

# TELEMONITORING IN PATIENTS WITH HEART FAILURE, a health economic evaluation and decision analysis



UNIVERSITEIT TWENTE.



# **TELEMONITORING IN PATIENTS WITH HEART FAILURE,** a health economic evaluation and decision analysis

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## Summary

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**Background:** Telemonitoring for the management of congestive heart failure (CHF) is regarded as a promising innovation for dealing with the economic burden of this chronic disease. However, its widespread adoption into practice has not yet been achieved. Recent studies call for more rigorous economic evaluations on which decision makers can base their decision whether or not to adopt telemonitoring in practice. However, how important is evidence on cost-effectiveness actually in this kind of decision making and which other factors are considered?

**Objective:** The objective of this research was twofold. The first objective was to investigate the cost-effectiveness of a telemonitoring system for CHF patients in order to add a good methodological economic evaluation to existing evidence. The second objective was to analyse the relative importance of economic outcomes and other factors in decision making regarding the adoption of telemonitoring in CHF. Combined, findings allow to eventually predict how likely it is that the telemonitoring system as evaluated in the economic analysis, will be adopted by involved stakeholders.

**Method:** A health economic evaluation was performed alongside a randomized controlled trial (RCT) as conducted by the Maastricht University Medical Centre. This RCT was a prospective, two-arm, open-label randomized controlled trial, carried out at three hospitals in the South Limburg area in the Netherlands and conducted with a follow-up period of 12 months. 382 patients with HF were randomized to receive care using telemonitoring or usual care. The telemonitoring system patients used was the Health Buddy®. The health economic evaluation used a health system perspective and was based on chronic care management evaluation frameworks. The primary outcome measure was cost-effectiveness. For the second objective of this study a multi criteria decision analysis (MCDA) was conducted. Through the analytic hierarchy process (AHP) with 7 respondents, the relative importance was determined of several criteria considered in decision making regarding telemonitoring. Respondents were stakeholders involved with telemonitoring in CHF, operation at the local level. In addition, group and individual interviews were conducted to examine arguments for the hierarchy given to the criteria.

**Results:** Results of the health economic evaluation are currently confidential. The MCDA showed that effectiveness and cost-effectiveness appeared to be important factors in decision making regarding the adoption of telemonitoring. Other factors like safety; budget impact; patient and professional satisfaction; and financing were also considered important in decision making. Stakeholders assigned the highest relative weight to safety.

**Conclusion:** The more telemonitoring proves to be cost-effective, the greater the chance that it will be adopted into practice, as effectiveness and cost-effectiveness are considered important criteria in decision making.



## Table of content

<b>1. INTRODUCTION</b> .....	<b>1</b>
1.1 INTRODUCTION .....	1
1.2 PROBLEM STATEMENT .....	1
<b>2. THEORETICAL FRAMEWORK</b> .....	<b>3</b>
2.1 TELEMONITORING IN CONGESTIVE HEART FAILURE.....	3
2.1.1 <i>Telemonitoring compared to telehealth and telemedicine</i> .....	3
2.1.2 <i>Congestive heart failure</i> .....	3
2.1.3 <i>Telemonitoring and chronic care management</i> .....	4
2.2 HEALTH TECHNOLOGIES AND DECISION MAKING .....	5
2.2.1 <i>Evidence based medicine and HTA</i> .....	5
2.2.2 <i>Multi criteria decision making</i> .....	5
2.2.3 <i>The value of economic outcomes in decision making</i> .....	6
<b>3 RESEARCH AIM &amp; QUESTIONS</b> .....	<b>7</b>
3.1 RESEARCH AIM .....	7
3.2 QUESTIONS .....	7
<b>4. METHODS</b> .....	<b>9</b>
4.1 REVIEWS OF THE LITERATURE.....	9
4.1.1 <i>Search strategy telemonitoring in CHF</i> .....	9
4.1.2 <i>Search strategy Multi Criteria Decision Making critical attributes</i> .....	9
4.2 METHODS FOR THE HEALTH ECONOMIC EVALUATION.....	10
4.2.1 <i>Description of the TEHAF trial design</i> .....	11
4.2.2 <i>Health economic evaluation alongside the RCT</i> .....	12
4.3 METHODS FOR THE MULTI CRITERIA DECISION MAKING ANALYSIS.....	15
<b>5. RESULTS</b> .....	<b>17</b>
5.1 RESULTS LITERATURE REVIEWS.....	17
5.1.1 <i>Evidence on telemonitoring in CHF</i> .....	17
5.1.2 <i>Hypothesis 1</i> .....	19
5.1.3 <i>Evidence on attributes in Multi Criteria Decision Making in health care</i> .....	20
5.1.4 <i>Hypothesis 2</i> .....	22
5.2 RESULTS OF THE HEALTH ECONOMIC EVALUATION.....	23
5.2.1 <i>Outcomes on effectiveness</i> .....	23
5.2.2 <i>Outcomes on costs</i> .....	23
5.2.3 <i>Sensitivity analysis</i> .....	23
5.3 RESULTS OF THE MULTI CRITERIA DECISION MAKING ANALYSIS .....	24
5.3.1 <i>Respondents</i> .....	24
5.3.2 <i>Identification of criteria for the AHP</i> .....	24
5.3.3 <i>Relative weight of criteria</i> .....	25
5.3.4 <i>Arguments of respondents behind the weighing</i> .....	25
<b>6. DISCUSSION</b> .....	<b>29</b>
6.1 HEALTH ECONOMIC EVALUATION .....	29
6.1.1 <i>Summarization and interpretation of results</i> .....	29
6.1.2 <i>Study limitations</i> .....	29
6.1.3 <i>Related studies</i> .....	29
6.2 MULTI CRITERIA DECISION MAKING ANALYSIS.....	30
6.2.1 <i>Summarization and interpretation of results</i> .....	30
6.2.2 <i>Study limitations</i> .....	30
6.2.3 <i>Related studies</i> .....	31
<b>7. CONCLUSION</b> .....	<b>33</b>
<b>REFERENCES</b> .....	<b>35</b>
<b>APPENDICES</b> .....	<b>39</b>



## Preface

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This report presents the results of my master thesis research of the study program Health Science. As some results of this study are currently confidential, not all results are reported in this version. It is expected that the full version can be made public at least before 2012.

Without the help of others, this master assignment could not be performed. First of all I would like to thank my supervisors dr. Lotte Vrijhoef-Steuten and dr. Lisette van Gemert-Pijnen of the University of Twente for their guidance, that led to the successful completion of this research I am very proud to present. Especially, Lotte for asking me to participate in the TEHAF trial and who really supported and stimulated me through the whole process.

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# 1. Introduction

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## 1.1 Introduction

Epidemiologic studies suggest that the prevalence of congestive heart failure (CHF) will rise in aging populations and so will the costs related to the care of these patients<sup>1-2</sup>. CHF is a clinical syndrome consisting of a combination of signs and symptoms directly or indirectly caused by an inadequate pumping function of the heart<sup>3</sup>. CHF is a progressive disease with high morbidity and mortality. It is estimated that healthcare expenditure on CHF in developed countries consumes 1-2% of the total healthcare budget. Given this trend there is also a risk that demand for care will exceed its supply, because resources in health care are limited. Therefore government, health insurers, health care providers and patients explore new opportunities for improving effectiveness and efficiency of CHF care.

Telemonitoring for the management of congestive heart failure (CHF) is regarded as a promising innovation for dealing with the economic burden of this chronic disease. It has the potential to leverage scarce human resources and to improve patient outcomes such as mortality and reduce hospitalizations. Telemonitoring can be defined as the monitoring of a patient's health situation in the context of prevention, diagnostic and/or aftercare by means of registration, transport, storage and analysis of data without immediate physical presence of caregivers, by applying medical technology and information and communication technology in a sophisticated manner<sup>4</sup>. Telemonitoring allows measuring the health situation of a patient at a distance. According to the ministry of Health Welfare and Sports (ministerie van Volksgezondheid, Welzijn en Sport: VWS) remote care is one of the necessary innovations to ensure that quality, accessibility and affordability of care can be maintained in the future.

Although telemonitoring is recognized as a promising innovation, its widespread adoption has not yet been achieved. In the Netherlands project funding can be acquired from various sources, including government, the innovation platform and research funding bodies for research and pilot projects in the field of telemonitoring. However, when it comes to implementation, structural investment from the key players, including health insurers, hospital, primary care groups, home care, etc. is needed. Decision makers, like health insurers and health care providers are reluctant to invest in telemonitoring, since studies showing cost reductions do not convince them due to a lack of consistent methodology<sup>5</sup>. In the Netherlands several telemonitoring projects have been undertaken, but these often did not evolve beyond the pilot stage. If they do, they are only offered locally.

## 1.2 Problem statement

Currently, high quality cost-effectiveness analyses on telemonitoring in CHF are scarce. Some have called for more rigorous economic evaluations on which decision makers can base their decision whether or not to adopt telemonitoring in practice. The same time, the relative importance of economic outcomes on decision making regarding the adoption of telemonitoring is questioned. Although evidence on effectiveness and costs is assumed as being important in decision making, practice shows that cost-effective innovations are not necessarily being adopted, as there are often other factors that impede their adoption. This appears also to be the case for telemonitoring. As different stakeholders, like health insurers, health care providers and physicians have influence on the adoption of telemonitoring, different and conflicting interests may exist.



## 2. Theoretical framework

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This chapter contains a review of scientific literature on telemonitoring in CHF and on health technology decision making.

### 2.1 Telemonitoring in Congestive Heart Failure

#### 2.1.1 Telemonitoring compared to telehealth and telemedicine

The terms telemonitoring, telemedicine and telehealth are at times wrongly interchanged with each other. In order to get a better understanding of what telemonitoring is about, these terms are discussed briefly. Telemonitoring is a form of telemedicine, which includes providing medical care at a distance. Telemedicine involves the use of communication technologies to connect healthcare professionals to patients, situated at different locations<sup>6</sup>. Telehealth is an expansion of the functionality of telemedicine. It encompasses not only clinical, but also preventive and promotive, applications like patient education, public health and training for professionals<sup>6</sup>. Telemonitoring as narrower targeted service of telehealth and telemedicine is the monitoring of a patient at distance using audio, video and other telecommunications, and transferring the information to a caregiver<sup>7</sup>. It supports better informed clinical decision making and active involvement of patients in their own care. Telemonitoring programs may include objective technological monitoring and/or subjective questioning regarding the patient's health. Questioning can take place via the telemonitoring software and allows patients to keep in touch with the health care professional. The professional can in turn make decisions about the patient's treatment based on the objective and subjective information.

#### 2.1.2 Congestive heart failure

Congestive heart failure (CHF) can be described as a clinical syndrome consisting of a combination of signs and symptoms directly or indirectly caused by an inadequate pump function of the heart: the heart is unable to pump blood efficiently through the body<sup>3</sup>. Most common causes of heart failure are: myocardial infarction, cardiomyopathies (diseases of the heart muscle), (long) hypertension, heart valve defects and rhythm- or conduction disorders. The main symptoms of heart failure are fatigue, shortness of breath, decreased exercise tolerance and fluid accumulation, especially in the legs and lungs<sup>8</sup>. The typical treatment during the admission includes reducing the volume of fluid, thereby relieving chest congestion and improving the efficiency of the pump function of the heart.

Heart failure is a progressive disease with high morbidity and mortality. One year after diagnosis approximately 70% of the patients survive and 35% after 5 years<sup>9</sup>. In the Netherlands approximately 39.400 patients are diagnosed with heart failure per year. In 2007 there were about 160.000 patients living with heart failure in the Netherlands<sup>10</sup>. The prevalence of heart failure increases significantly with age<sup>1</sup>.

Costs related to care for heart failure were 387.2 million Euros in 2005. This amounts to 0.6% of total healthcare costs in the Netherlands. More than half of the costs are caused by hospital care. In 2005, 43% of all costs of heart failure went to men and 57% to women. Most costs of care for heart failure are made in the age group 75 - to 89-years old<sup>11</sup>.

### 2.1.3 Telemonitoring and chronic care management

Telemonitoring is often part of chronic care management as it can be instrumental to its components e.g. self-management support, clinical information system and decision support. Different models of chronic care management exist. Disease management is a concept that has been developed in the mid-nineties in the United States (US). It has evolved internationally as a response to the current limitations of the health care system for chronically ill patients<sup>12</sup>. Disease management programs operate at the level of the health plan; so called disease management companies directly work with chronically ill patients via telephone or other distance media, thereby bypassing the physician practice<sup>13</sup>. They aim to identify patients with serious chronic illnesses to enable them to better self-manage their illnesses<sup>14</sup>. The chronic care model (CCM) was developed by Wagner and also focuses on creating informed, active patients with improved self-management<sup>13</sup>. Unlike the disease management model, the CCM tries to improve the way care is managed within physician practices. Disease management as applied in Europe today is conceptually most akin to the CCM as it is integrated in regular primary care and regular hospital care. In Europe disease related care is not provided by independent (commercial) disease management programs, which work in stead of regular health care, like in the US. Since European chronic care management programs are most akin to the CCM, this model is further described.

