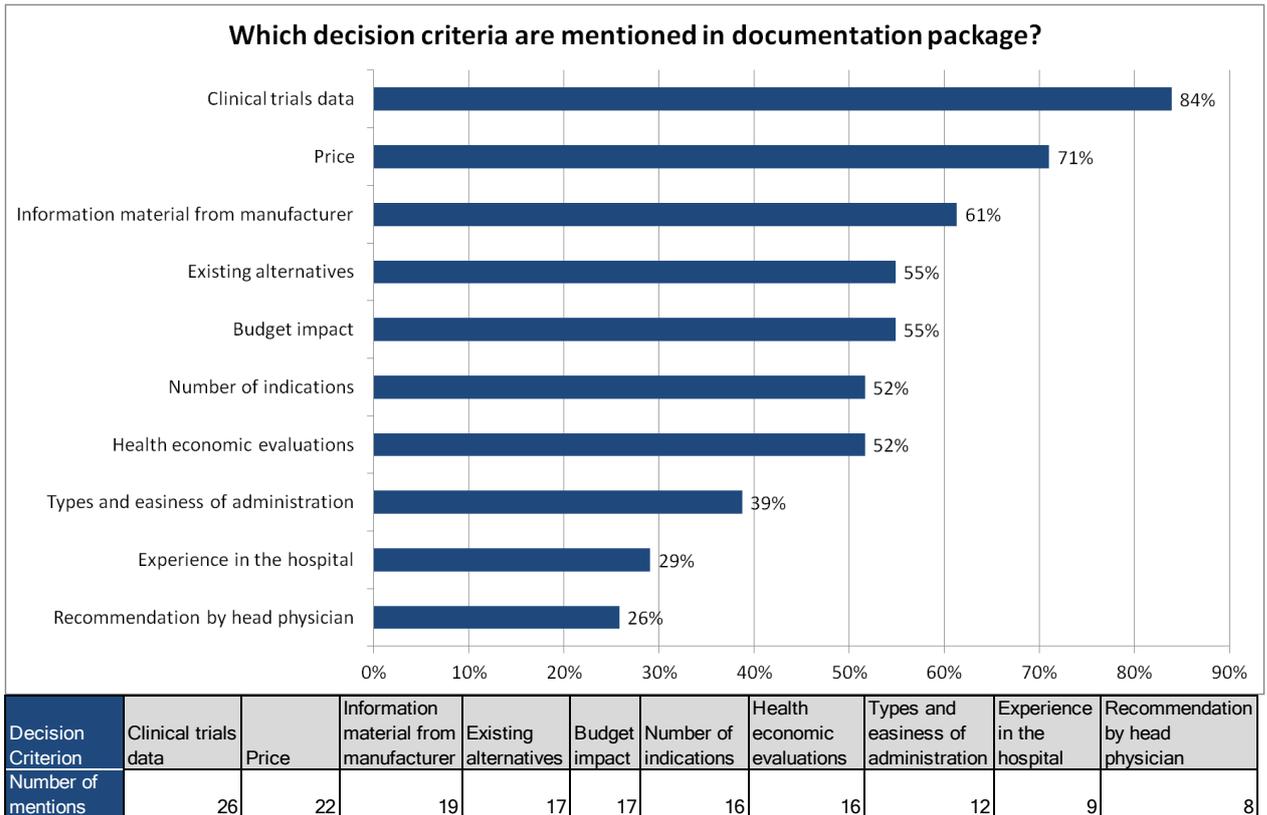


Figure 27: Decision criteria in the documentation package.

5.6 Decision-makers and other decision-making aspects

Despite the high response rate by hospital pharmacists in comparison to physicians, the results for the question of impact level are balanced. For the question of pharmaceutical drug listing decision-making, the respondents indicate a similar impact level for pharmacists and physicians. Managing directors or financial administrators (here: Controlling) do not have significant level of impact (Figure 28).

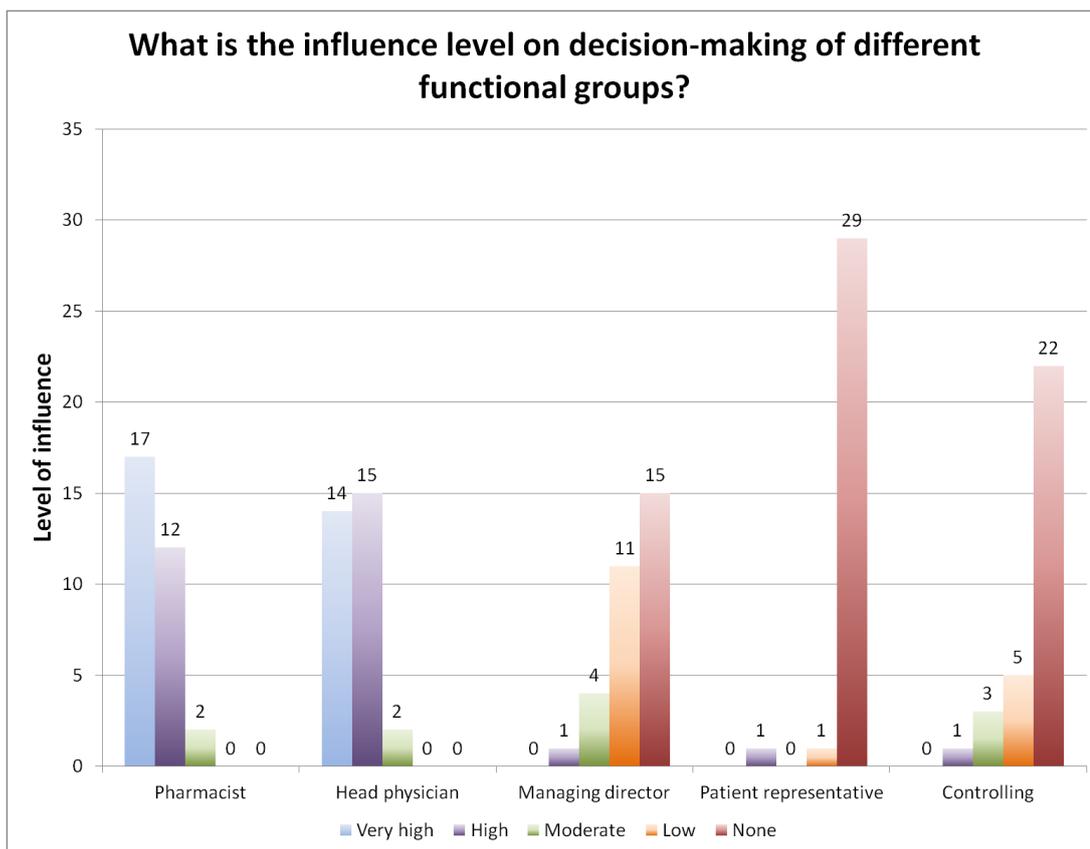
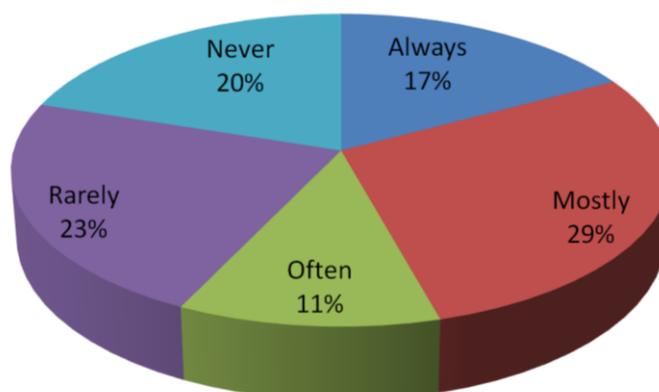


Figure 28: Decision-makers with higher influence.

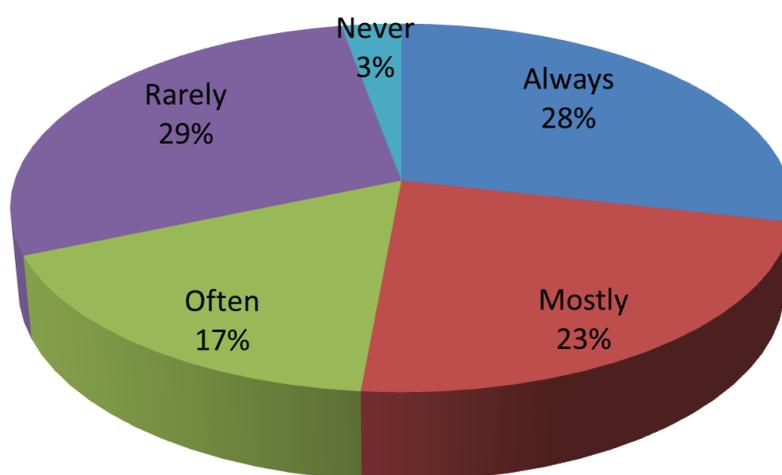
Regarding transparency, the respondents of the survey indicated that the cooperation (e.g. clinical trials) between members of the hospital formulary and a pharmaceutical manufacturer is seldom communicated. 43% of the respondents stated that this happens rarely or never (Figure 29).



Number of mentions	never	rarely	often	mostly	always
Transparency regarding pharma cooperation	7	8	4	10	6

Figure 29: Transparency regarding committee members and pharmaceutical manufacturers' cooperation.

There are a relatively high number of economic decision-making criteria mentioned in the documentation packages of hospital formularies. Together with the difficult economic situation of many German hospitals this suggests that the financial situation of the hospital could be a discussion point in hospital formulary meetings. This is confirmed by the survey data which show that the financial situation is a discussion topic for 97% of the respondents. 52% of the respondents even stated that this topic is most of the time (23%) or always (29%) brought up in the formulary discussions (Figure 30).

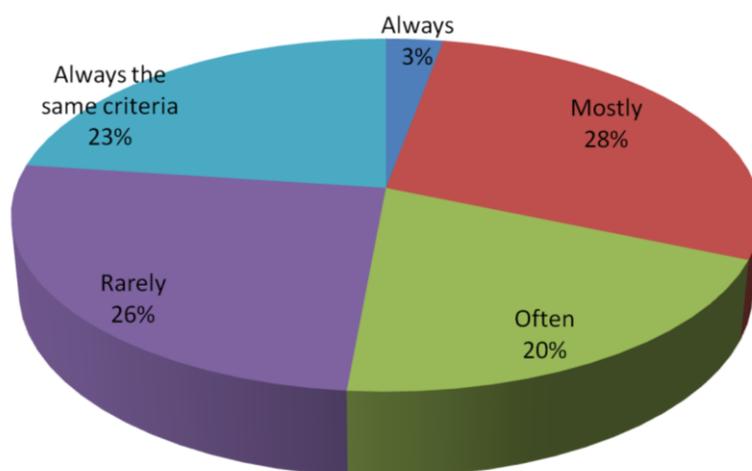


Number of mentions	never	rarely	often	mostly	always
Financial situation discussed during committee meetings	1	10	6	8	10

Figure 30: Is the financial situation a topic in the hospital formulary discussions?

5.7 Decision-making criteria for drug funding cases

77% of the respondents (n=27) said that they use different decision-making criteria for different types of pharmaceutical drugs. In contrast 23% (n=8) always use the same criteria to decide on drug funding, independent of the therapeutic class of the drug (Figure 31).



Number of mentions	never	rarely	often	mostly	always
Use of different decision-making criteria dependent on the drug type	1	10	7	9	8

Figure 31: Impact of the therapeutic class of a drug on the applied decision-making criteria.

Considering only the respondents who use different decision-making criteria for different therapeutic classes of drugs, they use different decision-making criteria most often in the class of monoclonal antibodies. In order to get a better understanding of the relative importance of decision criteria and how they are used depending on different type of drugs, the participants were asked to rank 20 different criteria according to their importance. It was not possible to assign a rank twice to avoid indifferent answers and thus participants were forced to compare different criteria. In case participants do not make use of a criterion at all, it was possible to classify this criterion or these criteria as non-applicable. Results are shown in Figures 32-34. The maximum rank, the minimum rank and the median is shown in the graphs.

For smaller (n=8 with valid responses) and bigger (n=14 with valid responses) hospitals considering the therapeutic class of monoclonal antibodies/immunomodulators, the clinical trials data is the most important criterion. The bandwidth for the ranking values is also very narrow which means that all hospitals see this criterion similarly important. However, on the following ranks there is a clear difference between the smaller and the bigger hospitals. When bigger hospitals focus on budget impact as an economic criterion and also have a high rank for the price of a drug, smaller hospitals assess the importance of hospital experience much higher. Nonetheless, the importance of budget impact in all hospitals seems to be controversial as the bandwidth of ranking values is very broad. Besides objective decision-making criteria, perceived subjective criteria, such as the hospital experience and the recommendation by a head physician, can be found in the list of most important criteria. Smaller hospitals put a higher weight on the severity of disease which is not mentioned for the bigger hospital group in the top ten criteria. Instead, bigger hospitals focus more on criteria which influence the economic aspects of a drug, such as number of indications or existing alternatives.

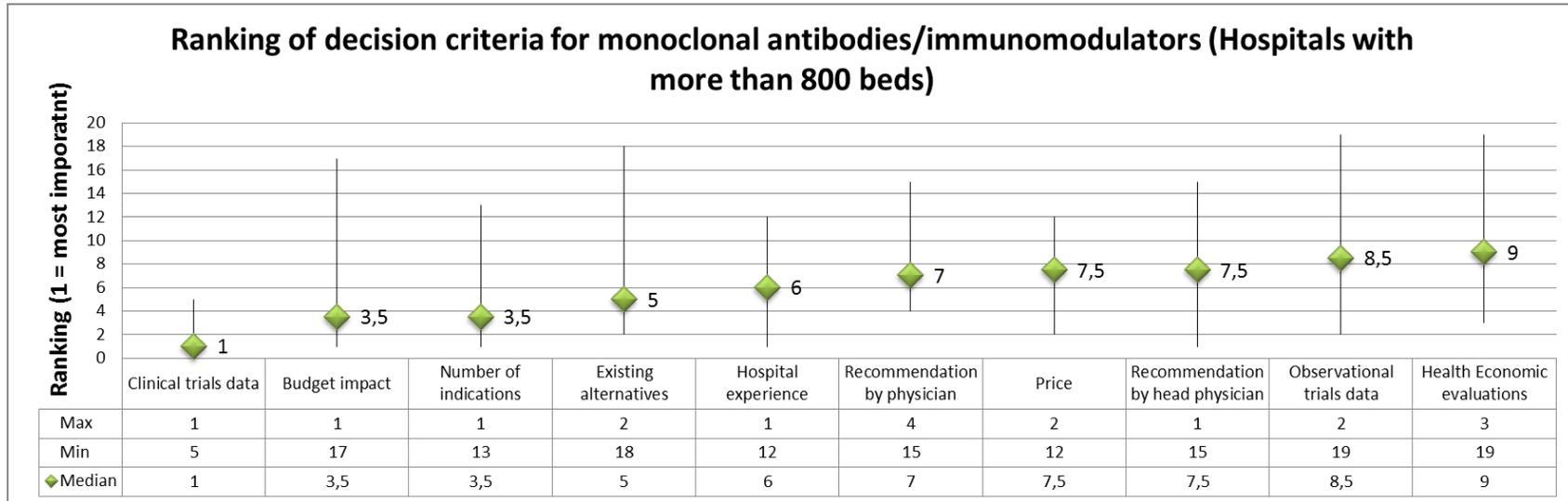
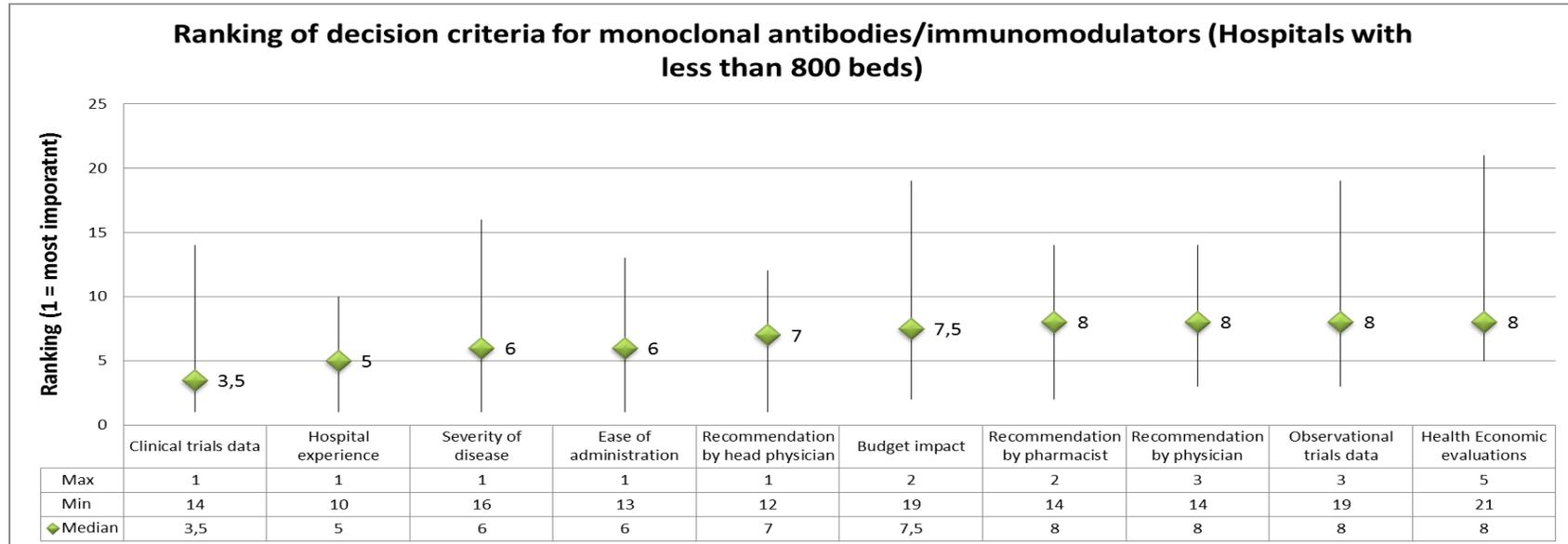


Figure 32: Decision criteria for monoclonal antibodies/ immunomodulators (hospitals with < > 800 beds)

Medical devices are evaluated differently to monoclonal antibodies/ immune modulators. Clinical trials data, although in total ranked very high, seems to be less important for medical devices than for the group of monoclonal antibodies/ immune modulators. This can be seen in the very broad bandwidth of ranking values for clinical trials data.

In general, the importance of economic criteria is higher for the group of medical devices. Budget impact and price are both mentioned in the group of the top six criteria for all hospitals (n=12 with valid responses). Besides this economic focus, decision-makers see a bigger importance also for the physician's experience with a medical device, independently of the hospital size.

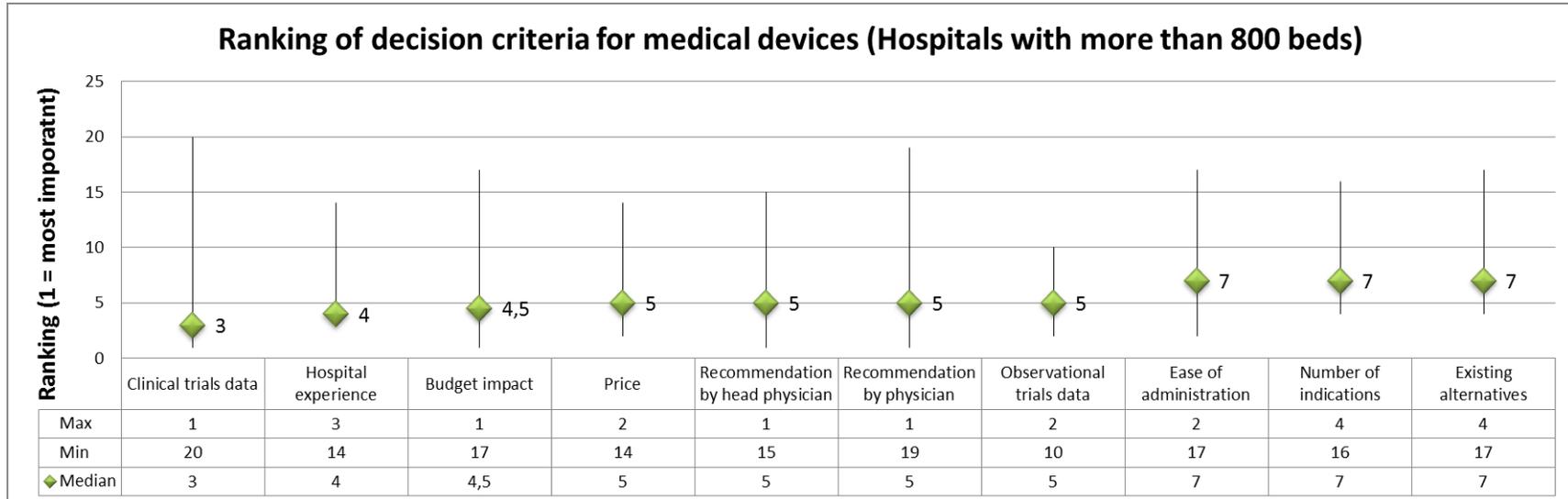
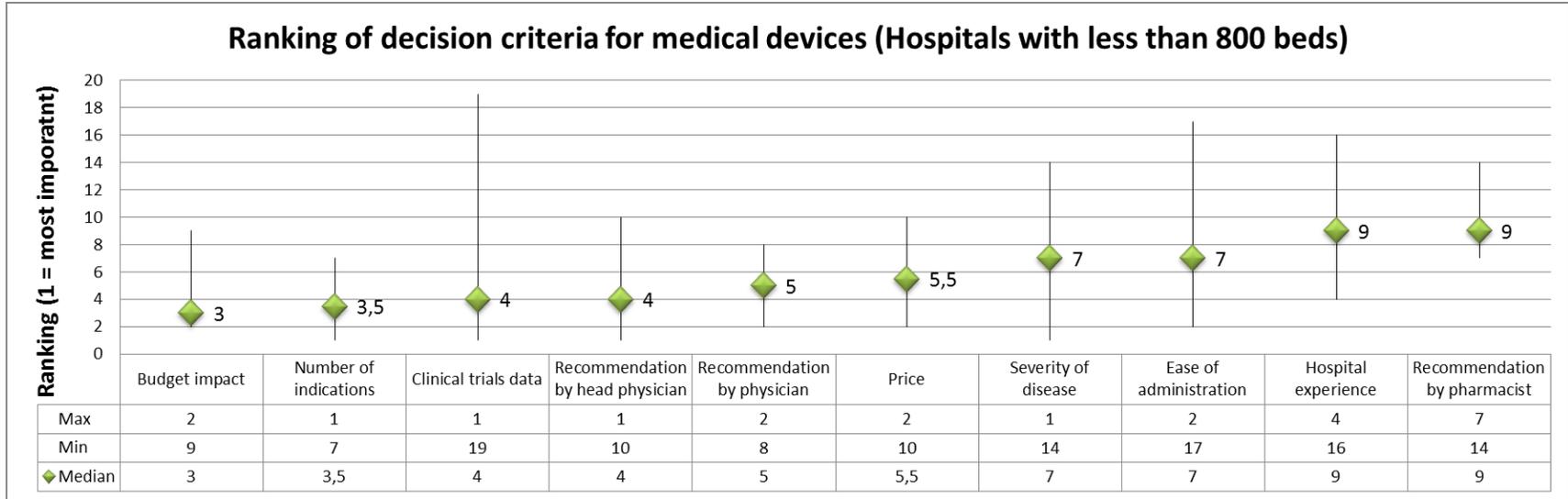


Figure 33: Ranking of decision criteria for medical devices (hospitals with < > 800 beds)

Pharmaceutical drugs to treat orphan diseases often do not have the same level of clinical trials data compared to regular drugs. Hence, the decision-making criteria for this drug class were listed in the survey without the possibility to select clinical trials data. Consequently, the hospital experience received a high ranking value as a quasi-substitute for missing clinical trials data. In contrast to all other types of pharmaceutical drugs, the severity of disease has the strongest impact on decision-making.

Other subjective decision criteria, such as the clinical experience or the recommendation by the head physician are ranked in the top five important criteria.

Orphan drugs are often expensive which is also reflected in the high ranking values for budget impact and price. For health economic evaluations the result is differentiated. Smaller hospitals (n=11 with valid responses) assess the importance very high, whereas bigger hospitals (n=20 with valid responses) rank health economic evaluations only on the 10th rank.

It is important to mention that the pilot interviewees indicated that pharmaceutical drugs to treat orphan diseases are mostly not listed by the hospital formulary committee but ordered on a case by case basis.

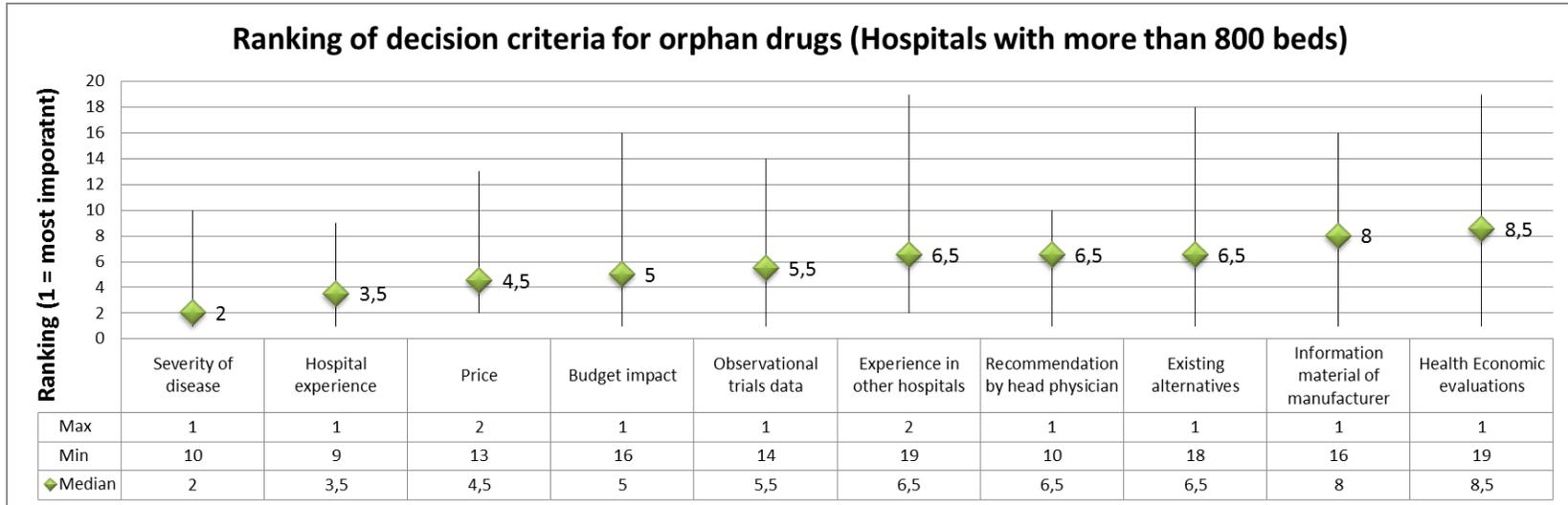
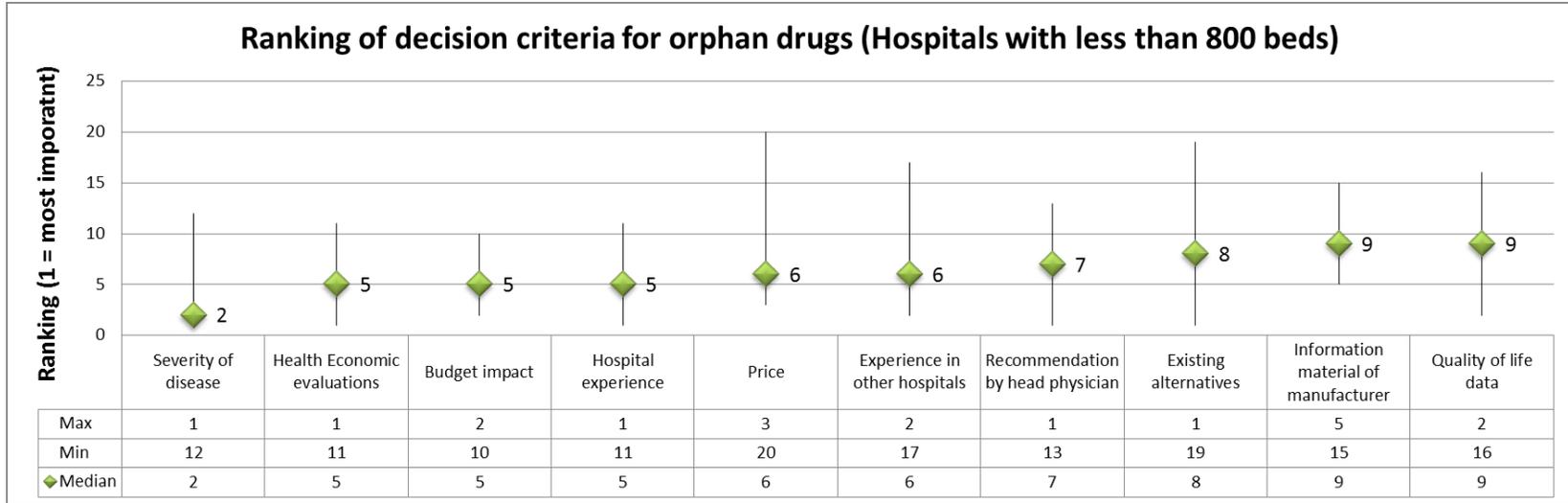


Figure 34: Ranking of decision criteria for orphan drugs (hospitals with <> 800 beds)

5.8 Summary

This chapter summarized the most important outcomes of the quantitative analysis of the survey data. The survey aimed to primarily answer RQ-1 and RQ-2, meaning to answer which criteria in funding decisions for pharmaceutical drugs in hospital formulary committees are applied and what their relative importance is.

Hospital formulary committees apply different criteria for different classes of pharmaceutical drugs. The most important criterion for most types of drugs is data from clinical trials. In cases where this data is not available, for example with orphan drugs, decision-makers try to use a substitute criterion, such as hospital experience. Independently of the type of drug, economic criteria, such as budget impact or price are of high importance. In some cases the survey showed a bigger importance of health economic evaluations. This result is surprising due to the literature review results suggesting a minor impact of health economic evaluations in hospital formulary committee decision-making. The following, qualitative parts of this thesis further explored the reasons for these results.

In addition to this, the survey revealed ideas on how to answer RQ-3 and RQ-4. It showed that pharmacists and physicians have the highest influence on the decision-making process of the hospital formulary and that pharmacists usually have the role of the committee chair. The reasons for this high influence were further elucidated in the expert interviews. It was also indicated that many hospital formulary committees have no guidelines which regulate the decision-making on drug listings. In cases where guidelines exist they do not mention details, such as the relative importance, on decision-making criteria.

