Cost-effectiveness, Care Coordination, and Business Model Innovation in Telehealth for Chronic Heart Failure Patients

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Cost-effectiveness, Care Coordination, and Business Model Innovation in Telehealth for Chronic Heart Failure Patients

Kosteneffectiviteit, zorgcoördinatie en bedrijfsmodelinnovatie in telezorg voor patiënten met chronisch hartfalen

Thesis

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by

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Chapter 2

Cost-Effectiveness of Telehealth Interventions for Chronic Heart Failure Patients: A Literature Review

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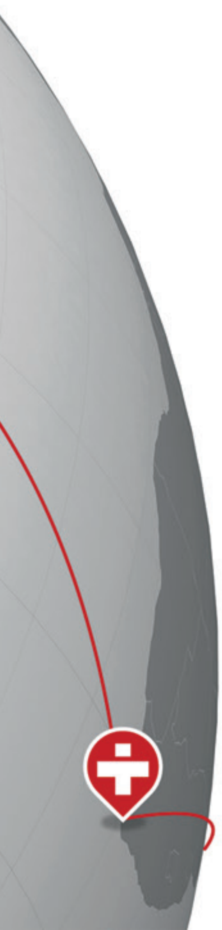

ABSTRACT

Objectives: Evidence exists that telehealth interventions (e.g. telemonitoring, telediagnostics, telephone care) in disease management for chronic heart failure patients can improve medical outcomes and we aim to give an overview of the cost-effectiveness of these interventions.

Methods: Based on the literature search on ‘heart failure’ in combination with ‘cost’ and ‘telehealth’ we selected 301 titles and abstracts. Titles and abstracts were screened for a set of inclusion criteria: telehealth intervention, heart failure as the main disease, economic analysis present and a primary study performed. In the end thirty-two studies were included for full reading, data extraction, and critical appraisal of the economic evaluation.

Results: Most studies did not present a comprehensive economic evaluation, consisting of the comparison of both costs and effects between telehealth intervention and a comparator. Data on telehealth investment costs were lacking in many studies. The few studies that assessed costs and consequences comprehensively showed that telehealth interventions are cost saving with slight improvement in effectiveness, or comparably effective with similar cost to usual care. However, the methodological quality of the studies was in general considered to be low.

Conclusions: The cost-effectiveness of telehealth in chronic heart failure is hardly ascertained in peer reviewed literature, the quality of evidence is poor and there was a difficulty in capturing all of the consequences/effects of telehealth intervention. We believe that without full economic analyses the cost-effectiveness of telehealth interventions in chronic heart failure remains unknown.

INTRODUCTION

On a global scale populations are aging, the prevalence of chronic diseases is on the rise and healthcare budgets are strained. One of the most common chronic diseases is chronic heart failure (CHF) with 1-2% prevalence and a 1-2% toll on healthcare budgets of the developed countries.[54] Telehealth, being the use of telecommunication technologies in healthcare, is about to emerge as one of the tools to help solve the ever-increasing number of people suffering from chronic diseases. In the current healthcare climate where a quarter of countries worldwide have a telehealth policy in place,[55] we need to know to what extent telehealth is an effective solution in addressing the rise in chronic diseases, and moreover whether it is a cost-effective solution.

The Whole System Demonstrator program,[56] the largest randomized control trial of telehealth and telecare in the world, has reinforced the knowledge how telehealth improves clinical outcomes, but our understanding of the impact on costs of such technology is vague. The limited evidence from systematic reviews indicates some promising results in the field of chronic heart failure. Klersy et al.[57] performed a meta-analysis of 21 randomized controlled trials (RCTs) where economic modelling was used to bridge the gap of economic data. They have showed for the first time that the management of congestive heart failure by telemonitoring is cost-saving. The cost-savings were linearly related to the implementation rate of remote patient monitoring, due to the savings in hospitalizations. They believe that “the scientific community should acknowledge the lack of prospectively and uniformly collected economic data and should request new studies incorporating full economic analyses.” Inglis et al.[58] have found comprehensive evidence, in their systematic review of the outcomes of structured telephone support or telemonitoring, that telehealth interventions are effective and cost-effective in CHF management. Out of twenty-five studies, eleven studies reported the effect of the intervention on the cost of care, and all but three reported on reduced costs.