The CCM assumes that outcomes of care will improve by providing productive interactions between informed patients, who take an active part in their care, and providers with resources and expertise. To achieve this, physicians practices should be reorganized by including the following processes<sup>15</sup>:

- *Self-management Support*: emphasizing the patient's crucial role in maintaining health and the importance of setting goals, establishing action plans, identifying barriers and solving problems to overcome barriers. Routine assessment of self-management practices and the inclusion of self-management goals in the registry helped many organizations to keep attention focussed on self-management.
- *Delivery System Redesign*: creation of a proactive system with high-quality chronic illness demands planning and coordinated actions of multiple caregivers. Follow-up is a part of standard procedure and more complex patients get intensive management (care or case management) for a period of time to optimize clinic care and self-management. Providers respond effectively to the diverse cultural and linguistic needs of patients.
- *Decision Support*: ongoing training for healthcare providers, using new models of provider education that improve upon traditional continuing medical education. Guidelines should be integrated into daily practice, through timely reminders, feedback, standing orders and other methods that team members at the time that clinical decisions are made.
- *Clinical Information Systems*: an information system that assure ready access to data on individual patients as well as populations of patients. The system provides access to summary of patient data, facilitating individual patient care planning and information sharing with patients and providers to coordinate care.

There are three key elements that can be identified in these processes: 1) patient-related interventions, to increase patient knowledge and self-management; 2) professional-directed interventions, to educate professionals on the guidelines and program; 3) organizational interventions, the organizational design of the healthcare system at different levels. Not all chronic care management programs include all these key elements. Some programs only include self-management support. Such programs can be classified as 'educational'. A program that focuses on changing the performance of care providers, can be classified as 'professional' and one that interferes in the structure of the primary care process as 'organizational'<sup>16</sup>.

## 2.2 Health technologies and decision making

Decision making in any health care system is a complex set of interactions amongst different parties. Decisions on the use of technology are made at all levels in the health care system. The different types of decisions made at these different levels can be categorized into three levels<sup>17</sup>:

- Macro, decisions made at national level, provincial or insurance company level.
- Meso, decisions made at regional health authority or hospital level;
- Micro, decisions made at provider or patient level.

Decisions on telemonitoring are generally made at the regional health authority and hospital level, given its lower capital costs.

### 2.2.1 Evidence based medicine and HTA

Over the past decades, the value of evidence based decision making in health care is increasingly recognized. Concerns about practice variation, uncertainties regarding health effects of multiple therapies and awareness of the fast growth of health care expenditure have caused the emergence of approaches such as Evidence Based Medicine (EBM) and Health Technology Assessment (HTA). EBM is a systematic approach to analyze published research as the basis of medical decision making. It dates back to the beginning of the last century, but was institutionalized by the Cochrane Collaboration in 1993<sup>18</sup>. The Cochrane Collaboration produces systematic reviews on health interventions, which are published online in 'The Cochrane Library'. EBM consists of two parts<sup>19</sup>. One part is evidence based individual decision making (EBID) and focuses on the evidence regarding an individual patient and his or her management. The other part is evidence based guidelines (EBGs) or more generally evidence-based policy making, including the production of guidelines, policy and regulations. HTA is concerned with the potential medical, organizational, economic and societal consequences of implementing health technologies within the health system. It had its origin in the mid-70s as a response to the uncontrolled diffusion of expensive medical equipment<sup>20</sup>. HTA is increasingly used to inform decision- and policy-making on health technologies. HTA is a multidisciplinary process, which systematically evaluates the effects of a technology on health, on the availability and distribution of resources and on other aspects of health system performance such as equity and responsiveness<sup>21</sup>. The information needs depend on the type of decision and the level of decision-making; they also vary depending on the actors involved<sup>21</sup>. EBM can be seen as part of HTA as HTA begins with an evaluation of the evidence for the technology being assessed<sup>19</sup>.

### 2.2.2 Multi criteria decision making

Multiple criteria decision making (MCDM) refers to making decisions in the presence of multiple, potentially conflicting, criteria. Decisions on the choice of health interventions at a corporate level are complex, multifaceted and involve different stakeholders. Multi criteria decision analysis (MCDA) provide analytic support to decision making by evaluating preferences between options by reference to explicit objectives that the decision making body has identified and for which it has determined measurable criteria to assess the extent to which the objectives have been achieved<sup>22</sup>. MCDA techniques can be used to identify a most preferred option, to rank options, to short-list a limited number of options, or to distinguish acceptable from unacceptable possibilities<sup>22</sup>. MCDA methods arose as a response to the observed inability of people to effectively analyze large amounts of complex information. Current approaches to support medical decision making (e.g. evidence based medicine, cost-effectiveness analysis, HTA, etc) offer little guidance on how to integrate or judge the relative importance of information from each source<sup>23</sup>. This stressed the need for MCDA to guide an support decision making. There are many methods available for solving MCDM problems. MCDA techniques used in healthcare includes the elimination and choice translating reality (ELECTRE), the simple multi-attribute technique (SMART), the analytic hierarchy process (AHP) and the multi-attribute

utility technique (MAUT) and conjoint analysis<sup>24</sup>. Main differences between these techniques lie in their approach to elicit weights and the statistical techniques to model the preferences of the decision makers for the alternatives.

### 2.2.3 The value of economic outcomes in decision making

The influence of economic evidence on decision making in health care has been an upcoming subject of interest over recent years. Several studies investigated the use of economic evaluation in decision making. Given the scarce resources in health care one would expect that optimal allocation of resources is important in decision making. Economic evaluation is primarily concerned with efficiency or obtaining the maximum benefit and it is considered rational to include these arguments in decision making. However, it is found in the literature that the use of economic outcomes in supporting health care decision making is not self-evident and is less used in practice than expected<sup>25-28</sup>. There appeared to be a range of barriers to using it, which can roughly be divided into two groups: issues concerning the *accessibility* and issues concerning *acceptability* of the research evidence<sup>27</sup>. Issues of accessibility include interpretation difficulties, mainly concerned with the presentation of information and the shortage of relevant skills of policy makers in research methods; difficulties in accessing results, due to the shortage of relevant economic analyses and problems with accessing those studies that are published; and timeliness, availability of relevant research in a timely manner<sup>27</sup>. Acceptability issues refer to all barriers that arise after economic evaluations have been accessed and understood. One of the most severe barrier in this group is the inflexibility of the health care budget (structural/institutional acceptability): it is difficult to reallocate resources to fund a new technology<sup>25</sup>. As a result health insurers focus on the immediate costs of adopting technologies rather than future savings. Incentives can be insufficient for physicians and health insurers to act toward the relative efficiency of new healthcare technologies. Political objectives can also form a barrier to the implementation of economic outcomes (ethical/political acceptability): the requirement to follow national policies as there are incentives to follow government directives<sup>25</sup>. These incentives may constrain the use of results from economic evaluation. Other barriers of acceptability are concerned with the relevance of results as considered by end-users and the quality of research methodologies (scientific/technical issues)<sup>25, 27</sup>. The barriers to using economic outcomes may explain preferences of decision makers for certain topics.

## 3 Research aim & questions

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After an exploration of the main subjects of this study in the theoretical framework, the research aim and questions are formulated.

### 3.1 Research aim

This objective of this research is twofold. The first objective is to investigate the cost-effectiveness of a telemonitoring system for CHF patients in order to add a good methodological economic evaluation to the existing evidence, which should support decision making. The telemonitoring system that will be evaluated is the Health Buddy® System that is offered by three hospitals in Limburg: Maastricht University Hospital, Atrium Medische Centrum (Heerlen), Orbis Medische en Zorgconcern (Sittard). This evaluation is performed in close cooperation with the University of Maastricht.

The second objective is to give an indication of the relative importance of economic outcomes and other factors in decision making regarding the adoption of telemonitoring for CHF patients in order to increase transparency in decision making about telemonitoring in CHF. Combined, the findings allow to eventually predict the chance that the Health Buddy® will be adopted by stakeholders, given the results of the economic evaluation.

### 3.2 Questions

Part 1: What is the impact of telemonitoring, in particular the Health Buddy® system, on effectiveness and costs?

- What is described in the literature about the cost-effectiveness of telemonitoring?
- What are the main characteristics of the Health Buddy® and its target population?
- To what extent does the Health Buddy® approach, meet components of the chronic care model?
- What are important cost components in health care for heart failure patients?
- What is the incremental cost-effectiveness of the Health Buddy® for CHF-patients as compared to usual care in the region of Maastricht, Heerlen and Sittard?

Part 2: What is the relative weight of effectiveness, costs and other factors in decision making regarding the adoption of telemonitoring for CHF, taking the Health Buddy® system as reference sample?

- Which parties have influence on decision making regarding the Health Buddy®?
- What other factors may influence the adoption of innovations according to the literature?
- What are the relative weights of these factors?
- What are the arguments of stakeholders to prefer one factor over an other?

#### *Hypotheses*

Hypothesis will be derived from (systematic) literature reviews on cost-effectiveness of CHF telemonitoring and on attributes in multi criteria decision making (chapter 5).



## 4. Methods

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This chapter describes the methods used for the literature reviews, the health economic analysis and the multi criteria decision making analysis.

### 4.1 Reviews of the literature

#### 4.1.1 Search strategy telemonitoring in CHF

The PubMed database is searched for relevant articles reviewing recent evidence about telemonitoring in CHF. Over the last ten years more than hundred studies have been published on telemonitoring in CHF of which 35 systematic reviews and four meta-analysis. Therefore only systematic reviews and meta-analysis are included in this literature review. The following terms were searched in title or abstract of published papers: (*telemonitoring* OR *telemedicine* OR *telecare* OR *remote monitoring* OR *telehealth* OR *teleconsultation*) AND *heart failure*. The search was further limited to articles published after 2000 and in English or Dutch. Articles examining evidence on outcome indicators or the current state of telemonitoring programs are included in this literature search. Exclusion criteria are: 1) other intervention reviewed, such as: implantable devices, single telephone calls, without specialized home monitoring equipment or educational messaging, without monitoring signs and symptoms; 2) not focused on outcome indicators or the current state of telemonitoring; 3) HF patients were not included, not reported or outcomes on HF telemonitoring were pooled with other diseases; 4) the results of telemonitoring in CHF were based on similar articles reviewed in more recent reviews; 5) article could not be obtained from university library or open access databases. Full texts were reviewed to assess whether the papers met the inclusion and exclusion criteria. The literature search is performed in June 2010.

#### 4.1.2 Search strategy Multi Criteria Decision Making critical attributes

A systematic review on critical criteria in health care decision making is conducted. The PubMed database is searched for articles that describe the relative weight or importance of criteria in multi criteria decision making in health care. As decisions regarding telemonitoring are generally made at the regional and hospital level, it is tried to find articles on local level decision making. The main keyword combinations that are used include: *health technology* AND (*multi criteria decision* OR *decision making process* OR *priority setting*) AND (*criteria* OR *attributes* OR *factors*). These terms are searched in title or abstract. The search is limited to articles published in English or Dutch and published after 2000. Exclusion criteria include: 1) irrelevant study context i.e. focused on developing countries or a specific disease other than CHF 2) importance of criteria in decision making not analyzed in article; 3) other study subjects than health care decision makers (i.e. general public). All abstracts are screened to only include articles that met the in- and exclusion criteria. Reference lists are hand-searched for additional relevant articles. The literature search is performed in June 2010.