The central role of pharmacists is also emphasised by the responsibility of many pharmacists to prepare the documentation package for each drug listing case. Most formulary committees prepare documentation packages and members use them for informed decision-making. The survey revealed a perceived low transparency in hospital formulary committees in regards to the cooperation between members of the committee and the pharmaceutical industry.

These perceptions from the *empirical* domain were used in the discussion part which merged the quantitative and qualitative analyses to identify the underlying structures of the *real* domain.

6 Expert interview data analysis

6.1 Introduction

The expert interview data analysis represents step six in the research design (Figure 35). According to the convergent parallel database mixed-methods design (Creswell, 2003), the expert interview data is analysed separately in the first step and is then combined with the hospital survey data and the company market research data in a second step.

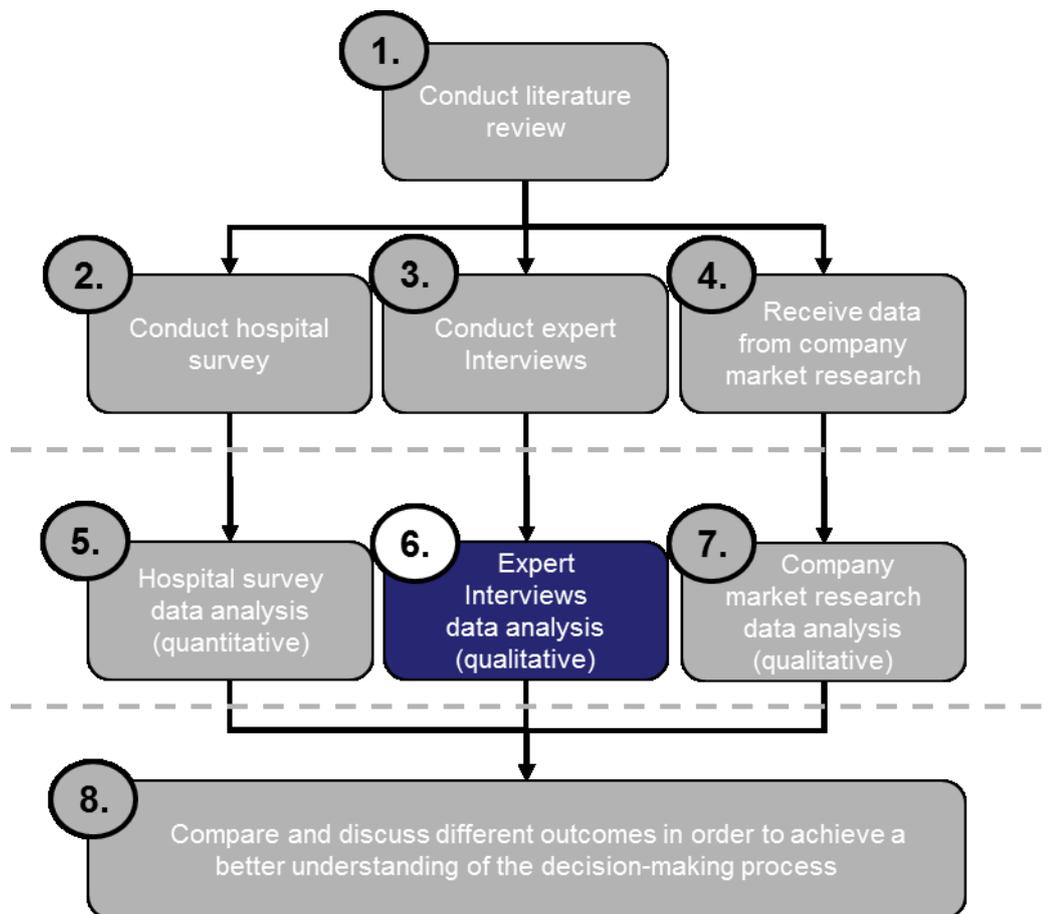


Figure 35: Expert interview data analysis.

The expert interview data was conducted to answer primarily RQ-3 and RQ-4 but also to provide more in-depth information on RQ-1 and RQ-2.

The analysis of the expert interview transcripts was based on the structure of the thematic networks approach (Attride-Stirling, 2001). The following eleven codes were derived from the literature review and the preliminary decision-making

framework. They were used in the first step of the analysis in order to slice up the interview transcripts into text segments:

1. **Group** (Tindale, Kameda & Hinsz, 2003): This code contains text passages which describe the decision-making process in regards to the hospital formulary committee members and their relationship to each other. It refers to comments on how the group influences the individual member. According to the literature review, the group has a strong influence on the individual member's decision-making behaviour. It is the second step in the hospital formulary committee decision-making framework (Figure 16) shaping the final decision of each member of the group.
2. **Individual** (Davis, 1973; Stasser, Kerr & Davis, 1989): This code contains text passages which describe the decision-making process in regards to the individual hospital formulary committee member. It refers to comments on what is important for the individual member and how the individual member comes to his or her decision. This is the first step of the full decision-making process shown in the hospital formulary committee decision-making framework (Figure 16).
3. **Centrality** (Kameda, Ohtsubo & Takezawa, 1997): This code refers to all text which describes how much influence individual members have in the group. It also looks at hints which help to understand why respective individuals have more influence than others.
4. **Dependencies** (Dranove et al., 2003; Gibson et al., 2005): According to the literature review, power relationships between group members can influence decision-making. This code describes all text passages referring to dependencies and how they change decision-making behaviour.
5. **Information sharing** (Gigone & Hastie, 1993, 2013; Stasser & Titus, 1985, 1987): A key result of the literature review was the relevance of knowledge or information sharing between different group members. This code shows all

comments in regards to the level of information sharing and the impact it has on the individual and group decision-making behaviour.

6. **Objective information** (Jenkins & Barber, 2004; Vuorenkoski, Toivianinen & Hemminki, 2003, 2008): This code contains text passages which describe the importance and formulary committee member use of perceived objective information.
7. **Subjective information** (Wirtz et al., 2005): This code contains text passages which describe the importance and formulary committee member use of perceived subjective information.
8. **Structure** (Thürmann, Harder & Steioff, 1997): In order to better understand the group dynamics and the relationships between the respective group members, it is necessary to understand the structure of a hospital formulary committee. This code contains all text which provides more details on this question.
9. **Process** (Martin et al., 2003): Text passages which describe the process of decision-making as well as special circumstances leading to exceptional decisions were collected under this code.
10. **Transparency** (Fijn et al., 1999; Plet et al., 2013): This code contains text passages which describe the interviewer's understanding of transparency and how this is reflected in the behaviour of the hospital formulary committee members.
11. **External impact** (Dranove et al., 2003; Jenkins & Barber, 2004; Späth et al., 2003): The hospital formulary committee is relatively closed to any external influence. However, single members are not and they have contact to potential external influencers such as patients or the pharmaceutical industry. Additionally, the hospital (and also the formulary committee) is not isolated and part of the highly regulated health system of the country. This code

provides all comments which refer to any external impact source and how it impacts decision-making.

In order not to limit this research and to allow explorative information, the initial list of codes was not closed. During the coding phase, two additional codes were added:

12. **Type of drug:** One important topic from the expert interviews was the distinction made during the decision-making process which was dependent on the type of drug. Hence, a separate code was used to make the additional topics around differentiation also clear in the analysis.
13. **Role:** During the coding phase it also became obvious that each member's understanding of their role (as a physician, pharmacists or something else) impacted their decision-making behaviour. Thus, an additional code was required to capture important details on this aspect.

Following the coding phase, the text segments were re-read to identify and refine themes which represent the second step of building thematic networks. Table 13 shows the sample result of this procedure related to the code "subjective information". The identified items for all 13 codes amounted to 134 basic themes.

Code (1st step)	Themes (2nd step) --> Basic Themes
Subjective information	Members try to avoid difficult final decisions
	Own clinical trial involvement has strong influence
	Subjective criteria are difficult to use as a justification for a decision
	High patient empathy in combination with low budget impact means an easier listing decision
	Strong emotional arguments absorb objective criteria
	Argumentation needs to be convincing
	Stronger characters convince more easily
	The way of communicating an opinion is vital
	Expert opinion alone is not sufficient for a positive decision
	Expert opinion becomes more important if other data does not allow differentiation
	Expert opinion is of high value
	Less available data increases the importance of practical experience
	Practical experience must fit to the clinical trials data in order to be accepted
	Subject areas are protected

Table 13: Themes identified for the code "subjective information".

The identified basic themes were clustered into groups of similar issues. Based on these issues, an organizing theme was created which contains the different basic

themes. Again, this is shown exemplary for the organising theme “Value of expertise” in Table 14.

Themes (2nd step) --> Basic Themes	Organising Themes (3rd step)
Expertise of different functions is valued, accepted and protected	Value of expertise
The role perception influences the member's expectations	
Important decisions decrease trust in expert's opinion	
Individual experience alone is not sufficient to convince	
Practical experience becomes more important if other data does not allow differentiation	
For important decisions members prepare additional information	

Table 14: Basic themes identified for the organising theme “Value of expertise”.

From the basic and the organizing themes, the main propositions, issues and arguments were taken to deduce a global theme which is the core component of one thematic network (Attride-Stirling, 2001). The last step in this analysis stage is the verification of the identified thematic networks. Hence, the basic themes and the underlying text segments were again read and checked if the text segments support the basic, organizing and global themes as well as the themes reflect the propositions, issues and arguments of the text segments. One final thematic network with all organising and basic themes is shown in Table 15.

Themes (2nd step) --> Basic Themes	Organising Themes (3rd step)	Global Themes
Pharmacists have the strongest impact on decision-making	Key decision-makers	Physicians and pharmacists are the decision-makers, but practical experience has impact on decision-making independent of functional roles
Pharmacists have a central role in preparation of the documentation		
Physicians have pre-discussions with the pharmacist to estimate chances of success		
Physicians and pharmacists also align outside of the committee		
	Value of expertise	
Expertise of different functions is valued, accepted and protected		
The role perception influences the member's expectations		
Important decisions decrease trust in expert's opinion		
Individual experience alone is not sufficient to convince		
Practical experience becomes more important if other data does not allow differentiation		
For important decisions members prepare additional information	Role of the function	
Importance of department leads to more central role		
The chair of the committee is of diverse importance		
Some medical departments are more involved in the committees than others		
Group consensus can mean a consensus between the two most powerful members		
Direct hierarchical dependencies have less impact on decision-making		
Difficult decision situations require an individual for final advice		
Members should participate in order to increase transparency		

Table 15: Thematic network with all organising and basic themes.

This was done for all 134 basic themes. After all verification and refinement steps and elimination of double themes, five thematic networks with 16 organising themes were defined and will now be discussed in detail. Table 16 shows the overview of all thematic networks.

Global Themes	Organising Themes (3rd step)
Physicians and pharmacists are the decision-makers, but practical experience has impact on decision-making independent of functional roles	Key decision-makers
	Value of expertise
	Role of the function
The personality of the individual committee member has strong impact on the group decision-making behaviour	Role of the individual
	Impact of communication
External factors have a significant impact on the formulary committee decision-making	Pre-meeting decision-making
	External impact by the industry
	Importance of cross-sectional treatment
	Reputation of the hospital
Subjective criteria impact decision-making but the open use is limited due to perceived difficulties in justification	Justification
	Role of subjective criteria
	Information sharing
Despite the strong importance of budget impact, economic criteria rarely lead to rejection	Budget impact
	Real costs
	Importance of economic criteria
	Type of drugs

Table 16: Five thematic networks with all 16 organising themes.

Figure 36 summarises the process of building the thematic networks:

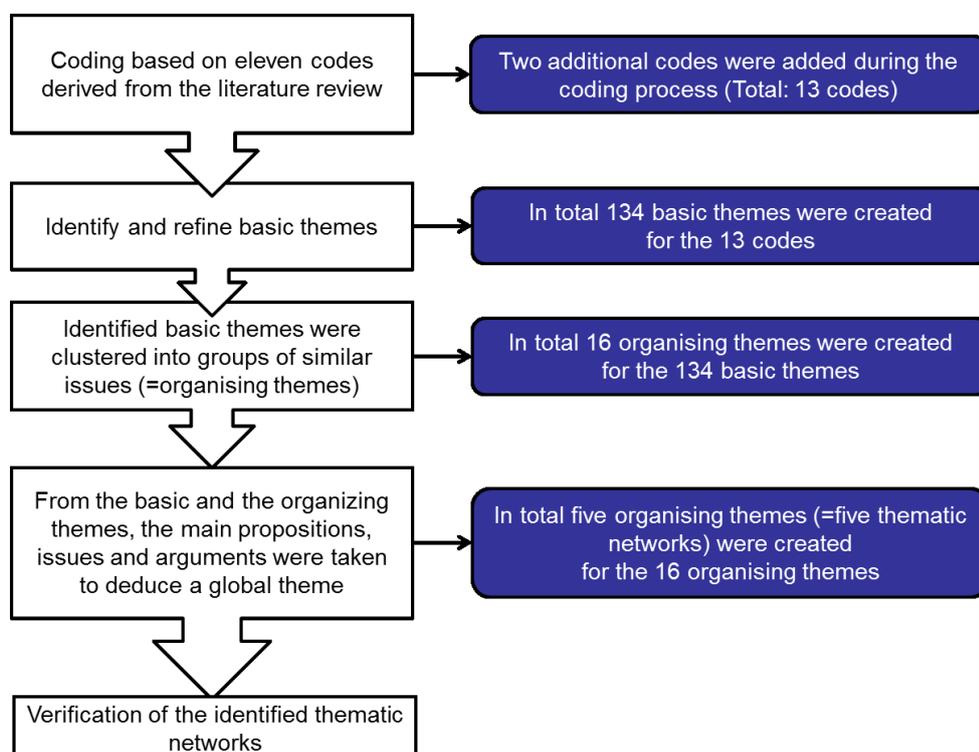
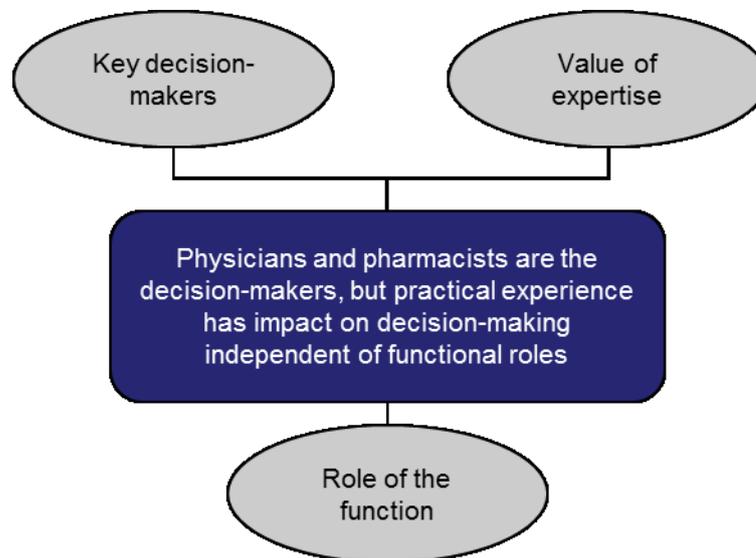


Figure 36: Process of building thematic networks.

6.2 Physicians and pharmacists are the decision-makers, but practical experience has impact on decision-making independent of functional roles

This thematic network comprises of three organising themes and 17 basic themes (Figure 37). It describes the strong influence of physicians and pharmacists on the decision-making process of the hospital formulary committee group. Besides the functional role of a formulary committee member, experience with a pharmaceutical drug (either own experience or experience from another member) can impact decision building. In this context, this thematic network also describes the relationship between the two most important roles in a hospital formulary committee.



Organising Themes	Basic Themes
Key decision-makers	Pharmacists have the strongest impact on decision-making
	Pharmacists have a central role in preparation of the documentation
	Physicians have pre-discussions with the pharmacist to estimate chances of success
	Physicians and pharmacists also align outside of the committee
Value of expertise	Expertise of different functions is valued, accepted and protected
	The role perception influences the member's expectations
	Important decisions decrease trust in expert's opinion
	Single experience alone is not sufficient to convince
	Practical experience becomes more important if other data does not allow differentiation
Role of the function	For important decisions members prepare additional information
	Importance of department leads to more central role
	The importance of the chair of the committee varies
	Some medical departments are more involved in the committees than others
	Group consensus can mean a consensus between the two most powerful members
	Direct hierarchical dependencies have less impact on decision-making
	Difficult decision situations require an individual for final advice
Members should participate in order to increase transparency	

Figure 37: Thematic network describing the dominance of physicians and pharmacists.

6.2.1 Key decision-makers

Pharmacists have the strongest impact on decision-making. Despite the important role of physicians, pharmacists have the advantage of a broader total view on all decisions. Usually they are heavily involved in the agenda preparation, preparation of case documentation and they can decide for which topic they would like to prepare additional data.

B3 (pharmacist): *But I believe the one who facilitates and prepares the meetings, this is the one with the greatest influence. It is as simple as that.*

B8 (physician): *Basically in the committee meeting, someone has the best chances to prevail, if this person is best prepared. That is always the case. Usually the pharmacists are best prepared.*

Even physicians utilise pharmacists to prepare documentation for their listing applications. On the one hand, physicians do realize the strong position of pharmacists and they regret this, but on the other hand some physicians seem to accept their role and let pharmacists take over the control.

B3 (pharmacist): *I wish specific groups would have more interest in the formulary listing, for example the physicians. But they often prefer to sit back and say: this is done by my pharmacist.*

B9 (pharmacist): *The meetings of the committee are accompanied by presentations [...]. The content is mainly prepared by the pharmacists, partly from the respective medical department. I would have said this is done by the head physician, but the head physician is rarely doing this on his own, maybe in 20% of the cases. In 80% of the cases this is done by the pharmacist.*

Physicians are seen as the experts for medical questions, but they also need to convince other physicians. Pharmacists usually have a standalone position in the committee. They combine medical and economic knowledge and for some topics they are the only ones with subject specific knowledge, such as logistics of pharmaceuticals or pharmacoeconomics. Even in hospitals where the pharmacists do not have the formally powerful function as the chair of the committee, they have indirect power due to their involvement in preparation of meetings or the close

alignment with the chair. The committee meeting facilitation and negotiation is also done by the pharmacist, independent of whether he or she is the chair or not.

B2 (pharmacist): *Most influence has the chair of the committee. This is one of our head physicians... and the director of the committee, because he steers the meetings well, right. And...I will say it like this...I am the director...in principle I prepare and steer this as best as I can.*

B4 (pharmacist): *With his style to facilitate the committee meeting, it is clear that the chair has impact and we have impact on the chair, because we [the chair and the pharmacist] align very closely and additionally we have, from my perspective, a substantial direct impact in the committee meeting.*

B9 (pharmacist): *The chair of the meeting is usually restricted to the welcome and introduction of participants and to hand over the negotiation lead to the pharmacists.*

Sometimes the pharmacists even have the possibility to decide without any formal approval by the committee. Those situations might be specific and not the normal case, but they are examples for the autonomy of the pharmacist's role. Another example is the possibility for pharmacists to decide on the manufacturer without committee approvals in case of generic drugs or drugs who are perceived to be generic.

B2 (pharmacist): *If we...I do not know, receive a special request [for a pharmaceutical drug] twenty times, then I can probably decide without any formal agreement by the committee.*

B2 (pharmacist): *And it happens sometime, that we take drugs on the list without any formal agreement.*

B8 (physician): *Right now we have the opinion that the standard [DRUG TYPE], independent which brand, is relatively uniform or similar. This means, that the pharmacist selects based on economic grounds.*

Pharmacists do not make use of their influence for all decisions. They carefully weigh up the opportunities and risks to interfere. In the event of important decisions, such as decisions with high budget impact, pharmacists are more active than in other situations.

B4 (pharmacist): *Well, for very important decisions we partly interfere and...prepare data, in order to simply have objective data available for the committee meeting.*

And pharmacists do not have the last word for all questions in the committee. They acknowledge the differing perspectives from physicians and often do not interfere in those questions considered highly sensitive. Pharmacists have a key role in decision-making for those decisions with very similar pharmaceutical drugs, drugs with a high budget impact and in cases of existing alternatives. Other cases, such as decisions about new and innovative drugs or drugs for specific therapeutic areas, are heavily influenced by the physician's opinion.

B3 (pharmacist): *There are situations where the financial issues by the pharmacy are ignored and people say: we need this for specific medical reasons. And this is what I accept then.*

B7 (pharmacist): *The pressure, the pressure...well we could call it the pressure from a department or from, from a specific...physician. But that...that must be massive pressure then, ok. [...] As a pharmacist I would not interfere with the depth of cardiologic therapy or we prefer not to do this here. And if one physician decides to, I do not know, take [PRODUCT X] but not [PRODUCT Y], then, then I cannot do very much.*

B7 (pharmacist): *If a specific department, such as cardiology, decides to list three or four drugs, and they make a big effort, get studies and then they discuss, this leads to a real discussion in the committee. I mean, well, there they naturally...the department naturally has a significant impact.*

In spite of these specific situations where physicians have the potential last word in the decision-making process, physicians are cautious about the formulary committee meeting and the influencing power of pharmacists. Because of this, they have pre-

discussions with the pharmacist to estimate their chances of success. This pre-meeting alignment shows that physicians take the role of the pharmacist very serious, since they are afraid to hear about the pharmacist's objection against their proposal during the committee meeting and in front of their medical colleagues.

B1 (physician): *If I want to introduce a new drug the first thing I do is to call the pharmacist, ask him about his opinion about this drug, the pros and cons, also about the manufacturer, pricing, price negotiation. This means, if we go to the hospital formulary, I have already coordinated with the pharmacist.*

B5 (pharmacist): *Then they [the physicians] ask in advance, if that, if this really makes sense. This has already happened, that they have asked very carefully in advance, if this works or not.*

6.2.2 Value of expertise

Subject matter experts and members with experience in using a specific pharmaceutical drug are generally well accepted. If the member is accepted as an expert for this therapeutic area, other committee member's trust in his opinion and practical experience achieved in the hospital has a good reputation with impact on decision-making. However, there can be doubt about the expert opinion if it is in conflict with existing perceived objective data, such as data from clinical trials. Despite the trust in the expert's opinion this implies a predominance of specific perceived objective data and confirms the dominant position of clinical trials data.

B1 (physician): *In the first place I trust the presentation or the statements of the respective department which tries to list a specific pharmaceutical drug.*

B6 (pharmacist): *If the pharmaceutical drug is used mainly in the Intensive Care Unit, the respective lead physician has a key say in talking about this [...].*

B6 (pharmacist): *Actually he must present plausible...from his department clinical experience. Clinical trials data and the other data need to match somehow.*

B7 (pharmacist): *On the opposite this implies that the experience you have done in your own hospital, this means the practical application, this is quite an important criterion for the decision.*

The level of importance of a decision (in regards to costs or budget impact) might also be a reason for hospital formulary members not to trust the opinion of an expert. For example, in cases where the pharmaceutical drug is very expensive, committee members do not trust the presented data alone but rather try to prepare their own data or the committee might decide to simply restrict usage with a dual control (e.g. approval from a second physician required). This does not mean that formulary committee members have less trust in the experts, but they are more cautious since the potential damage for the hospital can be higher.

B4 (pharmacist): *Well, for very important decisions we partly interfere and...prepare data, in order to simply have objective data available for the committee meeting.*

B9 (pharmacist): *Then the price...does not prohibit the use of a drug, like it is possible in the outpatient sector, but it leads to...a dual control before approval.*

Non-pharmacists or non-physicians seem to play a secondary role in the decision-making process of a hospital formulary committee. The committee asks subject matter experts about their opinion and their recommendation, but the decision-making itself is only done by physicians and pharmacists. For example, nurses are being asked about the advantages and disadvantages of drug handling or dosage issues. If the respective drug is not appropriately covered by the hospital reimbursement system, financial administrators are being asked about possibilities to solve this issue and to get adequate funding for the drug. Often, non-pharmacist or non-physician functions are not part of the regular committee or they have a special membership status. In strategic cases, where the use of the drug is loss-making, but from the hospital perspective makes sense due to reputation gain, the medical director and general manager are the decision-makers.

B1 (physician): *No, I have commented on it in the questionnaire, because the financial administrator definitely provides impact or his recommendation, but he does not decide.*

B1 (physician): *And there is the financial administrator, who says, we have this or that possibility to get reimbursement. If there is no special allocation, this would stress our budget significantly.*

B2 (pharmacist): *If a department is established in a sector and they would like to treat some patients, although the drug is not covered by hospital reimbursement with the health insurances, in this case one must discuss this with the general manager and the medical director, how important it is to enable this treatment for the department [...].*

B4 (pharmacist): *Nursing services can generally participate as...with observation status, means without voting rights.*

In the formulary committee, members protect their subject areas. This means that they easily accept other member's opinions only for the topics which do not belong to their respective functional area. Physicians have trust in physician's opinions if the topics relate to medical topics, such as efficacy or safety. The economical or logistics expertise is assigned to the pharmacist. The competence around the application of the pharmaceutical drug is assigned to nurses. Hence, if a physician proposes a change of a pharmaceutical drug this is automatically associated with medical reasons. If the pharmacist proposes the same change, other (medical) members associate this with economic reasons.

B1 (physician): *[...] because I trust on the vote of the respective department which applies for the listing of a pharmaceutical drug. If a pharmacist proposes a change for a drug, I see this differently. There I question myself, if...I better take an example. If product A can be purchased cheaper from a different company, the presence of company A or B plays a role for me.*

B1 (physician): *Especially from the pharmacy on the one hand. Clearly they have the responsibility to present the price, the supplier issues of company X for example, which we do not know and cannot estimate.*

Despite the high value of the colleague's opinion an expert opinion alone does not seem to be sufficient in order to achieve a listing of the pharmaceutical drug. This again shows that a perceived subjective criterion, such as practical experience or expertise does not convince other formulary members if there are no additional criteria to support.

B3 (pharmacist): *Hmm [...], actually only the recommendation of a colleague is not sufficient for a listing.*

B5 (pharmacist): *The listing, I believe, will not be done based on a single experience. I think I can say this pretty clearly [...]. But finally, without good clinical trials data one would not put this drug on the list.*

B7 (pharmacist): *There is no evidence and the physician made good experience with it – this is something we would block!*

The expert opinion is seen as an addition to other data, specifically in cases where the perceived objective data does not allow clear decisions or at least makes it hard to differentiate between alternatives. In addition, the expert opinion becomes increasingly important if there is lack of other data. For example, this is often the case with new innovative pharmaceutical drugs where only a few clinical trials exist.

B6 (pharmacist): *And then it happens that with new drugs there is lack of experience because they have not been on the market for very long. And...but he has experience that in special cases the new drug has a higher efficacy. And based on this the discussion was held.*

6.2.3 Role of the function

In section 2.1.8 the impact of the individual role of a physician or pharmacist has already been discussed. In addition to that, the perceived importance of a full department can also have influence on the decision-making impact. Some

departments, such as cardiology or oncology seem to have more weight in the decision-making process due to their strategic and economic importance for the hospital.

B5 (pharmacist): *[...] I mean, if one is sort of really important and earns a lot of money for the hospital, then it is not completely absurd to claim a certain level of weight in the decision-making.*

B7 (pharmacist): *[...] as a pharmacist I would not interfere with the depth of cardiology therapy or we prefer not to do this here. And if one physician decides to, I do not know, take [PRODUCT X] but not [PRODUCT Y], then, then I cannot do very much.*

B7 (pharmacist): *If a specific department, such as cardiology, decides to list three or four drugs, and they make a big effort, get studies and then they discuss, this leads to a real discussion in the committee. I mean, well, there they naturally...the department naturally has a significant impact.*

The role of a department is also important in regards to the involvement in the hospital formulary discussions. Some departments are more focused on the use of pharmaceutical drugs than others. Hence, their efforts in the committee discussions are bigger than the efforts of other departments.

B3 (pharmacist): *If I look at one hospital, I have here 13 different departments, and of those 13 different departments only I as a pharmacist and 2 or 3 who really discuss, who have really dealt with the case, those are the...internists, who work a lot with drugs, and there are the anaesthetists, who work a lot with drugs, and possibly also the pain therapists. But all others are not very interested. [...] I said already I have 13 hospitals – this is a problem in all hospitals. Those who work a lot with drugs, they are very knowledgeable and the others, well, well... [laughs].*

Nevertheless, participation in the hospital formulary committee meetings is very important in order to guarantee transparent communication. The different functions, such as physicians, pharmacists, nurses or financial administrators have the responsibility to inform their respective departments and colleagues about decisions

which have been taken in the committee, specifically about the reasons behind decisions. Notwithstanding the individual member's involvement in the use of pharmaceutical drugs and the resulting level of effort in the discussions, every role has a representative function and serves as an information source for non-committee members.

B4 (pharmacist): *[...] who participates in committee meetings should also inform his or her department. Well, we take meeting minutes, even very detailed meeting minutes, nevertheless there are always argumentative nuances, which you need to report back from the live meeting.*

The chair of a committee formally has a higher importance than other members of the committee. But the impact of this higher importance of the committee chair is inconclusive. As a consequence of his position, he has a central role in the committee as a facilitator and moderator. Difficult decision situations require an individual for final advice.

In those cases where no majority vote is possible, the chair has a clear responsibility to take a decision. Noticeably he has a very important role in such a situation. Nonetheless, often the importance seems to be only on paper due to other members who utilise their influence on the chair.

B3 (pharmacist): *But I believe the one who facilitates and prepares the meetings, this is the one with the greatest influence. It is as simple as that.*

B4 (pharmacist): *With his style to facilitate the committee meeting, it is clear that the chair has impact and we have impact on the chair, because we align very closely and additionally we have, from my perspective, a substantial direct impact in the committee meeting.*

B4 (pharmacist): *[...] for the theoretical case of equality of votes, the vote of the chair would be decisive.*

B9 (pharmacist): *The chair of the meeting is usually restricted to the welcome and introduction of participants and to hand over the negotiation lead to the pharmacists.*

The different importance of different functional roles might lead to concentrated power. Taking decisions becomes easier but the risk of having biased decision-making swayed by small groups or individual members is higher. For example, close relationships between the powerful function of the pharmacist and the committee chair can lead to decision-making situations where no other function dares to take an opposite position.

B2 (pharmacist): *Most influence has the chair of the committee. This is one of our head physicians... and the director of the committee, because he steers the meetings well, right. And...I will say it like this...I am the director...in principle I prepare and steer this as best as I can. And if the chair then says: "Well, we decide this now!" then this is consensus, right.*

B4 (pharmacist): *With his style to facilitate the committee meeting, it is clear that the chair has impact and we have impact on the chair, because we align very closely and additionally we have, from my perspective, a substantial direct impact in the committee meeting.*

Direct hierarchical dependencies do not seem to have influence on hospital formulary decision-making. Most of the members of the committee are on the same or a similar seniority level in the hierarchy. Only the medical director and the general manager can be more senior than other members of the committee. In case of the general manager, the members of the committee respect his position, but they also recognise a lack in medical competency, since usually he has a business management background. In case of the medical director, functional competency beats hierarchy. If another member has the highest competency level he or she is able to prevail against the medical director. Likewise, members sometimes seem to use the hierarchy in order to push their application for drug listing if they lack a convincing argument. In this case, they try to end a discussion with the hint that the listing is a wish of their boss.