The cost and cost-effectiveness of telehealth is becoming increasingly important in policy-making and reimbursement schemes.[59] It seems historically neglected within this field, but cost-effectiveness will play a critical role in implementation of future services and technologies. Telehealth in fact contains a promise to tackle the rising costs in healthcare, but its own cost is not fully apprehended. If proved cost-effective, it is very likely that telehealth will be more readily adopted and utilized.

The aim of our research is to assess the methodological quality and results of economic evaluations of telehealth for patients with chronic heart failure and to provide guidance in devising a full economic analysis in telehealth.

Theoretical considerations

A full economic evaluation must include both inputs and outputs, usually called costs and consequences.[38] If only costs, or only consequences, are examined the study is referred to as a partial evaluation. Considering at least two alternative solutions is perceived important as it allows others to “a) judge the applicability of the programme to their own settings, b) understand if any cost or consequence has been omitted from the analysis, c) potentially replicate the study”.[38] A full economic analysis thus presents choices between two or more competing alternatives, in our case costs and consequences of usual care and a telehealth intervention. One can argue that when the effectiveness is equal for alternatives it is sufficient to focus on differences in costs and to perform a so-called 'cost-minimization analysis'.

Cost analyses can be found in the literature. They deal with resources used to deliver the intervention and evaluate the costs of opportunities lost (the value of the best alternative forgone by the investment), although these cannot be considered a full economic evaluation. The most common full economic evaluations in telehealth are cost-effectiveness analysis and cost-benefit analysis.[60] Cost-effectiveness analysis compares monetary investments of at least two interventions and a common nonmonetary outcome (e.g. life-years gained, hospital days prevented, clinical parameters). Cost-benefit analysis is the most comprehensive economic evaluation as it compares economic cost with monetized economic benefits. It aims at analyzing if the intervention is economically justified and better than the competing alternative.[38]

Telehealth is seen as an innovative way of health services delivery, which can empower chronically ill patients in an outpatient setting. Telehealth entitles a broad set of telecommunication solutions which allow for health related activities between parties involved and over a distance. It is the field that includes all other sub-fields, interchangeably named in the scientific literature as telemedicine, telecare and telemonitoring. The World Health Organization[61] provides the mainstream definition of telemedicine as

> "the delivery of healthcare service, where distance is a critical factor, by all healthcare professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of healthcare providers, all in the interest of advancing the health of individuals and their communities."

Chronic Heart Failure (CHF) is a deterioration of pumping function of the heart accompanied by typical signs or symptoms, such as shortness of breath or fatigue. Chronic Heart Failure is a severe disease that has 3-year mortality rate of approximately 60%.[20] After a person is admitted to a hospital with CHF, there is a one in four chance of patient's re-hospitalization or death within 12 weeks.[21] One of the causes for the re-hospitalization of CHF patients is worsening of the disease as a result of nonadherence to treatment. The "usual care" for CHF abides to the international and national guidelines.

METHODS

Retrieval of studies and data extraction

We searched for key papers published in English since 1999, presenting economic data in telehealth trials for CHF. We considered the time frame of 12 years to be optimal, as "the interest in telemedicine increased dramatically in the 1990s", followed by an increased interest in economic evaluation of medical technologies from newly created National Institute for Health and Clinical Excellence (NICE) in the United Kingdom in 1999.[62] We have not distinguished between different types of telehealth interventions, because we did not know in advance which properties of telehealth contribute the most to the cost-effectiveness and overall success.[63]

We used The Scientific & Technical Information Network (STN), a database from FIZ Karlsruhe and Chemical Abstracts Service, Columbus/Ohio,[64] which provides access to an integrated network of the most important and comprehensive scientific databases, including MEDLINE, EMBASE, and WOK. The subject of our search had three topics: chronic heart failure, cost and telehealth. For each of the three topics, we defined the queries (with similar keywords) and combined them in a final query (Table 4).

Table 4. Detailed query list for the literature search.