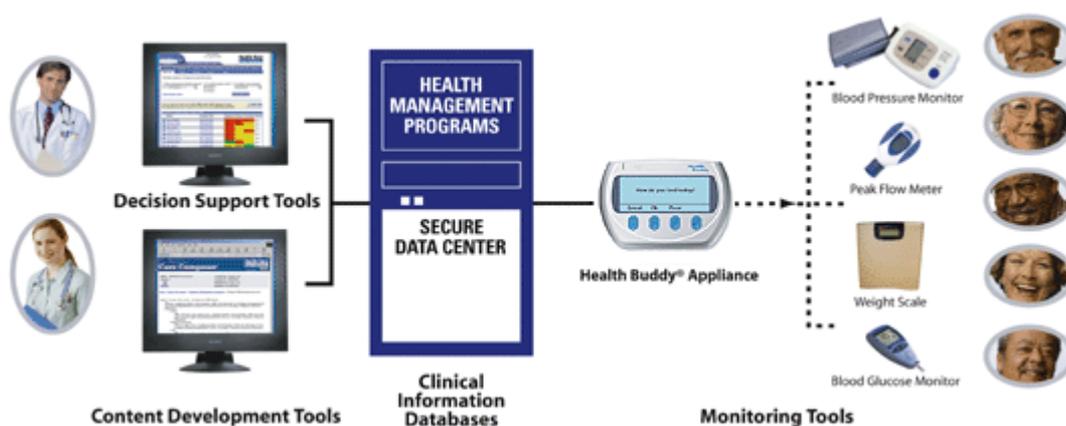
## 4.2 Methods for the health economic evaluation

This part of the research aims to investigate the cost-effectiveness of a telemonitoring system for CHF patients. The telemonitoring system that is evaluated is the Health Buddy®. The evaluation is performed in close cooperation with the Maastricht University Medical Centre, who is the initiator of the so called ‘Telemonitoring in patients with heart failure’ (TEHAF) trial. The primary objective of the TEHAF trial is to investigate if telemonitoring results in a decrease in hospital admissions, with equal quality of care defined as mortality, quality of life and unplanned visits with caregivers. The study is being conducted in three hospitals in South-Limburg: ‘Maastricht University Medical Centre’, ‘Atrium Medical Centre’ (Heerlen) and ‘Orbis Medical and Care Concern’ (Sittard). The study performed for this Master thesis contributes to the cost-effectiveness analysis of the Health Buddy®. The University of Maastricht is responsible for the trial design and data collection. This chapter describes the methods used for the health economic evaluation of the Health Buddy®, starting with a brief description of the Health Buddy®.

### *The Health Buddy®*

The Health Buddy® is designed to monitor and manage patients symptoms and the potential for problems or complications from a distance. It also manages participant compliance with and response to treatment; and reinforces health behaviors or changes in methods of disease management<sup>29</sup>. The Health Buddy® is a simple telehealth device, equipped with a crystal display screen and four buttons. Patients use the Health Buddy® in their home environment and receive a set of questions and health-related comments daily, provided by an automatic dataset and focused on symptoms, health behavior and disease-specific knowledge. Patients can respond to questions by pressing buttons on the Health Buddy®. Once the patient’s responses have been downloaded from the Health Buddy® to a central computer, data are transferred into risk profiles (low, medium and high), depending on patients’ response to dialogs. Consequently a healthcare professional is enabled to quickly select high risk patients from the data and determine the need for intervention. Involved care providers include specialized Heart Failure Nurses (HFNs), a nurse assistant (caregiver at a lower educational nursing level) and cardiologist. The HFN and nurse assistant check the incoming information on a daily basis except for the weekends.

**Figure 1:** Health Buddy® system<sup>30</sup>



The content of the Health Buddy® is tailored to distinguishing characteristics of patients, regarding symptoms, level of disease specific knowledge and behavior. Out of a combination of these characteristics four programs are offered (table 1). During the first 90 days all patients receive the same program so that an indication can be made of the allocation of the next program.

**Table 1:** Characteristic of the programs<sup>31</sup>

	Symptoms	Education/adherence	Days
Program 1	+	+	90
Program 2	+	+/-	30
Program 3	-	+	90
Program 4	-	-	180

+: Strongly focused on; +/-: moderate focused on; – less focused on.

Considering the chronic care model, the Health Buddy® does not reflect all of its components. The Health Buddy® is rather offered in addition to the original primary care process than that it changed the delivery system design. Only the HFN has some additional tasks, whereas tasks of other professionals remain the same. The Health Buddy® mainly reflects self-management support and clinical information systems. However, with regard to clinical information systems, access to the current information system is restricted to the HFN, her assistant and the cardiologist. Furthermore, there is no decision support for professionals.

#### 4.2.1 Description of the TEHAF trial design

Information on the TEHAF trial design is obtained from interviews with the main researchers and from the article of Boyne et al<sup>31</sup> describing the protocol of the trial.

##### *Population and sampling*

The study population consists of patients with CHF, meeting the following inclusion criteria: NYHA classification II-IV, treated by a cardiologist and followed-up by a HFN. Selection of patients occurs in the outpatient clinics of the three participating hospitals (by cardiologists and HFNs) and in the home situation when patients are visited by a HFN. Patient are excluded if being unable to give informed consent, do not have adequate knowledge of the Dutch language, have visual limitations, hard hearing or deaf in combination with living as a single person, were planned for a hospital admission within 3 months, suffer from COPD (Gold classification 3 or 4), Parkinson disease, dialysis patients, (pre)dementia or another disease with a prognosis of < 1 year.

##### *Research design*

The TEHAF trial is a prospective, two-arm, open-label randomized controlled trial and is conducted with a follow-up period of 12 months. After given informed consent, patients are randomized by a dedicated software system (SPSS 15.0) to one of the study arms. The two arms consists of a control group, receiving usual care according to European guidelines and an intervention group, receiving the Health Buddy®. Patients assigned to the control group are planned to have 1 visit to the cardiologist and 3 to the HFN per year. For the intervention group, 2 visits are scheduled: 1 to the cardiologist and 1 to the HFN. Telephone contacts with the alert are considered as planned contacts. Unscheduled contacts with a care provider are allowed at any time for both patient groups. The research method includes questionnaires and an existing data research. Before start of the intervention (T<sub>0</sub>) patients fill out a questionnaire. Patient baseline characteristics are retrieved from the medical chart. Follow-up questionnaires are released after 3, 6, 9 and 12 months in order to provide subjective information on functional health status, disease specific knowledge, therapy compliance, quality of life and health care utilization. In addition to these questionnaires, hospital registrations are used to provide data on mortality and health care use in the hospitals.

##### *Key clinical outcomes*

The primary outcome includes the effectiveness of the Health Buddy® in terms of hospital admissions for HF and cost-effectiveness, as expressed in costs per quality adjusted life years (QALY's). Also quality of care is studied, comprising mortality, planned and unplanned HF related contacts with caregivers. Secondary outcomes include therapy adherence, level of disease specific knowledge and quality of life. In addition patient determinants affecting the outcomes of the Health Buddy® in terms of consumption, level of knowledge and adherence are investigated.

### *Operationalization*

Via the questionnaires that patients are asked to fill out, information is gathered about prescription of medication, medical history and socio-demographics. Measurement of quality of life occurs by means of Kansas City Cardiomyopathy Questionnaire (KCCQ) and the EQ-5D, disease specific knowledge by the Dutch Heart Failure Knowledge Score (DHFkSc) and self-management by the European Self Care Behavior Scale (ESCBSc). Adherence for pharmacological and non-pharmacological prescriptions is measured by respectively the Heart Failure Compliance Questionnaire (HFCQ) and the Hospital Anxiety and Depression Scale (HADS). Dyspnea and tiredness are assessed by the Borg scale, self efficacy by the Barnason Efficacy Expectation Scale and personal individual characteristics by the DS-14. Care consumption and mortality are based on hospital registrations, costs by hospital registration and a cost-diary by the Charlson index.

### *Power*

Sample size calculation is based on minimum reduction of 38% and a reduction of 48% for hospitalization for heart failure, using an alpha of 0.05 and a power of 0.80. A sample size of 188 patients was calculated. It is planned to enroll 10% more patients for both groups to compensate for non-evaluable patients. This results in a total of 390 patients enrolling into the study.

#### 4.2.2 Health economic evaluation alongside the RCT

This part includes a description of the method used for cost-effectiveness analysis conducted alongside the before described randomized clinical trial designed to test the cost-effectiveness of the Health Buddy® for CHF-patients as compared to usual care.

### *Perspective and type of analysis*

A health system perspective is chosen to evaluate the cost-effectiveness of the Health Buddy®, which means that direct costs within health care are analyzed. This perspective seemed most appropriate, given the focus of this study on decision making regarding telemonitoring at the meso-level. As such, the impact of telemonitoring on different parties in health care (e.g. health insurers, hospitals, GP-practices, etc) is at particular important in this evaluation. The influence of the Health Buddy® on patient costs and costs outside health care is also very relevant when it comes to the wider societal impact of this type of technology - especially because of its role in access to care - but falls outside the scope this study. The analysis has adopted the form of a cost-effectiveness analysis (CEA) as benefits are measured in natural (health) units, rather than in terms of money (as in a cost-benefit analysis). The purpose is to identify where more effectiveness can be produced at the same costs or lower costs can be achieved for the same effect.

### *Framework for the evaluation*

Given the fact that telemonitoring is often delivered as a component of the chronic care model, evaluation frameworks for chronic care management are appropriate to determine indicators for the evaluation on effectiveness and costs of the telemonitoring system. Chronic care evaluation frameworks aim to improve comparability of the results of chronic care management programs. The study of Steuten et al<sup>16</sup> suggested a framework for the evaluation of disease management programs in which structure, process and outcome indicators for effectiveness and efficiency are recommended for each type of disease management, including patient-educational focused, professional focused and organizational focused chronic care management (see appendix 1). This framework is used as basis to determine the ultimate focus of the current analysis. As the telemonitoring system of the current study is considered a patient-educational chronic care management program, the indicators for this type of intervention should be analyzed. However given time constraints and the ultimate goal of this economic analysis, the focus will mainly rest on outcome indicators. For information on structure and process outcomes one is referred to the larger trial. The evaluation framework of Polisena et al<sup>32</sup> is eventually used to determine outcome indicators for the current evaluation, as this framework specifically focuses on economic evaluation of home telehealth projects.

### *Identification of outcomes of interest*

The outcome indicators that Polisena et al determined to be included in the evaluation will be used in the current evaluation, including effectiveness in terms of quality of life, mortality and event rates; and costs. Event rates include emergency visits to GP or hospital, visits to HFN, hospital admissions and length of hospital stay. These outcomes are distinguished in events related to heart failure and events related to any cause (see table 2).

**Table 2:** Disaggregation of the outcome: event rates

---

<b>Event rates</b>
number of general practitioner after office time visits (all-cause)
number of specialist outpatient visits (CHF-related)
number of face-to-face visits with HFN
number of telephonic visits with HFN
number of emergency department visits (all-cause)
number of emergency department visits (CHF-related)
number of coronary care unit visits (all-cause)
number of coronary care unit visits (CHF-related)
number of hospital admissions (all-cause)
number of hospital admissions (CHF-related)
length of hospital stay (all-cause)
length of hospital stay (CHF-related)

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Cost components related to health care for heart failure patients were determined by the TEHAF trial. Direct costs within health care are derived from those cost components. Using the literature (articles of the literature review on evidence of telemonitoring in CHF - chapter 5) the relevance of these components is determined. A distinction is made between costs related to the intervention (including hosting costs, helpdesk costs, user costs, lease costs and connection fee) and costs related to health care utilization (see table 3).

**Table 3:** Disaggregation of the outcome costs related to health care utilization

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<b>Cost components related to health care utilization</b>
general practitioner visits
general practitioner after office time visits
heart failure nurse outpatient visits
specialist outpatient visits
emergency department visits
coronary care unit visits
length of hospital stay
professional household care, personal care and nursing care
physiotherapy and mental health care related visits
medication

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### *Data for the economic study*

Data collected as part of the clinical trial is described in the previous paragraph. Data not collected as part of the trial include: unit costs. These are derived from the manual for cost-investigation of the 'college for health insurances' (College voor zorgverzekeringen: CVZ) and from the billing system of participating hospitals. The price index of 2008 is used to calculate cost prices, because most respondents consume care in 2008.

### *Methods of analysis*

SPSS statistical software (SPSS 18.0) is used to analyze the data. Data of questionnaire T0 (baseline) and T12 (12 months of follow up) are compared to each other to test for important differences between the intervention and control group. The analysis is based on intention to treat and last observation

carry-forward principles for missing data. The last response is sought in follow-up questionnaires after 3, 6 or 9 months. Categorical variables are presented as the observed number and percentage. The Mann Whitney U test is used to test for significant differences in categorical variables at the ordinal level. Continuous variables are reported as the mean and standard deviation (SD) in case of normal distributed data, whereas in case of a skewed distribution, the median and interquartile range (IQR) are reported. Differences for continuous variables are tested with the independent t-test if data is normal distributed and with the Mann Whitney U test if data distribution is skewed. The p-value of  $<0.05$  is considered as statistically significant. A sensitivity analysis is performed in order to test the robustness of the findings. As this analysis is a CEA, the incremental cost-effectiveness ratio (ICER) is calculated. The numerator of the ICER is the difference in cost between patients in the intervention arm and those in the comparator arm; the denominator is the difference in outcomes, expressed as QALY's. A bootstrap approach is used to analyze the uncertainty surrounding the ICER. There was no discounting since costs are calculated over a time horizon of only one year.