B1 (physician): *Formally, the general manager is boss of everyone, who works in the committee. But he is a businessman. Thus, he has no medical competency.*

B3 (pharmacist): *No, this [the decision-making] should happen on a competency level. And there it happens that a physician prevails against his boss.*

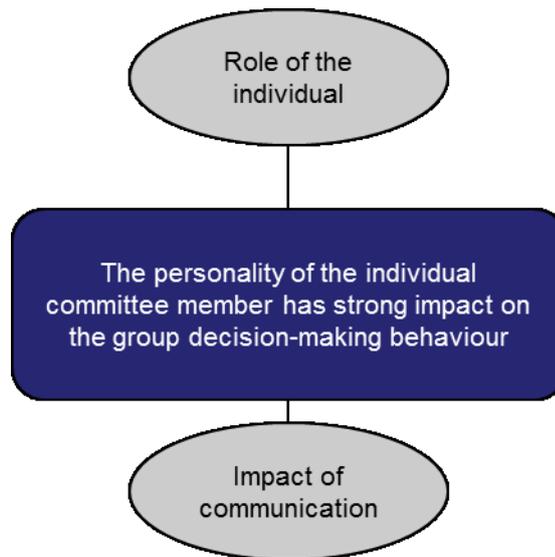
B4 (pharmacist): *The, the routine work in the committee is delegated to senior physicians and not very often, but sometimes, there is this argument, if there is no other argument: Yes, my boss wants it this way!*

B5 (pharmacist): *Somehow they must be seen as separate. Well, I do not believe that this has any influence. In a hospital you will always find strategically more important departments than others, but this has nothing directly to do with hierarchies [...].*

B9 (pharmacist): *This does not depend on the position! [...] the medical director prevails not because he is the medical director, but probably because his arguments are better.*

6.3 The personality of the individual committee member has strong impact on the group decision-making behaviour

This thematic network comprises of two organising themes and eight basic themes (Figure 38). It describes how the character of individuals in the committee has influence on the decision-making process. In addition, this thematic network broaches the issue of communication and how the way the formulary committee members communicate decisions impacts other member’s opinions.



Organising Themes	Basic Themes
Role of the individual	The individual personality influences other committee members
	The individual ability to communicate influences the impact on the group
	Stronger characters convince more easily
Impact of communication	Strong emotional arguments can change decision-making
	Presentations are short and thus presenters can place their important messages
	Argumentation needs to be convincing
	The way of communicating an opinion is vital
	Information advantages support the power of argumentation

Figure 38: Thematic network describing the impact of personality and communication.

6.3.1 Role of the individual

Formulary committee members have a significant influence on the committee decision-making process if they are perceived as strong personalities by other committee members. The perceived strength of personality derives from several criteria, which combined make this member a leader with an impact on decision-making. Value of expertise is one of the criteria which were discussed in section 2.1.8. In spite of being a subject matter expert the member needs good

communication skills to persuade other members of this expert role. Good meeting preparation which leads to information advantages compared to other committee members also strengthens the member's ability to convince the committee. Partly the position, for example being the chair of the committee, plays a role but is not sufficient as a criterion alone. Finally, a member needs to show leadership values, such as determination to complete the picture of a strong personality.

B1 (physician): *There was a little bit of an uproar, but finally this has been implemented. In this case there was a command of the medical director necessary to put the people...a little bit under pressure.*

B9 (pharmacist): *The pharmacists are usually best prepared. This is why they are so convincing. The power of pharmacists in the committee is not dependent on their position, sometimes this is good, sometimes this is bad, but this dependent on their...good knowledge about the topic of negotiation. This is one criterion.*

B9 (pharmacist): *The second criterion is the personality. A weak pharmacist prevails not as easy as a strong pharmacist. But also a weak head physician can prevail not as good as a strong head physician [...]. In a discussion the strong personalities prevail and those people who have information advantages which they can clever use in the discussion.*

6.3.2 Impact of communication

Communication has a key role in the decision-making of the hospital formulary committee. On the one hand it is the way how members communicate and on the other hand it is the way how members select the content of their communication. For example, even if an opinion is correct in terms of the technical perspective, this opinion needs to be "sold" to other members of the group. The reason is that many questions are very specific to the respective function and experts need to explain their opinion in a way that other members with less expertise also understand the rationale. Otherwise they would not be convinced despite the high acceptance of and trust in the role of the expert. As such, the way the formulary committee members communicate their opinion is vital. The presented data is often not sufficient and

members need to convince their colleagues in regards to the necessity of adding the respective drug. Thus, it is not only the perceived objective or subjective information about a drug, but it is also the ability of an individual member to transfer convincing messages which supports a listing. This can be done with good rhetorical capabilities and clever communication.

B1 (physician): *Well...usually there is a trial listing for a drug, if the head physician defends the case intensively, if he really needs it.*

B6 (pharmacist): *Perhaps all of the mentioned reasons were not solid enough and he was not able to convince people [...].And then it depends, how someone is able to present this in a convincing way.*

B6 (pharmacist): *Thus, it also depends how well-grounded the arguments are communicated and how well-grounded...how well-grounded those arguments are.*

Interviewer: *Well, the position counts less, but it is rather the personality of the individual, right?*

B9 (pharmacist): *The personality and the power of his argumentation. This is fair to say.*

Interviewer: *Does rhetoric play a role?*

B9 (pharmacist): *For sure!*

Besides the way how to communicate it is decisive how members build up their argumentation and what kind of arguments they select to support their case. Some members prepare their own case presentations and thus have a chance to filter the presented information to best support their argumentation. Due to the limited time for the presentation in the committee, not all information can be showed. This also means that the presenter usually has the best knowledge about his or her pharmaceutical drug which derives into an information advantage compared to other committee members.

B9 (pharmacist): *Thus, he has compiled the publications in a way that his opinion is supported. This is the same way we do it.*

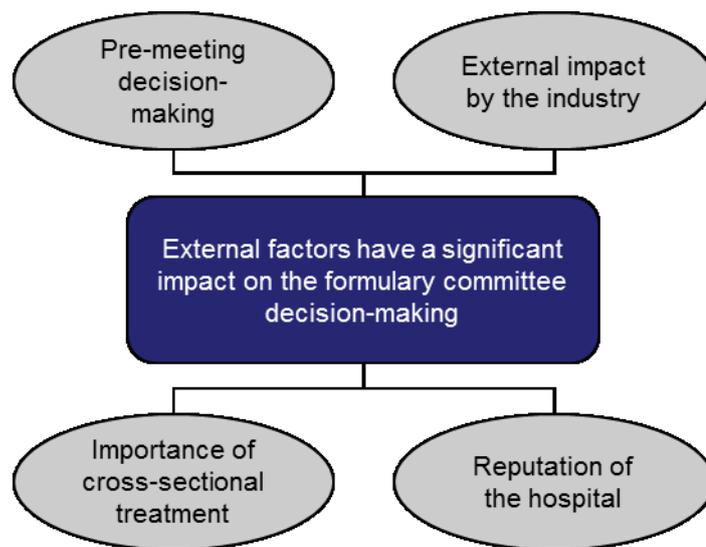
B9 (pharmacist): *The applicant of the drug listing prepares a small dossier, two pages, not a big folder with all possible studies, but two pages with the most important attributes of the drug.*

Another example to show the significance of the way to communicate is the use of strong emotional arguments, such as the life of a patient. Combining these arguments with the argumentation makes it harder for other members to contradict.

B3 (pharmacist): *Somebody said...somebody just said [during the discussion]: Well, this is enough! We talk about patient's lives and this is what we need! Full stop! This is independent of the costs.*

6.4 External factors have a significant impact on the formulary committee decision-making

This thematic network comprises of four organising themes and 21 basic themes (Figure 39). It describes the impact of external factors on the hospital formulary decision-making. Two main areas are important: factors within the hospital, but outside of the hospital formulary and factors external to the hospital, such as the pharmaceutical industry, regulations or the patient perception of the hospital.



Organising Themes	Basic Themes
Pre-meeting decision-making	Consensus decisions are preferred
	Members try to ally with others before the meetings
	Many decisions are not fully discussed during the committee meetings
	Critical points of the discussion might not be shared with the group
	Pre-committee alignment is used as a strategic method
	Members expect to have difficult discussions before the committee meeting
External impact by the industry	Members do have an opinion before they go into the meeting
	Members believe they decide independently
	External impact by the industry has a negative connotation
	Business relationships with the pharmaceutical industry influence decision-making
	Pharmaceutical industry has more impact with new and innovative drugs
	External impact of the pharmaceutical industry is strong on the listing application
Importance of cross-sectional treatment	Own clinical trial involvement has strong influence
	The hospital must take cross-sectional responsibility towards patients
	Continuation of patient treatment is crucial
	Health insurances have no direct impact on decision-making
	Health insurances have strong indirect influence on decision-making
Reputation of the hospital	Relationships to the outpatient physicians are considered for decision-making
	Positive reputation is a strong argument against costs
	Some treatments are crucial for the representation of the hospital expertise

Figure 39: Thematic network describing how external factors impact decision-making.

6.4.1 Pre-meeting decision-making

Members have an opinion about specific topics before they go into the hospital formulary committee meeting. As already discussed above, they usually receive an agenda and some kind of documentation in advance which they review and prepare themselves for those topics in which they have an interest. The individual pre-meeting opinion is then challenged during the meeting with arguments of other group members, but it marks the reference point for each member.

B1 (physician): *The topics for the bi-annual committee meeting are known to everyone in advance, they will be communicated by the pharmacist who organises everything and who is also the chair.*

Interviewer: *But you have already an opinion, yes or no, for the specific drug, before you go into the meeting? Or is this wrong?*

B5 (pharmacist): *Exactly, most probably you will have an idea, mhm. Someone would have reviewed the studies and found out; if one believes that there is a benefit, and a place where the usage is justified with us.*

Interestingly, a lot of the potential group discussion is already done in advance to the committee meetings. Members expect to have very difficult or controversial discussions with colleagues before the meeting. For some, it has a strategic component to ally with other influential members before the actual meeting starts. This increases the chances to successfully argue ones case and to convince others, specifically if the case is supported by influential members. However, if critical discussions are conducted before the actual formulary committee meeting, cases are not appropriately considered during the committee meeting. Members of the committee get a biased, positive picture of the case, since critical points might not be shared with the group. In addition, this pre-meeting arrangement also leads to a strong supporter alliance for the respective case which makes it difficult to challenge for other committee members.

B1 (physician): *If I want to introduce a new drug the first thing I do is to call the pharmacist, ask him about his opinion about this drug, the pros and cons, also about the manufacturer, pricing, price negotiation. This means, if we go to the hospital formulary, I have already coordinated with the pharmacist.*

B1 (physician): *If I want to introduce a drug in my department, I expect colleagues to accept my proposal, unless they have a really big counter-argument, but then I would expect to hear this in advance.*

B5 (pharmacist): *Then they [the physicians] ask in advance, if that, if this really makes sense. This has already happened, that they have asked very carefully in advance, if this works or not.*

This pre-meeting alignment is useful for the committee members in regards to their preference of deciding on a consensus basis. Hospital formulary committee members prefer to take decisions without being too aggressive against other member's opinions. Hence, pharmaceutical drugs are seldom fully rejected. It is more likely that committee members decide to allow a test run, apply restrictive criteria to its use and often postpone a difficult decision. With this approach they also have the opportunity to create and gather more data for a drug to take a better informed decision at a later date.

B5 (pharmacist): *Well, a rejection is very seldom. But that someone says, somehow we cannot...we are not really convinced, yet, actually we would like to see more data, more...very often just more treated patients [...]. Sometimes someone just says, we postpone the application for half a year and wait how the data looks like. This happens.*

B6 (pharmacist): *Then in most cases we came to the conclusion, if the budget was really impacted, then we said: we observe this for another three or four months [...]. But it was not the case that we said, well that...that the committee has forbidden something.*

B9 (pharmacist): *A department would like to have this and we think it does not make sense. Then we try to block this. Or we say we could have a try. Having a try means, this is what I said already before, just see, if the drug finds its area of application.*

6.4.2 External impact by the industry

Although hospital formulary committee members believe that they take independent decisions, when asked in more detail, many acknowledge a significant influence by external factors, such as the pharmaceutical industry. Especially for new pharmaceutical drugs, the industry provides the majority of the published information and in this way has the opportunity to have an indirect impact on formulary committee decision-making. In addition, committee members recognise the efforts of the industry to influence committee members to promote their products.

B1 (physician): *I believe that in the initial phase, the introduction of a new substance, the pharmaceutical industry has a big influence, inevitably.*

B3 (pharmacist): *It depends, how often the drug gets promoted, how often the frequency of the sales force visits is and the more often the drug is pushed the easier it is in the heads, we should not fool ourselves. This is the case. [...] I believe the...pharmaceutical industry has influence on the listing applications but if the applications get approved, there they actually have no influence.*

Interviewer: *How strong would you see the influence of the pharmaceutical industry on the committee's decision-making?*

B6 (pharmacist): *Yes, definitely, definitely significant, I need to say and in fact...this is not meant in a bad way, but it is primarily a fact that a lot of well-prepared information comes from the pharmaceutical industry.*

In general, this is a sensitive topic where external impact by the industry has a negative connotation. This negative connotation might even lead to a very negative impression of the application, since the assumption of external influence decreases the trust in the expert's opinion of an application. Committee members refuse a direct impact of the pharmaceutical industry on their decision-making and they assume that listing applications may be affected but not the listing decisions. They have an ambivalent opinion about external relationships and the potential influence on decision-making. On the one hand, members see the external relationships positively, for example in cases where industry asks committee members about their expert opinion. On the other hand they do not want any external influence on their

decision-making and like to keep their independence. In addition, they seem to be afraid of the impact this could make to their justification towards the public.

Interviewer: *How would you describe the influence of the pharmaceutical industry on your decision-making? Does this exist? If yes, how can it be best described?*

B5 (pharmacist): *... well, ultimately I would think, that this is [...] I would say this [any impact] is impossible. But now you are asking me and not the applicant.*

B8 (physician): *Well, I am saying this pretty clear, because if I – I refer this to me personally – if I have the suspicion that an application [...] yes, is directly initiated by the pharmaceutical industry [...] this would be a negative criterion.*

B8 (physician): *I mean, if someone is NOT in the public in seminars or as a consultant for a company, then this person is probably wrong at our hospital, saying this very explicitly. This is hard to understand by the public, but this is logical. If I have experts, then those experts also work somewhere else.*

If members are involved in clinical trials they have a special bond to the respective pharmaceutical drug. Clinical trial participation is good for the physician's reputation and it is even better for his reputation if the trial is successful. Hence, the physician has a personal interest in positive data for the respective pharmaceutical drug. For this reason, the participation in a clinical trial can make a member a very strong advocate for this drug in the formulary committee.

B7 (pharmacist): *Well, especially those...those who were involved in the development or participated in big clinical trials, those people insist heavily on their drugs.*

B7 (pharmacist): *You have head physicians, who participated long ago in a [COMPANY] [PRODUCT] study and they want their [PRODUCT], there is nothing else, they do not care about current clinical trials.*

6.4.3 Importance of cross-sectional treatment

All of the interviewed hospital formulary committee members agreed that health insurances have no direct impact on decision-making. However, for certain questions they do have indirect impact. This can be the case for pharmaceutical drugs which are used for treatments initiated in the hospital and which are continued afterwards in the outpatient sector (cross-sectional treatment). As a result of reimbursement regulations, health insurances have a good level of pharmaceutical drug control in the outpatient sector. This has even increased with a law implemented in 2011 (Arzneimittelneuordnungsgesetz = AMNOG) and regulates an evaluation process for new pharmaceutical drugs in parallel to their market start. The evaluation process takes six months and a negative outcome can have significant impact on the outpatient reimbursement. This impact can be so significant, that the outpatient physician might refuse to prescribe the drug.

However, hospital formulary committee members have a strong interest to make continuation of drug treatment possible for two main reasons. Firstly, treatment only makes sense, if the patient can continue with it after the hospital stay. Secondly, hospitals have an interest in good relationships with the outpatient physicians in their domain as they are dependent on the willingness of outpatient physicians to allocate patients to the hospital.

B2 (pharmacist): *There we have decided as the formulary committee to delete this drug from the list to prevent any issues with outpatient physicians, ok. They would have run into problems with the health insurances. If it is not reimbursable, the patients need to pay out of their own pockets and this would have been...mmh...just a little bit difficult [...]*

B3 (pharmacist): *I hear more and more often: we cannot prescribe this, because the outpatient colleagues with their budgets, they would change this anyways. And this is actually too bad.*

B4 (pharmacist): *Indirectly this actually plays a role: what can be prescribed in the outpatient setting? Well, we try to avoid having drugs on the list which cannot be prescribed in the outpatient setting.*

B5 (pharmacist): [...] someone cannot see the hospital fully isolated at this point [...] but I believe as long as someone talks about treatment continuation, it becomes difficult, if someone is not considering how much the treatment costs.

6.4.4 Reputation of the hospital

The importance of costs, prices and reimbursement issues of a pharmaceutical drug was discussed earlier in section 2.1.8, but one external factor strongly mitigates against these cost issues: the reputation of the hospital. When hospital formulary committees think about a certain drug listing they consider if this new drug can be used for new and innovative treatment. Even in cases where the reimbursement of the drug leads to a negative financial outcome, the decision might turn positive, if the drug allows a treatment which increases the reputation of the hospital.

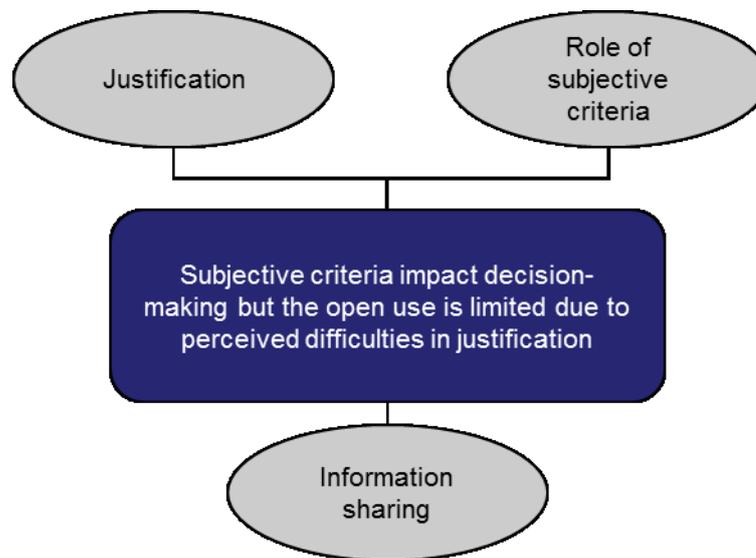
B1 (physician): *If a physician can argue why a therapy, which is not appropriately reimbursed and thus loss-making, makes sense because of the department reputation, in order to create awareness for the special expertise of this department, then the vote of the head physicians is surely important for the general manager.*

Another example of this external factor is the hospital reputation with the patient. If a competitor hospital offers a more innovative therapy or a more convenient therapy for the patient this is a disadvantage for the hospital. This is why committee members for their drug listing decision-making also consider what is offered in other competitor hospitals.

B9 (pharmacist): [...] with the neighbouring hospital you have these competitor thoughts: “They now offer this treatment method. This is why we also need to have that!” [...] If the patient says: “There you can take a pill and there you get an injection with a needle...” There you would not like to be the hospital with the needle. Such an argument also plays a role.

6.5 Subjective criteria impact decision-making but the open use is limited due to perceived difficulties in justification

This thematic network comprises three organising themes and 14 basic themes (Figure 40). It describes the impact of subjective criteria on the decision-making process of the hospital formulary committee group as well as issues related to the use of subjective criteria and justification of decisions. In addition this thematic network refers to the implications of information sharing between the formulary committee members.



Organising Themes	Basic Themes
Justification	It is easier to justify decisions based on objective criteria
	The documentation of decisions is very limited in reflecting the main discussion points
	In regards to applied decision criteria, transparency is limited
	Transparency means to report all conflicts of interest
	Transparency is needed to avoid being accused of bribery
	Transparency means to have process clarity
Role of subjective criteria	Gut feel decisions are accepted if pure objective decision-making is difficult
	Assessing the importance of subjective criteria is difficult
	High patient empathy in combination with low budget impact means an easier listing decision
	Quality of subjective criteria is measured with objective criteria match
Information sharing	Documentation provides only filtered information
	Information sharing is key for willingness and ability to discuss
	Preliminary discussions preclude members to get all information
	Preparation prior to the meetings allows informed decision-making

Figure 40: Thematic network: the role of and issues with subjective decision-making criteria.

6.5.1 Justification

Transparency is an important topic for the members of the hospital formulary although the understanding of the meaning can be different for each member. Hospital formulary committee members feel that a certain level of transparency is necessary to protect them from being accused of any form of corruption. It is also important as decisions have an impact on a limited budget where decisions can potentially lead to limitations of treatment to other departments or patients and it is their responsibility to explain why a specific drug is justified. However, this level of transparency can be achieved in different ways and members have different focal points. The basic understanding of transparency includes the documentation of the decision-making process or the reporting of any business relationships between formulary committee members and the pharmaceutical industry.

B1 (physician): *Because decisions of the hospital formulary committee are budget relevant [...] this is an expensive decision which possibly limits the resources for other things, at least temporarily.*

B3 (pharmacist): *[...] and that everybody discloses their relationships...or the pros and cons and not till then a mutual decision is taken for or against a listing. And this is transparency for me. [...] that you are not doing a listing just to please a certain sales force representative and that we are not corrupt, neither on the physician's side nor on the pharmaceutical side.*

B4 (pharmacist): *On the one hand we would like to have clarity on the processes here; this means how the decision-making works, this is a basic principle. We would like to have legal certainty. This also means, well, how should I express this, defence against corruption accusation or prevention of being accused of corruption. (...) Yes, I believe, those are the relevant criteria.*

Members find it easier to justify their decisions with objective criteria instead of mention any perceived subjective criteria. Hence, the documentation only concentrates on the final decision and is either describing the decision-making process or the decision of the committee only. The documentation of decisions is very limited in reflecting the main discussion points related to the decision and it

does not specify any decision criteria. Furthermore, the documentation is limited to perceived objective information, such as medical, safety or economic criteria. Due to the perceived issues with justification, the formal process can even block the actual decisive subjective criteria and make members think of ways to justify based on other, more accepted perceived objective criteria.

B4 (pharmacist): *We are doing this on purpose and do not specify the decision criteria. It...That means, it is, of course it is mentioned that decisions should be taken based on medical, pharmaceutical and economic criteria. This of course is clear.*

B5 (pharmacist): *[...] probably because we are doing this [process] very strictly, probably they [any subjective criteria] are not presented openly. I would not exclude that people make their experiences [with the drug] but would not name it this way, just because it is not allowed here.*

B6 (pharmacist): *Well, only the decision was documented but not the discussion leading to the decision.*

B7 (pharmacist): *There is no need to publish all discussion points, but in any case the decision. [...] You cannot explain to everyone why you have chosen a specific cardiological drug. [...] This is why the hospital formulary committee exist. Well, in principle this is like a parliament.*

6.5.2 Role of subjective criteria

The impact of perceived subjective criteria on the decision-making process is difficult to describe for the members of the hospital formulary committee. There is awareness that these criteria potentially have influence on the member's opinion, but it is difficult for members to estimate the importance compared to other criteria. In case the available objective criteria fail to help making an easy decision, committee members accept the potential use of perceived subjective criteria, such as gut feelings or practical experience.

B1 (physician): *If it is just a small difference in price, I would decide based on my gut feeling always for the company, which is more present in my area. Decisions based on gut feeling do exist.*

B4 (pharmacist): *Of course it plays a role if somebody has experience with the drug, which you can use for decision-making. But it is really difficult for me to rate the importance quantitatively.*

Although, hospital formulary committee members generally accept the existence and impact of perceived subjective criteria, they have concerns in using them for an official justification. Even in cases where subjective criteria, such as practical experience, are recognised, members try to make a connection to existing perceived objective information. For example, this is the case when practical experience results may not match clinical trials data in order to be valid.

B4 (pharmacist): *[...] and I need to make a decision, then gut feeling and similar things have an impact. This is true. But it depends on how you translate gut feeling: If I translate this with “irrational decision” – this is something we cannot accept, of course.*

B5 (pharmacist): *Well, such subjective criteria do not exist here. Nobody could understand such criteria.*

B5 (pharmacist): *But, if the physician is more willing to apply for funding if he made good experience, this is something I would not exclude. This is human, probably. But this way you cannot justify your decision here. This would be difficult.*

B6 (pharmacist): *Actually he must present plausible...from his department clinical experience. Clinical trials data and the other data need to match somehow.*

Higher empathy with patients due to the severity of their disease or because they are children can lead to easier discussions. In these cases, members tend to accept more easily perceived non-objective information. In some cases, discussions are

interrupted by very strong emotional arguments. Members try to convince other members with reference to the moral and ethical goal to save patients' lives.

B1 (physician): *But with oncology patients, if the oncologist argues intensively that he needs his product A or B, you would rather agree without discussing too much.*

B3 (pharmacist): *Somebody said...somebody just said: Well, this is enough! We talk about patient's lives and this is what we need! Full stop! This is independent of the costs.*

B7 (pharmacist): *For the paediatricians you have sometimes slightly emotional decisions, and there, there nobody interferes. You have low costs and then everybody thinks, alright, we can provide this, and then everybody smiles and approves.*

6.5.3 Information sharing

Information sharing is a key factor in the decision-making process of a hospital formulary committee as it determines the willingness and ability of committee members to have a serious discussion. If members do not have all information to make a decision, the perceived expert level of other members with more knowledge creates a barrier for the discussion.

However, the majority of hospital formulary committee members might miss key information as many colleagues have pre-discussions, during which critical and difficult aspects of the decision task are already addressed. Members also align their opinion already upfront if possible. In those cases, other committee members get a biased presentation of the decision and probably do not realize that key information is missing.

B1 (physician): *If I have an important counter-argument against a specific drug which a department head would like to introduce, then I would call him in advance and ask him, why exactly this drug, why not the alternative? [...] If I want to introduce a new drug the first thing I do is to call the pharmacist, ask him about his opinion about this drug, the pros and cons, also about the*

manufacturer, pricing, price negotiation. This means, if we go to the hospital formulary, I have already coordinated with the pharmacist.

B5 (pharmacist): Then they [the physicians] ask in advance, if that, if this really makes sense. This has already happened, that they have asked very carefully in advance, if this works or not.

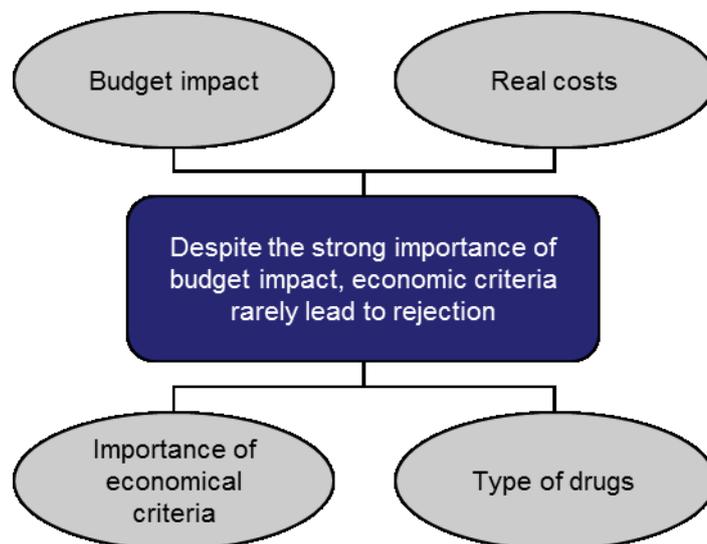
In addition, the information provided in advance to the meetings is already biased as the content of the documentation depends on the willingness of the person who is responsible to share information with other members of the committee. This willingness is dependent on the applicant's individual goals and as the applicant wants a positive decision, the provided documentation is favourable to the case. Furthermore, the content of the documentation is limited by the amount of time members have for the preparation of the documentation and then also the time for discussions in the committee.

B9 (pharmacist): [...] we try to form our opinion and we then try to present this opinion. This is... this is done the same way by the others [...] Thus, he has compiled the publications in a way that his opinion is supported. This is the same way we do it.

B9 (pharmacist): The applicant of the drug listing prepares a small dossier, two pages, not a big folder with all possible studies, but two pages with the most important attributes of the drug.

6.6 Despite the strong importance of budget impact, economic criteria rarely lead to rejection

This thematic network comprises of four organising themes and 20 basic themes (Figure 41). It describes the role of economic criteria and specifically the important role of budget impact in the decision-making process of the hospital formulary committee group. Despite the importance of budget impact, economic evaluations have no significant impact. This is due to their universal implementation and thus they often lack a hospital specific focus. Another important aspect of this thematic network is the difference in decision-making in regards to the type of the pharmaceutical drug. The applied decision criteria are dependent on what type of drug is under consideration.



Organising Themes	Basic Themes
Budget impact	Level of budget impact influences the willingness for compromise
	High budget impact limits flexibility for other departments
	Very high budget impact can limit the funding decision
	Big difference in overall costs are handled more formally
	Impact on the department increases member's willingness to get involved in the discussion
Real costs	Costs of switching to a new drug is relevant
	Safety of a drug means patients safety and cost savings
	Total costs include drug costs and process costs
	Clinical trials data often do not properly reflect the hospital population
Importance of economical criteria	Importance of economic criteria is too big
	Economic evaluation has not a big impact
	Economic criteria do not lead to a total rejection
	Importance of economic criteria increase in case the committee sees similiarity for two drugs
Type of drugs	Members differentiate between different types of drugs
	If drugs are used in more than one department, members increase their discussion efforts
	Decisions on very new drugs are often preliminary
	Members trust the opinion of experts in cases of therapy area specific drugs
	Orphan drugs are usually not listed
	Specific drugs are challenged less than others

Figure 41: Thematic network describing the importance of several economic criteria.

6.6.1 Budget impact

Budget impact plays a central role in the decision-making process. One main reason for this importance is the potential limitation for the different departments of a hospital. That is, a high budget impact for a specific drug used in one department limits the possibilities of other departments due to the decreased total budget. In consequence this means that members are more willing to compromise if the budget impact is lower. Hence, members supporting a request for funding for a high budget impact will often need to justify this as this complicates the listing decision. For example, a restricted listing might require certain senior physicians who need to sign-off every use of the drug. Or the drug will only be listed for a sub population with the highest efficacy.