General Search Strategy

The subject of our search had three topics: chronic heart failure, cost & telehealth:

A. chronic heart failure: "CHRONIC HEART FAILURE" OR "CHRONIC HEART DISEASES"
B. cost: (COST OR COSTS) (P) (HOSPITAL? OR HEALTH? OR CARE OR READMISSION?)
C. telehealth: TELEPHONE OR TELEMEDICINE OR TELEHEALTH OR TELEMETRY

The operators we used here were “string”, (sub queries), boolean OR, (P:in same paragraph as) and “?” for zero to any number of characters. We learned not to use “cost?” and “tele?” because in the MeSH of MEDLINE there are over 600 terms starting with “tele” and telephone is not within the first 600. So we only used the most-used terms. In certain thesauri, like the MeSH from MEDLINE, these topics (A, B and C) are merged with subheadings, like “economics”. We did find several relevant papers having one of the following terms/subheading which would not have been found with plain keyword searching only:

D. heart failure/economics OR heart diseases/economics
E. telemedicine/economics OR self care/economics OR telemetry/economics

Our final query was: ((A and B) or D) AND ((B AND C) OR E)

Specific Search in Medline

We analyzed relevant results of the general search strategy in different databases, and adopted a more focused search for Medline with only Medical Subject Headings. When we used the combination of several MeSH we found 113 results. This was the query:

- ("Cost-Benefit Analysis"[mesh] or "Heart Failure/economics"[mesh] or "Telemedicine/economics"[mesh] or "Costs and Cost Analysis"[mesh])

AND

- ("telemedicine"[mesh] or "telephone"[mesh] or "home care services"[mesh] or "telemetry"[mesh] or "remote consultation"[mesh])

AND

- "heart failure"[mesh]

Papers were selected based on title and abstracts reading (double reading by A.G. and J.S. and mediation by H.V. in case of a disagreement). The abstract/title exclusion criteria were: a) telehealth not as the main intervention, b) heart failure not the main disease, c) full economic analysis not present, and d) not a primary study (i.e. review, letter to the editor, opinion, commentary). References of the retrieved papers (J.v.N.) were checked (“snowballed”) to certify if all relevant articles have been selected.

Full papers were scrutinized (A.G.) using data extraction form based on a modified Cochrane Collaboration Summary Table[65]. We supplemented the extraction form with an entry on ‘frequency of contact’ as this is of interest to the economic evaluation for the purpose of costing.

Data was mined in accordance to the recommendations from the Cochrane Collaboration and summarized on all important domains: source/disease, methods, participants, intervention, outcomes and results/costs.[65] We divided the outcomes in three categories: usage related (admission rate/hospitalization, readmissions, length of stay, ER visits, service utilization, etc.), patient related (quality of life, satisfaction of care, mortality, depression, etc.) and cost related (intervention costs, total costs, hospitalization charges, cost of personnel, etc.) outcomes. Both the summary of the studies and the data mining are available at request.

Data-analysis: appraisal of economic evaluation

We collected data on two proxies of the quality of the study design: concerns about bias and participants blinding. For this we followed the instructions from the Cochrane Handbook for Systematic Reviews of Interventions.[65] The Handbook presents the tool for assessing the bias in reviews which encompasses six domains: adequate sequence generation, allocation concealment, blinding of participants, addressing incomplete outcome data, selective reporting, and other sources of bias. The tool recognizes ‘low’, ‘high’ and ‘unclear’ risk of bias. If one of the domains was marked with ‘unclear risk’, the whole study was deemed ‘risk unclear’.

To assess the validity of the economic evaluation, the methodological quality of each paper was assessed according to the 10-item-checklist from Drummond et al.[38] Quality check of the assessment (J.S.) was performed on a random sample of five papers with an overlap of 85 percent with the first author (A.G.).

RESULTS

Search strategy

Our search strategy identified 301 publications in total. After abstract assessment phase, 190 papers were excluded. Twenty-seven papers called for the selection mediation after full text reading. In total we included thirty-two articles in our analysis. Three of those articles by Riegel et al.[66–68] described the same intervention and two papers by Wootton et al.[69,70] described similar intervention in two consecutive years. Thus, we were able to retrieve thirty-two papers on twenty-nine interventions. The findings from the search process and the exclusion criteria are listed in Figure 2.