### 4.3 Methods for the Multi Criteria Decision Making analysis

This part of this study aims to determine the relative importance of criteria (e.g. costs, effectiveness, etc) in multi criteria decision making (MCDM) regarding telemonitoring in CHF according to different stakeholders. This chapter describes the procedure used to test hypotheses regarding the relative importance of decision criteria (chapter 5).

#### *Research design*

The research design employed in this study part is partly explorative i.e. to identify relevant attributes for decision making regarding telemonitoring. Based on this hypothesis will be generated. These will subsequently be tested for which an explanatory design is appropriate. The methods used to test hypotheses and gain new insights on this topic include: a MCDA to examine the importance of selected criteria; and interviewing stakeholders in a group meeting to examine arguments behind the hierarchy given to the criteria. Prior to the MCDA, stakeholders are asked to indicate which criteria they consider important. Using this information together with evidence from the literature, criteria are selected to be included in the MCDA. The intention is to bring together six stakeholders in the group meeting to engage in a guided discussion on the critical decision criteria regarding telemonitoring. The number of stakeholders for the group meeting is limited to six because otherwise it is not feasible to clarify arguments of all participants. The reason to choose a group discussion above individual interviewing is because a group discussion may bring more arguments to the table, since each stakeholder has a different point of view on the topic. Another advantage of bringing together these stakeholders is that some consensus might be reached on the adoption of telemonitoring. A disadvantage may include that stakeholders may speak less during the group discussion than during an individual interview. Other reasons to choose for a group meeting are time constraints and distance to the stakeholders (Enschede-Maastricht). Individual interviews are offered as alternative when a stakeholder is not able to be present at the group meeting. Individual interviews will simulate the group discussion as much as possible by presenting arguments given in the group meeting in the interviews. Data collection is performed in July 2010.

#### *Population and sampling*

The population consists of stakeholders who are involved or have an interest in telemonitoring projects for heart failure patients and have influence on decisions regarding the adoption of telemonitoring at the institutional level, like cardiologists, heart failure nurses, health insurers, hospital managers, representatives of a primary care organization and advocates of a patient association. The government is not included in this list, because this party is not involved in adoption or funding decisions about telemonitoring at the institutional level. Initially, stakeholders who are closely involved in the telemonitoring project in Limburg are approached in order to enhance the chance of cooperation in the study. Also given the motive to obtain some consensus, there is initially chosen for these stakeholders. Seven identified stakeholders are approached by email for participation.

#### *Outcome measures*

Outcome measures include the relative importance of attributes in decision making regarding telemonitoring in CHF according to participating stakeholders and the arguments of these stakeholders to prefer one attribute over another.

#### *Data collecting technique*

To examine the preferences of stakeholders for criteria in MCDM regarding telemonitoring, the Analytic Hierarchy Process (AHP) is used. AHP is one of the techniques for multi criteria decision analysis. The AHP has been developed by Saaty (1989), an American mathematician. It involves structuring multiple criteria into a hierarchy, assessing the relative importance of these criteria, comparing alternatives for each criterion, and determining an overall ranking of the alternatives. The application of the AHP in this study only involves assigning the relative importance of criteria in decision making as there are no alternatives (e.g. different interventions/technologies) that are to be

compared. AHP seemed the most appropriate instrument out of other MCDM techniques, because it allows quantifying and comparing qualitative elements of a decision and because the current study involves only a limited number participants, whereas other MCDM methods often require a relative high number participants. In addition the AHP is easy to apply and assures timely results. AHP allows giving a weight to qualitative outcome measures (criteria) by pair wise comparison. A nine-point scale ranging from extreme to indifference refines the preferences concerning the pair wise comparison. The AHP structure consists of a goal or focus at the topmost level and criteria and sub-criteria at the intermediate levels. The goal of the AHP in this study is to compare the importance of criteria in decision making regarding telemonitoring in CHF. The criteria used includes the most commonly reported study outcomes of scientific evaluations on telemonitoring in CHF and the criteria that are considered most important in health priority setting according to the literature. The selection and definition of these criteria are described in chapter 5 (after the literature reviews). Before building the AHP hierarchy, stakeholders are asked whether they think the selected criteria need to be included in weighting and whether they think certain criteria are missing. The results from this process are also presented in chapter 5. The AHP is used to structure the group discussion and the individual interviews.

#### *Data analysis*

Using AHP, a relative score for each criterion is calculated. The arguments of stakeholders obtained from interviews are analyzed by first sorting them by using topics from the interview and then comparing them to each other. Important agreements and differences are reported.

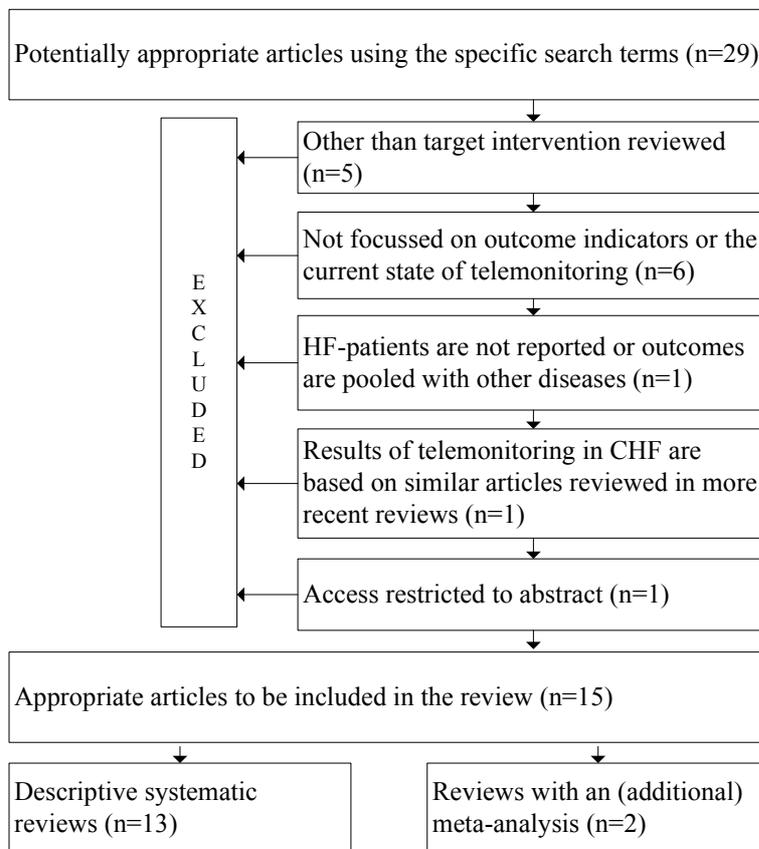
## 5. Results

### 5.1 Results literature reviews

#### 5.1.1 Evidence on telemonitoring in CHF

The search strategy as described in chapter 4.1.1 resulted in 29 potentially appropriate systematic reviews. Based on the exclusion criteria 14 articles were excluded from this review. The 15 remaining articles were included in the literature review (see figure 2 for an overview the selection process).

**Figure 2:** Selection process for the articles reviewed



Recent systematic reviews with the aim to investigate current evidence on the use of remote monitoring of HF patients as compared to usual care, found that the impact of remote monitoring on mortality, all-cause hospitalization and HF-related hospitalization appeared to be positive in the majority of the reviewed studies<sup>33-39</sup>. However not all studies included in the reviews, reported consistent outcomes on these variables. For example the results of Dang et al<sup>33</sup> showed that studies classified with the highest strength of evidence i.e. level II of the Jovell/Navarro-Rubio rating scale (there were no individual studies classified with level I), showed fewer significantly positive effects on admission rates than studies with strength of evidence level III. The other variation in outcomes is likely due to the fact that the interventions used for remote monitoring varied from study to study in terms of the technology used, duration of the intervention, the process in which information was transferred and/or analysed and the final health care provider (e.g. nurse or specialist). In addition the patients in the studies were heterogeneous with regard to the NYHA classification, HF duration and socioeconomic status had likely led to the variance in study outcomes. The systematic review of Maric et al<sup>40</sup> focused on the nature of the modality of telemonitoring interventions. They concluded that

studies showed a general trend towards improvement associated with the use of most modalities; however, inconsistent evidence between trials for the same modality and differences between modalities prevent a definitive conclusion. Many papers included in this review were non-randomized, had small sample sizes and NYHA classification varied, so the evidence is not as robust as it could have been.

There were three reviews that performed a meta-analysis on specific outcome measures in the included studies. Polisena et al<sup>41</sup> performed a meta-analysis on all-cause mortality in which five RCTs and one observational study were included. They found that patients in the telemonitoring group had a lower risk of death compared to usual care. There was little heterogeneity between studies. Clark et al<sup>36</sup> performed a meta-analysis on all-cause mortality, all-cause and CHF-related admission to hospitals; 14 RCTs were included in this analysis. The authors concluded that remote monitoring reduced admissions to the hospital for HF and all-cause mortality by nearly 20%. However, remote monitoring had no significant effect on all-cause admissions. Also in this meta-analysis there was little heterogeneity between studies. Klersy et al<sup>42</sup> published a meta-analysis in which mortality, all-cause and HF-related hospitalization were analysed; 20 RCTs and 12 cohort studies were included in the meta-analysis. It showed that remote patient monitoring significantly reduced the risk of death, hospitalization for any cause and HF-related hospitalization compared with usual care in RCT's. The heterogeneity of RCTs was small in this review. The outcomes of these meta-analyses were consistent, except for all-cause hospitalization.

The review of Seto<sup>43</sup> aimed to analyze existing economic data to determine whether remote monitoring of patients with HF will result in decreased costs. It was the only review that especially focused on the cost-impact of telemonitoring. It reported that all 10 studies included in this review found cost reductions with HF telemonitoring compared to usual care. However these studies also had small sample sizes. The amount of cost reduction was highly variable between the studies, ranging from 1.6% to 68.3%. This variation was likely due to differences in the monitoring system used, study populations, study duration and items included in the cost analysis. The majority of the studies included the following items in the cost analysis: hospitalization costs, telemonitoring equipment costs, nursing time costs and emergency visits costs. Further, a reduction in hospitalization and nursing time were considered as potential significant areas of cost savings associated with telemonitoring. It was also stated that the initial costs of telemonitoring equipment may be an obstacle to widespread use of telemonitoring. However, articles used in the review suggest that long-term savings, such as reductions in hospitalizations could more than compensate for the start-up costs, without compromising quality of care. There were four other systematic reviews within this literature review that analysed cost benefits of telemonitoring<sup>33, 36, 38, 44</sup>. These reviews reached generally similar conclusions and sometimes included the same articles in their analysis. Systematic reviews suggest that rigorous cost-effectiveness analysis are scarce and that future research should focus on this<sup>33, 35, 38, 40, 43</sup>. Dang et al<sup>33</sup> suggested that cost will be the big driver of policy; studies showing cost-effectiveness can have the greatest impact on policy regarding funding of telemedicine.

Most reviews used hospitalization and mortality as primary outcomes. Other variables that were reviewed more than once, were quality of life, in terms of quality adjusted life years (using various instruments)<sup>34, 36, 38-39, 41</sup>; patient satisfaction<sup>39, 41</sup>; and acceptability<sup>36, 38-39</sup>. Generally it was found that telemonitoring was associated with a good acceptability and an improved quality of life and patient satisfaction, although the results were not strong. The impact of telemonitoring on primary care visits, specialist visits and home care visits was examined in only one review<sup>41</sup>. This study found that the number of these visits increased in the group of patients using telemonitoring. However, it was noted that the number of studies was limited for some of these outcomes and there was substantial heterogeneity, suggesting that those findings are yet inconclusive. Martinez et al<sup>37</sup> sought for evidence regarding the impact on organization when introducing the telemonitoring system and on the system's acceptability by health professionals. However, the articles reviewed did not provide information about these topics. Kobb et al<sup>45</sup> used a different approach of reviewing the literature on evidence of home telehealth. They reviewed developments, current status, opportunities and challenges of home telehealth. The authors described that there are two issues that must be addressed in order to move

home telehealth forward. The first issue includes the lack of rigorous methodologies (RCT studies) and lack of longitudinal studies and data sharing. The second issue is that there is a critical need for consistent policies about implementation, coverage and reimbursement if private sector agencies are to adopt its widespread practice into their business models. Meystre<sup>46</sup> also reviewed the current state of telemonitoring and stated that obstacles to telemonitoring development include the initial costs of systems, physician licensing, and reimbursement.