B1 (physician): *Because decisions of the hospital formulary committee are budget relevant [...] this is an expensive decision which possibly limits the resources for other things, at least temporarily.*

B5 (pharmacist): *The single departments have global budgets and they are of course interested to meet their budget goals or even to free up money to use it somewhere else to invest. Or to put it into the opposite: If the money is spend for...mostly expensive pharmaceutical drugs, it is missed somewhere else.*

B5 (pharmacist): *[...] you look at the total costs of the current therapy and compare this with the costs of the new therapy. And if there is a big discrepancy, then the additional benefit needs to be significantly higher. Or you would, this also happens, list the drug only for a small portion of the patients.*

B9 (pharmacist): *Or it [the drug] is listed and in principle known for regular usage but very expensive, a second person should approve. [...] but a head physician needs to sign-off each usage.*

The impact of a pharmaceutical drug on the budget also influences the efforts of members to participate in the discussion. For low budget impact drugs, members might even accept a drug without any discussions or questions, since they feel that the effort is not worth any action. In addition, budget impact influences the

willingness to accept other usually strong data, such as efficacy data from clinical trials. If a drug shows efficacy superiority in comparison to the current drug, but its costs are significant higher, then the requirement for the presented evidence would be higher than it would be in case of a small difference in total costs.

B4 (pharmacist): *Let's say, if the ophthalmologist asks for a tear substitute, this does not really matter. [...] If it is about changing Heparins, which affects the whole hospital, then of course we put a high effort into collecting all facts.*

B7 (pharmacist): *For the paediatricians you have sometimes slightly emotional decisions, and there, there nobody interferes. You have low costs and then everybody thinks, alright, we can provide this, and then everybody smiles and approves.*

B7 (pharmacist): *The reason is that those drugs are not expensive. You would not invest more energy if you talk about 3,000 EUR yearly costs [...].*

6.6.2 Real costs

Hospital formulary committees consider the total costs that the introduction of a drug will make rather than just considering the acquisition costs. Cost assessments appreciate that safety of a drug is relevant for savings due to increased patient safety and less adverse events, unexpected hospitalisations and other resource implications which otherwise would need to be dealt with in the hospital. Besides the drug costs, the calculations include process costs and also costs for switching from one drug to another. A major challenge for committee members is that clinical trials often do not fully reflect the patient population characteristic for the hospital. This might lead to imprecise assumptions regarding the specific hospital costs.

B2 (pharmacist): *Yes, yes, but this does not help us at all. These studies are actually, there are so many exclusion criteria and they are done with, let's say, relatively healthy, younger patients, right. If someone...half of our patients are older, let's say, and they also have all different kinds of co-morbidities, right.*

B6 (pharmacist): [...] and then we save time in the surgery preparation and then of course we can...we can support our staff.

Interviewer: *Should the importance of economic data [...] from your perspective be higher than today?*

B7 (pharmacist): [...] that this is not yet the case, the reason for this is that those data, well let's say, first needs to be collected or that the data is different in every hospital. This is why every hospital needs to find its own data.

B7 (pharmacist): *What kind of process costs are behind this? And this is what we need to consider in our price negotiations, because you cannot change everything for...for 1,500 EUR, if everybody is involved and then you save 1,500 EUR and you have all this effort to change everything.*

6.6.3 Importance of economic criteria

The feeling of hospital formulary committee members is that the impact of economic criteria has increased and that its level of importance to decision-making should not be higher. This concern has been mentioned by both physicians and pharmacists. Especially in situations where the committee members have difficulties in differentiating two drugs, the importance of economic criteria increases.

B3 (pharmacist): *Actually today, people consider the money too much. [...] It should not be more important than this.*

B4 (pharmacist): *In the meantime we have the hard-core money-saver on the medical side, and we need to stop here, money is important, but it is not everything. The quality...should play the biggest role.*

B8 (physician): *Right now we have the opinion that the standard [DRUG TYPE], independent which brand, is relatively uniform or similar. This means, that the pharmacist selects based on economic grounds.*

One interesting outcome is that even big concerns about economic criteria usually do not lead to a total rejection of listing a pharmaceutical drug. Members are reluctant in

issuing final negative decisions and rather allow a trial period in which additional data should be generated. For hospital formulary committee members the postponement has the advantage that they are no losers in these discussions. The applicant can try the pharmaceutical drug and use it with patients on a case-by-case basis, but the drug is not on the list, yet.

B1 (physician): *One wants to gather personal experience if the drug is convincing but the clinical trials data not sufficient, the head physician gets the chance to place single orders or a restricted volume to make his experience. And then he is allowed, as discussed before, to report back about his experience.*

B4 (pharmacist): *For orphan diseases the products will usually not be listed, but they will be ordered on special request. And here we are more flexible, I would say...allowing the physician to gather experience.*

B8 (physician): *On the other hand I have the advantage to have additional cases over the year which helps to gather experience, and very often these are special drugs, very often these are oncology drugs.*

In spite of the high significance of economic criteria in general, economic evaluation as a more specific decision-making criterion is of low importance. The biggest obstacles for a higher acceptance of economic evaluations are preparation time, skills of the formulary committee members and the lack of hospital specific evaluations. Economic evaluations can be complex and without dedicated experts it takes often much too long to fully assess an economic evaluation. In addition, physicians often lack the basic knowledge and understanding of the economic evaluation concepts resulting in low interest. Besides time and skills, economic evaluations are not well accepted because they do not show numbers which are comparable to the individual hospital situation. Thus, the outcomes of an economic evaluation are worthless for the decision-making process.

B6 (pharmacist): *[...] Then the efforts to explain the calculations are too high. Ideally would be if participants would have more knowledge [on health economics], how this works, then this would be much easier.*

Interviewer: *How do you estimate the impact of, let's say in general health economic evaluations [...]?*

B7 (pharmacist): *Actually I do not consider this. I...have currently not very much time to work on this in detail. [...] And...I do not really know, frankly speaking, where I would need such a general pharmacoeconomic...health economic study for my specific portfolio.*

6.6.4 Type of drugs

Different types of pharmaceutical drugs are evaluated differently. Members of the hospital formulary use different decision-making criteria dependent on the type of drugs. This becomes very clear in case of drugs for the treatment of rare diseases (orphan drugs). These drugs are usually not put on the formulary list due to their irregularity of use. Physicians need to order those drugs always on specific request.

B4 (pharmacist): *For orphan diseases the products will usually not be listed, but they will be ordered on special request.*

B7 (pharmacist): *If it is really an orphan drug, it will not be added to the list, that is...that will be ordered in those rare cases with approval and eventually cost commitment and so on. You would not find this in the list.*

In cases of drugs specific to a therapeutic area, members trust the opinion of the concerned department and the respective subject matter expert. Members also make a differentiation in regards to the therapeutic area: oncology drugs, although often expensive, and paediatric drugs seem to be less challenged than others. However, if drugs are used in more than just a single department, the concerned members put more efforts in the discussion about the listing.

B1 (physician): *On the other hand you are in a different situation with oncology patients compared to patients who require a new hip, where drug A and drug B are quite comparable.*

B3 (pharmacist): *Normally it is the same criteria with...maybe with slightly different focus. Let's say, for oncology drugs the tolerance or the patient outcomes have...a bigger weight than probably for a cardiovascular drug or so.*

B4 (pharmacist): *If it is about changing Heparins, which affects the whole hospital, then of course we put a high effort into collecting all facts.*

B4 (pharmacist): *And then I would like to add: It really depends on what you are talking about. If you discuss antibiotics, the microbiologists has the highest influence, if you talk about cardiovascular drugs, it is the cardiologist and so on. This is dependent on the functional focus.*

B7 (pharmacist): *If some paediatricians state that this is better, than, than this would normally be approved, yes, than...nobody discusses this, because, because no one would like to become acquainted with this. Those are special things.*

There is also a differentiation between drugs with existing active substances and new and innovative drugs. For new drugs there is usually a lack of available data or the available data is limited. Members accept this by taking decisions on new, innovative drugs on a preliminary basis. This way, the applicants of the drug listing application get a chance to try a new drug and make practical experience regarding efficacy, safety, but also costs. Following this trial period, they need to report back to the group who then take a final decision. Another preliminary decision might postpone the whole discussion to a later time point, also having in mind that the chances for more available data are then higher.

B4 (pharmacist): *If the situation is really unclear, I am a little bit reluctant. Then you could probably say we take the decision now to have a trial on this drug for half a year or a year. This would most probably go into this direction.*

B5 (pharmacist): *Especially for new drugs there is a lack for big patient studies, which are not initiated until the marketing authorization is there. When this happens you also have bigger studies with much more patients. Sometimes someone just says, we postpone the application for half a year and wait how the data looks like. This happens.*

B7 (pharmacist): *You always give people the opportunity to make their experience or to have trial or whatsoever.*

B9 (pharmacist): *We just do this and have a trial. And then at the end we have a result, after half a year or when we meet again, if this was ordered at all.*

6.7 Summary

This chapter summarised the findings of the qualitative expert interview analysis. The analysis identified five thematic networks about the decision-making process of hospital formulary committees.

The first thematic network describes the strong influence of physicians and pharmacists on the decision-making process of the hospital formulary committee group and that the experience with a pharmaceutical drug can impact other members' decision building. Especially the dominant role of the pharmacists is also topic in other thematic networks. Pharmacists usually prepare most of the information which is used in the hospital formulary committee discussions. Hence, depending on the pharmacists' willingness and ability to communicate issues, other committee members receive more or less information (thematic network four). In addition, pharmacists are often approached already before formulary committee meetings by physicians who want to have pre-alignment which adds additional power to the pharmacists (thematic network three).

Following this, the second thematic network describes how the character of individuals in the committee has influence on the decision-making process and how the way the formulary committee members communicate decisions impacts other member's opinions. A member who has more information than other members regarding a case can make better arguments which overlaps with the issue of biased information sharing (thematic network four). It is also decisive how processes of the formulary committee impact the influence level of certain members. Due to a limited time to present a case during the committee meetings, the member who prepares the

case information selects the most favourable argument. This issue is also addressed in thematic network four.

The impact of external factors on the hospital formulary decision-making is the focus of the third thematic network. Two main areas are important: the factors inside the hospital, but outside of the hospital formulary and factors outside of the hospital, such as the pharmaceutical industry, regulations or the patient perception of the hospital. A key topic is a discrepancy between the big importance of relationships to the pharmaceutical industry and the perceived low impact on decision-making. Formulary committee members confirm different aspects which underline the importance of those relationships but they also deny any bias on their decision-making.

Then, the impact of subjective criteria on the decision-making process of the hospital formulary committee group is described in the fourth thematic network. This network includes a description of committee member's issues in regards to the use of subjective criteria and justification of their decisions. Official documentation of formulary committee decisions does not provide hints for the acceptance or usage of subjective criteria but committee members make regularly use of them. This network also refers to the implications of information sharing between the formulary committee members. Thus it overlaps with thematic network one, two and three.

The last thematic network describes the role of economic criteria and specifically the important role of budget impact in the decision-making process of the hospital formulary committee group. Despite the importance of budget impact, economic evaluations have no significant impact and often are not hospital specific enough. Another important aspect of this thematic network is the difference in decision-making in regards to the type of the pharmaceutical drug. The applied decision criteria are dependent on what type of drug is under consideration. This thematic network, like thematic network one, emphasises the importance of pharmacists with the focus on economic measures. However, it also confirms the acceptance of subjective criteria, as described in thematic network four, because rejections are seldom made only based on the economic criteria.

7 Company market research data analysis

7.1 Introduction

The company market research data analysis represents step seven in the research design (Figure 42).

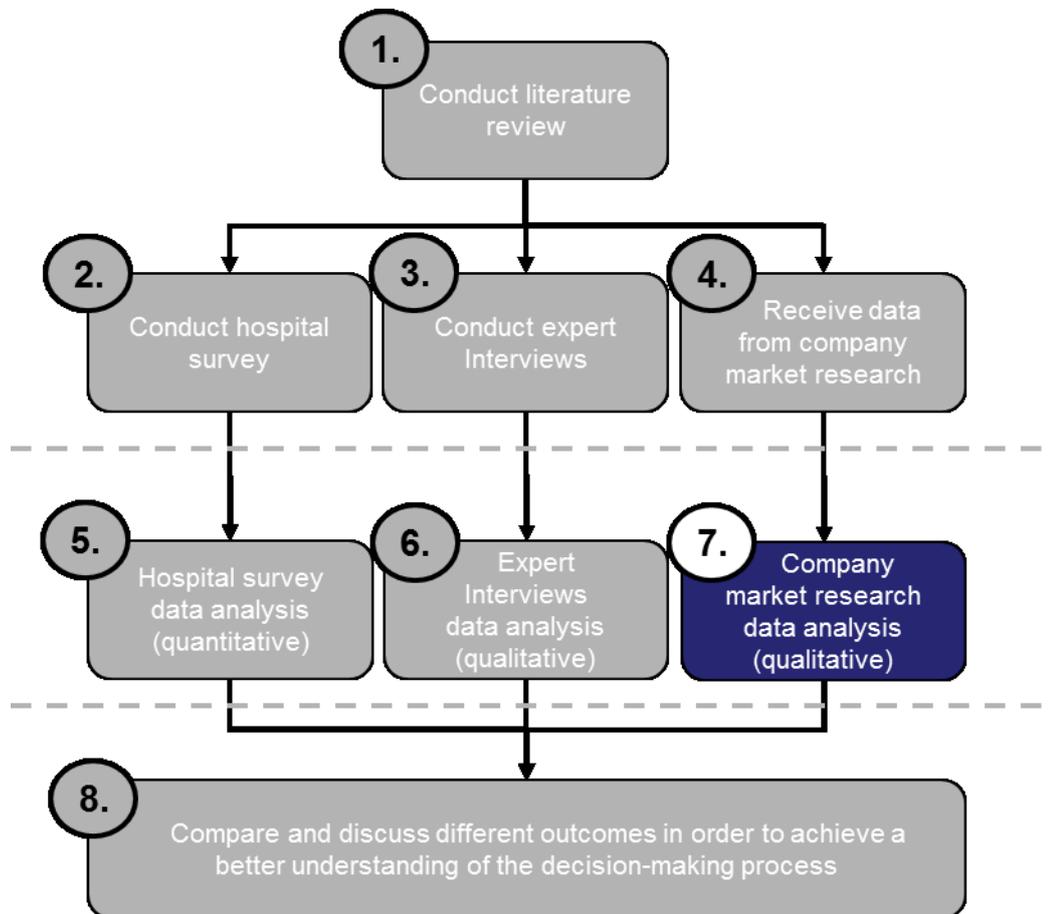


Figure 42: Company market research data analysis.

The company market research data represents an additional data source which was not specifically conducted for this thesis. All interviews for this market research were conducted by a pharmaceutical company in order to better understand hospital formulary committee decision-making for a specific pharmaceutical drug of the company.

The analysis of the company market research interview transcripts was based on the structure of the thematic networks approach (Attride-Stirling, 2001) as described

already for the expert interview data analysis in chapter 6. The same eleven codes from the literature review were used in the first step of the analysis in order to slice up the interview transcripts into text segments:

Group, Individual, Centrality, Dependencies, Information sharing, Objective information, Subjective information, Structure, Process, Transparency, External impact.

In order not to limit this research and to allow explorative information, the initial list of codes was not closed. However, during the coding phase, no additional codes derived from the interview transcripts.

Following the coding phase, the text segments were re-read to identify and refine topics which represent the second step of building thematic networks. This was done for all codes which resulted in twelve different basic themes (Table 17).

Code (1st step)	Themes (2nd step) --> Basic Themes
Centrality	Nurses have no direct impact on the decision-making process
Centrality	Pharmacists and physicians are the decision-makers
Centrality, Subjective information, Type of drug	Expert opinions and experience are accepted as valuable input
Centrality, Group	Selected key people have pre-meeting discussions
Centrality	Pharmacists have a gatekeeper function
Centrality, Type of drug	In case of generic drugs the decision is taken by the pharmacist
Group	The formulary committee is used to legitimise pre-meeting decisions
Group	Concerned departments have a higher decision-making weight
External impact	Pharmacists have pre-discussions with the pharmaceutical industry
Objective information	Cost considerations are dominant in the decision-making process
Objective information, Subjective information	Cost concerns do not only consider the price of a drug
Information sharing	The committee members often receive filtered information

Table 17: Twelve different basic themes.

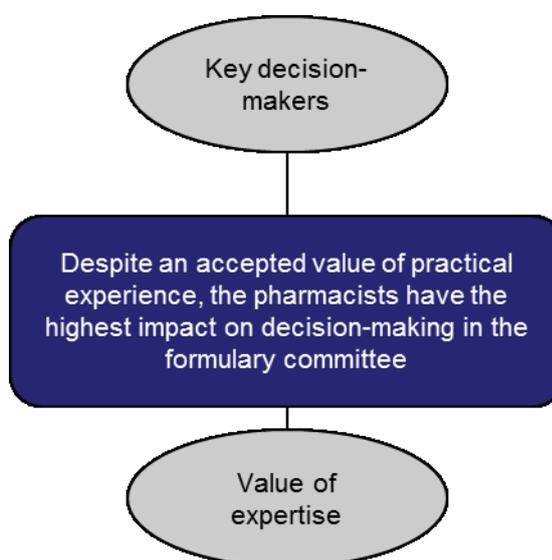
All thematic networks with organising, basic and global themes are shown in Table 18.

Basic Themes	Organising Themes (3rd step)	Global Themes
Nurses have no direct impact on the decision-making process	Key decision-makers	Despite an accepted value of practical experience, the pharmacists have the highest impact on decision-making in the formulary committee
Pharmacists and physicians are the decision-makers		
Pharmacists have a gatekeeper function		
In case of generic drugs the decision is taken by the pharmacist		
Expert opinions and experience are accepted as valuable input	Value of expertise	
Concerned departments have a higher decision-making weight		
Selected key people have pre-meeting discussions	Pre-meeting decision-making	Pre-meeting alignment leads to decision-making outside of the formulary committee and reduces the committee to a legitimisation role
The committee members often receive filtered information		
The formulary committee is used to legitimise pre-meeting decisions		
Pharmacists have pre-discussions with the pharmaceutical industry		
Cost considerations are dominant in the decision-making process	Importance of economic criteria	Costs are the dominant criterion for specific pharmaceutical drug groups
Cost concerns do not only consider the price of a drug		

Table 18: Global themes to formulate a proposition for the organising and basic themes.

7.2 *Despite an accepted value of practical experience, the pharmacists have the highest impact on decision-making in the formulary committee*

This thematic network comprises of two organising themes and six basic themes (Figure 43). It describes the key role of pharmacists as the decision-makers with the highest impact on the hospital formulary committee decision-making. In addition, this thematic network also refers to the importance of practical experience and the value of expertise for the members of the committee.



Organising Themes	Basic Themes
Key decision-makers	Nurses have no direct impact on the decision-making process
	Pharmacists and physicians are the decision-makers
	Pharmacists have a gatekeeper function
	In case of generic drugs the decision is taken by the pharmacist
Value of expertise	Expert opinions and experience are accepted as valuable input
	Concerned departments have a higher decision-making weight

Figure 43: Thematic network describing the high impact position of pharmacists.

7.2.1 Key decision-makers

Pharmacists and physicians are the key decision-makers in a hospital formulary committee. Despite the central role of nurses in regards to the operational usage of pharmaceutical drugs, the decision-making process role is of minor importance. If

nurses want to address any concerns about a drug they need to discuss this with one of the direct decision-makers, such as physicians or pharmacists. Especially pharmacists have a very prominent position since they often take responsibility as a gatekeeper. Thus, pharmacists can significantly influence the decision-making process of the hospital formulary with their possibility to allow or block an application for drug listing.

P4 (pharmacist): *In the hospital formulary committee you have physicians, then pharmacists, accordingly the general management. Those are the decision-makers in the hospital.*

NG1.1 (nurses): *I believe that nurses have the weakest voice in the decision-making process. In the end we have the “executive” but the actual decision is taken by the physicians and pharmacists.*

NG1.2 (nurses): *In our hospital it is mainly the pharmacist, with 99%.*

NG1.3 (nurses): *In our hospital it is mainly the head physician. [...] I need to pass him, the head physician. I would need to get his attention and then tell him the advantages and disadvantages. He is then the one to decide if we will try it. He is the one to pass it on to the pharmacist and says that we will give it a try or not.*

Interviewer: *You see yourself more in the operational role?*

NG1.1 (nurses): *I can talk a lot. But is somebody interested?*

NG2.1 (nurses): *You can say it if you have seen or heard something. But if somebody is listening, that is the question. You need to have very strong arguments that the pharmacy contemplates.*

In case of generic drugs or very similar drugs the decision power lies with the pharmacist. Those cases are often not even discussed in the hospital formulary committee meeting and can be fully decided by the pharmacist.

P2 (pharmacist): *If it is a comparable drug. [...] Then it would not necessarily be required to go via the hospital formulary committee, but can be decided by the pharmacy.*

P7 (pharmacist): *If it is comparable to the current drug. [...] then it is not a topic for the hospital formulary committee. It is then one of my basic tasks to assess, what kind of product it is. Is it really comparable? And then to contact the manufacturer to talk about prices.*

7.2.2 Value of expertise

Hospital formulary committee members accept the opinions of experts and experience is seen as a valuable input for an informed decision-making.

Consequently this also means that concerned departments with the experience have more weight in the decision-making process. On the contrary, departments which are not directly concerned and thus do not directly represent expert opinions, have less weight.

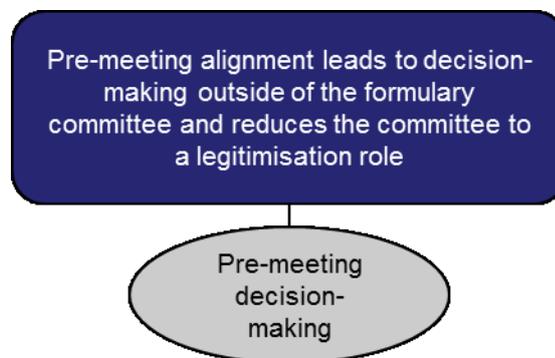
P1 (pharmacist): *I would talk to my [SPECIALIST], how they assess the drug. Before I propose a listing, I would talk to the opinion leaders or people who use the drug already; with them I would sit at one table and discuss the case.*

P2 (pharmacist): *We always ask the users of the drug first, if they see any problems, if we change the drug. [...] In addition we have a [SPECIALIST] in the committee. This does not have everyone. His opinion is of great importance. Those are the opinion leaders.*

P5 (pharmacist): *Then you have a decision. This does not need to be unanimously, but it needs to be by the majority. Of course, the urologist would not be in a decisive role. He raises his arm or not [in a discussion about an anti-coagulant drug].*

7.3 *Pre-meeting alignment leads to decision-making outside of the formulary committee and reduces the committee to a legitimisation role*

This thematic network comprises of one organising theme and four basic themes (Figure 44). It describes a possible second way of decision-making outside the hospital formulary committee meetings and its impact on the decision-making process of the committee. The pre-meeting discussions do not only include discussions between (internal) members of the hospital but also external stakeholders, such as the pharmaceutical industry.



Organising Themes	Basic Themes
Pre-meeting decision-making	Selected key people have pre-meeting discussions
	The committee members often receive filtered information
	The formulary committee is used to legitimise pre-meeting decisions
	Pharmacists have pre-discussions with the pharmaceutical industry

Figure 44: Thematic network describing the influence of pre-meeting discussions.

7.3.1 Pre-meeting decision-making

A certain level of discussions happen outside of the hospital formulary committee meetings between selected members who want to either clarify difficult decisions upfront or who want to align with others to increase chances to have a successful application. This way, other committee members might be in a situation where they do not receive all available data for an informed decision-making. For example, physicians might talk to the pharmacist in advance or the pharmacists have already pre-discussions with the pharmaceutical industry about pricing. Additionally, the members who present their application have the opportunity to prepare their

messages in the best possible way for a positive outcome. Due to the limitation of the presented data for each case, members of the committee only get a snapshot of the case, where the content is compiled by the applicant.

P3 (pharmacist): *All that information is then used in the committee meeting. Or even in advance.*

Interviewer: *Does it happen that in those pre-discussions you already talk to the manufacturers, eventually already talk about prices?*

P4 (pharmacist): *Yes, of course. [...]Everybody prepares themselves, on the physician's side, as well as on the pharmacist's side. There it sometimes happens that, depending on the urgency, you have discussions or telephone calls in advance to the meeting. This means you have certain agreements. You discuss, what is really important!*

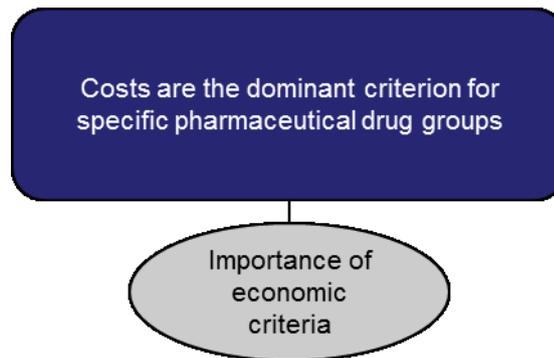
P6 (pharmacist): *The applicants present their case in 10-12 sentences, what is essential for them and in addition the most important references. That is sufficient for a decision.*

The formulary committee is also used to legitimise those pre-meeting decisions. In these cases members coordinate with others, already take a decision and then put an application into the hospital formulary committee process in order to get an official approval.

P3 (pharmacist): *This means, one would like to achieve a consensus. However, this does not need to be during a committee meeting. This can be prepared also in advance to the meeting, but then needs to be officially approved in the meeting, since you would like to have your decision legitimised.*

7.4 Costs are the dominant criterion for specific pharmaceutical drug groups

This thematic network comprises of one organising themes and two basic themes (Figure 45). It describes the dominant role of cost considerations on the decision-making behaviour of hospital formulary committee members.



Organising Themes	Basic Themes
Importance of economic criteria	Cost considerations are dominant in the decision-making process
	Cost concerns do not only consider the price of a drug

Figure 45: Thematic network about the dominant role of costs.

7.4.1 Importance of economic criteria

The importance of economic criteria is very high for the hospital formulary committee decision-making process. Even in cases where the alternative drug has advantages compared to the current drug, the cost criterion has a significant impact on the decision-making discussion. The price of a pharmaceutical drug is important but the cost discussions of the committee members can be broader, more comprehensive considering also process costs.

NG2.1 (nurses): *Most of the time, the cost factor is the main criterion.*

P4 (pharmacist): *Nowadays it is always important to focus on the available data; data in the sense of costs. What does it all cost? [...] Data in regards to the frequency of use, so that you can include the importance level and the cost factor into your calculations. Is it for a broad spectrum or is it a very narrow indication.*

PG2.1 (physicians): *It needs to be massively better, or cheaper. But if it is more expensive, then it needs to be massively better.*

PG2.2 (physicians): *Finally, the killing argument is always the cost factor. This is where it always ends up, unfortunately. I can only agree. Even if it is massively better and more expensive, a lot of argumentation effort would be needed. The pressure on costs is so strong.*

PG3.1 (physicians): *It is not uncommon that drugs are changed due to better handling which finally leads to an improved workflow to decrease costs, even if the price of the drug is higher.*

7.5 Summary

This chapter summarises the findings of the qualitative company market research interview analysis. In general, the company market research data generated far less themes than the expert interview data analysis. The reason for this was the original purpose of the company market research which was different to the goals of this research. A description of the hospital formulary decision-making process was only a small part of the company market research interviews. Hence, the depth of the captured interview information was less detailed and only eleven basic themes could be extracted. Out of these eleven themes, three thematic networks about the decision-making process of hospital formulary committees were identified.

The first thematic network describes the key role of pharmacists as the decision-makers with the highest impact on the hospital formulary committee decision-making. In addition, this thematic network also refers to the importance of practical experience and the value of expertise for the members of the committee. Most of the outcomes of this thematic network were not new but confirmed findings from the expert interview data analysis. One exception was information regarding the role of nurses in the hospital formulary committee. This was already topic in the literature (Martin et al., 2003; Plet et al., 2013) but not much insight could be extracted from the expert interviews. In contrast, the company market research data analysis

confirmed a small impact of nurses on hospital formulary committee decision-making despite their direct role in providing pharmaceutical drugs to patients.

Following this, the second thematic network reveals a possible second way of decision-making outside the hospital formulary committee meetings and its impact on the decision-making process of the committee. The pre-meeting discussions do not only include discussions between (internal) members of the hospital but also external stakeholders, such as the pharmaceutical industry.

Cost considerations and their dominant role on the decision-making behaviour of hospital formulary committee members are described in the last thematic network and confirmed findings from the expert interview data.

Despite the low level of detail of the interview data, it is a valuable add-on to the overall analysis. The company market research interviews were conducted with very different functional roles (physicians, pharmacists and nurses) and thus covered additional groups who were not considered for the expert interviews. It added some new insights on the role of nurses and also showed some dissatisfaction with the current situation from the nurses' perspective. This added additional perceptions to the data analysis and facilitated the identification of underlying generative mechanisms which will be discussed in the next sections.

8 Discussion

8.1 Introduction

The literature review showed, that besides perceived objective criteria, subjective criteria have a strong impact on hospital formulary committee decision-making, specifically in cases where the perceived objective criteria is subject to uncertainty. *Dual processing systems*, such as Hammond's *cognitive continuum* model (1996, 2000), represent a good theoretical basis for decision-making in hospital formularies and help to understand the different use of analytic or intuitive decision-making. But hospital formulary committee decision-making is more complex combining individual decision-making and group decision-making. According to the *Social Decision Scheme Theory* (Davis, 1973, 1996), group decision-making processes function as a combination of all group members' preferences which are aggregated to form a group response. In addition, a study by Wirtz et al. (2005) showed that decision-making is not only bound to a fixed relative importance of decision criteria but is mainly impacted by group discussions and other group decision-making phenomena, such as influential individuals or information sharing. Based on these results, a hospital formulary committee decision-making framework was constructed to visualise the complexity of the process (Figure 46).

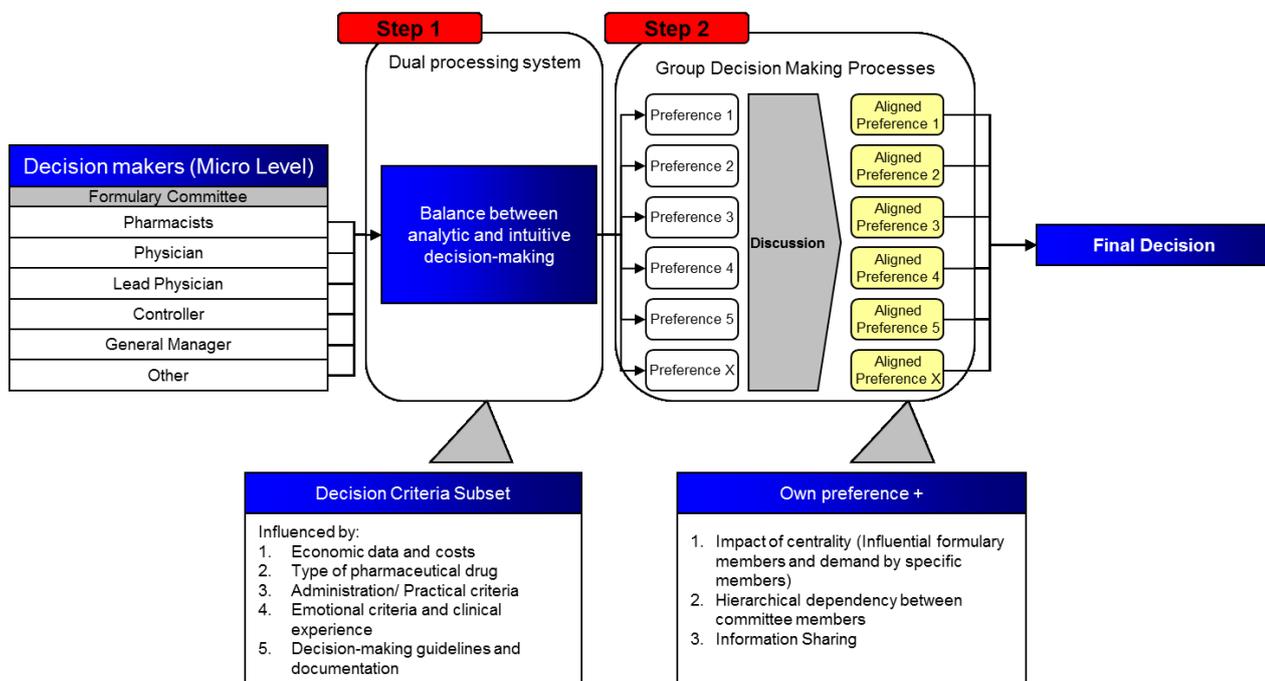


Figure 46: Hospital formulary committee decision-making framework.