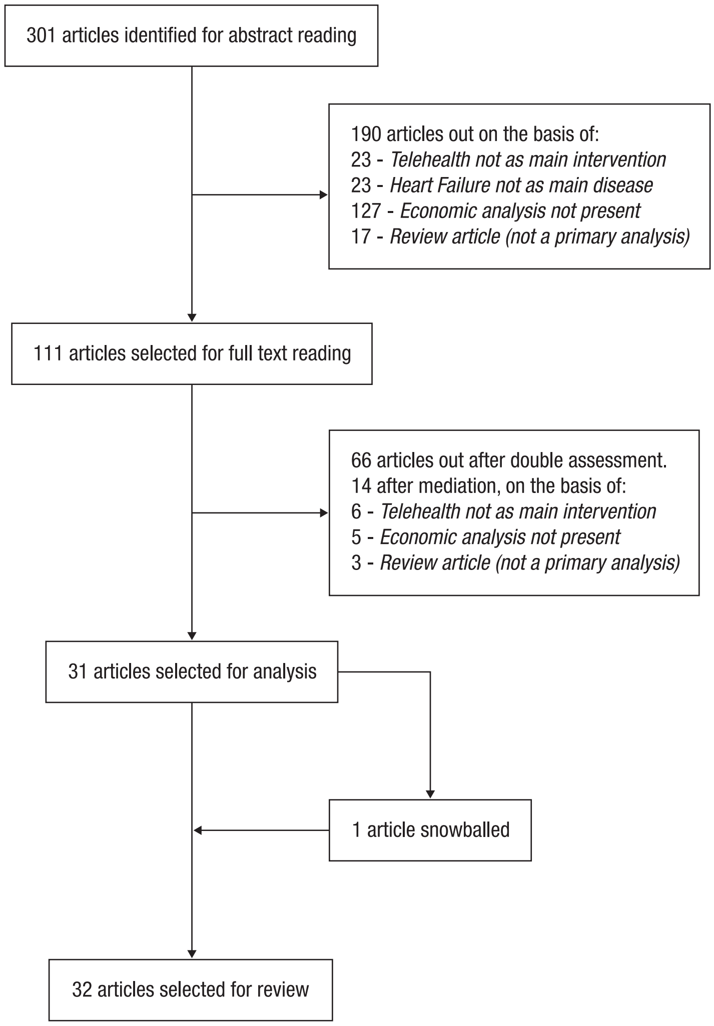

Figure 2. The search process and exclusion criteria.

We have retrieved twenty-six papers dealing with chronic heart failure only, and six more[70–75] dealing with CHF and co-morbidities. The study that dealt with the most chronic diseases was by Johnston et al.[72] who reported on CHF, chronic obstructive pulmonary disease, cerebral vascular accident, cancer, diabetes, anxiety, and chronic wound care.

Description of the studies: design, participants and interventions

Design

Regarding the design, twenty-one papers reported on the RCT design and two on quasi-experimental design.[72,76] One paper each reported on the evaluation of RCT,[70] a stratified randomization design,[75] concurrent matched-cohort,[77] nonconcurrent prospective design,[78] prospective cohort study,[79] cost-effectiveness analysis conducted alongside a randomized trial,[80] pre-post study,[81] matching of the retrospective control data with the observed intervention data,[82] and a prospective study.[83]

Participants

Twenty-five articles originated from the United States, two from Australia,[69,70] two from Italy,[84,85] one from the United Kingdom,[86] one from China,[78] and one from Taiwan.[83] Almost all of the studies were published after the year 2000 except for one.[79] In most of the studies the mean age of participants was more than 60 years, except in nine.[70,75,80,81,83–85,87,88] In terms of sex, all studies had mixed populations, where percentage of females ranged just above 1%, in a study done by the US Department of Veterans Affairs,[87] to 63%.[54] All of the studies explicitly stated the home (outpatient) setting except for one.[69]

Interventions

Fifteen studies described a telephone case management, seven a combination of telephone case management and telemonitoring,[54,73,76,81,84,85,89] and another seven described only telemonitoring intervention.[79,82,86,90–93] Three studies reported on video visits: one on bare video conferencing,[71] one on video visits accompanied with telephone 'visits',[94] and one on video system that included peripheral equipment for assessing cardiopulmonary status in combination with in-person and telephone contact.[72] Of all the papers, only two reported on two distinct intervention arms. Finkelstein et al.[71] had two intervention groups, first receiving video visits and the second monitoring equipment. Smith et al.[89] reported on a two-arm intervention in addition to the comparison group. Subjects in the intervention arm were assigned a disease manager, a registered nurse who performed patient education and medication management with the patient's primary care provider, while subjects in the augmented disease management group received in-home devices for enhanced self-monitoring.