In summary most reviews concluded that it is too early to make definitive conclusions about the effectiveness of telemonitoring in HF. Reductions in hospitalizations, mortality and cost appeared to be positive in more cases than not. The variation in study outcomes of high quality studies is likely due to the variety of interventions used for telemonitoring, study populations and study duration. Multiple reviews described that there is a shortage of rigorous cost-effectiveness analyses and that strong evidence on this is needed to support informed decision making. The reason that telemonitoring is not widely adopted is in many reviews attributed to this lack of evidence on cost-effectiveness that is required for well informed decision making.

### 5.1.2 Hypothesis 1

Based on the findings of the systematic review on telemonitoring in CHF, the following hypothesis can be stated.

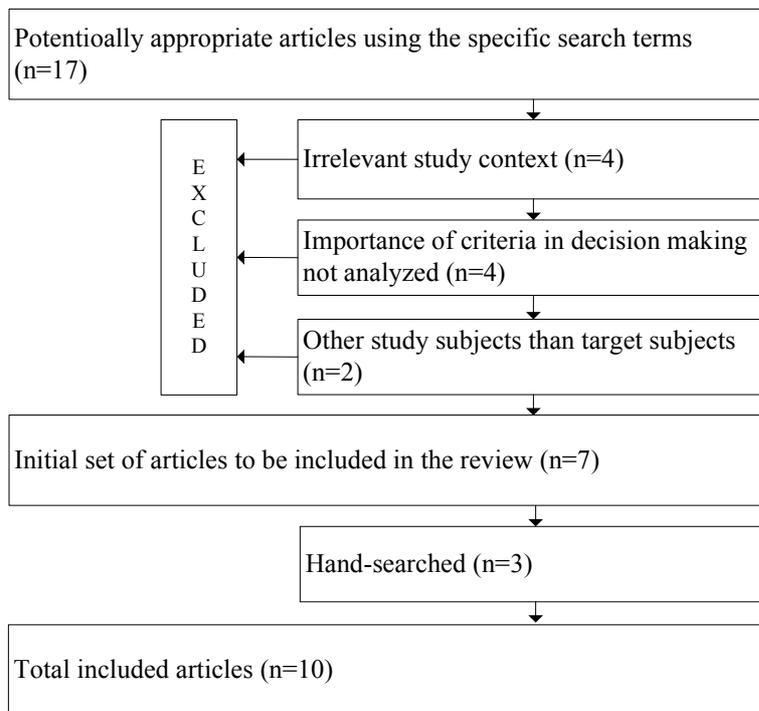
Telemonitoring for patients with CHF as integrated into routine care and compared to usual care

1. has a positive impact on effectiveness in terms of increased quality of life (in QALYs) and reduced mortality and hospitalization;
2. leads to a reduction in total costs of health care, since a reduction in health care consumption costs will compensate the intervention costs of the telemonitoring system;
3. leads to cost savings in secondary care, since it reduces all-cause and CHF-related admissions;
4. leads to cost increase in primary care, since telemonitoring increases the number of home and office visits of general practitioners.

### 5.1.3 Evidence on attributes in Multi Criteria Decision Making in health care

The systematic search resulted in 17 potentially appropriate articles. Based on the exclusion criteria ten articles were excluded from this review. The seven remaining articles were included in this literature review. Scanning reference lists yielded three additional articles (see figure 3 for an overview of the selection process).

**Figure 3:** selection process of the articles reviewed



Studies evaluating the importance of criteria in multi criteria health care decision making at the local level were scarce. Most articles found, focused on the national level and on health technology assessment (HTA) priority setting. These articles were included in the current literature review as criteria on priority setting for HTA might be important in decision making regarding the adoption of technologies at the local as well.

Several countries have established frameworks for priority setting in health technology assessment, as the number of health technologies needing evaluation far overweighs available resources<sup>47</sup>. Literature has reviewed HTA processes and priority setting in various countries and across countries. Most frequently reported HTA priority setting criteria among developed countries can be categorized into: disease burden, clinical impact, economic impact, budget impact, available alternatives and available evidence<sup>47-48</sup>. The active role of the Netherlands in HTA dates back to the early 1980<sup>49</sup>. Since then, several attempts have been taken by the Health Council to rationalize priority setting for health technologies, using multiple criteria. During the end-eighties, begin nineties the main criteria of consideration included: burden of disease; potential benefit for the individual patient; number of patients; direct costs of the intervention; and financial consequences<sup>50</sup>. In 1992 the Dutch Committee on Choices in Health Care (a.k.a. the Dunning report) called for interventions to be of proven efficiency and effectiveness before being allowed entry within the social insurance basic package<sup>51</sup>. The priority setting process and criteria used in this process changed over time. One recent article was found that examined what criteria as represented in HTA are important for decision makers in priority setting in the Netherlands<sup>52</sup>. This study was conducted among Dutch health care professionals, including policy makers, HTA experts and advanced HTA students, faced with priority setting on the national level. The most decisive decision criteria appeared to be: severity of disease, cost per quality-

adjusted life year gained, individual health gain and the budget impact. Respondents preferred health gains that include quality of life improvements over extension of life without improved quality of life. Policy makers in particular found disease severity and QALY gain dominant factors in their decisions. In the Netherlands budget impact has an important influence on decision making regarding reimbursement policies, as in social insurance-type systems, budget silos are in place<sup>53</sup>.

Two articles were found that focused on local decision making in particular<sup>54-55</sup>. These studies included examination of perceptions of decision makers in Australia on health technology decision making at the regional and institutional level. It was found that total cost impact to the area, hospital or department; safety; and effectiveness were considered most important criteria in decision making about the uptake and diffusion of new technologies. Patient preferences and equity were considered to be least important. Another study that included analysis of attributes in decision making at the local level, was that of Ratcliffe et al.<sup>56</sup> It aimed to describe views of health care providers operating in the United Kingdom National Health Service (at macro- meso- and micro levels) about concepts of cost-effectiveness, equity and access using a discrete choice experiment including attitudinal questions. It was found that decision makers at macro-levels were more likely than hospital managers (meso-level) to favour programmes that targeted the worst-off. Those who were clinically trained and currently in a clinical post had stronger preferences for programmes with shorter waiting times compared to those in managerial posts, who had stronger preferences to equity.

Attributes in multi criteria decision making regarding health technologies are context (i.e. type of health care system, level of decision making and involved decision makers) and technology specific. Literature showed that criteria of importance in national decision making, generally differed from those considered important in local decision making. In the Netherlands policy making regarding the uptake and reimbursement of health technologies are generally made at meso- and micro levels, where professionals, institutions and health-care insurers are important actors. However, the current literature search did not found articles reporting on factors that are considered important by decision makers at these levels in the Netherlands. Therefore an additional search was conducted, searching for articles on the adoption of health technologies. Adoption theories might help to identify criteria of consideration in local decision making. Since the type of technology is a factor that determines the criteria of importance in decision making, there was also searched for articles that specifically focused on the adoption of telemedicine devices.

The diffusion of innovation theory<sup>57</sup> provides an appropriate framework to understand the adoption of technologies. Everett Rogers suggests in his theory of innovation diffusion that there are five attributes of innovations that influence the rate of adoption for innovations. 1) *Relative advantage*, the degree to which an innovation is perceived better than the idea it supersedes; 2) *compatibility*, the degree to which an innovation is perceived as consistent with decision makers' existing values, past experiences, and needs of potential adopters; 3) *trialability*, the degree to which an innovation may be tried on a limited basis; 4) *observability*, the degree to which the benefits of the innovation are visible to decision makers; 5) *complexity*, the degree to which an innovation is perceived as relatively difficult to understand and/or use. In addition to these innovation characteristics, health technology adoption rates are further determined by the characteristic of adopters, the organization and the structure of the environment in which the technology is supposed to be adopted. Menachemi et al.<sup>58</sup> utilized the diffusion of innovation framework to discuss factors affecting adoption of telemedicine, considering viewpoints of key-stakeholders, including physicians, hospital administrators, patients and health care payers. Major factors of concern faced by physicians were on quality of care, quality of service, and complexity issues. Patient's key uncertainties included adjustments to a new way of interacting with healthcare providers and concerns over security, confidentiality, and privacy. Administrators were concerned about cost effectiveness, reimbursement, and legal issues. Concerns of payers were centred on overall healthcare costs. An other article reported on determinants that influence the implementation of telemedicine<sup>59</sup>. Five categories of determinants were identified: 1) *technology*, including support and training offered at the technical level and the usability and quality of the technology; 2) *Acceptance*, by patients and professionals; 3) *financing*, including investment, maintenance and operational costs of the new system; 4) *organization*, intramural and extramural work

practices; and 5) *policy and legislation*, suitable legislation and policy, standardization and security (patient physical safety and patient information security) of telemedicine implementations.

#### 5.1.4 Hypothesis 2

Based on the previous literature review, a hypothesis was stated on decision making regarding the adoption of telemonitoring (considering the Health Buddy® in specific). The hypothesis was mainly based on criteria as recently considered important in Dutch health care decision making and on factors of influence on the adoption of telemedicine in specific:

Decision making regarding the adoption of telemonitoring for HF patients is according to the involved stakeholders mainly determined by:

- 1) its cost-effectiveness in terms of costs per quality-adjusted life years gained;
- 2) its clinical effectiveness (e.g. reducing mortality and hospitalization and improving quality of life);
- 3) and other factors including its budget impact, acceptance by patients and professionals, financing, safety, and legislation.

## **5.2 Results of the health economic evaluation**

This part is confidential until the TEHAF trial published its own results regarding the cost-effectiveness of the Health Buddy® system. These results are expected to be published before 2012.

### 5.2.1 Outcomes on effectiveness

### 5.2.2 Outcomes on costs

### 5.2.3 Sensitivity analysis

### 5.3 Results of the multi criteria decision making analysis

#### 5.3.1 Respondents

Five out of the seven stakeholders who were initially approached, were willing to enrol into the study, including a director R&D, heart failure nurse, hospital manager, health insurer and the supplier of the Health Buddy® system. These stakeholders were all closely involved into the telemonitoring project in Limburg. Since two important stakeholders were still missing, including a cardiologist and someone representing a primary care organization, four more stakeholders were approached. It succeeded to enrol a cardiologist and a representative of a GP association. Although these two stakeholders were not directly involved into the project in Limburg, they had experience with other telemonitoring projects. Our efforts to enrol an advocate of a patient organization did not succeed. Table 9 gives some additional information about the stakeholders.

**Table 9:** Exact function and background of respondents

<b>Respondent</b>	<b>Exact function</b>	<b>Background</b>
Cardiologist	Cardiologist at Martini hospital and Cavari Clinics	ICT consultant and health innovator
Director R&D	Director research & development integrated care at MUMC	Professor chronic care
Health insurer	Medical consultant at UVIT	Anaesthesiologist
Heart failure nurse	Coordinating heart failure nurse & health scientist at MUMC	Heart failure nurse
Hospital manager	Director integrated care at MUMC	Internist
Policy maker	Policy maker at Meditta (GP organization)	Health scientist
Supplier	Director of Sananet	Health scientist and medical computer informatics specialist

#### 5.3.2 Identification of criteria for the AHP

Prior to building the AHP, participants were asked to indicate which criteria should be included in the weighting. Frequently reported outcomes in scientific literature on telemonitoring in CHF, were listed as potential criteria to be included in the AHP (see appendix 3), as these criteria are suggested to be important in decision making. The sub-criteria were by two researcher logically categorized into: effectiveness, health care consumption, costs, safety and satisfaction. Participants were asked by email to review the list of criteria and provide additional criteria that they believed should be considered when making decisions regarding the adoption of telemonitoring. Three of the seven participants reviewed and returned the list of criteria. Added and excluded criteria are summarized in table 10. Combining the information from the literature and respondents, a hierarchy of criteria was constructed for the AHP and is represented in figure 11.