This chapter represents step eight in the research design (Figure 47). According to the convergent parallel database mixed-methods design (Creswell, 2003), the results of the quantitative analysis (step five) and the qualitative analyses (step six and seven) were compared and discussed for final conclusions. Generative mechanisms were identified to allow the evaluation of potential practical implications. The outcomes of the three data analyses (survey, expert interviews and company market research interviews) were basis for the identification of underlying mechanisms. These mechanisms and conclusions were used to specify and extend the preliminary hospital formulary committee decision-making framework and to formulate implications for stakeholders.

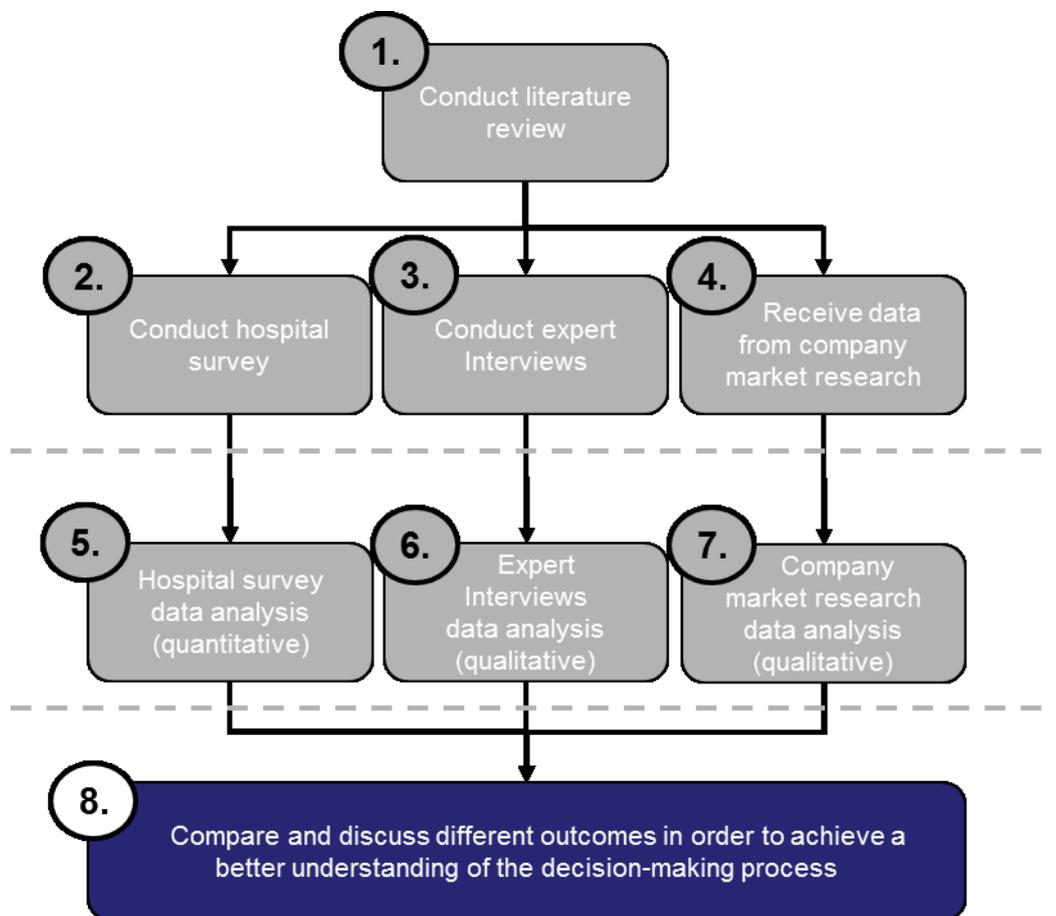


Figure 47: Comparison and discussion of the combined results.

In the course of these conclusions the research questions RQ-1 to RQ-4 will be answered and discussed.

8.2 The balance between intuitive and analytic decision-making

This section mainly answers research questions RQ-1 and RQ2:

- RQ-1. What are the criteria in funding decisions for pharmaceutical drugs in hospital formulary committees?
- RQ-2. What is the relative importance of each of those criteria in funding decisions for pharmaceutical drugs in hospital formulary committees?

The literature review demonstrated that the *cognitive continuum* model (Hammond, 1996, 2000) fits well as a theoretical basis for healthcare decision-making. It describes the decision-making of individuals as an oscillation on a continuum ranging between intuition and analysis.

The results of the quantitative analysis showed that formulary committee members use a mix of perceived objective and subjective criteria for their decision-making. Nonetheless, the survey did not ask questions to explore if and how members of the committee actually decide based on a *cognitive continuum* type of model. This is different for the qualitative analyses which confirm that members of the committee balance the weighting of the different decision criteria dependent on surrounding conditions. The results show a clear preference for perceived objective criteria and data from clinical trials is the most important criterion for all decision tasks. It is also visible in the qualitative analyses results that the preference for perceived objective data derives from the impression of members of the committee that decisions are easier to justify. For example, this can be seen in the way the documentation of formulary committee decisions is done. Perceived subjective criteria are not documented, even though members of the committee apply them for their decision-making. This outcome is supported by the findings of other studies which showed that written decisions as part of drug funding decision documentation are mostly justified with scientific or economic reasons independent how many other perceived subjective criteria have been adopted (Dean et al., 2013).

In addition, the qualitative analyses also revealed that perceived subjective criteria is challenged if it shows different conclusions than the available perceived objective criteria.

All data analyses showed that in some cases practical experience as a decision-making criterion becomes more important. This phenomenon of the *empirical/actual* domain is based on committee members' increasing willingness to accept subjective data if uncertainty increases. In the *real* domain there is an uncertainty mechanism which opens hospital formulary committee members to accept subjective data, even if they usually have a clear preference for perceived objective data.

All data analyses also showed for the *empirical/actual* domain that perceived objective data, if available, create more trust than practical experience. In some cases this was argued with less risk of bias and a higher scientific rigor. The phenomena in the *empirical/actual* domain demonstrate that perceived objective criteria are favoured even though they are not always available. One explanation is the decision-making mechanism in the *real* domain based on the scientific background of most members of the formulary committee and the resulting importance of perceived objective data. This leads to the observed preference of objective criteria and the reluctance of committee members to mention practical experience in the official justification.

The *empirical/actual* domain also indicated a big difficulty for committee members to quantify the importance of subjective data for the decision-making process. Thus, the mechanism in the *real* domain is that decision-makers make use of subjective criteria but this happens more intuitively and implicit.

One outcome visible in the *empirical/actual* domain which was mentioned in the expert interviews and which weakened the acceptance of perceived objective data was a lower willingness to discuss an application for an oncology drug or a drug used for children. For the *real* domain, this shows that an increase in empathy can positively influence the acceptance of subjective criteria which is described more in detail in section 8.2.3.

8.2.1 Economic data and costs

Within the literature, health economic evaluations, and specifically cost-effectiveness analyses (CEA), are used seldom in decision-making at the hospital level (Gallego et al., 2009; Williams & Bryan, 2007). In most cases the results of the quantitative analysis confirmed this assumption with one exception for orphan drugs where health economic evaluations had a high importance ranking. This result for orphan drugs

cannot be fully explained since the qualitative data analysis revealed a very consistent low importance of health economic evaluations in hospital formulary decision-making. One possible explanation could be a confusion of the meaning of health economic evaluations with other economic measures. All three data analyses showed a high importance of economic measures evidenced in the *empirical/actual* domain. Budget impact and costs were identified as dominant decision-making criteria especially for pharmacists. This represents a cost orientation of the pharmacists and assumes that hospitals have put economic topics on high priority. The mechanism behind this is the financial pressure on hospitals which is reflected in the formulary committee's decision-making. Results of the qualitative analyses demonstrated that members of the committee are more willing to discuss if the budget impact is higher and thus they might face restrictions on their own financial flexibility. This result from the *empirical/actual* domain supports the assumption that committee members defend their departments. The mechanism behind this behaviour is the limit on the total budget and a potential restriction for one department if another department causes higher costs. It also revealed grounded in the *real* domain that physicians and pharmacists are afraid of losing importance and power compared to other departments. Budget impact as a criterion is more pronounced in this study than in other research. There might be various reasons for this outcome. The relatively high importance of budget impact as a criterion might reflect an increased financial pressure on German hospitals in recent years compared to earlier studies or other countries. Differences might also be derived from the way this research was conducted. Many earlier studies on decision-making criteria used a survey-only methodology to evaluate the importance of decision-making criteria. Physicians or pharmacists were probably more reluctant to rank budget impact higher in a survey without a possibility to further explain this as it was possible in the expert interviews.

Despite this strong influence on hospital formulary committee decision-making, economic criteria usually do not lead to rejection of a drug listing which was one important result of the qualitative analyses. It is more likely that the committee decides to allow a drug on a temporary basis. In the *real* domain this relates to a power mechanism. This means that formulary committee members are afraid of voting against a drug, proposed by a (powerful) colleague, and potential consequences if there are no clear facts which support a rejection. A vote against a

drug request from another member might lead to a negative opinion from this member on their next own application.

Literature showed that one of the issues around the data provided to hospital formulary committees is the lack of local adaptation. Very often the data is used in a general way instead of adapting to the local hospital situation which makes it very difficult for the decision-makers of a formulary committee (Späth et al., 2003; Williams & Bryan, 2007; Walkom et al., 2006). Clinical trial populations often do not match with the patient population of the respective hospital. The qualitative analyses endorsed this assumption. For the *real* domain this means that hospitals are not interested in general costs, but they are only interested in costs relevant for the specific hospital situation.

When hospital formulary committees consider the cost of a drug, they usually do not only refer to the price. They rather consider total costs including drug costs and process costs. Hence, the costs of switching to a new drug are important as well as costs associated with side effects of a drug.

8.2.2 Type of pharmaceutical drug

The literature was only vague in regards to the question if the type of a pharmaceutical drug influences the decision-making process in hospitals. Only two studies (Gallego et al., 2009; Motheral et al., 2000) looked more closely at this question and came to the conclusion that formulary committee members consider different aspects in the decision-making process if the drug is used for treatment of a severe disease and no comparable alternatives are available.

The quantitative results of the survey analysis demonstrated that 51% of the respondents use different decision-making criteria for different types of pharmaceutical drugs. Detailed results from the quantitative analysis for different classes of drugs emphasised the use of different criteria for different types of drugs. For orphan drugs, members of the committee apply different criteria due to the lack of clinical trials data and most of the time a high price. However, orphan drugs are usually handled outside the hospital formulary committee listings because they are not used on a regular basis. Physicians can order them on special request and the

qualitative analyses results confirmed that physicians have the highest impact on orphan drug decision-making.

Newly developed drugs are treated differently compared to already established drugs. The reason for that is the lack of available data and the resulting uncertainty. Hospital formulary committee members take decisions on those drugs very often on a preliminary basis to allow experience gathering for other members.

8.2.3 Emotional criteria and clinical experience

The literature review confirmed the use of perceived subjective criteria such as ethics or clinical experience in decision-making of hospital formulary committees (Wirtz et al., 2005). It is also important that pharmaceutical drug funding decisions have impact on patients, physicians and clinical staff which adds an emotional component to the complex decision situation enticing committee members to consider perceived subjective criteria (Janknegt, 2001).

The importance of clinical experience was confirmed by the quantitative and the qualitative data analyses. Hospital experience and recommendations by other committee members were always ranked in the top ten decision criteria for all types of drugs in the survey. In addition, the interview data endorsed the impact of this criterion. Nonetheless, the interviewees stressed that recommendations by other members are not sufficient as a standalone reason and thus cannot be used alone for a positive decision.

The interviews indicated also that emotional criteria have an impact on the decision-making behaviour of committee members. For example, the qualitative interview data analyses showed that drugs for patients with oncology indications or children are less challenged than other drugs due to the member's empathy. The interviews also provided examples, where members made use of emotional criteria to defend their argumentation against perceived objective criteria, such as costs of the drug. In contrast to severity of disease, patient's quality of life is another subjective criterion of minor importance. Especially health related quality of life studies were not ranked in the top ten criteria in the quantitative data analysis. In addition, the

qualitative data analyses also did not show any significant impact of quality of life information on the decision-making process. However, hospital formulary committee members consider the patient's perspective with another criterion: severity of disease. Ranked high in the quantitative data analysis and also mentioned as very important during the interviews, decision-making is influenced by a high severity of disease. This is usually always valid for oncology and orphan diseases.

These observations from the *empirical/actual* domain directly counteract the preferred usage of perceived objective criteria as mentioned in section 8.2.1. Hence, the educational background and training of physicians and pharmacist which is the generative mechanisms for the experienced preference of perceived objective criteria conflicts with the generative mechanism of human empathy which strengthen the acceptability of subjective data.

8.2.4 Administration/ Practical criteria

Although ranked in the quantitative data analysis in the top ten important criteria for monoclonal antibodies/ immunomodulators and medical devices, the qualitative data analyses did not show a very high importance for administration criteria. This might be a consequence of the low impact of nurses in the hospital formulary decision-making process. Some interviewees indicated that they consider feedback and objections by nurses because they are usually the concerned people regarding the administration of pharmaceutical drugs. However, these criteria seem to be only of minor importance.

8.2.5 Decision-making guidelines and documentation

Previous research indicated that most of the time there is no guideline and in cases where a guideline is available, the criteria which should be used in the decision-making process are often not explicitly mentioned or there is no information on relative importance (Martin et al., 2003; Mittmann & Knowles, 2008; Plet et al., 2013). Findings from the survey data and the expert interviews confirmed this and demonstrated for the *empirical/actual* domain that guidelines on the decision-making process rarely exist and if they exist, they only provide rough guidance with no details. Additionally, the survey had a very low response rate. Hence, visible in the

empirical/actual domain is a reluctance of formulary committee members to support transparency in decision-making. The mechanism in the *real* domain is the reluctance of hospitals to justify their decisions and the concern to be vulnerable to outside critique. For example, results from the quantitative data analysis showed that only 49% of the respondents have guidelines in their hospital. In addition, the qualitative data analyses indicated that the written guidelines only mention perceived objective criteria, such as clinical trials data or economic data, and seldom refer to a relative importance of decision criteria. This outcome was not so clear in the quantitative data analysis. Approximately one third of the respondents who have written guidelines stated that the guidelines also refer to perceived subjective criteria, such as recommendation by the pharmacist or clinical experience. These different results cannot be fully explained.

Another outcome for the *empirical/actual* domain, taken from the expert interviews, was that the case documentation for an application usually has no standard format and it always shows only specific facts making the overall case positive. In particular the short time to present the case during the committee meetings limits the possibilities to show all relevant data. Hence, the mechanism behind this is that case documentation is influenced by the individual goals of the applicant and the limited time to present case data.

8.2.6 External impact

The impact of external influences on decision-making and the relative importance of this criterion are vaguely described in the literature. Possibly because of the sensitivity of the topic, only three studies (Dranove et al., 2003; Jenkins & Barber, 2004; Späth et al., 2003) gained insights on the external influence on hospital formulary committee decision-making.

Späth et al. (2003) recognized in their study that relations between the pharmaceutical industry and the decision-makers influence the decision of those committees. Dranove et al. (2003) identified a positive correlation between the number of sales force visits and the possibility of making a positive adoption decision for a pharmaceutical drug. A study by Jenkins and Barber (2004) showed

that hospital formulary committees seem to adapt their discussion behaviour dependent on the relationship between the industry and the hospital.

The quantitative survey results confirmed the perceived sensitivity of this topic since they revealed a lack of transparency in regards to the relationships between committee members and the pharmaceutical industry. Respondents' answers in the survey indicated that the cooperation (e.g. clinical trials) between members of the hospital formulary and a pharmaceutical manufacturer is seldom communicated. 43% of the respondents stated that this happens rarely or never. In addition, it was also shown that formulary committee members try to justify close connections to the industry and emphasise independent decision-making. Altogether this indicates that working with the industry has a negative undertone. This means for the *real* domain that committee members are afraid of being suspected for biased decision-making and/or for bribing. The qualitative analyses results revealed more details on external influence. Although members of the committee emphasise their independence in decision-making, the qualitative data also demonstrated a strong influence of external factors. Listing applications are often initiated by the pharmaceutical industry. Especially for new drugs the pharmaceutical industry has a strong influence due to the lack of available data. In addition, the industry "builds" convinced advocates if they involve committee members in clinical trials. Supported by the quantitative and qualitative data analyses which show limited transparency in regards to external influence it can be assumed that members of the committee do not like to talk very openly about those relationships.

Literature also revealed a potential negative influence of this external influence. Pressure from the industry's sales force or potential bribing was seen critically and usually led to a more rigid evaluation of the pharmaceutical drug (Jenkins & Barber, 2004). This outcome was also confirmed by the expert interviewees. Committee members were aware of the external influence but did not seem to be very happy about it. They tried to put emphasis on their independence in the final decision.

Other research concentrated very much on the external impact by the pharmaceutical industry but missed information on other external influencing factors, such as health insurances or the importance of external reputation. In the *empirical/actual* domain it

was observed that hospitals are very interested that therapies initiated in the hospital are not interrupted, continue in the outpatient setting and that hospitals care about their relationships with physicians in the outpatient setting. Having in mind that the German hospital system works with Diagnosis Related Groups (DRG) payment (a fixed fee payment) in the hospital setting, this usually means that payers have very limited influence on pharmaceutical drug use (in the hospital). Despite this, the identified mechanism in the *real* domain is that payers have an impact on the hospital decision-making due to the reimbursement power of health insurances in the outpatient setting. Consequently, pharmaceutical drugs are only listed if funding is also ensured outside of the hospital which means a strong but indirect impact of health insurances on the committee's decision-making due to the funding mechanisms in the German healthcare system.

The external reputation of the hospital was not mentioned in the identified literature but plays an important role in the drug funding decision-making of the hospital formulary committee. Interview data showed that hospitals compete against each other in providing innovative and patient-friendly therapies and some treatments are crucial for the representation of the hospital expertise, independent of any economic criteria. Hence, a generative mechanism is the motivation of hospitals to optimise their external reputation. This is based on observations in the *empirical/actual* domain that innovative, new pharmaceutical drugs are often handled differently compared to existing drugs, especially when those drugs are already used for therapies in competitor hospitals. Besides the motivation of hospitals to optimise their external reputation, this event of the *empirical/actual* domain was also mentioned in the context of high uncertainty about new pharmaceutical drugs. This shows that different generative mechanisms can be deduced from the same observable event and that generative mechanisms might overlap.

In conclusion this means that the decision-making framework needs to be adapted to reflect the strong influence of budget impact, type of a drug or the clinical experience. On the other hand, administration and patient's quality of life do not influence the decision-making a lot. Members of the committee rather apply empathy for their decision-making. The framework needs to consider the impact of the case documentation and the different external influences, such as the pharmaceutical industry or health insurances.

8.3 Decision-makers in the hospital formulary committee

This section mainly answers research question RQ-3:

- RQ-3. What is the level of influence of each stakeholder group on drug funding decisions of hospital formulary committees?

Literature showed that depending on the hospital formulary committee, the involvement of nurses, financial administrators, pharmacologists, patients and hospital administration is different. Whereas nurses, pharmacologists and hospital administration are part of some hospital formularies it is very seldom that financial administrators or patients are involved (Plet et al., 2013; Späth, Charavel, Morelle & Carrere, 2003). This was also confirmed for German hospitals by the quantitative and qualitative analyses.

Different studies confirm a strong influence of physicians and specifically pharmacists on the hospital formulary committee decision-making (Alsultan, 2011; Fijn et al., 1999; Gallego et al., 2009). This result from other countries can also be confirmed for Germany. The quantitative survey showed a similar importance ranking for pharmacists and physicians but confirmed the general high importance of these two groups. It also showed that other functional groups, such as financial administrators, nurses or the general manager, do not have significant impact on the decision-making process. Other roles than pharmacists or physicians can have influence on the process in very specific cases. For example, financial administrators can provide functional expertise in case the reimbursement of a specific drug is difficult to achieve. Or nurses might have impact on a decision if it is dependent on the administrative handling of a drug. Hence, non-pharmacists or non-physicians are not decision-makers in a hospital formulary committee. However, their opinion can potentially influence the decision-making by pharmacists or physicians. The conclusions from the qualitative interviews emphasised these results. Furthermore, the qualitative interviews revealed an even stronger influence on the decision-making process by the pharmacists compared to physicians. This generative mechanism can be indirectly observed by specific events, such as the behaviour of physicians when they try to convince pharmacists in advance to the committee meetings or if physicians talk to pharmacists in advance to the meetings to verify their chances of

success. Specific roles or an activity, such as the pharmacist as a chair of the hospital formulary committee or the key responsibility for preparation of documentation, is evidence for the strong influence of pharmacists in the committee. This has been confirmed by the literature review, the quantitative survey and the qualitative analyses.

In conclusion this means that the decision-making framework needs to be adapted to reflect that pharmacists and physicians are the decision-makers. Besides, the framework needs to show that other functional roles might have influence on the decision-makers but they are no decision-makers themselves.

8.4 Group dynamics and impact on decision-making

This section mainly answers research question RQ-4:

- RQ-4. What are the motives and objectives of decision-makers when applying quantitative and qualitative criteria for drug funding decisions in hospitals?

The qualitative data analysis confirmed that members do have an opinion before they go into the committee meeting. This individual preference is then adapted during the group discussion and dependent on many different variables.

8.4.1 Power relationships

Information on the influence of power relationships in hospital formulary committee decision-making is scarce. Outcomes of the literature review indicated that power relationships (e.g. hierarchical dependencies) have influence on hospital formulary committee member's decision-making (Dranove et al., 2003; Gibson et al., 2005). In the study of Gibson et al. (2005), participants doubted a true representation of member's opinions due to the fact that some formulary committee members reported directly to other more senior members. Formulary committee members were reluctant to discuss against the opinion of their bosses.

These assumptions could not be confirmed by this study. Results from the qualitative data analyses emphasised the independence of member's decision-making and

hierarchical dependencies. Findings from the interviews showed for the *empirical/actual* domain a low level of influence of hierarchical structures. Most formulary committee members were on the same or similar hierarchy level. In many cases there is no direct hierarchical dependency due to the structure of the hospital formulary, with one representative for each department. The mechanism in the *real* domain is that between physicians, the seniority level is not the most decisive factor for decision-making. This does not fully preclude the impact of power relationships. Departments with a higher financial weight for the hospital have a higher importance which might increase the power in the decision-making process. In these cases it is the structural power which dominates the power of the individual.

The chair of the committee usually has a central function and if yes and no votes are equal, the chair has the decisive vote. However, this formally most powerful position is not necessarily the position which influences decision-making of the hospital formulary most. The interview data analyses indicated that strong individuals in the committee can have influence on the committee chair. In some cases this is derived from the importance of a specific department as described above and in some cases this is derived from the communication strengths and skills of individuals. This means for the *real* domain that the role of the committee chair represents formally the most powerful position but often does not reflect reality or does not consider other potentially even more influential members. Sometimes this formal role is even abused by other more powerful members to build alliances which are hard to "fight" in the committee discussions.

Findings from the survey data and the expert interviews demonstrated for the *empirical/actual* domain that some physicians are very passive during discussions on economic questions in the formulary committee meetings. For the *empirical/actual* domain this means that physicians usually do not interfere or are critical when it comes to questions outside of their competency area. One mechanism for this is the focus of physicians on their own department, as mentioned before, anchored in the *real* domain by physicians' view of themselves more as medical experts, than as managers. They realise a lack of expertise and appreciate the pharmacist's knowledge of economic issues. This is true, especially in cases where the physician does not need to defend his/her own competency area. A similar finding relates to passiveness

of physicians during discussions on medical questions. For the *empirical/actual* domain this means that some physicians and their departments are less influential than others. The mechanism in the *real* domain is that the level of strategic and economic importance of one department determines its potential impact on decision-making. Another explanation for passiveness is the information advantage of the applicant and the pharmacist. This concludes into the mechanism that the perceived expert level of committee members with more knowledge creates a barrier for other members in the discussions.

All data analyses showed for the *empirical/actual* domain that non-physicians and non-pharmacists have low influence on the decision-making process and from the groups who work closely with patients or nurses have a weak representation in the formulary committee. For the *empirical/actual* domain this means that other functions than physicians or pharmacists are only considered during decision-making if medical or economic criteria are not sufficient. Hence, the mechanism behind this is that physicians and pharmacists have a perception about other functional roles as being less qualified to contribute to decision-making. For example, nurses are part of the operations but not part of the decision-making process and thus they are usually not considered.

8.4.2 Centrality and group size

Results of the literature review identified an impact of the hospital formulary committee size which can negatively affect an adoption decision if the committee is larger (Dranove et al., 2003). The authors assumed a difficulty to reach a consensus in a bigger group or in a group with more diversity in terms of the represented functions. This cannot be confirmed by the qualitative data analysis. To the contrary, the interviews indicated that the group size does not have impact on the group's decision-making.

The *empirical/actual* domain identified committee members' desire for reliable information and a certain level of fear or uncertainty. Considering that the members of the hospital formulary committee are usually very influential and powerful people in the hospital, the mechanism behind this is the fear of committee members to be blamed in front of this important audience potentially losing power and compromising their further career. During these pre-discussion, members also want

to convince other members of their application and to build alliances. For the *real* domain, this shows the committee members' motivation to build barriers for counter-argumentations and to increase the chances of success for their own applications.

This also means that other members in the formulary do not get all critical information on a case which in consequence can lead to perceived easier decision-making. It also means that group consensus can be a consensus between the two most powerful members with the additional effect that other members do not want to vote in opposition. This effect was also found in a study by Gibson et al. (2005) where participants described a "feeling pressured to conform and reluctant to vote in opposition [...] or to express dissent [...]" (p. 2359).

This research also revealed knowledge about the centrality of specific committee members. In general, expertise of different functions is valued and accepted. Findings from the *empirical/actual* domain indicated that decision-making is dominated in some cases by physicians and not pharmacists. The level of physician's dominance varied with the specificity of the decision and that the physician's opinion was more important if there was lack of other data. For the *real* domain, this finding suggests that formulary committee members believe in expert colleagues in difficult decision situations but they also try to avoid taking responsibility in cases of great uncertainty. In combination with individual characteristics, such as a strong personality or strong rhetorical skills, the expert status can be very convincing.

8.4.3 Role of the individual and the personality

Several studies (Alsultan, 2011; Fijn et al., 1999; Gallego et al., 2009; Wirtz et al., 2005; Gibson et al., 2005; Janknegt, 2001; Jenkins & Barber, 2004; Motheral et al., 2000) revealed the existence of an advocate as an important decision criterion. In this context an advocate is meant to be the person who supports the drug addition to the formulary listing.

This is also valid for German hospital formulary committees but needs to be differentiated.

Results from the quantitative analysis showed that recommendations by individuals and experience made in the hospital are always ranked high independently from the type of drug. However, the qualitative analyses also showed that the respective impact of an individual is dependent on several other factors, too. One is the personality which means that members of the committee who are perceived to be strong individuals can easier convince others. Another factor is the ability of a member to communicate, such as rhetorical skills, and the operational way how a member communicates his argument. A phenomenon observed in the *empirical/actual* domain, based mainly on the expert interviews, was that formulary committee members emphasize positive facts in their argumentations to support their cases with different skills. Members with good communication skills have advantages and chances of success are more likely only based on their individual ability to present and argue. For the *real* domain, this shows that individual character and communication skills of each formulary committee member are decisive for his ability to convince other members. For example, members present their case in front of the hospital formulary committee and the time for the presentation is limited. Hence, members need to decide how they present their case in a convincing manner in this limited timeframe. This becomes also visible when members use strong emotional arguments to support their case.

In conclusion this means that the decision-making framework needs to be adapted to reflect the specific importance of experience and also the impact of the individual personality. The framework also needs to consider the two ways of how communication impacts the opinion of committee members: either depending on the general communication skills of a presenter or the way the presenter argues the case.

All identified findings for the *empirical, actual* and *real* domain are shown in Table 19. These findings on the generative mechanisms were used in chapter 9 to identify potential implications for different stakeholder groups.

Empirical/ Actual	Real (potential structures)
Budget impact mentioned as most important criterion	Financial pressure on hospitals is reflected in the formulary committee's decision-making
Strong price orientation of pharmacists	
Strong economic focus of the hospital	
Pharmacists usually lead the formulary committee + the financial situation is often discussed during formulary committee meetings	
Cost is a dominant criterion for decision-making	
Higher budget impact means higher involvement by formulary committee members	Higher costs in one department potentially means restrictions in others
Formulary committee members defend their budgets	
Clinical trial populations often do not fit the real world hospital patient population	
There is reluctance regarding economic data (also from clinical trials)	Hospitals are interested in total costs (not only drug costs) and costs individual for the respective hospital
Some situations allow physicians to dominate decision-making	Formulary committee members trust in expert colleagues in difficult decision situations and they try to avoid taking responsibility in cases of great uncertainty
The influencing power of physicians increases or decreases with the level of specialization	
Expert opinions become more important if there is lack of other data	
Often there is a low activity of committee members other than the applicant or the pharmacist	The perceived expert level of committee members with more knowledge creates a barrier for discussions
The applicant and the pharmacist have much more possibilities to prepare themselves for discussion	
Formulary committee members have already discussions about controversial topics before the committee meetings	Formulary committee members do not want to be blamed in the committee meeting and in front of other members. Because the committee is a group with important representations of the most powerful players in the hospital.
Formulary committee members want to increase reliability of the information they hold and they are afraid of controversial discussions	
Formulary committee members clarify the opinion of other important members before the meeting.	Formulary committee members try to build barriers for counter-argumentation in order to increase the chances of success for their cases
Formulary committee members try to build alliances with other important decision-makers to make it more difficult for other members to argue against their case	
Cooperation between members of the formulary committee and the industry is seldom made transparent	Committee members are afraid of being suspected for biased decision-making and/or for bribing
Despite strong bonds between committee members and the industry, industry cooperation is perceived to be suspicious	
Formulary committee members try to justify close connections to the industry and emphasise an independent decision-making	
Pharmaceutical industry has influence on drug listings	The pharmaceutical industry knows most about their own drug but participants' perception is that the pharmaceutical industry also wants to use all possibilities to get a favorable decision
Pharmaceutical industry provides information and holds close contact to members of the formulary committee	

Table 19: Findings for the empirical, actual and real domain.