In most studies a specialized nurse case management and nurse contact was reported (others reported on use of disease managers and physicians). In all studies, the telehealth intervention also included some form of health education. In most cases a nurse specialist supervised automatic patient data transmission by means of telemonitoring devices and provided telephone support and education. Majority of studies provided a detailed description of the content of the intervention. Four studies did not provide details of the comparison group,[75,83,87,93] where the rest was mostly the usual care for chronic heart failure patients. Seven studies provided details on the usual care group, receiving traditional home healthcare for a similar time period. Capomolla et al.[95], in their study, compared home monitoring to 'usual care' (i.e. referring a patient to a community primary care physician and cardiologist at the discharge). During the follow-up period patients were managed by different providers applying a range of strategies: emergency room management, hospital admissions, and outpatients access.

The frequency of contact ranged from once per day, up to once per quarter. Six studies reported daily interaction,[76,81,82,86,91,93] five intermittent interactions,[66–68,72,74] five reported a median of five interactions,[75,77,83,85,87] four weekly interactions, [79,84,88,96] and two studies weekly interactions spreading to monthly.[90,97] One study each reported on a two times per week interaction,[71] three times per week and decreasing,[54] biweekly,[78] and quarterly contact.[80] Six studies did not specify the frequency of contact.[69,70,73,89,92,94] The length of intervention was 2, 3, 6, 12, and 18 months predominantly. One study[87] reported on a 1-year preintervention data collection period and a 1-year intervention and follow-up period (totaling to 24 months), one on 17 months in total,[72] one on 11 months period,[83] and one ranging from 11 days to 10.9 months.[79]

Methodological quality and bias of design

Regarding the bias, sixteen studies did not report any concern, fourteen provided caveats and two were explicit about no concerns at all.[83,88] This finding called for meticulous exploration of the possible induced bias. In the summary assessment (across domains) we ascertained unclear risk of bias for the grand majority of the papers, 24 of them, low risk of bias for seven studies, and high risk of bias for one study by Finkelstein et al.[71]. Results are summarized in the Supplementary Table 1, which can be viewed online at https://doi.org/10.1017/S0266462313000779

Twenty studies did not provide information on blinding, six studies reported on blinding procedure,[69,70,80,86,88,97] three explicitly said no blinding was attempted,[73,74,96] and three studies reported on partial blinding.[67,68,92] Soran et al.[92] confirm that "because of the nature of the intervention, both patients and the primary research teams could not be blinded… [which] might have introduced bias into the trial". To address the issue of bias by the study design, authors blinded the staff to group assignments and the adjudication of events was carried out by an independent committee.

Regarding the methodological quality of the studies, our analysis show that the major deficiencies were in identifying relevant costs and consequences for each alternative (71.9 percent of the studies), lack of incremental analysis (78.1%) and issues regarding the uncertainty of the analysis (93.7%). The overview is presented in the following table:

Table 5. Overview of the methodological quality of the studies.

Methodological quality check list* Question	Number (%) of studies			
	Yes	No	Can't tell	N.A.
1. Was a well-defined question posed in answerable form?	23 (72)	6	3	0
2. Was a comprehensive description of the competing alternatives given?	30 (94)	1	1	0
3. Was the effectiveness of the programmes or services established?	28 (87)	0	4	0
4. Were all the important and relevant costs and consequences for each alternative identified?	2	23 (72)	7	0
5. Were costs and consequences measured accurately in appropriate physical units?	29 (91)	0	3	0
6. Were costs and consequences valued credibly?	3	3	26 (81)	0
7. Were costs and consequences adjusted for differential timing?	2	5	0	25 (78)
8. Was an incremental analysis of costs and consequences of alternatives performed?	7	25 (78)	0	0
9. Was allowance made for uncertainty in the estimates of costs and consequences?	2	30 (94)	0	0
10. Did the presentation and discussion of study results include all issues of concern to users?	10	21 (66)	0	0

Derived from Drummond et al.[38]