**Table 10:** Summary of excluded and added sub-criteria

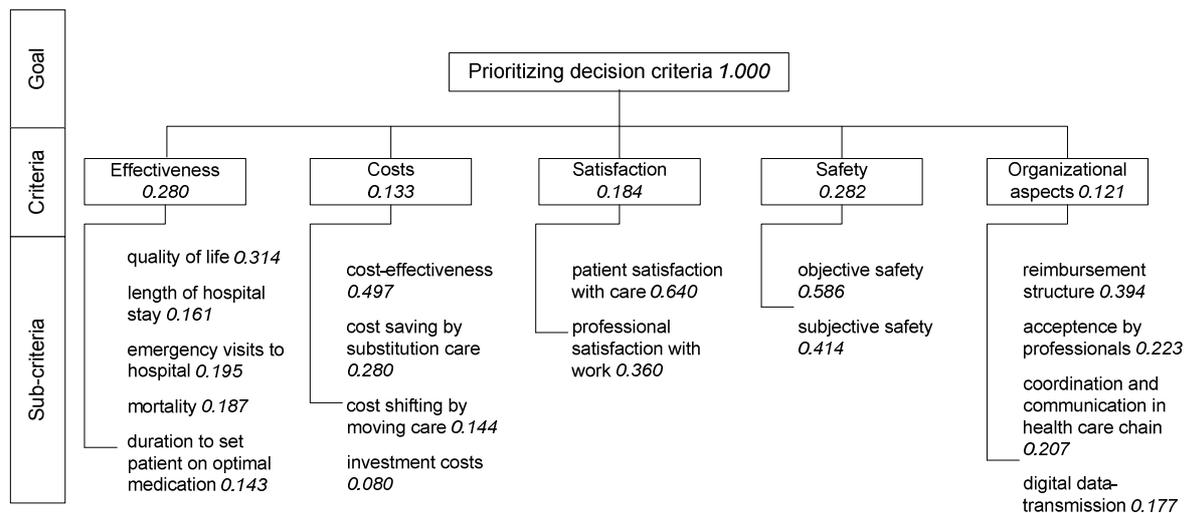
<b>Respondent</b>	<b>Added main-criteria</b>	<b>Added sub-criteria</b>	<b>Excluded main-criteria</b>	<b>Excluded sub-criteria</b>
<i>Hospital manager</i>	-	1) Reimbursement structure 2) Cooperation and communication in the chain	-	-

<i>Health insurer</i>	-	1) Focused medical attention 2) Invasive treatments 3) Safe after teething and acceptance	-	1) NYHA-class 2) Number of hospital admissions 3) Length of hospital stay 4) Safety of care
<i>Cardiologist</i>	Integration in care	1) Faster optimal medication 2) Medication compliance 3) More care by nurse and less by cardiologist 4) Values of telecare in EPD 5) Integration in disease management	-	1) NYHA-class

### 5.3.3 Relative weight of criteria

The combined relative weight of criteria as given by stakeholders is presented in figure 11. Analyzed by their judgements, respondents attached most weight to safety and the least weight to organizational aspects. An overview of weights given by individual stakeholders is presented in appendix 5.

**Figure 11:** Hierarchical representation of the criteria and criteria weights for prioritizing decision criteria regarding the adoption of telemonitoring in CHF



Note: for a more detailed description of the criteria see appendix 4

### 5.3.4 Arguments of respondents behind the weighing

Five stakeholders were able to join the group discussion to explain their arguments for the weighting. The other two were individually interviewed after the group session. In this paragraph the arguments for the weighting, given by the seven stakeholders are described, starting with the sub-criteria and eventually the comparison of the main criteria

#### *Effectiveness*

The criterion that was generally preferred over the other criteria was quality of life. Stakeholders preferred quality of life improvements over extension of life and reduction in hospitalization without improved quality of life. Stakeholders agreed that people with heart failure are in a life stage where the quality of life is deemed very important. The hospital manager argued however that although quality of life is very important, this should not lean to the extreme by means of: if quality of life is good, one

may die tomorrow. The health insurer had a different view on the importance of quality of life as compared to mortality; he felt that it is more important whether someone survives with this new technique than improving quality of life.

Mortality was by half of the stakeholders considered more important as compared to hospitalization and duration to set patient on optimal medication. The heart failure nurse, policy maker and researcher however questioned whether a technology like the Health Buddy® can directly affect mortality as it is a light intensive therapy and therefore found mortality least important. They thought mortality not unimportant, but placed it in the second place as the other factors might directly be influenced by telemonitoring.

Opinions were divided regarding length of hospital stay as compared to emergency visits to the hospital. Purely considering effectiveness, the health insurer found that it does not make much difference what is more important. The cardiologist felt that an emergency visit to the hospital is generally perceived worse by the patient than staying a few more days in the hospital. From this point of view, more weight is placed on emergency visits. However from a societal perspective, most stakeholders thought length of hospital stay more important, since a day in a hospital is more expensive than a visit to the emergency department. Moreover, it was argued by the health insurer that given the diagnosis-related-group (DRG) reimbursement system whereby a price is given per treatment, the number of hospital days is not included. Therefore the number of hospital days should be minimized. The cardiologist added that if there are less hospital days, beds can be used more efficiently. However, the hospital manager argued that from a hospital perspective, reducing the number of hospitalizations is a very difficult issue. It might be comfortable for the patient, but for the hospital it can be very detrimental as it may lose budget.

### *Costs*

Investment costs was by all stakeholders considered less important as compared to the other criteria. Arguments included: 'It is obviously not about a huge investment, because if you have very large initial costs, it will play a different role' (hospital manager); 'The challenge is to keep investment costs as low as possible and offer a price per use; the faster the cost-effectiveness ratio gets acceptable, the easier telecare is accepted (cardiologist); 'The price of a device might be low, but the whole process surrounding it might be very expensive' (policy maker).

All stakeholders thought cost-effectiveness more important compared to the other factors. The policy maker found the aspect 'effectiveness' in cost-effectiveness very important, saying: 'We can invest in something, but if we do not know the effect, we better stop'. The cardiologist thought that cost-effectiveness ratio is simply more interesting than cost-shifting by moving care and cost savings by substitution of care, because the last will never occur without the first half. The health insurer weighed cost-effectiveness also higher than cost shifting and cost saving, saying: 'Savings by substitution of care, does not mean that it has become better. The supplier was inclined to think cost savings more important than cost-effectiveness, assuming that quality of care remains the same.

Given cost shifting as compared to cost savings, the following was said: 'A cost shift from second to first line for example, has not shown yet to be cheaper, therefore I choose for cost saving' (health insurer); 'It is better to save costs than shifting them' (policy maker). The supplier stated: 'where money is saved, money is lost, which makes the widespread adoption of this kind of technologies in the Netherlands difficult'. The hospital manager argued that cost savings mean for a hospital something else than for a health insurer. A hospital has a budget to keep, so if costs become lower, the health insurer will pay less, which is in favor of the health insurer. The health insurer did not totally agree with this and argued that health insurers take the quality of care and health benefit per euro into account and not just what is cheapest.

### *Satisfaction*

Patient satisfaction with health care was weighed equally or more important than professional satisfaction with their work. Arguments behind the weightings included: 'Patient and professional should form a team together in order to make a good care process' (policy maker); 'If both are not satisfied it will not work, so there must be a balance (cardiologist); 'Patient satisfaction is important, but not at any price, since the patient can not foresee the total' (supplier). The heart failure nurse and hospital manager thought that the care provider should make concessions regarding a patient. The cardiologist however argued that professionals feel that they are already doing so. He said: 'over about 15 years, health care professionals will be very scarce, with the consequence that they can barely work customer-centred.

### *Safety*

Objective safety was by most stakeholders thought more important as compared to subjective safety. The supplier and heart failure nurse were the only ones who thought subjective safety more important. The supplier argued that with telemonitoring patients experience a certain feeling of safety, because they are virtually remotely monitored. It is for example possible for a patient to push every day on the button, indicating he is alive. The hospital manager agreed that when it is about telemonitoring, subjective safety is important as you want the patient to use something. He said: 'If the patient himself does not believe that it is safe, you are obviously nowhere'. The cardiologist thought objective safety more important, saying: 'If the objective safety of a technique is not good, it will soon disappear from the market and the subjective feeling of security shall pass soon, so objectively unsafe is unthinkable. Also the health insurer attached more value on objective safety, as he felt that this should initially be safeguarded. The policy maker thought objective and subjective safety are intertwined with one another and therefore equal important.

### *Organizational aspects*

Reimbursement structure was most often chosen as more important as compared to the other criteria. Therefore this criterion appeared to be most important. Opinions were divided regarding the importance of cooperation and communication in the health care chain with respect to reimbursement structure. The health insurer and policy maker thought these aspects were equal important, saying that they are inherent to each other. Stakeholders shared the opinion that reimbursement structure is necessary to facilitate cooperation in the chain. The cardiologist argued that it is always about money and without money something will not work. According to the health insurer, everyone in the chain should be paid within a particular DRG. Currently, there is conflict between the modernization and innovation (M&I) modules of the GP and the DRG-structures of the hospital. If this could be overcome by introducing one overall reimbursement system, this may solve the organizational problems, so telemonitoring should not be paid separately, but embedded in a DRG. The hospital manager agreed with this, although he felt that it is very difficult to organize a comprehensive reimbursement structure in which all parties feel that they get their fair share. He found cooperation and communication more important as without these aspects telemonitoring would not work, despite it is financed.

Opinions were divided regarding the importance of digital data-transfer. The health insurer found it an important factor as it might influence costs, since costs become better visible when introducing a digital patient record. The heart failure nurse felt that digital data-transfer can improve cooperation in the health care chain, when everyone has access to the data via their own system. The cardiologist found it an important criterion, saying that it is his goal to make digital data-transfer possible. The other stakeholders weighted digital data-transfer less important compared to the other factors.

The criterion, acceptance of health professionals was seen as an important pre-requisite for telemonitoring to succeed. Stakeholders agreed that without acceptance of health professionals, telemonitoring will not work: 'It is not dominant important, but a threshold to reach something' (hospital manager). Reimbursement structure was thought more important than acceptance.

Arguments included: 'When reimbursement is granted, acceptance comes naturally' (...) Professionals will not accept something if they do not get their fee' (supplier); 'As long as the doctor gets his fee' (health insurer).

#### *Main criteria*

Starting with looking at effectiveness, opinions differed regarding its importance as compared to other criteria. As compared to costs, effectiveness was generally favored. The following arguments were given: 'If one nowadays continues to be fixated on costs, little is getting done' (cardiologist); 'I find costs not important, as long as something is effective' (policy maker); 'I thought that if something is very effective, it might reduce costs automatically' (heart failure nurse). The hospital manager thought these criteria were equally important and said: 'The first can not exist without the second. The health insurer slightly favored costs, as he wanted the most health benefits for minimal euros.

Satisfaction was often thought equally important as compared to effectiveness, since it was thought inherent to each other or seen as important precondition to make something succeed. 'If something is not safe, I would not know how it could be effective' (director R&D). The cardiologist found effectiveness, satisfaction and safety important preconditions. The policy maker however, preferred effectiveness very strongly above safety. Her argument included: 'Something should work in the first place and then you see if it is safe' (...) 'Of course it should be safe when testing it on patients'.

Given effectiveness versus organizational aspects, stakeholders agreed that effectiveness was more important. Arguments included: 'Effectiveness should firstly be proven before the organization will be inclined to adapt to it' (cardiologist and policy maker); 'It does not matter whether an organization messed things up, as long as the technology is effective' (health insurer). Although, when the health insurer took costs into consideration he argued that health benefits per euro can only be achieved when organizational aspects are well arranged. This was also what the director R&D thought, although he questioned whether organizational aspects like 'transmural' cooperation would actually lead to cost-savings. The policy maker thought costs least important and very strongly favored all other criteria above it. She was convinced that a health insurer will pay when a technology has proven to be effective and safe and when people are satisfied. The hospital manager argued that it appeared that costs often really work against cooperation and therefore found costs more important than organizational aspects. The cardiologist however, felt that the biggest problem with implementation, are organizational aspects and not always the money. He explained: 'You can always get subsidy to start something, but if the organization can not be adjusted to the new technology, then it will end as soon as subsidy ends.

Satisfaction versus safety was often thought of equal importance, although the hospital manager found it a difficult balance and said: 'A caregiver is more inclined to choose safety, but reality shows that satisfaction of people makes that safety has become less' (...) 'how long did it take before people used their seatbelt? How safe it was, people were not satisfied with it'. The policy maker thought that if something is not safe, one will not be satisfied'. Satisfaction and safety were generally thought more important than organizational aspects. The policy maker said: 'Although the organization is not running as it should, as long as people are satisfied and the technology is safe, organizational issues can be solved later.

## **6. Discussion**

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### **6.1 Health economic evaluation**

This part is confidential until the TEHAF trial published its own results regarding the cost-effectiveness of the Health Buddy® system. These results are expected to be published before 2012.