Empirical/ Actual	Real (potential structures)
For therapies which continue in the outpatient sector the committee members consider the impact on outpatient physicians	Due to the reimbursement power of health insurances in the outpatient setting, the payers also have an indirect impact on the hospital decision-making
Hospitals want their therapies not to be interrupted and they also do not want any arguments with outpatient physicians	
Innovative therapies or more patient convenience especially when already offered by competitor hospitals are considered differently in decision-making	
Patients and other hospitals consider and assess the therapy portfolio of the specific hospital	Innovative therapies are positive for the hospital reputation. Hence, external reputation of the hospital might overrule economic considerations
Pharmaceutical drugs with existing substances and new substances are handled differently. New substances are seldom rejected in the first place	
Formulary committee members emphasize positive facts in their argumentations to support their cases	
It is decisive how committee members build up their argumentation and what kind of arguments they select to support their case	The individual character and communication skill of each formulary committee member is decisive for his ability to convince other members
Low number of written guidelines and low response rate	
The hospital formulary committee is a closed system and no transparency is wished	Hospitals do not want to justify their decisions and be vulnerable to outside critique
The case documentation, either from the applicant and/or the pharmacist, shows only specific facts making the overall case positive	
Provided information in advance to the committee meetings is biased as individuals are responsible for compiling these information	Case documentation is influenced by the individual goals of the applicant and the limited time to present case data
Practical experience becomes more important	
Uncertainty increases willingness to accept softer criteria	Formulary committee members do not feel comfortable in cases of uncertainty --> this opens them to accept additional data
Perceived objective data creates more trust than expert opinions	
Objective criteria are perceived to be less biased and with more scientific rigor	This is probably derived from the scientific background of pharmacists and physicians
Practical experience alone is not sufficient for decision-making	
Mistrust against colleagues if objective data is contradictory	
Committees are very in transparent in regards to decision criteria specifically on subjective criteria	
Formulary committees are afraid to admit the use of subjective criteria	Formulary committees protect themselves. Subjective criteria are less accepted as members feel a lack of scientific rigor
The importance of subjective criteria is diffuse and hard to quantify	
Formulary committee members do not think too much if they make use of subjective criteria	Subjective criteria are used more intuitively
Pharmaceutical drugs for oncology patients or children shorten the committee discussions	
Formulary committee members accept the complexity of specific indications, such as oncology therapies, and are generally reluctant to have costs discussions regarding therapies for children	Increase in empathy can positively influence the acceptance of subjective criteria

Table 19: Findings for the empirical, actual and real domain (continued).

Empirical/ Actual	Real (potential structures)
Economic evaluations are not accepted as decision criterion	Formulary committee members have lack of expertise and time regarding economic evaluations
Economic evaluations are complex models with many input variables	
GMs are seldom part of the formulary committee	Physicians + pharmacists are very protective to their area of competency. They are afraid of losing importance and they do not want to leave their comfort zone.
Physicians + pharmacists do not want influence from the GM or other members regarding their own topics	
The level of impact on the formulary committee member's competency area influences their efforts for decision-making	
Formulary committee members value other opinions as long as they are limited to topics outside of their own competency area	
For certain decisions, formulary committee members prepare additional data. The active participation increases.	
Some physicians are very passive during the discussions in the formulary committee meetings	
Physicians usually do not interfere or are critical when it comes to questions outside of their competency area	
Some departments have more influence than others on decision-making	The strategic and economic importance of departments determines their potential impact on decision-making.
Non-physicians/ non-pharmacists have much lower influence on decision-making than physicians or pharmacists	Physicians and pharmacists have a perception about other functional roles as being less qualified. For example, nurses are part of the operations but not part of the decision-making process.
Due to the dominance of medical and economic criteria, other functions are only considered if those criteria are not clear enough	
Nurses have a weak positioning in the formulary committee	
Despite the organisational lead of the committee chair, this role is not necessarily the most influencing person	The role of the committee chair represents the formal most powerful position but often does not reflect reality. Sometimes this formal role is even abused by other more powerful members to build allies which are hard to "fight" in the committee discussions.
Other formulary committee members can be more powerful with more impact on decision-making	
Hierarchical structures do not impact decision-making very much	Between physicians, the seniority level is not the most decisive factor. Perceived level of expertise for the specific question or the strategic/economic importance of the respective department is more important.
Most members are on the same or similar seniority level	
Full rejections of pharmaceutical drugs are seldom. It is more likely that the committee decides to allow a drug on a temporary basis	Formulary committee members are afraid of voting against a drug and potential consequences if there are no clear facts which support the rejection. A vote against a drug request from another member might lead to a negative opinion from this member on their next own application.
Formulary committee members do not want to finally decide in cases of great uncertainty	

Table 19: Findings for the empirical, actual and real domain (continued).

8.5 Conclusion

This research identified many potential structures for the *real* domain derived from the empirical findings. In the discussion it was shown that some empirical findings lead to more than one potential structure in the *real* domain, in some cases even with contradictory goals or connections to each other. For example, the motivation of decision-makers to consider the reputation of the hospital and thus the higher willingness to accept expensive therapies is contrary to the difficult economic situation of hospitals and the resulting cost awareness. Another example is the potential focus of physicians and pharmacists on objective data due to their scientific training background which conflicts with the potential impact of empathy which can lead to acceptance of weak objective data for oncology treatments. The impact of external stakeholders on decision-making, such as the influence of the pharmaceutical industry, contradicts the justification behaviour of decision-makers who emphasise the independence of their decision-making.

Hence, different generative mechanisms have a positive influence on the use of either perceived objective or subjective decision criteria and their effect might compete during the decision-making process. This again confirms the theoretical fit of a *dual processing system*, such as Hammond's *cognitive continuum* model (1996, 2000), as a basis for the hospital formulary decision-making framework. And it explains more in detail how a *dual processing system* looks like for this specific process. This research also confirmed that the relative importance of the decision-making criteria varies and is individual for each question. Thus, it does not make sense to determine fixed numbers for relative weights. In addition to the mechanisms which influence the choice of perceived objective or subjective criteria, two other main mechanisms have impact on the use of these criteria: uncertainty and power. These two main mechanisms are displayed in Figure 48 and show their influence on the choice or rejection of either subjective or objective decision criteria. Examples of these criteria are shown in the blue boxes. The green circles show examples for different aspects which can increase or decrease uncertainty or power. For example, mistrust towards the pharmaceutical industry increases uncertainty and can lead to rejection of objective criteria, such as data from the pharmaceutical manufacturer. Lack of training of decision-makers can cause uncertainty and rejection of health economic

evaluations. In addition, power can have significant impact on the decision-making process. The communication skills or the perceived expert status of an individual decision-maker can create power to more easily convince other members in the committee even with weak objective data.

Generative mechanisms are not necessarily discrete. On the one hand, the level of individual communication skills of a decision-maker can lead to uncertainty if he lacks certain abilities. On the other hand, good communication skills can create power to convince. Hence, uncertainty and power both influence the acceptance or rejection of perceived objective and subjective criteria. These relationships as well as the *dual processing system* concerned with the use of objective and subjective data are shown in Figure 48.

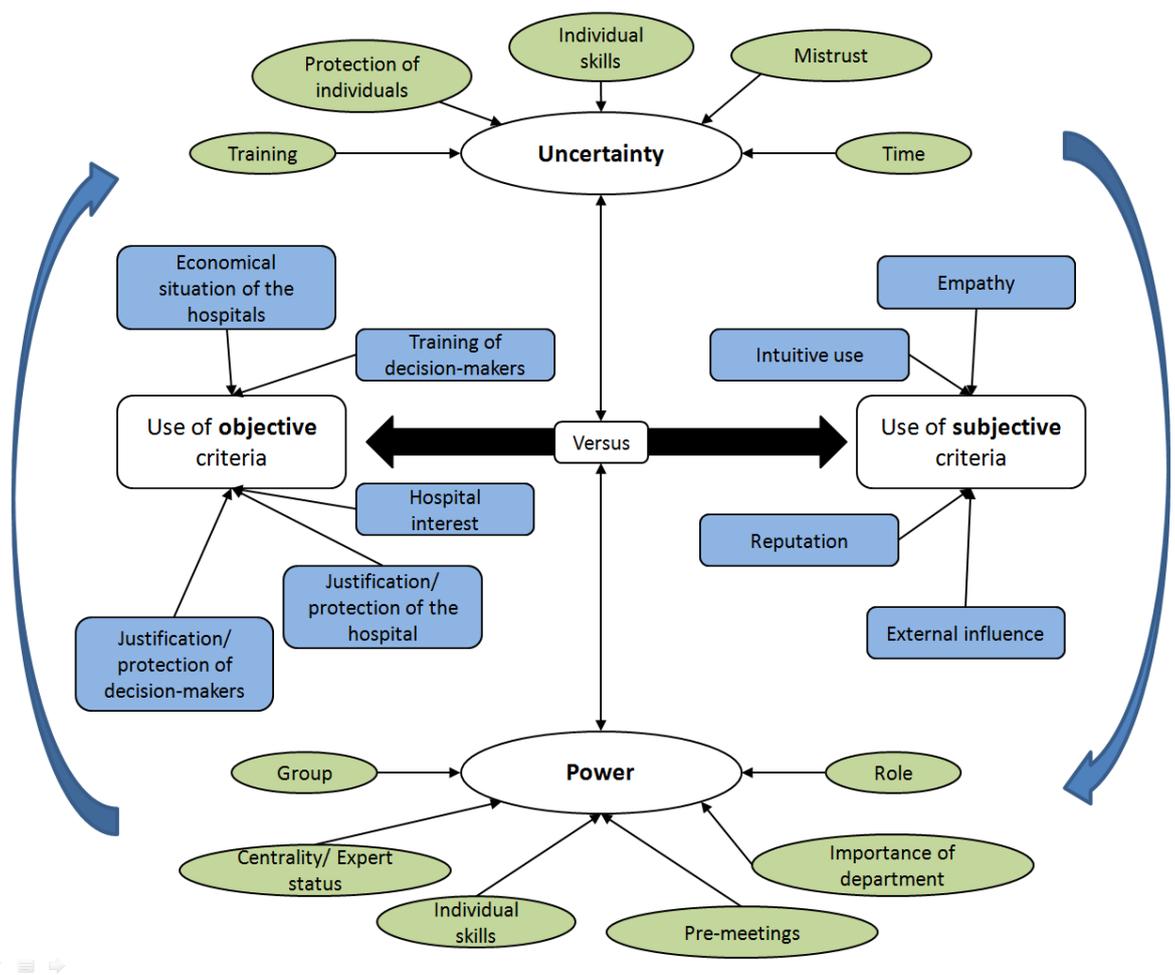


Figure 48: Dual processing system with impact of uncertainty and power.

8.6 The final hospital formulary decision-making framework

The final decision-making framework now displays the two main decision-making groups: pharmacists and physicians. Additionally, other members of the hospital formulary or non-formulary members of the hospital are added as “Influencers”.

In the first step, a dual processing system works for the individual preference building. It is influenced by perceived objective and subjective criteria sub-sets as well as external impact by the pharmaceutical industry, health insurances or other hospitals. One additional factor is the case documentation which is usually prepared by the pharmacist.

A possible pre-alignment with other selected members of the hospital formulary is in between the individual preference building and the following group decision-making process. Every member of the hospital formulary has an individual preference which can be adapted during the group discussion. The group discussion is influenced by strong individuals, the strengths of the alliances of the pre-meeting alignments, the level of involvement of the respective committee member, the level of information and the importance of the respective department.

Finally, all individual preferences are aggregated into one group decision.

The final hospital formulary decision-making framework with all mentioned changes is shown in Figure 49.

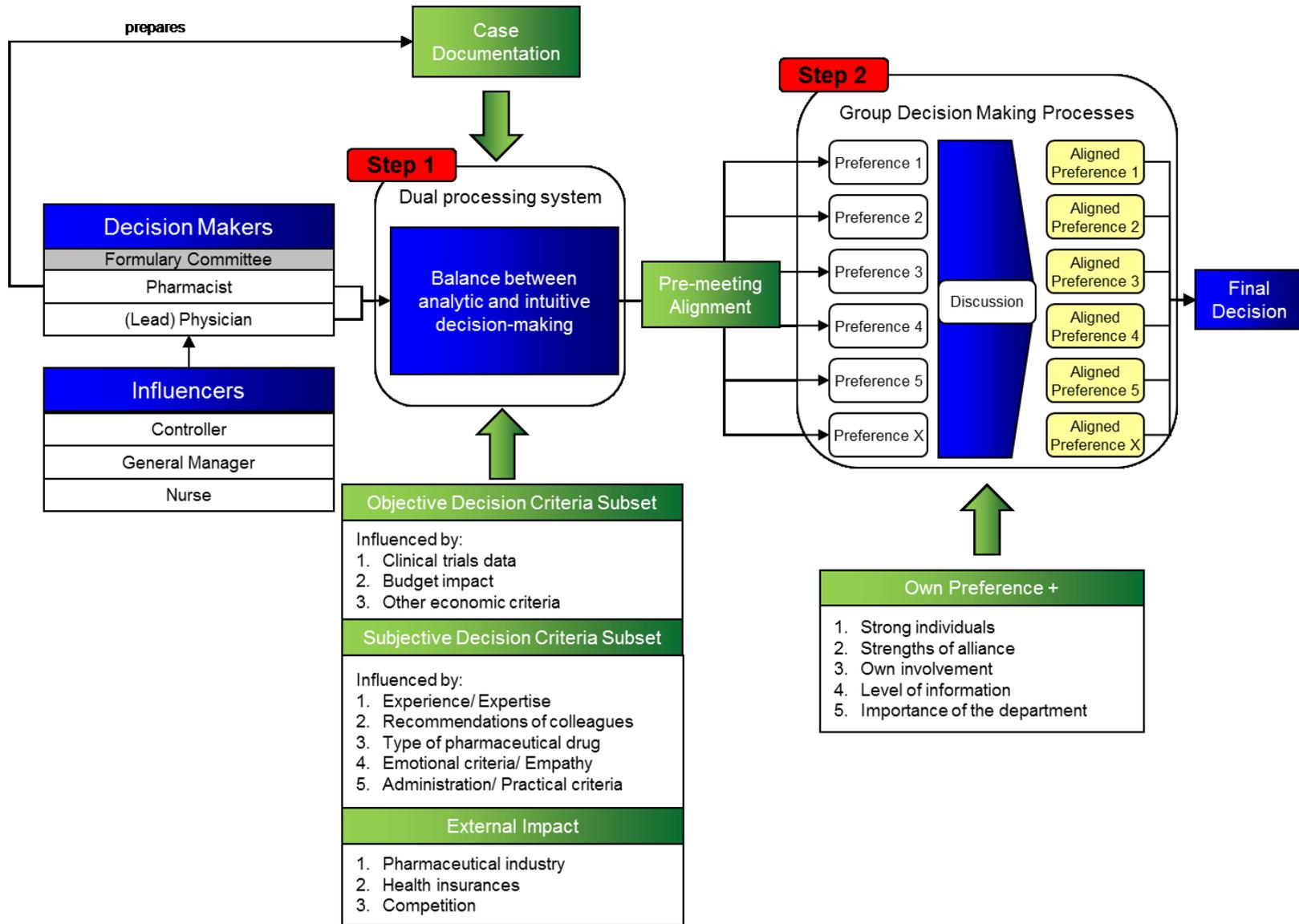


Figure 49: Final hospital formulary decision-making framework.

9 Implications for stakeholders

The final hospital formulary decision-making framework (Figure 49) is the graphical representation and the summary of the hospital formulary decision-making process. Figure 48 shows more in detail how the dual processing system with impact of uncertainty and power influences step 1 of the final hospital formulary decision-making framework. It allows a better understanding of how the individual formulary committee member decides on the use of objective or subjective decision criteria to form his preliminary decision preference. In step 2 of the final hospital formulary decision-making framework, group decision-making mechanisms can impact the individual preferences to form an aggregate group decision. Table 19 shows detailed findings for the *empirical*, *actual* and *real* domain including potential explanations for generative mechanisms. This adds further descriptive information to the understanding of the whole decision-making process. Hence, Figure 48, 49 and Table 19 are the main outcomes of this thesis and should ideally be used in combination to understand the drug funding hospital formulary decision-making process. The following implications for stakeholders were deduced from the combined view of the main outcomes.

9.1 Transparency

Transparency seems to be low for some parts of hospital formulary committee decision-making. In regards to an official documentation or protocol the transparency exists to protect members from being accused of bribery. Nonetheless, this transparency is only formal and does not fully reflect how decision-making is done. Usually only the decision is documented but not the reasons for the decision. This lack of transparency makes hospitals vulnerable. If, however, sufficient documentation exists and the rationale is explained the decision should be less vulnerable to outside critique. If committee members believe that they take well-founded decisions then there should be no problem to show this, at least to the hospital employees.

Another aspect of lack of transparency is the missing clear communication to other members of the committee of existing relationships between members of a hospital

formulary and the pharmaceutical industry. Considering the strong influence of individual members of the hospital formulary, more explicit communication including a clear description and guidance for the decision-making process and a more detailed documentation of decisions could simplify the understanding of decisions. This increase of transparency can avoid suspicions by other members, facilitate the retrospective understanding of decisions and increase the acceptance of decisions also for non-formulary members of the hospital.

9.2 Acceptance of subjective criteria

The use of perceived subjective criteria is not fully accepted by the formulary committee members. Either this is due to the scientific background of committee members or the fear that subjective criteria can only be used as a weak justification for decisions or that people just do not realise that they use such criteria. However, decision-making involves the use of subjective criteria and this happens with a significant impact on decision-making. Hence, physicians, pharmacists and all other involved stakeholders should accept this in order to make decision-making more honest and transparent. Subjective criteria should also be formally accepted as a normal and valuable component of a decision-making process. For example, this could be done with listing them in a decision-making guideline.

9.3 Economic implications

Generally the focus on economic issues is strong. Critical medical decisions are probably still independent of economic considerations but economics have already an influence. This should not increase as medical reasons should be leading in taking those decisions. The study showed that economic criteria are very important for hospital formulary committee members but that local adaptation of economic calculations, such as health economic evaluations, is often missing. This outcome has the implication for the pharmaceutical industry to produce economic data which is interesting for their customers. Economic measures, including budget impact calculations or health economic evaluations, should consider the individual local situation as much as possible.

This can be done with co-operations, post authorisation studies together with hospitals to challenge the economic data with real world environments.

There is high medical expertise in a hospital. It does not make sense that medical decisions taken in the hospital are changed or discontinued in the outpatient area as it jeopardises the treatment success. One considerable change would be necessary to ensure the independence of decision-making and a successful treatment. Ideally reimbursement for those therapies should be independent of the two different budgets (inpatient/outpatient) and should be guaranteed if initiated in the hospital. This structural change would require significant efforts from different stakeholders in the German healthcare system, such as politicians, health insurances and hospitals. However, due to the fact that health insurances would lose the indirect power to influence such treatments (and costs) it is highly unlikely that this change will happen.

9.4 More knowledge sharing and training

In regards to the local adaptation of economic data, there is also an implication for hospital formulary committees. Many members of the committee do not have the basic understanding for economic concepts, such as health economic evaluations. In order to allow an optimised informed decision-making, it is necessary that hospital formulary committees improve training on such topics. Economic topics might not be the main competence of physicians but it supports a better understanding of key criteria which can be used for decision-making and which are increasingly more important for hospitals. Physicians could also be trained on economics or health economics already during their studies. This allows them to better assess interrelations between medical and economic issues and to discuss at the same level as the pharmacists. In addition, training in communication skills supports formulary committee members with lower communication skills to better present their cases. It also facilitates that committee members express themselves.

Either the chair of the formulary committee or senior management executives should encourage committee members to take their roles serious and to prepare themselves appropriately.

In addition, timelines for preparation should be extended, provided documentation should be more extensive and standardised to allow easy reading and less bias. Case documentation should be based on standard forms or questions to reduce potential bias. A framework should be generated which facilitates the compilation of documentation and a level of standardization.

Pre-meeting discussions should be avoided and more time to discuss topics would be beneficial. To allow more in-depth discussions, the frequency of committee meetings could be increased. An open and respectful discussion culture should be established to allow an honest exchange of opinions. An overall goal for the hospital should be guidance for all discussions.

Most of the proposed changes in this section are not difficult to implement. However, some of the changes, such as the discussion culture require an active change management which needs buy-in and active support by the hospital's top management. Otherwise the changes would only be formal changes without impact on the real situation. Additionally, these changes require time from all participants which could be an obstacle for implementation.

9.5 Governance and group involvement

Hospital formularies seem to have an indirect governance issue characterised by single, highly influential members who basically steer the listing of pharmaceutical drugs. As a result, decision-making in formularies is operationally seen easier but might miss the goal of having a real discussion and consensus in the group. Hospital formulary committees need to decide if they want to act as dependent on single individuals as they do today and to use the committee only as a formal justification body. Or if they want to broaden the discussion, actively involve more members of the committee and thus enrich also the roles of people. For example, the administration of a pharmaceutical drug is an important dimension of the drug's profile. Stronger representation of nurses in the formulary committees is an important change to appreciate this fact. One major prerequisite is that people want to be more involved, since a higher involvement requires

more efforts of the single member of the committee. In this respect, the business unit organisation structure of many hospitals is probably counter-productive. This works perfectly well in other business areas, but hospitals are different to enterprises. To finish, the chair of a committee should not be biased and considering the already strong roles of physicians and pharmacists it makes sense to have a chair from a different professional function.

In this section the proposed changes have political weight. As discussed in the chapter before, usually the formulary committee is led by strong individuals or people working in the (financially) most important departments. The consequences of the proposed changes would mean a decrease of power in this group and an increase of power in other groups. Hence, today's influential committee members would need to accept these changes as they usually drive structural changes. Since those are local changes in the hospital they are not impossible but difficult to implement.

10 Reflexive view

In this thesis, there are some specific aspects to consider which might have impact on the thesis results. These aspects are induced by the professional role of the researcher as a healthcare professional working for a pharmaceutical company. Due to this role, the researcher's interpretations of data might be influenced and the professional experience of the researcher might have impacted resulting conclusions (Creswell, 2003). In addition, all interview respondents were aware of the researcher's professional role, because of the transparency principle of this research. This knowledge might have influenced the interviewee's willingness to reveal all of their opinions.

The professional role of the researcher also potentially impacted the chances to get access to hospital formulary committee members. For example, this is reflected in the low response rate of the survey and the low willingness to participate in the expert interviews. On the other hand, the professional role of the researcher also facilitated access to all of the interview participants, since they were all part of the professional network. For future research this obstacle needs to be considered. If people were not willing to participate mainly due to the sensitivity of the topic, it would be difficult to do research on this topic without an appropriate professional network. Other studies in this field also experienced lower response rates specifically for German hospitals (Haslé-Pham et al., 2005; Thürmann et al., 1997). In addition, the professional role of the researcher also enabled access to a data source which is usually non-accessible for scientific research. The company market research data which contributed to the explanation of the hospital formulary decision-making process was originally meant to be used only for the creation of market access strategies. One of the goals was to increase the understanding of the hospital formulary committee decision-making to optimize the targeting for market access and marketing activities. Despite some limitations to use this data which were described earlier, the closeness of this goal to the goals of this research made it a valuable data source to add further perspectives.

11 Concluding remarks and future research

This study aimed for an explorative research on hospital formulary decision-making in Germany. The objectives of this study were to identify the generative mechanisms which influence decision-making of pharmaceutical drug funding. In this regard, the research objectives were the identification and assessment of criteria used in funding decisions for pharmaceutical drugs in hospital formulary committees and their relative importance, the evaluation of the influence each stakeholder group has on drug funding decisions and the identification and evaluation of the motives and objectives of decision-makers when making funding decisions for pharmaceutical drugs.

The outcomes of this study should motivate future research on hospital formulary decision-making, since information about this topic is scarce. Due to the resource limitations of this study, future research could look more detailed on differences between hospitals and more in-depth research could be done for specific decision criteria. The governance aspect (as described in section 9.5) and an increased involvement of committee members could be an interesting topic for further research. Are other less powerful members of the committee interested to be more involved? Are they aware of their smaller impact possibilities?

The descriptive hospital formulary committee decision-making framework as well as the detailed outcomes of this study could be used in combination to allow hospitals to better understand their own processes and compare it to other hospitals with the aim for improvement. Interview participants remarked that the exchange of information with colleagues from other hospitals regarding the formulary committee decision-making happens rarely. For that reason many hospitals cannot compare their own process and identify potential strength and weaknesses. This study helps those hospitals to get a clearer picture of what is happening in other German hospital formularies.

12 Personal Reflection

During the last years writing my doctoral thesis, I gained knowledge about research philosophies, the ways of knowing and creating knowledge and the underlying theories. Of course I have learned much about my research topic and the issues around it. My behaviour in regards to time balancing and time planning as well as my self-discipline has significantly improved.

Regarding the reflection process my opinion is that reflection is not only helpful for research projects but can also be supportive in my work life. The reflection process by Biggs (1998) allows people and in this case specifically practitioners to constantly think about their behaviour and possible alternatives.

I believe that my research topic and the research questions have changed significantly over time. In summary the research questions have become very specific compared to the questions I were able to ask at the beginning. I was actually very surprised with the low response rate of my survey although former research indicated low participation willingness, especially for German hospitals. For this reason I was very pleased with my expert interviews which I think provided in-depth information on this very confidential decision-making process.

But this whole development of my research project is just one achievement. Over this whole journey I have changed as a person. I have learned a lot about other people who can broaden my views although they might be very different in their ideas and their characters. Speaking to other researchers from very different disciplines I discovered that working in heterogeneous teams might lead to better results than working in very homogeneous teams due to the broad variety of perspectives and opinions which come together.

13 References

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14 Appendix

Appendix 1: Final result of the first systematic literature review.

#	Title	Author	Journal	Level	Year	Region	Focus on	Methodology
1	Decision makers' views on health care objectives and budget constraints: results from a pilot study	Al, Feenstra, Brouwer	Health Policy	National	2004	NL	Several criteria	Semi-structured interviews
2	The role of pharmacoeconomics in formulary decision making in different hospitals in Riyadh, Saudi Arabia	Alsultan	Saudi Pharm. J.	Regional	2011	Saudi Arabia	Economic data and other criteria	Structured survey questionnaires
3	Drug formulary decision-making in two regional health authorities in British Columbia, Canada	Armstrong, Mitton, Carleton, Shoveller	Health Policy	Regional	2008	Canada	Political and social factors	Observation of Pharmacy and Therapeutics meetings, analysis of meeting documentation and semi-structured interviews
4	Priority setting of health interventions: the need for multi-criteria decision analysis	Baltussen, Niessen	Cost-Effectiveness and Resource Allocation	National, regional	2006	not specified	Several criteria	Literature review
5	Setting healthcare priorities in hospitals: a review of empirical studies	Barasa, Molyneux, English, Cleary	Health Policy and planning	National, local	2014	Various	Several criteria	Systematic review
6	"Yes", "No" or "Yes, but"? Multinomial modelling of NICE decision-making	Dakin, Devlin, Odeyemi	Health Policy	National	2006	UK	Several criteria	Quantitative analysis on NICE decisions
7	Transparency in Evidence Evaluation And Formulary Decision-Making	Dean, Ko, Graff, Localio, Wade, Dubois	Pharmacy and Therapeutics	Regional	2013	USA	Several criteria and transparency of the process	Expert panel to develop tool which was validated by a survey + pilot test of the tool
8	Determinants of HMO Formulary Adoption Decisions	Dranove, Hughes, Shanley	Health services research	Regional	2003	USA	Relationships and motivations	Focus group and surveys
9	A systematic review of the use of economic evaluation in local decision-making	Eddama, Coast	Health Policy	National, regional, local	2008	UK, USA	Economic evaluation	Systematic review

#	Title	Author	Journal	Level	Year	Region	Focus on	Methodology
10	Use of economic evaluation in local health care decision-making in England: A qualitative investigation	Eddama, Coast	Health Policy	Regional	2009	UK	Economic evaluation	In-depth interviews, observations of decision-making meetings and analysis of result documents
11	Drug and Therapeutics (D&T) committees in Dutch hospitals: a nation-wide survey of structure, activities, and drug selection procedures	Fijn, Brouwers, Knaap, De-Jong-Van den Berg	British journal of clinical pharmacology	Regional	1999	NL	Several criteria	Structured survey questionnaire
12	Decision maker's perceptions of health technology decision making and priority setting at the institutional level	Gallego, Fowler, van Gool	Australien Health Review	Regional	2008	Australia	Political and social factors	Semi-structured interviews
13	Funding and access to high cost medicines in public hospitals in Australia: Decision-makers' perspectives	Gallego, Taylor, Brien	Health Policy	Regional	2009	Australia	Criteria for high cost drugs	In-depth semi-structured interviews
14	Cost-Effectiveness Analysis and the Consistency of Decision Making	George, Harris, Mitchell	Pharmacoeconomics	National	2001	Australia	Cost effectiveness and other criteria	Submissions to the national HTA organization were analyzed
15	Priority setting in hospitals: Fairness, inclusiveness, and the problem of institutional power differences	Gibson, Martin, Singer	Social science & medicine	Regional	2005	Canada	Power differences	Case study
16	Role of clinical, patient-reported outcome and medico-economic studies in the public hospital drug formulary decision-making process: results of a European survey	Haslé-Pham, Arnould, Späth, Follet, Duru, Marquis	Health Policy	Regional	2005	France, Germany, NL, UK	Clinical studies, patient-reported outcomes and medico-economic studies	Postal survey
17	Rewarding innovation? An assessment of the factors that affect price and reimbursement status in Europe	Hutchings	Journal of Medical Marketing	National	2009	Germany, UK, France, Italy, Spain	Different systems have different weights	Literature review