Limitations

Davalos et al.[60] suggested that there are many limitations to performing an economic evaluation in telehealth. We used their research to address the reported issues in our batch of retrieved publications. The authors of the reviewed studies have listed following as the main challenges: limited generalizability,[75,80,84,87–89] disparate estimation methods,[90] few completed cost-benefit analysis,[70,73,74,84,87,94] lack of randomization,[75,78,79,81,83,87,97] lack of long-term evaluation studies,[73,78,80,81,83,86,89] absence of quality data and appropriate measures,[69,76,79,84,86,89–92,96] and small sample sizes.[54,71,73,81,86,88]

Valuation of costs and consequences

The majority of the studies were RCTs where the researchers considered the comparison of two alternatives. Although some questions were not well specified, they solicited the answer to whom the intervention was effective and in comparison to what. Thus more than 70% of the studies posed a well-defined question in an answerable form. However, most of them did not consider the 'ripple effect' when stating their viewpoint of the analysis, and the (potentially) far reaching consequences to society were not considered.

In 87.5% of the studies, the effectiveness of the intervention was established. In other words, a telehealth intervention indeed brought improvement in outcomes of chronic disease management. Almost every study provided a comprehensive description of the competing alternatives but none considered the 'do-nothing' alternative.

More than 70% of the studies did not take into account expenses in one of the following categories: healthcare sector, other sectors, patient/family expenses or productivity losses. As a positive example, Wennberg et al.[75] estimated the total cost and not just the marginal cost. They included salaries and benefits, training expenses, amortized capital expenditures, data and coaching operations, fulfilment, and overhead. The same study provides an exhaustive list of resources used and costs according to each cohort group. However, they did not provide an explanation of the allocation of shared costs (overhead) to services or programs, which is a common omission in economic evaluations. None of the studies analyzed a shift of costs, from specialist to heart failure nurse to general practitioner, for instance.

The biggest problem we encountered in this overview is with the valuation of costs and consequences. In more than 80% of the studies the sources and methods of the evaluation were not clear. Authors mostly focused on direct costs and benefits (i.e. resources in the healthcare sector) while omitting indirect costs (i.e. productivity gains and losses) and intangible costs (consequences that are hard to value, like relief from pain, lost leisure time for patient or family, etc.). The sources of all values could potentially include market values, patient, policy-makers' or health professionals' perspectives. However, most of the studies did not provide necessary viewpoint of the analysis. In addition, the market values were not used for resources gained or depleted, or there is no account of this being performed. Principally, the costs that were missing across majority of the studies are those of the intervention overheads, training of personnel, and patient related costs (travel, productivity loss, etc.).

In 78% of the studies adjustment for differential timing was not applicable due to the time horizon shorter than one year. In the remaining studies however, the costs and consequences were not adjusted for differential timing. For instance, Smith et al.[89] run the intervention for eighteen months but did not discount the costs in respect to the elected time horizon.
In 78% of the studies the incremental analysis was not the basis of the evaluation. From the ones that did perform an incremental analysis, Hebert et al.[80] provided the best methodological clarity. In the same study, which ranked the highest in our methodological quality assessment, the allowance for uncertainty in the estimates of costs and consequences was made.

On the account if study results included all issues of concern to users, our sample was overly negative (65.6%). The conclusions of the studies were rarely based on some index or ratio of costs to consequences. There was barely a discussion on generalizability of the results and usefulness for the reader. The implementation issues, such as the feasibility of adopting the preferred program (given existing financial or other constraints) and whether any freed resources could be redeployed to other worthwhile programs, were seldom discussed.

We tried to explore the two dimensions of interest for cost-effectiveness of telehealth: costs and effects in terms of patient outcome. Presented in the cost-effectiveness plane, introduced by Black[98], the cost-effective intervention sits in the south-east quadrant and is called "dominant". Results of our review suggest that nineteen authors, out of thirty-two, reported on a dominant intervention (saved costs with increased effectiveness). Eight authors reported same costs and equal effectiveness and three incurred costs with equal effectiveness. One author reported on an intervention with same costs and increased effectiveness,[90] and one on incurred costs but increased effectiveness.[89] The overview is presented in the following table:

Table 6. Reported costs and effects.