#### 6.1.1 Summarization and interpretation of results

#### 6.1.2 Study limitations

#### 6.1.3 Related studies

## 6.2 Multi Criteria Decision Making Analysis

### 6.2.1 Summarization and interpretation of results

The a priori formulated hypothesis regarding the relative impact of cost-effectiveness outcomes on decision making regarding telemonitoring for patients with heart failure read: ‘Decision making regarding the adoption of telemonitoring, considering the Health Buddy® for heart failure patients, is mainly determined by its cost-effectiveness and (clinical) effectiveness’. Furthermore, it was hypothesized that other factors like budget impact, acceptance by patients and professionals, financing, safety and legislation also determine decision making regarding telemonitoring. The results from the MCDA showed that stakeholders assigned the highest weight to safety and effectiveness, when considering factors in decision making regarding the adoption of telemonitoring. Furthermore, while effectiveness appeared to be a very important main-factor, the cost-effectiveness ratio was found to be a focal sub-factor. ‘Other factors’ as described in the hypothesis, like budget impact, acceptance by professionals, financing and safety were also considered important in decision making. The factor ‘budget impact’ came up during the discussion, but was not explicitly included in the AHP. Therefore, its relative weight is unknown. Legislation did not emerge as an important factor. This might be explained by the fact that the Health Buddy® system is already implemented in practice for a while, so in this context legislation issues were not of concern.

There were some notable similarities and differences in opinions between stakeholders. The health insurer and supplier generally had other preferences than the health care providers. The health insurer aspired most health benefit for minimal euros, whereas ‘providers’ were less concerned about costs. They felt that they would be able to acquire reimbursement or subsidies as soon as the technology proved to be effective. The supplier considered effectiveness and costs most important as products that are not only effective but also cost-effective have a better prospect for sales. The health insurer and hospital manager were the ones who considered budget impact as important, but provided opposite perspectives on this issue. The health insurer did not want to see an increase in the required hospital budget due to additional costs of telemonitoring, while the hospital manager was concerned that hospital cost savings, as might be generated by implementation of the telemonitoring system, would eventually reduce the hospital budget that they receive annually from the health insurance companies. Considering the standpoints of (representatives of) health care providers, including the heart failure nurse, cardiologist, director R&D, hospital manager and policy maker, they were generally most concerned about safety and effectiveness. Notable was that the heart failure nurse focussed particularly on patient interests. The policy maker was very clear in that she thought a technology should be effective in the first place, before considering the other factors. The cardiologist felt that both safety and effectiveness are important prerequisites, but at the same time considered organizational aspects very important as these often impede the implementation of new technologies.

### 6.2.2 Study limitations

The MCDA aimed to explore the importance of specific criteria in decision making regarding the adoption of telemonitoring. Therefore, several important stakeholders involved in decision making regarding telemonitoring were included and the results shed light on pivotal arguments regarding decision making about telemonitoring, about which currently little is published in the scientific literature. However, as the analysis was based on only a limited number of stakeholders (n=7), no strict conclusions can be drawn and the generalizability of outcomes should be tested in a larger study. Further, the efforts to include a representative of a patient organization did not succeed. This can be seen as an important limitation of this study as in the Netherlands patient organizations are involved in many formal decision making processes.

The AHP is a useful method to analyse the factors that are considered important in decision making. However, it does not account for value trade-offs across criteria, which might have been interesting additional information in this context. The factors as included in the current AHP hierarchy were based on the literature and factors as suggested by stakeholders. It should be mentioned however that only three out of seven stakeholders suggested factors to be included in the AHP. Therefore it is questionable whether the AHP design completely reflects the factors as considered important by all stakeholders. It may be that some important factors are missing. The supplier for example argued during the group meeting that he missed patient behavior and knowledge in the range of sub-criteria. However, one could say that these criteria reflect effectiveness and might directly affect quality of life or hospitalization. Still, in future research it is important to identify most important criteria of consideration by a larger study.

An important condition for using the AHP is that overlap in factors is avoided and that factors are interpreted in an unambiguous manner. However, during the discussion it became clear that, notwithstanding the provided definitions, cost-effectiveness somewhat overlapped with effectiveness in people's minds. With regard to the interpretation of factors, length of hospital stay and emergency visits were judged from an effectiveness perspective, but also from a cost perspective. Furthermore, the cardiologist mentioned that the current AHP design did not reflect the future health care situation well, in which care for chronic ill patients will largely disappear from hospitals and be facilitated by first-line GP practices. This, however, is a matter of study-perspective, which was chosen to focus on the current situation. The fact remains that health care is about to change, which might affect judgements of stakeholders. In addition, judgements may be affected when another functionality of telemonitoring is considered. During the group discussion it was argued that a telemonitoring system, with for example a more direct impact on mortality (e.g. an implantable pacemaker), may mean that factors are weighted differently.

### 6.2.3 Related studies

Although the results of other studies that analyzed the importance of attributes in health care decision making, vary with regard to context and research objects, this study largely confirms their results. Koopmanschap et al.<sup>52</sup> studied views of Dutch health care professionals operating at the national level and found that cost-effectiveness and budget impact were one of the most decisive criteria, which is in line with the results of the current analysis. In addition, they observed a similar trend, in that respondents preferred health gains in terms of quality of life over extension of life without improved quality of life. Ratcliffe et al.<sup>56</sup> analyzed the views of UK National Health Service decision makers and care providers. They studied the attributes: health benefits (in QALYs), the share of QALYs gained for the worst off, waiting time for treatment and travel distance to facilities. It appeared that health benefits dominated decision making. Gallego et al.<sup>54</sup> analyzed perceptions of Australian decision makers at the local level. They found that safety and effectiveness were considered most important criteria in decision making, although budgetary impact often drove decisions about the uptake and diffusion of new technologies. The first exactly reflects what was found in the current analysis; budget impact was also considered in decision making in the current analysis, but its relative importance as compared to other factors could not be derived from the results.



## 7. Conclusion

The conclusion of the health economic evaluation is not reported as this is confidential.

The MCDA showed that effectiveness and cost-effectiveness appeared to be important factors in decision making regarding the adoption of telemonitoring. Other factors like safety; budget impact; patient and professional satisfaction; and financing were also considered important in decision making. Stakeholders assigned the highest weight to safety. There were similarities, but also important differences in judgements given by stakeholders, which might be explained by contradictions in interests that their role in health care entails.

### *Implications for policy, clinical practice and scientific research*

The implications as derived from the health economic evaluation are not reported as this is confidential.

In order to facilitate telemonitoring at the moment subsidy ends, health insurers should reimburse telemonitoring to ensure it is not only on a temporary basis. It is important to identify in future research which factors (e.g. patient, provider or technology characteristics, access to health care services, adherence to evidence based guidelines, patient self-management, etc.) are most relevant in the effect on quality of care. This can only be realised when scientific evaluations investigate the relation between structure, process and/or outcome indicators. In addition it is important to get insight into which set of components of the chronic care model has the largest impact on quality of care, to be included in telemonitoring programs.

Outcomes of the MCDA may support decision makers to identify possible bottlenecks between different stakeholders when implementing telemonitoring. Furthermore, results can inform researchers in selecting policy relevant topics, which may in turn lead to efficiently allocating resources available for research. The decision analysis gave an impression of critical factors in decision making regarding telemonitoring in a specific context by analyzing perceptions of a few stakeholders. Future research should test generalizability of outcomes in a larger study with more stakeholders and a wider study context (e.g. Netherlands-wide). Further, it might be interesting to add a stakeholder analysis, evaluating the relative weight of impact each stakeholder has on telemonitoring decisions. Combining these weights with the weights given to the decision criteria, may give a more precise approach of the actual importance of criteria in decision making. In addition, it might be interesting to focus future research on value trade-offs across criteria in order to gain a more precise approach of the probability telemonitoring will be accepted by stakeholders, given certain study outcomes. An appropriate method for this might be a discrete choice experiment. Finally, it may be important to find out whether stakeholders change judgements given the nearby future situation in which the reimbursement system has changed and health care has shifted from secondary to primary care.



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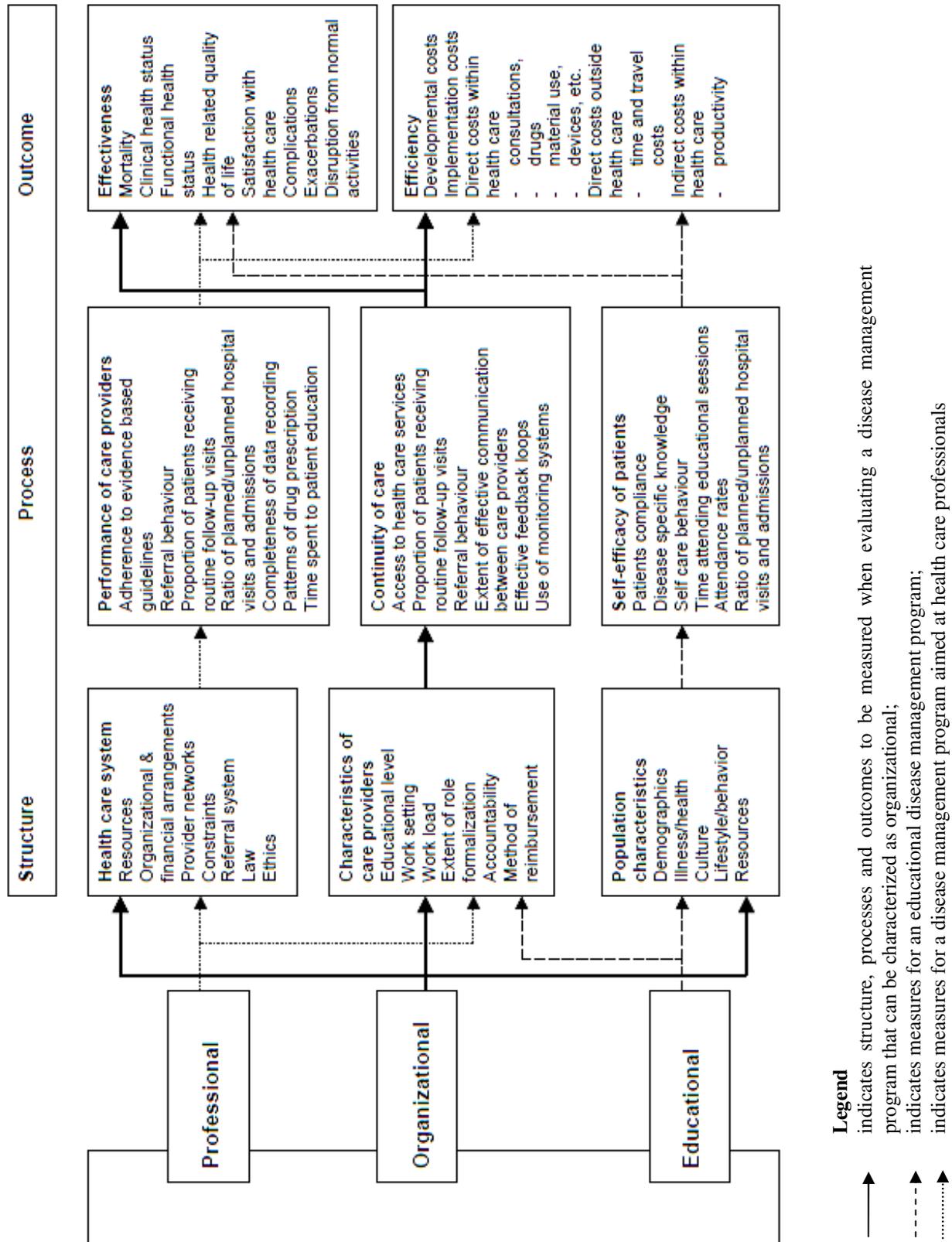
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# Appendices

## Appendix I: Framework for HTA of disease management<sup>16</sup>



## **Appendix 2: Additional outcome tables of the health economic evaluation**

Confidential

### Appendix 3

The empty cells are designed to fill factors that you think are missing

Factor	Sub-factor	Place X if you consider this factor important
Effectiveness	quality of life	
	mortality	
	NYHA class	
	...	
	...	
Health care consumption	number of hospital admissions	
	length of hospital stay	
	number of emergency visits to the hospital	
	number of outpatient visits	
	number of GP visits	
	...	
	...	
Costs	investment costs	
	cost(savings) in the long term in primary care	
	cost(savings) in the long term in secondary care	
	...	
	...	
Safety	safety of care	
	safety experienced by patients	
	...	
	...	
Satisfaction	patient satisfaction with care	
	professional satisfaction with work	
...	...	
...	...	
...	...	

## **Appendix 4: Definition of factors**

### **Effectiveness**

*Mortality:* number of deaths

*Quality of life:* functioning of persons at physical, psychological and social level, based on subjective evaluation

*Length of hospital stay:* number of admission days per year

*Emergency visits to the hospital:* number of visits to coronary care unit and emergency department per year

*Duration to set patient on optimal medication:* time required to set a patient on optimal medication

### **Costs**

*Investment costs:* acquisition costs of equipment, installation costs, etc.