#	Title	Author	Journal	Level	Year	Region	Focus on	Methodology
18	Using Health Outcomes Data to Inform Decision-Making	Janknegt	Pharmacoeconomics	Regional	2001	NL	Tool to support decision-making	Literature review
19	System of Objectified Judgement Analysis (SOJA) as a tool in rational and transparent drug-decision making	Janknegt, Scott, Mairs, Timoney, McElnay, Brenninkmeijer	Online Article	Regional	2007	NL	Tool to support decision-making	Literature review
20	The System of Objectified Judgement Analysis (SOJA)	Janknegt, Steenhoek	Drugs	Regional	1997	NL	Tool to support decision-making	Literature review
21	What constitutes evidence in hospital new drug decision making	Jenkings, Barber	Social science & medicine	Regional	2004	UK	Political and social factors	Observation and cross case analysis of Drugs and Therapeutic Committee meetings
22	Priority setting at the micro-, meso- and macro-levels in Canada, Norway and Uganda	Kapiriri, Norheim, Martin	Health Policy	National, regional, local	2006	Canada, Norway, Uganda	Several criteria	Case studies and key informant interviews
23	Dear policy maker: Have you made up your mind? A discrete choice experiment among policy makers and other health professionals	Koopmanschap, Stolk, Koolman	International Journal of Technology Assessment in Health Care	National	2010	NL	Several criteria	DCE + pilot study + follow-up focus group discussion
24	Pharmaceutical Technology Assessment: Perspectives from Payers	Leung, Halpern, West	J Manag Care Pharm	Regional	2012	USA	Several criteria	Semistructured telephone interviews
25	Priority setting in a hospital drug formulary: a qualitative case study and evaluation	Martin, Hollenberg, MacRae, Madden, Singer	Health Policy	Regional	2003	Canada	Several criteria	Qualitative case study
26	Priority-setting decisions for new cancer drugs: a qualitative case study	Martin, Pater, Singer	The Lancet	Regional	2001	Canada	Several criteria	Observation of provincial disease management organisation meetings, analysis of meeting documentation and interviews

#	Title	Author	Journal	Level	Year	Region	Focus on	Methodology
27	A survey of pharmacy and therapeutic committees across Canada: Scope and responsibilities	Mittmann, Knowles	The Canadian journal of clinical pharmacology	Regional	2008	Canada	Status of hospital P&T committees	Surveys
28	Role of pharmacoeconomics in drug benefit decision-making: Results of a survey	Motheral, Grizzle, Armstrong, Cox, Fairman	Formulary	Regional	2000	USA	Several criteria	Surveys
29	Finding legitimacy for the role of budget impact in drug reimbursement decisions	Niezen, de Bont, Busschbach, Cohen, Stolk	International Journal of Technology Assessment in Health Care	National	2009	NL	Budget impact	Literature review + semi-structured interviews
30	Use of pharmacoeconomic data in making hospital formulary decisions	Odedina, Sullivan, Nash, Clemmons	American journal of health-system pharmacy	Regional	2002	USA	Economic data and other criteria	Cross-sectional telephone survey
31	Ontario's Formulary Committee How Recommendations Are Made	PausJenssen, Singer, Detsky	Pharmacoeconomics	Regional	2003	Canada	Economic evaluation	Analysis of meeting transcripts, interviews with committee members
32	Drug and Therapeutics Committees in Danish Hospitals: A Survey of Organization, Activities and Drug Selection Procedures	Plet, Hallas, Nielsen, Kjeldsen	Basic & clinical pharmacology & toxicology	Regional	2013	Denmark	Hospital formularies	Descriptive cross-sectional survey
33	A Prescription for Improving Drug Formulary Decision Making	Schiff, Galanter, Duhig, Koronkowski, Lodolce, Pontikes, Busker, Touchette, Walton, Lambert	PLoS medicine	Regional	2012	USA	Tool to support decision-making	Literature review
34	A qualitative approach to the use of economic data in the selection of medicines for hospital formularies: a French survey	Späth, Charavel, Morelle, Carrere	Pharmacy World and Science	Regional	2003	France	Economic data and other criteria	Qualitative interviews
35	The greatest happiness of the greatest number? Policy actors' perspectives on the limits of economic evaluation as a tool for informing health care coverage decisions in Thailand	Teerawattananon, Russell	BMC Health Services Research	National, regional	2008	Thailand	Economic evaluation and political and social factors	Semi-structured interviews and simple descriptive statistics
36	Economic Evidence at the Local Level	van Gool, Gallego, Haas, Viney, Hall, Ward	Pharmacoeconomics	Regional	2007	Australia	Economic evaluation	Literature review

#	Title	Author	Journal	Level	Year	Region	Focus on	Methodology
37	Economic evaluations of healthcare programmes and decision making	van Velden, Severens, Novak	Pharmacoeconomics	National, regional, local	2005	USA, Canada, NL, Australia	Economic evaluation	Systematic review
38	Drug reimbursement in Finland - a case of explicit prioritising in special categories	Vuorenkoski, Toiviainen, Hemminki	Health Policy	National	2003	Finland	Political and social factors	Interviews with thematic framework analysis
39	Decision-making in priority setting for medicines - a review of empirical studies	Vuorenkoski, Toiviainen, Hemminki	Health Policy	National, regional	2008	Canada, France, Finland, UK	Decision making process and criteria used	Literature review of empirical studies
40	The role of pharmacoeconomics in formulary decision-making	Walkom, Robertson, Newby, Pillay	Formulary	Regional	2006	UK, USA, France, Canada, NL, Australia, Sweden, Spain,	Several criteria	Literature review
41	Reimbursement decisions in health policy - extending our understanding of the elements of decision-making	Wirtz, Cribb, Barber	Health Policy	National, regional	2005	UK	Political and social factors	In-depth interviews
42	Use of health-related quality of life information in managed care formulary decision-making	Wu, Sause, Zacker	Research in Social and Administrative Pharmacy	Regional	2005	USA	Health related quality of life	Mail survey
43	Cost-Effectiveness Analysis and the Formulary Decision-Making Process	Wang, Salmon, Walton	Journal of Managed Care Pharmacy	Regional	2004	USA	Cost effectiveness and other criteria	Literature review
44	Cost-effectiveness analysis and formulary decision making in England: Findings from research	Williams, Bryan	Social science & medicine	Regional	2007	UK	Cost effectiveness	Literature review

Appendix 2: Final result of the second systematic literature review.

#	Title	Author	Journal/ Book title/ Source	Year	Focus on
1	How individual preferences get aggregated in groups - An experimental study	Ambrus, Greiner, Pathak	UNSW Australian School of Business Research Paper	2013	Social Decision Scheme and centrality
2	Social choice and individual values	Arrow	Social choice and individual values	1963	Aggregated group preference
3	From novice to expert	Benner	The American Journal of Nursing	1984	Intuition
4	Clinical wisdom and interventions in acute and critical care: A thinking-in-action approach	Benner, Hooper-Kyriakadis & Stannard	Clinical wisdom and interventions in acute and critical care: A thinking-in-action approach	2011	Intuition
5	The theory of committees and elections	Black	The theory of committees and elections	1958	Aggregated group preference
6	Group Decision Making under Conditions of Distributed Knowledge: The Information Asymmetries Model	Brodbeck, Kerschreiter, Mojzisch & Schulz-Hardt	Academy of Management Review	2007	Group performance
7	Group decision and social interactions	Davis	Psychological Review	1973	Social Decision Scheme
8	Group decision making and quantitative judgements: a consensus model	Davis	In E. Witte & J. H. Davis (Eds.), Understanding group behavior: Consensual action by small groups	1996	Social Decision Scheme
9	Intuition from the perspective of cognitive-experiential self-theory	Epstein	Intuition in judgment and decision making	2008	Dual Processing
10	The heuristic-analytic theory of reasoning: extension and evaluation	Evans	Psychonomic Bulletin & Review	2006	Dual Processing
11	Beyond group-level explanations for the failure of groups to solve hidden profiles: The individual preference effect revisited	Faulmüller, Kerschreiter, Mojzisch, Schulz-Hardt	Group Processes & Intergroup Relations	2010	Individual preference
12	Altruistic punishment in humans	Fehr & Gächter	Nature	2002	Subjective factors
13	Thinking, feeling and deciding: the influence of emotions on the decision making and performance of traders	Fenton-O'Creevy, Soane, Nicholson & Willman	Journal of Organizational Behavior	2011	Rational decision-making
14	Conflict, decision and dissonance	Festinger	Conflict, decision, and dissonance	1964	Centrality
15	Gut feelings. The intelligence of the unconscious	Gigerenzer	Gut feelings: the intelligence of the unconscious	2007	Rational decision-making
16	The common knowledge effect: information sharing and group judgement	Gigone & Hastie	Journal of Personality and Social Psychology	1993	Information sharing
17	The impact of information on group judgement: a model and computer simulation	Gigone & Hastie	Understanding group behavior: Consensual action by small groups	2013	Information sharing
18	Heuristics and biases: the psychology of intuitive judgement	Gilovich, Griffith, Kahneman	Heuristics and biases: The psychology of intuitive judgment	2002	Dual Processing
19	Preference-Consistent Evaluation of Information in the Hidden Profile Paradigm: Beyond Group-Level Explanations for the Dominance of Shared Information in Group Decisions	Greitemeyer, Schulz-Hardt	Journal of personality and social psychology	2003	Individual preference
20	Human judgement and social policy: irreducible uncertainty, inevitable error, unavoidable injustice	Hammond	Human judgement and social policy: Irreducible uncertainty, inevitable error, unavoidable injustice	1996	Intuition versus analysis
21	Judgements under stress	Hammond	Judgments under stress	2000	Intuition versus analysis
22	Feelings and consumer decision making: the appraisal-tendency framework	Han, Lerner & Keltner	Journal of Consumer Psychology	2007	Subjective factors
23	Cognitive and consensus processes in group recognition memory	Hinsz	Journal of Personality and Social psychology	1990	Information sharing
24	The emerging conceptualization of groups as information processors	Hinsz, Tindale & Vollrath	Psychological bulletin	1997	Information processing systems

#	Title	Author		Year	Focus on
25	Victims of groupthink: A psychological study of foreign-policy decisions and fiascoes	Janis	Victims of groupthink: A psychological study of foreign-policy decisions and fiascoes	1972	Information sharing
26	A perspective on judgement and choice: mapping bounded rationality	Kahneman	American psychologist	2003	Rational decision-making
27	The American Jury	Kalven & Zeisel	The american jury	1966	Individual preference
28	Centrality in sociocognitive networks and social influence: an illustration in a group decision-making context	Kameda, Ohtsubo & Takezawa	Journal of personality and social psychology	1997	Cognitive centrality
29	Group decision making: the effects of initial preferences and time pressure	Kelly & Karau	Personality and Social Psychology Bulletin	1999	Information sharing
30	Intuition: a critical review of the research and rhetoric	King & Appleton	Journal of Advanced Nursing	1997	Intuition
31	Discussion of shared and unshared information in decision-making groups	Larson, Foster-Fishman & Keys	Journal of personality and social psychology	1994	Information sharing
32	Recalling Shared vs. Unshared Information Mentioned During Group Discussion: Toward Understanding Differential Repetition Rates	Larson, Jr., Harmon	Group processes & intergroup relations	2007	Recalling shared information
33	Portrait of The Angry Decision Maker: How Appraisal Tendencies Shape Anger's Influence on Cognition	Lerner & Tiedens	Cognition & Emotion	2006	Subjective factors
34	Beyond valence: Toward a model of emotion-specific influences on judgment and choice	Lerner & Keltner	Journal of Behavioral Decision Making	2000	Subjective factors
35	Reflective and reflexive judgement processes: a social cognitive neuro-science approach	Lieberman	Social judgments: Implicit and explicit processes	2003	Dual Processing
36	The role of affect in decision making	Loewenstein & Lerner	Handbook of affective science	2003	Rational decision-making
37	Two models of group behaviour in the solution of eureka-type problems	Lorge & Solomon	Psychometrika	1955	Aggregated group preference
38	Information Sharing and Team Performance: A Meta-Analysis	Mesmer-Magnus & DeChurch	Journal of Applied Psychology	2009	Group performance
39	Culture and systems of thought: holistic vs. analytic cognition	Nisbett, Peng, Choi, Norenzayan	Psychological review	2001	Dual Processing
40	Acceptance of uncommon information into group discussion when that information is or is not demonstrable	Parks & Cowlin	Organizational Behavior and Human Decision Processes	1996	Information sharing
41	The functions of affect in the construction of preferences	Peters	The construction of preference	2006	Rational decision-making
42	The multiplicity of emotions: a framework of emotional functions in decision making	Pfister & Böhm	Judgment and Decision Making	2008	Subjective factors
43	Unfairness, Anger, and Spite: Emotional Rejections of Ultimatum Offers	Pillutla & Murningham	Organizational Behavior and Human Decision Pr	1996	Subjective factors
44	Emotions in Finance. Distrust and Uncertainty in Global Markets	Pixley	Emotions in finance: Distrust and uncertainty in global markets	2004	Intuition versus analysis
45	Information processing theory of human problem solving	Simon	Handbook of learning and cognitive processes	1978	Rational decision-making
46	The empirical case for two systems of reasoning	Sloman	Psychological bulletin	1996	Rational decision-making
47	On the reliability of group judgments and decisions	Smoke & Zajonc	Mathematical methods in small group processes	1962	Aggregated group preference

#	Title	Author		Year	Focus on
48	Individual differences in reasoning: implications for the rationality debate	Stanovich & West	Behav Brain Sci	2000	Dual Processing
49	Pooling of unshared information in group decision making: biased information sampling during discussion	Stasser & Titus	Journal of personality and social psychology	1985	Information sharing
50	Effects of information load and percentage of shared information on the dissemination of unshared information during group discussion	Stasser & Titus	Journal of personality and social psychology	1987	Information sharing
51	Influence processes and consensus models in decision-making groups	Stasser, Kerr & Davis	In Psychology of Group Influence	1989	Social Decision Scheme
52	Expert roles and information exchange during discussion: the importance of knowing who knows what	Stasser, Stewart & Wittenbaum	Journal of experimental social psychology	1995	Centrality
53	Information sampling in structured and unstructured discussions of three- and six-person groups	Stasser, Taylor & Hanna	Journal of Personality and Social Psychology	1989	Information sharing
54	Group processes and productivity	Steiner	Group processes and productivity	1972	Aggregated group preference
55	Reflective and impulsive determinants of social behaviour	Strack & Deutsch	Personality and social psychology review	2004	Dual Processing
56	The interaction of the explicit and implicit in skill learning: a dual-process approach	Sun, Slusarz & Terry	Psychological review	2005	Dual Processing
57	Shared information, cognitive load, and group memory	Tindale & Sheffey	Group Processes & Intergroup Relations	2002	Information sharing
58	Group decision making	Tindale, Kameda & Hinsz	Sage handbook of social psychology	2003	Group decision-making
59	A model of the hierarchy of behaviour, cognition and consciousness	Toates	Consciousness and cognition	2006	Dual Processing
60	Assigned experts with competitive goals withhold information in group decision making	Toma, Vasiljevic, Oberlé, Butera	British Journal of Social Psychology	2013	Information sharing
61	Effects of partially shared persuasive arguments on group induced shifts: a group problem solving approach	Vinokur and Burnstein	Journal of Personality and Social Psychology	1974	Individual preference
62	Memory performance by decision-making groups and individuals	Vollrath, Sheppard, Hinsz & Davis	Organizational Behavior and Human Decision Processes	1989	Information sharing
63	The theory of games and economic behaviour	von Neumann & Morgenstern	Theory of games and economic behavior	1947	Rational decision-making
64	Strangers to ourselves	Wilson	Strangers to ourselves: Discovering the adaptive unconscious	2002	Dual Processing
65	A social validation explanation for mutual enhancement	Wittenbaum, Bowman	Journal of Experimental Social Psychology	2004	Centrality
66	On emotion specificity in decision making: Why feeling is for doing	Zeelenberg, Nelissen, Breugelmanns & Pieters	Judgment and Decision making	2008	Subjective factors
67	Heading into the unknown: Everyday strategies for managing risk and uncertainty	Zinn	Health, Risk & Society	2008	Intuition versus analysis

Appendix 3: Web-Survey.

English translation of all survey questions

1. What is your position in the hospital?
2. Are you personally involved in formulary decision-making (include or exclude a pharmaceutical drug)
3. How many hospitals do you represent in the hospital formulary committee?
4. Number of beds in the represented hospital/ hospital group?
5. How does formulary decision-making regarding inclusion/ exclusion of pharmaceutical drugs work in your hospital?
 - a. Committee with fixed members
 - b. Committee with varying members
 - c. Single discussions between pharmacist and physician
 - d. Other
6. How many people usually sit together to make those decisions?
 - a. 2 people
 - b. 3-5 people
 - c. 6-8 people
 - d. 9-12 people
 - e. More than 12 people
7. Who chairs the hospital formulary committee?
 - a. Pharmacist
 - b. Physician
 - c. Head physician
 - d. General Manager
 - e. Other
8. How many people from the respective functional role usually attend the committee meetings?
 - a. Pharmacist
 - b. Physician
 - c. Head physician
 - d. General Manager
 - e. Nurse/ Head nurse
 - f. Patients/ Patient representative
 - g. Controller/administrator
 - h. Other
9. How often does the committee meet to discuss inclusion or exclusion of pharmaceutical drugs?
10. Does your hospital have guidelines for the inclusion or exclusion of pharmaceutical drugs?

11. In the guidelines...
 - a. ...decision criteria are mentioned.
 - b. ... the relative importance of decision criteria is given.
12. My decision-making...
 - a. ...always follows the criteria given in the guidelines.
13. What decision criteria are given in the guidelines?
 - a. Number of indications
 - b. Type of administration
 - c. Budget impact
 - d. Data from observational trials
 - e. Data from clinical trials
 - f. Recommendation from physician/head physician
 - g. Recommendation from pharmacist
 - h. Recommendation from colleagues
 - i. Recommendation from patient groups
 - j. Former experience with manufacturer
 - k. Health economic evaluations
 - l. Information material provided by the manufacturer
 - m. None
 - n. Experience in the hospital
 - o. Experience from other hospitals
 - p. Quality of life data
 - q. Supply reliability of manufacturer
 - r. Price of the drug
 - s. Off-label potential
 - t. Disease severity
 - u. Existing alternatives
14. How do you feel about your current decision-making process?
15. Do hierarchical dependencies between members of the committee exist?
16. Is there transparency in regards to relationships between committee members and pharmaceutical manufacturers (e.g. participation in clinical trials)?
17. Are supportive tools applied, such as SOJA, Multi criteria decision analysis or computer software?
18. Does every committee member receive a documentation package which includes information on the respective pharmaceutical drug?
19. Who is responsible for this documentation package?
 - a. Pharmacist
 - b. Physician/ Head physician
 - c. General Manager
 - d. Other
20. What kind of information is included in the documentation package?

- a. Data from clinical trials
 - b. Disease severity
 - c. Health economic evaluations
 - d. Budget impact
 - e. Price of the drug
 - f. Experience in the hospital
 - g. Experience from other hospitals
 - h. Recommendation from colleagues
 - i. Information material provided by the manufacturer
 - j. Recommendation from pharmacist
 - k. Recommendation from physician/head physician
 - l. Data from observational trials
 - m. Quality of life data
 - n. Type of administration
 - o. Supply reliability of manufacturer

 - p. Number of indications
 - q. Recommendation from patient groups
 - r. Former experience with manufacturer
 - s. Existing alternatives
 - t. Off-label potential
 - u. Other
21. Do you use the information of the documentation package?
22. Do you have budget responsibility?
23. Is the financial situation of the hospital topic during the committee discussions?
24. In your opinion, what is the impact on decision-making of each functional group?
- a. Pharmacist
 - b. Physician
 - c. Head physician
 - d. General Manager
 - e. Patient/ Patient representative
 - f. Controller
 - g. Other
25. Which decision rule is applied for decision-making on inclusion or exclusion of pharmaceutical drugs?
- a. Simple majority – more than half of the members vote yes
 - b. Consensus – a decision is only taken if all members accept the decision
 - c. A single person decides
 - d. Other
26. Is your decision-making different for different types of pharmaceutical drugs?

27. For which types of pharmaceutical drugs do you apply different criteria?
- Antifungal
 - Enzyme replacement therapies
 - Medical devices
 - Monoclonal antibodies
 - Sera/ Immunoglobulins
 - Cytostatic
28. Which decision criteria do you apply for (see list in 27)?
- Number of indications
 - Type of administration
 - Budget impact
 - Data from observational trials
 - Data from clinical trials
 - Recommendation from physician/head physician
 - Recommendation from pharmacist
 - Recommendation from colleagues
 - Recommendation from patient groups
 - Former experience with manufacturer
 - Health economic evaluations
 - Information material provided by the manufacturer
 - Experience in the hospital
 - Experience from other hospitals
 - Quality of life data
 - Supply reliability of manufacturer
 - Price of the drug
 - Off-label potential
 - Disease severity
 - Existing alternatives
29. Which decision criteria do you apply for (see list in 27)?
- See list in 28
30. Which decision criteria do you apply for (see list in 27)?
- See list in 28
31. Which decision criteria do you apply for orphan drugs?
- See list in 28 without "data from clinical trial"
32. Do you want to receive the study results by email and do you agree that your email address is saved for this purpose only?

Screenshots of the online-survey

Entscheidungskriterien bei der Auswahl von Arzneimitteln im

*** 1. Was ist Ihre Position im Krankenhaus?**

*** 2. Sind Sie persönlich an Entscheidungen bezüglich der Arzneimittelliste (Hinzufügen/Entfernen von Arzneimitteln) beteiligt?**

bei jeder Entscheidung bei den meisten Entscheidungen bei vielen Entscheidungen bei wenigen Entscheidungen bei keiner Entscheidung

*** 3. Für wieviele Krankenhäuser treffen Sie Entscheidungen bezüglich der Arzneimittelliste?**

1 5-8
 2-4 >8

*** 4. Wieviele Betten hat das Krankenhaus / die Krankenhausgruppe für die Sie arbeiten?**

weniger als 600 Betten
 600-800 Betten
 mehr als 800 Betten

Entscheidungskriterien bei der Auswahl von Arzneimitteln im

*** 5. Wie werden Entscheidungen bezüglich der Arzneimittelliste (Hinzufügen / Entfernen von Arzneimitteln) in Ihrem Krankenhaus getroffen?**

(Bitte geben Sie eine Antwort für alle Auswahlmöglichkeiten! Sollte etwas nicht zutreffen, dann markieren Sie dies mit "trifft nie zu").

	trifft immer zu	trifft meistens zu	trifft oft zu	trifft selten zu	trifft nie zu
Arzneimittelkommission mit festem Teilnehmerkreis	<input type="radio"/>				
Arzneimittelkommission mit wechselnden Teilnehmern	<input type="radio"/>				
Einzelbesprechungen zwischen Apotheker(n) und Abteilungsleitern (Ärzten)	<input type="radio"/>				
Sonstiges	<input type="radio"/>				
Sonstiges (bitte angeben)	<input type="text"/>				

*** 6. Wieviele Personen sitzen üblicherweise zusammen um Entscheidungen bezüglich der Arzneimittelliste (Hinzufügen / Entfernen von Arzneimitteln) zu treffen?**

(Bitte geben Sie eine Antwort für alle Auswahlmöglichkeiten! Sollte etwas nicht zutreffen, dann markieren Sie dies mit "trifft nie zu").

	trifft immer zu	trifft meistens zu	trifft oft zu	trifft selten zu	trifft nie zu
2 Personen	<input type="radio"/>				
3-5 Personen	<input type="radio"/>				
6-8 Personen	<input type="radio"/>				
9-12 Personen	<input type="radio"/>				
mehr als 12 Personen	<input type="radio"/>				

Entscheidungskriterien bei der Auswahl von Arzneimitteln im

*7. Wer leitet die Besprechungen über die Arzneimittelliste?

(Bitte geben Sie eine Antwort für alle Auswahlmöglichkeiten! Sollte etwas nicht zutreffen, dann markieren Sie dies mit "trifft nie zu").

	trifft immer zu	trifft meistens zu	trifft oft zu	trifft selten zu	trifft nie zu
Apotheker	<input type="radio"/>				
Abteilungsleiter (Arzt)	<input type="radio"/>				
Chefarzt	<input type="radio"/>				
Verwaltungsdirektor	<input type="radio"/>				
Sonstiges	<input type="radio"/>				

Sonstiges (bitte angeben)

Entscheidungskriterien bei der Auswahl von Arzneimitteln im

*** 8. Wieviele Personen der jeweiligen Berufsgruppen nehmen üblicherweise an den Besprechungen zur Arzneimittelliste (Hinzufügen / Entfernen von Arzneimitteln) teil?**

(Bitte geben Sie eine Antwort für alle Auswahlmöglichkeiten! Sollte etwas nicht zutreffen, dann markieren Sie dies mit "keiner").

	1	2	3	4	>4	keiner
Apotheker	<input type="radio"/>					
Abteilungsleiter (Arzt)	<input type="radio"/>					
Chefarzt	<input type="radio"/>					
Verwaltungsdirektor	<input type="radio"/>					
Krankenschwester/-pfleger	<input type="radio"/>					
Patienten/ Patientenvertreter	<input type="radio"/>					
Controlleur	<input type="radio"/>					
Sonstige	<input type="radio"/>					

Sonstiges (bitte angeben)

*** 9. Wie oft finden üblicherweise Besprechungen zur Arzneimittelliste (Hinzufügen / Entfernen von Arzneimitteln) statt?**

Sonstiges (bitte angeben)

*** 10. Hat Ihr Krankenhaus Richtlinien für das Hinzufügen von Arzneimitteln zur Arzneimittelliste?**

Sonstiges (bitte angeben)

Entscheidungskriterien bei der Auswahl von Arzneimitteln im

*11. In den Richtlinien...

	Stimme voll zu	Stimme zu	Stimme nicht zu	Lehne ab	k. A.
...werden die Entscheidungskriterien für das Hinzufügen von Arzneimitteln zur Arzneimittelliste klar benannt.	<input type="radio"/>				
...wird die relative Wichtigkeit von Entscheidungskriterien für das Hinzufügen von Arzneimitteln zur Arzneimittelliste klar benannt.	<input type="radio"/>				

*12. Bei meiner Entscheidungsfindung...

	Trifft immer zu	Trifft häufig zu	Trifft selten zu	Trifft nie zu	k. A.
...folge ich immer den Entscheidungskriterien, die in den Richtlinien benannt werden	<input type="radio"/>				

*13. Welche Entscheidungskriterien werden in den Richtlinien benannt?

- | | | |
|---|--|--|
| <input type="checkbox"/> Anzahl der Indikationen | <input type="checkbox"/> Empfehlung von Kollegen | <input type="checkbox"/> Lebensqualitätsdaten |
| <input type="checkbox"/> Arten/Einfachheit der Administration | <input type="checkbox"/> Empfehlung von Patientengruppen | <input type="checkbox"/> Liefertreue des Herstellers |
| <input type="checkbox"/> Budgetauswirkung | <input type="checkbox"/> Frühere Erfahrung mit dem Hersteller | <input type="checkbox"/> Medikamentenpreis |
| <input type="checkbox"/> Daten aus Beobachtungsstudien | <input type="checkbox"/> Gesundheitsökonomische Bewertungen | <input type="checkbox"/> Off-Label Potential |
| <input type="checkbox"/> Daten aus klinischen Studien | <input type="checkbox"/> Informationsmaterial des Herstellers | <input type="checkbox"/> Schwere der Erkrankung |
| <input type="checkbox"/> Empfehlung von Abteilungsleiter (Arzt) | <input type="checkbox"/> Keine | <input type="checkbox"/> Verfügbare Alternativen |
| <input type="checkbox"/> Empfehlung von Apotheker | <input type="checkbox"/> Klinische Erfahrung im Krankenhaus | |
| <input type="checkbox"/> Empfehlung von Chefarzt | <input type="checkbox"/> Klinische Erfahrung in anderen Krankenhäusern | |

Entscheidungskriterien bei der Auswahl von Arzneimitteln im

*** 14. Wie beurteilen Sie den derzeitigen Entscheidungsprozess zur Arzneimittelliste in Ihrem Krankenhaus?**

	sehr zufrieden	zufrieden	weniger zufrieden	sehr unzufrieden	k. A.
Ich bin...	<input type="radio"/>				

*** 15. Gibt es in den Besprechungen zur Arzneimittelliste (Hinzufügen / Entfernen von Arzneimitteln) hierarchische Abhängigkeiten zwischen den Teilnehmern (z.B. Vorgesetzter und Mitarbeiter)?**

<input type="radio"/> Immer	<input type="radio"/> Meistens	<input type="radio"/> Oft	<input type="radio"/> Selten	<input type="radio"/> Nie
-----------------------------	--------------------------------	---------------------------	------------------------------	---------------------------

*** 16. Wird die Zusammenarbeit zwischen Beteiligten der Besprechungen zur Arzneimittelliste und der Hersteller von Arzneimitteln offengelegt (z.B. Teilnahme an klinischen Studien des Herstellers)?**

<input type="radio"/> Immer	<input type="radio"/> Meistens	<input type="radio"/> Oft	<input type="radio"/> Selten	<input type="radio"/> Nie
-----------------------------	--------------------------------	---------------------------	------------------------------	---------------------------

*** 17. Werden in den Besprechungen zur Arzneimittelliste unterstützende Werkzeuge (wie z.B. SOJA, Multi Criteria Decision Analysis oder Computersoftware) genutzt?**

<input type="radio"/> Immer	<input type="radio"/> Meistens	<input type="radio"/> Oft	<input type="radio"/> Selten	<input type="radio"/> Nie	<input type="radio"/> Keine Angabe
-----------------------------	--------------------------------	---------------------------	------------------------------	---------------------------	------------------------------------

*** 18. Bekommt jeder Beteiligte einer Besprechung zum Hinzufügen eines Arzneimittels zur Arzneimittelliste ein Dokumentationspaket, das Informationen zum jeweiligen Arzneimittel enthält?**

<input type="radio"/> Immer	<input type="radio"/> Meistens	<input type="radio"/> Oft	<input type="radio"/> Selten	<input type="radio"/> Nie
-----------------------------	--------------------------------	---------------------------	------------------------------	---------------------------

Entscheidungskriterien bei der Auswahl von Arzneimitteln im

*19. Wer erstellt dieses Dokumentationspaket?

(Bitte geben Sie eine Antwort für alle Auswahlmöglichkeiten!)

	Immer	Meistens	Oft	Seiten	Nie
Apotheker	<input type="radio"/>				
Abteilungsleiter (Arzt)	<input type="radio"/>				
Chefarzt	<input type="radio"/>				
Verwaltungsdirektor	<input type="radio"/>				
Sonstige	<input type="radio"/>				

Sonstiges (bitte angeben)

*20. Welche Informationen enthält das Dokumentationspaket

- | | | |
|--|---|---|
| <input type="checkbox"/> Daten aus klinischen Studien | <input type="checkbox"/> Informationsmaterial des Herstellers | <input type="checkbox"/> Anzahl der Indikationen |
| <input type="checkbox"/> Schwere der Erkrankung | <input type="checkbox"/> Empfehlung von Apotheker | <input type="checkbox"/> Empfehlung von Patientengruppen |
| <input type="checkbox"/> Gesundheitsökonomische Bewertungen | <input type="checkbox"/> Empfehlung von Chefarzt | <input type="checkbox"/> Frühere Erfahrung mit dem Hersteller |
| <input type="checkbox"/> Budgetauswirkung | <input type="checkbox"/> Empfehlung von Abteilungsleiter (Arzt) | <input type="checkbox"/> Verfügbare Alternativen |
| <input type="checkbox"/> Medikamentenpreis | <input type="checkbox"/> Daten aus Beobachtungsstudien | <input type="checkbox"/> Off-Label Potential |
| <input type="checkbox"/> Klinische Erfahrung im Krankenhaus | <input type="checkbox"/> Lebensqualitätsdaten | <input type="checkbox"/> Andere |
| <input type="checkbox"/> Klinische Erfahrung in anderen Krankenhäusern | <input type="checkbox"/> Arten/Einfachheit der Administration | |
| <input type="checkbox"/> Empfehlung von Kollegen | <input type="checkbox"/> Lieferzuverlässigkeit des Herstellers | |

*21. Nutzen Sie die Informationen aus dem Dokumentationspaket für Ihre Entscheidungsfindung (bezogen auf die Arzneimittelliste)?

- Immer
 Meistens
 Oft
 Seiten
 Nie

Entscheidungskriterien bei der Auswahl von Arzneimitteln im

*22. Haben Sie Budget-Verantwortung?

*23. Wird die allgemein finanzielle Situation des Krankenhauses in den Besprechungen zur Arzneimittelliste thematisiert?

Immer
 Meistens
 Oft
 Selten
 Nie
 Keine Angabe

*24. Was ist Ihrer Meinung nach der Einflussgrad der jeweiligen Gruppen auf die Entscheidungen bezogen auf die Arzneimittelliste (Hinzufügen / Entfernen von Arzneimitteln)?

(Bitte geben Sie eine Antwort für alle Auswahlmöglichkeiten!)

	Sehr hoch	Hoch	Moderat	Niedrig	kein Einfluss
Apotheker	<input type="radio"/>				
Abteilungsleiter (Arzt)	<input type="radio"/>				
Chefarzt	<input type="radio"/>				
Verwaltungsdirektor	<input type="radio"/>				
Patienten/ Patientengruppen	<input type="radio"/>				
Controller	<input type="radio"/>				
Sonstige	<input type="radio"/>				

Sonstiges (bitte angeben)

*25. Welche Entscheidungsregel wird bei den Entscheidungen zur Arzneimittelliste (Hinzufügen / Entfernen von Arzneimitteln) befolgt?

(Bitte geben Sie eine Antwort für alle Auswahlmöglichkeiten!)

	Immer	Meistens	Oft	Selten	Nie
Einfache Mehrheit - wenn mehr als die Hälfte der Beteiligten dafür stimmen	<input type="radio"/>				
Konsens - eine Entscheidung wird nur getroffen, wenn alle Beteiligten dies akzeptieren	<input type="radio"/>				
Eine Person trifft die Entscheidung	<input type="radio"/>				
Sonstiges	<input type="radio"/>				

Sonstiges (bitte angeben)

Entscheidungskriterien bei der Auswahl von Arzneimitteln im

***26. Bei Entscheidungen bezogen auf das Hinzufügen von Arzneimitteln zur Arzneimittelliste: Verwenden Sie unterschiedliche Entscheidungskriterien abhängig von der Arzneimittelgruppe?**

- Immer
- Meistens
- Oft
- Selten
- Ich verwende immer die gleichen Entscheidungskriterien

Entscheidungskriterien bei der Auswahl von Arzneimitteln im

*27. Für welche Arzneimittelgruppen wenden Sie unterschiedliche Entscheidungskriterien an?

- | | | |
|--|---|---|
| <input type="checkbox"/> Antimykotika | <input type="checkbox"/> Medizinprodukte (z.B. Implantate,
Stents) | <input type="checkbox"/> Sera/ Immunglobuline |
| <input type="checkbox"/> Enzyersatztherapien | <input type="checkbox"/> Monoklonale Antikörper/
Immunmodulatoren | <input type="checkbox"/> Zytostatika |

Sonstiges (bitte angeben)

Entscheidungskriterien bei der Auswahl von Arzneimitteln im

***28. Welche Entscheidungskriterien wenden Sie bei monoklonalen Antikörpern/ Immunmodulatoren an?**

(Bitte ordnen Sie ALLE Kriterien nach Wichtigkeit (1=am wichtigsten)! Im Fall, dass Sie ein Kriterium nicht nutzen, markieren Sie bitte "k.A.")

<input type="checkbox"/> <input type="button" value="v"/>	Anzahl der Indikationen	<input type="checkbox"/> k.A.
<input type="checkbox"/> <input type="button" value="v"/>	Arten/Einfachheit der Administration	<input type="checkbox"/> k.A.
<input type="checkbox"/> <input type="button" value="v"/>	Budgetauswirkung	<input type="checkbox"/> k.A.
<input type="checkbox"/> <input type="button" value="v"/>	Daten aus Beobachtungsstudien	<input type="checkbox"/> k.A.
<input type="checkbox"/> <input type="button" value="v"/>	Daten aus klinischen Studien	<input type="checkbox"/> k.A.
<input type="checkbox"/> <input type="button" value="v"/>	Empfehlung von Abteilungsleiter (Arzt)	<input type="checkbox"/> k.A.
<input type="checkbox"/> <input type="button" value="v"/>	Empfehlung von Apotheker	<input type="checkbox"/> k.A.
<input type="checkbox"/> <input type="button" value="v"/>	Empfehlung von Chefarzt	<input type="checkbox"/> k.A.
<input type="checkbox"/> <input type="button" value="v"/>	Empfehlung von Kollegen	<input type="checkbox"/> k.A.
<input type="checkbox"/> <input type="button" value="v"/>	Empfehlung von Patientengruppen	<input type="checkbox"/> k.A.
<input type="checkbox"/> <input type="button" value="v"/>	Frühere Erfahrung mit dem Hersteller	<input type="checkbox"/> k.A.
<input type="checkbox"/> <input type="button" value="v"/>	Gesundheitsökonomische Bewertungen	<input type="checkbox"/> k.A.
<input type="checkbox"/> <input type="button" value="v"/>	Informationsmaterial des Herstellers	<input type="checkbox"/> k.A.
<input type="checkbox"/> <input type="button" value="v"/>	Klinische Erfahrung im Krankenhaus	<input type="checkbox"/> k.A.
<input type="checkbox"/> <input type="button" value="v"/>	Klinische Erfahrung in anderen Krankenhäusern	<input type="checkbox"/> k.A.
<input type="checkbox"/> <input type="button" value="v"/>	Lebensqualitätsdaten	<input type="checkbox"/> k.A.
<input type="checkbox"/> <input type="button" value="v"/>	Lieferzuverlässigkeit des Herstellers	<input type="checkbox"/> k.A.
<input type="checkbox"/> <input type="button" value="v"/>	Medikamentenpreis	<input type="checkbox"/> k.A.
<input type="checkbox"/> <input type="button" value="v"/>	Off-Label Potential	<input type="checkbox"/> k.A.
<input type="checkbox"/> <input type="button" value="v"/>	Schwere der Erkrankung	<input type="checkbox"/> k.A.
<input type="checkbox"/> <input type="button" value="v"/>	Verfügbare Alternativen	<input type="checkbox"/> k.A.

Entscheidungskriterien bei der Auswahl von Arzneimitteln im

***31. In Fällen bei denen die Datenlage der klinischen Studien schwieriger ist (z.B. bei Arzneimitteln gegen seltene Erkrankungen), wie wichtig sind Ihnen dann die anderen verfügbaren Kriterien?**

(Bitte ordnen Sie ALLE Kriterien nach Wichtigkeit (1=am wichtigsten)! Im Fall, dass Sie ein Kriterium nicht nutzen, markieren Sie bitte "k.A.")

<input type="text"/>	Schwere der Erkrankung	<input type="checkbox"/> k.A.
<input type="text"/>	Gesundheitsökonomische Bewertungen	<input type="checkbox"/> k.A.
<input type="text"/>	Budgetauswirkung	<input type="checkbox"/> k.A.
<input type="text"/>	Medikamentenpreis	<input type="checkbox"/> k.A.
<input type="text"/>	Klinische Erfahrung im Krankenhaus	<input type="checkbox"/> k.A.
<input type="text"/>	Klinische Erfahrung in anderen Krankenhäusern	<input type="checkbox"/> k.A.
<input type="text"/>	Empfehlung von Kollegen	<input type="checkbox"/> k.A.
<input type="text"/>	Informationsmaterial des Herstellers	<input type="checkbox"/> k.A.
<input type="text"/>	Empfehlung von Apotheker	<input type="checkbox"/> k.A.
<input type="text"/>	Empfehlung von Chefarzt	<input type="checkbox"/> k.A.
<input type="text"/>	Empfehlung von Abteilungsleiter (Arzt)	<input type="checkbox"/> k.A.
<input type="text"/>	Daten aus Beobachtungsstudien	<input type="checkbox"/> k.A.
<input type="text"/>	Lebensqualitätsdaten	<input type="checkbox"/> k.A.
<input type="text"/>	Arten/Einfachheit der Administration	<input type="checkbox"/> k.A.
<input type="text"/>	Lieferzuverlässigkeit des Herstellers	<input type="checkbox"/> k.A.
<input type="text"/>	Anzahl der Indikationen	<input type="checkbox"/> k.A.
<input type="text"/>	Empfehlung von Patientengruppen	<input type="checkbox"/> k.A.
<input type="text"/>	Frühere Erfahrung mit dem Hersteller	<input type="checkbox"/> k.A.
<input type="text"/>	Verfügbare Alternativen	<input type="checkbox"/> k.A.
<input type="text"/>	Off-Label Potential	<input type="checkbox"/> k.A.

Entscheidungskriterien bei der Auswahl von Arzneimitteln im

Vielen Dank für Ihre Zeit!

Sollten Sie Interesse an den Ergebnissen dieser Studie haben, geben Sie bitte unten Ihre E-mailadresse an! Ihre E-mailadresse wird nur für den Versand der Studienergebnisse verwendet und danach gelöscht. Die Auswertung der Studie erfolgt anonymisiert!

*** 32. Möchten Sie die Studienergebnisse per Email zugeschickt bekommen und sind Sie mit der Speicherung Ihrer Emailadresse zu diesem (und nur zu diesem) Zweck einverstanden?**

Ja

Nein

Appendix 4: Web-Survey cover letter.



Dear Sirs or Madam,

I am currently writing my doctoral thesis at the University of Gloucestershire, Cheltenham, UK. Within the scope of this thesis I conduct an online survey and expert interviews on decision criteria for drug funding decisions in German hospitals. Here I rely on your expertise!

What are your benefits?

- If you wish, you will receive the results of the online survey after finalisation of the analysis.
- You can compare your own decision process with decision processes of other hospitals.
- You support scientific work.

Background

Different studies have shown that the use of decision criteria varies in different countries and for different functional roles. In addition, there are big differences depending on the size of the hospital. Aim of this research is to analyse the drug funding decision process and the applied decision criteria in German hospitals. For this purpose this research considers hospitals in Germany with at least 300 beds.

How does the process look like?

This research has 2 parts:

- One online survey which takes approximately 30 minutes of your time
- And additionally one telephone interview which takes another 35-45 minutes only.

This research will be anonymous!

If you wish, you will receive the results of the online survey after finalisation of the analysis. Please add your email address at the end of the online survey questions. Your email address will be saved only for this purpose and will be deleted afterwards.

If you are interested to participate, please contact me via email! I will respond immediately.

Thank you very much for your support!

Yours Sincerely
Tim Rübésam
Doctoral (DBA) candidate
University of Gloucestershire
The Park,
Cheltenham.
GL50 2RH
01242 714700
Email: timrubesam@connect.glos.ac.uk

Privacy statement: This research is conducted within the scope of a doctoral thesis at the University of Gloucestershire, Cheltenham, UK. If you participate, your data and identity will be handled confidential. You neither will be contacted for any marketing or sales activity nor will your email address be added to any distribution lists.

Appendix 5: Interview guide

Introduction

Aim:

- Development of a decision-making framework with all relevant decision criteria for the specific situation of inclusion of a pharmaceutical drug on the formulary.
Consideration of: soft/ subjective criteria

→ Objective of the thesis: structured and transparent process, emphasise differences between hospitals and possible explanations.

Comment on:

Interview will be recorded; data of the interview will be made anonymous.

Ask for consent to use the data in the context of this thesis.

→ Interviewee needs to agree on this!

General information

What is the current position of the interviewee?

(For how long is the interviewee already involved in decision-making on inclusion of pharmaceutical drugs in the hospital formulary?)

Process

Is transparency important for decision-making?

Why yes/why no?

What kind of decision-making is conducted in the hospital (Committee, individuals, etc.)?

Who is involved?

Is time pressure an issue?

If yes, how is this being managed?

Decision-making criteria

Definition/ explanation for qualitative criteria → criteria which are not directly measurable

What are the most important qualitative decision-making criteria independent of the type of pharmaceutical drugs?

Probe for explanation!

What is the impact of gut feeling on decision-making?

Is decision-making always consistent (always based on the same criteria)?

If no, which factors lead to the inconsistencies?

Why do differences between the decision-making criteria exist?

Probe for reasons!

In case of weak quantitative data (e.g. not many clinical trials, not showing the right data) – how does decision-making work?

Probe for reasons!

How important are recommendations of colleagues (Physicians, pharmacists, etc.)?

Are those recommendations challenged? If yes, how?

Are recommendations of colleagues more important than "hard facts", such as clinical trials data?

Should the impact of economic data, such as health economic evaluations, budget impact, price, be bigger? Probe for reasons?

How does the interviewee manage conflicting goals, such as optimisation of the economic situation and the improvement of a treatment situation?

What impact does this have on decision-making?

Group

Who has the most influence on decision-making?

Probe for explanation!

How big is the impact of other group members on the interviewee's decision-making?

Probe for explanation!

Do hierarchical structures influence decision-making?

If yes, how and how much?

How does the interviewee think about involvement of patients/ patient groups in hospital formulary decision-making?

Should specific groups be more involved in the decision-making process?

Which groups?

Probe for reasons!

How big is the influence of pharmaceutical companies on the interviewee's decision-making?

How big is the influence of health insurances on the interviewee's decision-making?

How big is the influence of politicians on the interviewee's decision-making?

What types of compromises are accepted during discussions in the hospital formulary committee?

Appendix 6: Sample transcript for the expert interviews

I: First of all, thanks a lot for taking the time for this interview. As already emphasised before, this is a doctoral study conducted at the University of Gloucestershire, regarding a decision model adapted to the specific situation "addition of pharmaceutical drugs in the formulary list of hospitals". One specific focus of this thesis is the usage of soft criteria or qualitative criteria. The overall goal is to demonstrate a transparent decision process which could also be adopted by other hospitals. Another goal is to emphasise the differences between hospitals in Germany and possible explanations for this. Basically this interview is anonymous. This means that the interview data will be transcribed and made anonymous in order not to show your name anywhere. I will now ask formally: Do you agree that this interview can be used for this doctoral thesis, then please answer "yes"!

B1: Yes, no problem!

I: In addition, I will audio record this interview. Please also answer with "yes" if you agree!

B1: I agree to this!

I: Perfect, thanks! Two general questions: What type of positions do you have?

B1: I am Head Physician in a hospital.

I: How long have you been involved in decision-making on adding drugs to the hospital formulary list?

B1: 25 years.

I: Good. Let's talk about the decision-making process in your hospital. Which type of decision-making do you have there? Is it a formulary committee or do you have one to one discussions between pharmacist and physician?

B1: In our hospital we have regular formulary committee meetings, every half year. The pharmacist leads these meetings and invites a determined group of people, including the general manager, the Head of Nurses and of course the Medical Director. However, in our hospital the Medical Director is also Head Physician of one department. All Head Physicians of the departments are invited, as well as financial administrators and in rare cases also the Head of the Finance department. They will be invited separately like the specialist on hospital hygiene if special topics need to be discussed.

I: From your perspective, should decision-making be transparent?

B1: Definitely yes!

I: Why? What are the reasons?

B1: Because decisions of the hospital formulary committee are budget relevant. If one department for whatever reasons thinks about an artificial hip joint (as an example), then this is an expensive decision which possibly limits the resources for other things, at least temporarily. In this case there needs to be good reasons to argue in the hospital formulary committee meeting, why they want to use more or other products. This needs to be easy to understand, also for non-orthopaedists and non-orthopaedic surgeons, such as internal specialists.

It is also the other way round. If the internal specialist wants to introduce something which is new, which is innovative and has impact on the overall budget, he needs to be able to explain his request in a competent manner during the committee meeting. Others then need to agree since this is usually a majority decision.

In such a case, also the financial administrator and the general manager have to potentially agree.

I: The financial administrator decides?

B1: No, I have commented on it in the questionnaire, because the financial administrator definitely provides impact or his recommendation, but he does not decide.

I: OK, good. Do you face time pressure on your decision-making?

B1: No, no! The topics for the bi-annual committee meeting are known to everyone in advance, they will be communicated by the pharmacist who organises everything and who is also the chair. This allows members to prepare if the decision concerns them. The pharmacist provides recommendations what he wants to delete and which drugs should be discussed for addition to the formulary list (applied by whomever in advance). This way, everybody can well prepare if he wants to support the application or if he wants to stay neutral. Hence, there is no time pressure. If there are questions with time pressure, those will be temporarily solved between the pharmacist and the physician and afterwards be presented in the formulary committee meeting.

I: OK, does this mean that the discussions continue until every agenda item is considered? I assume the meeting has a fixed duration?

B1: Yes, every agenda item is considered. Many of those items are already prepared and distributed in advance via email. Everybody can think about agreement or disagreement with the protocol of the last meeting or the recommendations of the pharmacist. Many times, the presentations of the pharmacist are so well prepared that one can simply agree with it.

I: OK, good. Let's move to the next theme which is about the decision criteria. Could you please mention five qualitative criteria which are very important from your perspective? This should be independent of the type of drug.

B1: I need to differentiate between the drugs I apply for and the other ones where I need to agree or disagree. In the latter cases I heavily rely on the case presentation of the respective department. If we are talking about more general things, such as Heparin which is a common topic in all formulary committees, we want to limit this to one or two products for the hospital. Here the internal specialist, the orthopaedist, the orthopaedic surgeon, the neurologist as well as the psychiatrist need to find a consensus to agree on only two products. Often, this is not so easy. One needs to prepare for this discussion and the quality measures. Quality for me also means user quality. For example, how many employees are needed to prepare and infuse Heparin? In addition, you have quality of patient satisfaction and application safety which is sometimes heavily discussed. In these cases, a nurse needs to provide insights, how much time and resources are required to prepare one vial compared to a ready-to-use vial. You have a lot of different aspects with such decisions.

I: I believe there is a misunderstanding. If I talk about qualitative criteria, I mean criteria which are not directly measurable. I am not talking about quality measures, but about criteria which are not directly measurable. Regarding the comments you have just made: the time which is needed by the nurse to prepare an injection is a quantitative criterion since you can measure the time. And there are other criteria which are not directly measurable. Do you have any criteria in mind which you think are important to mention?

B1: For example, acceptance by the patient. If I get a subcutaneous injection once or twice daily or if I only need to take a pill with the same efficacy, this is a qualitative criterion. Another qualitative criterion is the safety of a drug. This is a criterion for me which is not directly measurable. You can read about this in assessment reports, pre-analysis reports and company reports but company information is always pro domo. This is why you need to read this critically! But if the patient safety is guaranteed, this is a qualitative criterion.

I: Are there any situations where you decide based on gut feeling? For example, situations in which the arguments are not sufficient to make a rational decision and where you decide rather emotionally? Can you remember a situation where this happened or would you exclude this?

B1: No, I would exclude this for me. In the first place I trust the presentation or the statements of the respective department which tries to list a specific pharmaceutical drug. If a pharmacist proposes a change for a drug, I see this differently. There I question myself, if...I better take an example. If product A can be purchased cheaper from a different company, the presence of company A or B plays a role for me. If it is just a small difference in price, I would decide based on my gut feeling always for the company, which is more present in my area. Decisions based on gut feeling do exist. Of course you have to argue this against the pharmacist. For example, I could mention that the company does a lot of services for me and for this small advantage in costs I would not risk to lose this service. Here you sometimes have these decisions. Certainly the other company might have a similar service, but this is not known to me.

I: Presence means in this case the service a company provides to your department?

B1: Exactly! This can be brochures for patients, this can be training or seminars for physicians or nurses, whatever is offered "around" the product and what is known to me.

I: Is your decision-making always consistent? Do you always use the same decision criteria, even if you think about different types of pharmaceutical drugs?

B1: Yes and no, this depends. One example is the oncologist who has a very broad spectrum of necessities. Oncology drugs are often very expensive and a difficult decision for many hospital budgets. However, with oncology patients one is also in a different situation compared to patients who require an artificial hip. Here a comparison between product A and product B seems much more feasible. But with oncology patients, if the oncologist argues intensively that he needs his product A or B, you would rather agree without discussing too much.

I: This means that you trust a lot in the expert opinion and the recommendation of the respective department?

B1: Exactly! But this is what I would also expect the other way round. If I want to introduce a drug in my department, I expect colleagues to accept my proposal, unless they have a really big counter-argument, but then I would expect to hear this in advance.

I: But this should happen in advance to the committee meeting, correct?!

B1: Exactly! This is what I would expect! If I have an important counter-argument against a drug proposed by one of my colleagues, I would call him in advance to ask why he wants to have this drug and not the alternative solution. And are the study results really so convincing? Here I would not wait for the next committee meeting, but rather talk to my colleague in advance to understand why he prefers this specific drug.

I: Then I need to dig deeper here! Is there no real discussion in the committee meeting?

B1: Of course, of course there is, especially from the pharmacy on the one hand. Clearly they have the responsibility to present the price, the supplier issues of company X for example, which we do not know and cannot estimate. In addition, to discuss all questions around drug safety, storage conditions, etc... These are a lot of aspects which play a role and where the pharmacist can have a different opinion than the physician who wants to have his drug added to the list. And there is the financial administrator, who says, we have this or that possibility to get reimbursement. If there is no special allocation, this would stress our budget significantly. Consequently there is a need for discussion.

I: And finally who gains the acceptance?

B1: Mmmmhh...

I: Well, you mentioned quite conflicting goals.

B1: Of course, on the one hand you have the medical perspective and on the other hand you have the economic perspective. A third aspect is something that we [as physicians] cannot really judge on: the reliability of the manufacturer, the supply reliability and so on. Well...usually there is a trial listing for a drug, if the head physician defends the case intensively, if he really needs it. And if there are open questions or discussions we cannot solve, we take the drug temporarily on the list until the next committee meeting where the pharmacist should report back on those questions, if he encountered problems with the supply, if the costs were higher than expected or others. In addition to the pharmacist, the physicians who used the drug should also report on their experiences.

I: In cases with a difficult evidence situation, such as a situation where the existing clinical trials data does not fulfil the gold standard of evidence-based medicine (no randomised, placebo controlled trial), how do you decide? Which criteria play a big role for you? For example, if you have clinical trials with small patient numbers...

B1: These pharmaceutical drugs will not be listed. Instead, they can be ordered on a case-by-case basis. It is a preference that people make their experiences if they are convinced by a substance. And if the evidence situation is not clear, the Head Physician of the department can place a single order or an order with a limited volume. Following this, he is then asked to report back to the committee and talk about his experience.

I: In this case this means that this type of drug has a good chance to be added to the formulary list, if the test order has successful outcomes?

B1: If this can be covered by a DRG (Diagnosis Related Group) and if this is reasonable from a cost perspective, then yes.

I: From your perspective, should the importance of economic data, such as health economic data, budget impact or procurement cost, be higher than today?

B1: No! In total, you might correct me if I am wrong, the cost factor drugs is about 10% of the total hospital costs. We have approximately 70-72% personnel costs. If we can improve the drug costs a little bit this would be good for the hospital. However, the impact is limited on the total budget even if we talk about several Millions.

I: Sounds right to me. How do you handle extreme expensive therapies, such as enzyme replacement therapies or haemophilia? In these cases, the impact of the drug costs...

B1: If a department is established in this sector and wants to treat a handful of patients who are not appropriately covered by the health insurance system, then we need to discuss this with the general manager and the Medical Director. The discussion will be about the importance of the treatment possibility for the hospital or if the opinion is: "We do not need to do everything. Let's forward them to the next bigger hospital with such a treatment focus". Of course there are single cases where the hospital needs to represent something to the outside and where the decision was positive for the drug even if it was not fully covered.

I: This probably would not be, as far as I understood this correctly, something for the hospital formulary but rather a separate discussion.

B1: The opinion of the experts is of course helpful. If a physician can argue why a therapy, which is not appropriately reimbursed and thus loss-making, makes sense because of the department reputation, in order to create awareness for the special expertise of this department, then the vote of the head physicians is surely important for the general manager. However, he finally decides what happens in the hospital.

I: Do you these cases very often? Or how many times does this happen? Is it once a year or am I completely wrong?

B1: No...Less than that!

I: Ok, let's move on to the last topic. I want to talk about the groups who are involved in decision-making. From your perspective, who has the biggest impact on decisions?

B1: The Head Physician! In our hospital. I know this can be totally different in other hospitals. For example, if the pharmacist and the general manager jointly prepare decisions and block other influences, but in our hospital this is, thanks god, still the physician who needs to take responsibility for the treatment. This is what you have to take yourself anyways. And this makes me very happy the way it is. The Head Physician of the department definitely has the biggest decision competency for the inclusion of a new drug on the formulary list. The pharmacist is his closest consultant. The general manager usually does not interfere.

I: Does this depend on hierarchical dependencies? Well, is the pharmacist in any way from an organisational, hierarchical perspective subordinated to the Head Physician? Or are these functions on the same level?

B1: He is a consultant. The pharmacist is our consultant. He can support the preparation of a decision. He can also report his arguments against the inclusion of a drug or a new substance, but thanks god this difficult discussion is often done in advance. If I want to introduce a new drug the first thing I do is to call the pharmacist, ask him about his opinion about this drug, the pros and cons, also about the manufacturer, pricing, price negotiation. This means, if we go to the hospital formulary, I have already coordinated with the pharmacist.

I: Generally speaking: are there any hierarchical dependencies between members of the formulary committee?

B1: Formally, the general manager is boss of everyone, who works in the committee. But he is a businessman. Thus, he has no medical competency.

I: Does he think the same way?

B1: In our hospital this was never different and he would be challenged if he had a different opinion. His lack of medical competency is a fact. Certainly he can ask for consultancy. If he informs himself upfront, he could theoretically ask other pharmacists or general managers or physicians to build his own opinion. However, this is no opinion based on his medical competency. This is external knowledge. He can use this for his argumentation or he can tell the committee that he has heard from a different hospital that this has worked well or not so well. And if this is a good argument, we need to face this and talk about it, this is clear. But he is well advised to focus on the economic side of things, if I may say so. For example, together with financial administration he could assess the possibility to get appropriate DRG reimbursement for an expensive new drug. If financial administration then says: "The consequence is that we have a deficit of 1,000 EUR for each treatment, we cannot do this!", then the respective department needs to reconsider the importance of the substance.

I: Good. In some countries, patient representatives or patients groups are invited to the formulary committee meetings to be part of decision-making. This usually happens in a consulting role of course. What is your opinion on this? Does this make sense to you?

B1: Rather no. There are definitely reasonable possibilities to involve patient representatives, specifically in areas such as oncology or with chronic inflammatory diseases. In these cases, the patient representatives usually try to add their wishes with support of the respective Head Physician of the department. If the Head Physician believes in the option, then he proposes this during the committee meeting. In my opinion it does not make sense to invite patient representatives to the committee meetings due to the fact that a lot of confidential internal topics are also discussed during these meetings. But if patient representatives use the Head Physicians of the respective departments to include their perspectives, this is something good.

I: Good, from your perspective should specific groups already participating in the committee meetings be more involved in decision-making? Or is the current distribution of functional groups optimal?

B1: I think this is optimal! Well, I would not know which group is missing to take a decision. For the hospital it is important to involve the general manager, the nurses and financial administration. Apart from that, the pharmacist and the physicians are the decision-makers in the hospital formulary committee.

I: How strong do you think is the impact of the pharmaceutical industry on your decision-making? You mentioned before that the provided service of a manufacturer does play a role and can influence positively or negatively. How would you describe this influence?

B1: The influence should not be underestimated.

I: Does this relate to the service of the pharmaceutical company? Or is that...

B1: If a new substance should be introduced, the decision-maker of the respective department needs to be armed appropriately. This means, if he has no own experience one needs to explain how he can gain experience. There are a lot of possibilities how he can achieve this. For example, he could be invited to treaters in other hospitals, in other departments or to congresses where the new substance is used or discussed. I believe that in the initial phase, the introduction of a new substance, the pharmaceutical industry has a big influence, inevitably.

I: How much do local or regional payers impact decision-making in your opinion?

B1: Health insurances?

I: Yes, health insurances.

B1: Concerning the hospital formulary committee I neither see any requirements for health insurances to influence decision-making nor I see that health insurances have tried this. I have never heard of this.

I: The drug costs are usually included in the DRGs and here I would see an already existing, potential influence...

B1: No. Health insurances do not assess a single activity. They pay a total sum of X for a treatment. How the total sum for a treatment was compiled, if hospital A invests more in nursing time or hospital B invests more for drugs to achieve the treatment goal and why there can be different negotiated prices, this depends on the negotiation skills of the General Management and the health insurances. This does not relate to single drug costs.

I: You have already indicated this before. Different stakeholders in the decision-making process have different goals. We have talked about the pharmacists who might focus on supplier reliability. We have talked about financial administration that might focus on DRG reimbursement questions and then we have talked about physicians with a medical goal. How can a balance be achieved?

B1: I think this works automatically since the respective Head Physician of a department is budget responsible at the same time. He has drug costs directly shown in his papers and he needs to justify those. Or he needs to save somewhere more money to spend it on very expensive drugs. In these cases financial administration can consult on how to manage and improve the DRG reimbursement of single treatments in order to come out positive and earn some money on a DRG treatment. The Head Physician of the respective department will inform himself already in advance about the economic consequences of a decision question before he hands in any application for inclusion. However, first of all the medical side is important and then comes the price.

I: OK, but due to the budget responsibility as a Head Physician of a department you cannot deny the importance of the economic aspects, independent of the medical...

B1: This does not play an important role in the hospital formulary anymore. These are single cases where one says: “You cannot allow this” or “We cannot allow this in this specific department”. And there are also single cases where we say: “OK, this is expensive and it will be impossible to manage the DRG reimbursement in a way to make this whole case positive, but the department needs to be representative to the outside.” For these cases there needs to be this possibility. Even if we know in advance that the case will be negative we need to swallow the bitter pill although this will never get out of hand. However, sometimes you have a situation where you need to act like this. For example, we have ten Heparins on the formulary list because every department had its own preference and here the pharmacist said: “I need to improve logistics. I cannot store all Heparins at the same time as we lack space. In addition, my negotiation power is limited due to the variety of Heparins. The Head of Nurses added: “The application safety is not optimal with many different Heparins due to a higher risk of confusion and a higher risk of over- or under-dosing. This is what I cannot expect from my team“. In this case we had a majority vote where we said: „We have limited the available Heparins to drug A and drug B. Everybody can decide on which of the two drugs to use, but the other eight drugs will no longer be used here“. Full stop! There was a little bit of an uproar, but finally this has been implemented. In this case there was a command of the medical director necessary to put the people... a little bit under pressure. Head Physicians of departments can sometimes be a little bit weird.

I: We are done with the interview! I would like to thank you very much for your participation!

B1: You are welcome. Good luck!