*Cost-effectiveness ratio:* difference in costs between usual care and care with telemonitoring, divided by the difference in outcome (quality of life)

*Cost shifting by moving care:* more first line – less second line costs in the long-term or vice versa

*Cost saving by substitution of care:* more nursing costs – less cardiologist costs on the long-term in the second line

### **Satisfaction**

*Patient satisfaction with care:* result of expectations that the patient had initially about health care and his/her actual experience

*Professional satisfaction with work:* result of expectations that the professional had initially about work and his/her actual experience

### **Safety**

*Objective safety:* (un)safety that is objectively ascertainable, e.g. by the number of recorded incidents

*Subjective safety:* the extent to which someone feels (un)safe.

### **Organizational aspects**

*Cooperation and communication in the chain:* between professional in primary and secondary care with regard to the management of the process.

*Reimbursement structure:* possibility of structural reimbursement for telemonitoring

*Digital data transfer:* data of telemonitoring of an individual patient visible in EPD

*Acceptance by professionals:* acceptance by involved health care professionals to work with telemonitoring

## Appendix 5: AHP scores of each stakeholder

Figure 1: Cardiologist

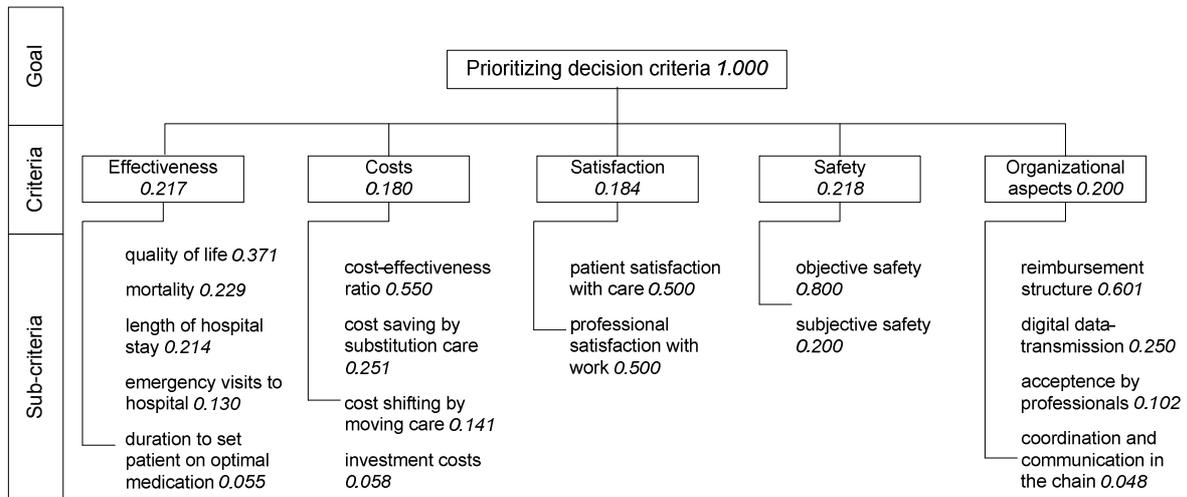


Figure 2: Director R&D

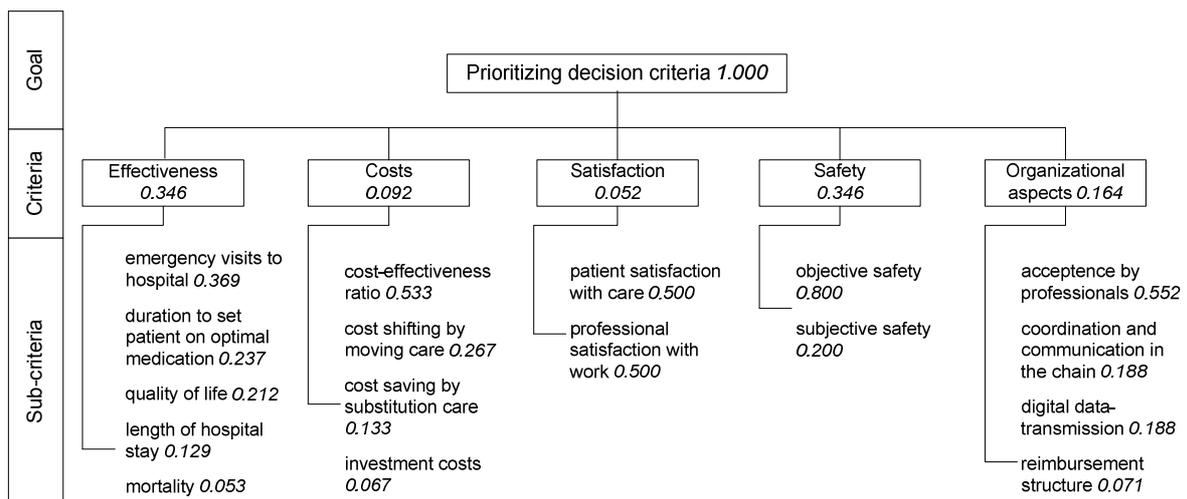
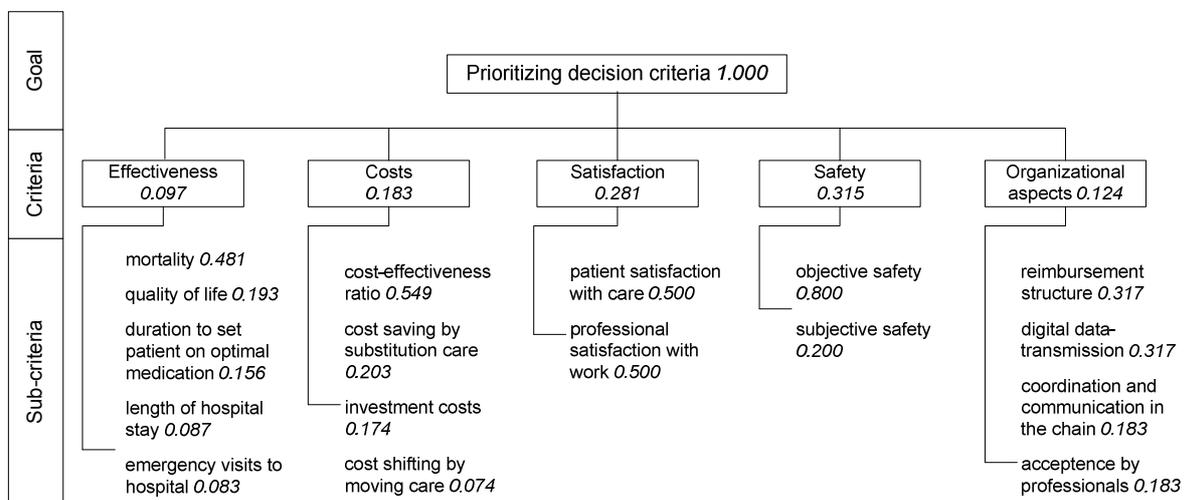
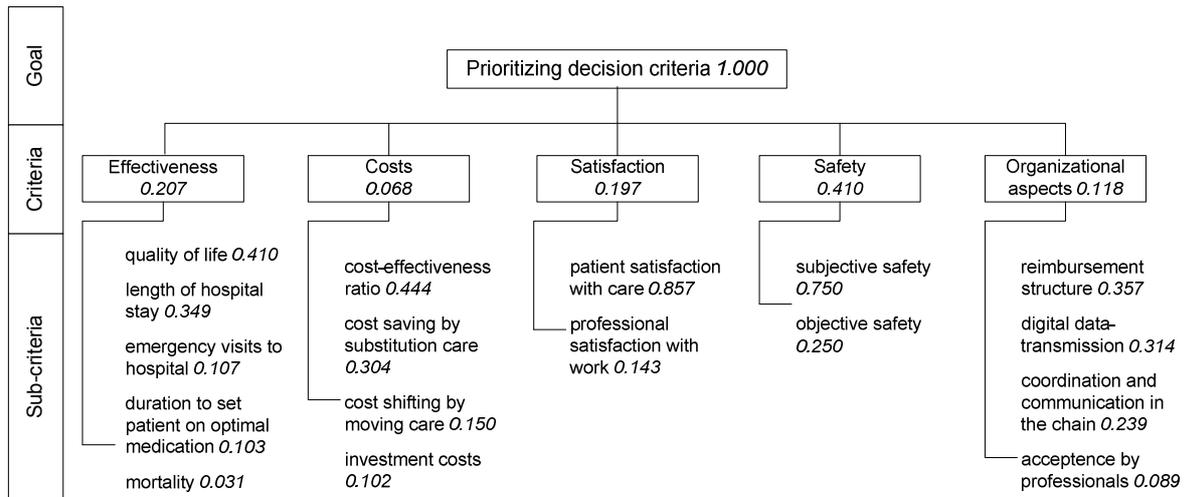


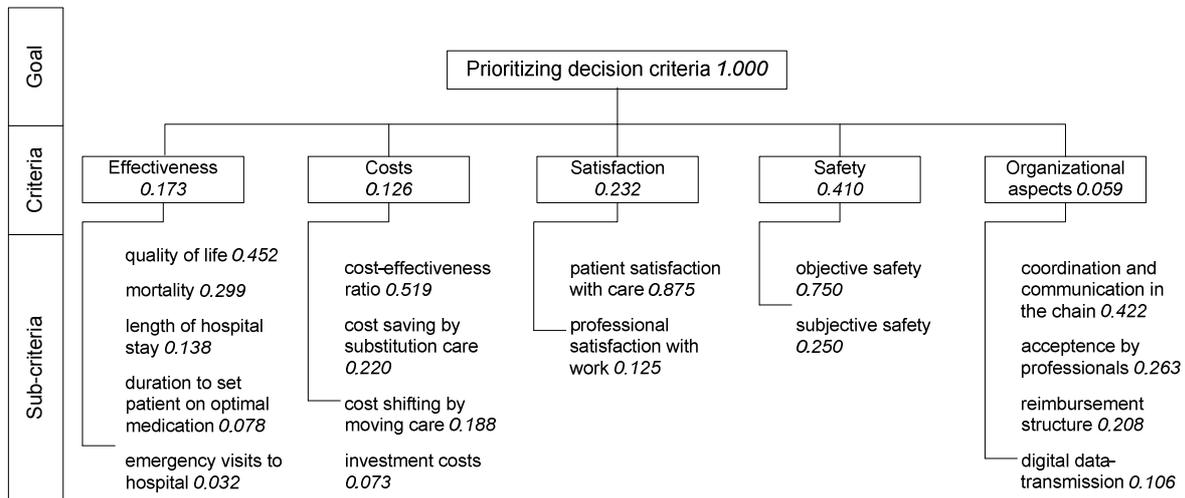
Figure 3: Health insurer



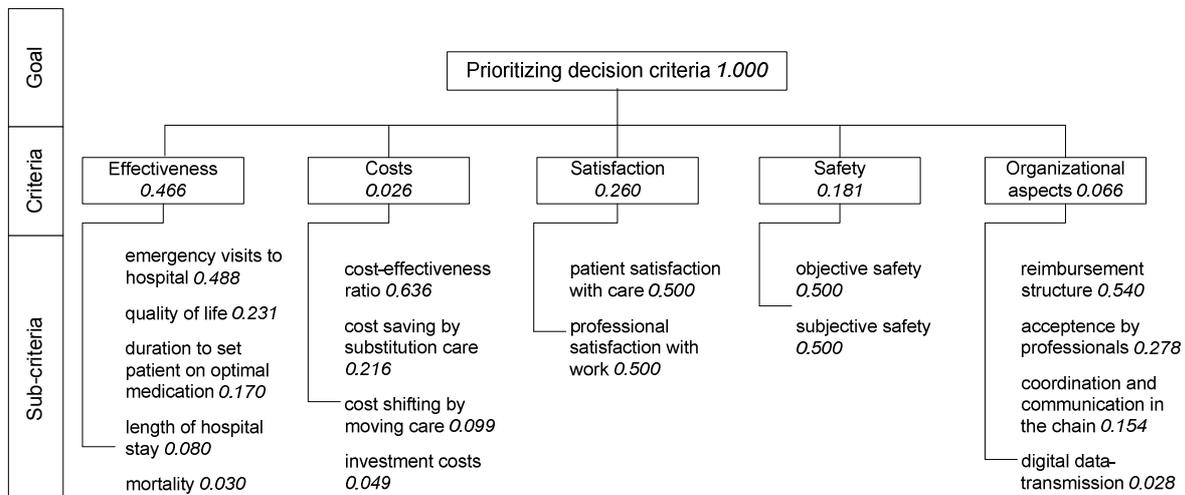
**Figure 4: Heart failure nurse**



**Figure 5: Hospital manager**



**Figure 6: Policy maker**



**Figure 7: Supplier**