Author	Costs reported	Cost change	Effects reported	Effect type
Benatar et al.[54]	*"..while reducing the cost of care"*	saved	*"..significantly improves HF management"*	increased
Berg et al.[77]	*"..intervention group had 10% lower costs"*	saved	*"..significantly reduced hospitalizations, emergency department visits, and SNF days"*	increased
Chen et al.[78]	*"..provide cost-savings"*	saved	*"..improve the clinical outcome"*	increased
Finkelstein et al.[71]	*"..at lower cost"*	saved	*"..improve patient outcome"*	increased
Giordano et al.[84]	*"Mean cost for hospital readmission was significantly lower in HBT group"*	saved	*"HBT programme reduce hospital readmissions"*	increased
Hebert et al.[80]	*"..the nurse-led disease management program was a reasonably cost-effective way to reduce the burden of heart failure in this community."*	saved	*"..a reasonably cost-effective"*	increased
Heidenreich et al.[79]	*"..medical claims per year decreased"*	saved	*"..reduce resource use"*	increased
Ho et al.[83]	*"..the cost was reduced"*	saved	*"..decreasing adverse outcomes, most notably hospitalization and length of stay"*	increased
Hudson et al.[81]	*"..significant reductions in per member per month"*	saved	*"..reductions in per member per month emergency room and hospital utilization."*	increased
Jerant et al.[94]	*"Substantial reductions in cost of care"*	saved	*"Substantial reductions in hospital readmissions, emergency visits"*	increased
Johnston et al.[72]	*"..have the potential for cost savings"*	saved	*"Remote video technology in the home health care setting was shown to be effective"*	increased
Myers et al.[76]	*"The cost savings of the telemonitor group was estimated to be $189.92 per patient"*	saved	*"The chief finding of this study is that statistically significantly fewer home nursing visits to classes III and IV patients with CHF are needed"*	increased
Noel et al.[73]	*"..healthcare costs decreased by 58% for the telehealth group"*	saved	*"Integrating home telehealth with the healthcare institution's electronic database significantly reduces resource use"*	increased
Riegel et al.[67]	*"The reduction in costs"*	saved	*"The reduction in hospitalization"*	increased
Riegel et al.[66]	*"The cost of inpatient care was more than $US1000 (2000 values) less"*	saved	*"The results of this study suggest that Hispanic patients with HF are receptive of, and responsive to, a case management intervention"*	increased
Scalvini et al.[85]	*"..there were substantial reductions in costs of care"*	saved	*"..there were substantial reductions in hospital readmissions"*	increased
Tompkins et al.[93]	*"..total cost was 12 percent lower in the intervention group"*	saved	*"The main finding was a tendency for lower total number of hospital days"*	increased
Vaccaro et al.[82]	*"Costs for hospitalizations and ER visits were reduced by 50.6%"*	saved	*"The program effectively reduced inpatient hospitalizations by 49.6%"*	increased
Wennberg et al.[75]	*"A targeted telephone care-management program was successful in reducing medical costs"*	saved	*"A targeted telephone care-management program was successful in reducing ... hospitalizations"*	increased

Galbreath et al.[90]	*"..it conferred no cost savings"*	same	*"..resulted in a significant survival benefit"*	increased
Dunagan et al.[88]	*"The number of admissions, hospital days, and hospital costs were significantly lower during the first 6 months after intervention but not at 1 year."*	same	*"Our intervention had little effect on functional status"*	equal
Kasper et al.[97]	*"..at a similar cost"*	same	*"There was no significant difference in resource use between the two groups"*	equal
Laramee et al.[96]	*"The intervention did not increase costs"*	same	*"..no significant differences were found in outpatient and inpatient resource utilization"*	equal
Peikes et al.[74]	*"None of the 15 programs generated net savings"*	same	*"Programs with substantial inperson contact that target moderate to severe patients can be cost-neutral and improve some aspects of care."*	equal
Riegel et al.[68]	*"No significant group differences were found"*	same	*"No significant group differences were found"*	equal
Schwartz et al.[91]	*"Telemonitoring by EHM did not reduce cost of care"*	same	*"There was no difference in hospital readmission"*	equal
Wootton et al.[69]	*"There were no significant differences in costs of care"*	same	*"Nor were there significant differences between the intervention and control groups in QOL measurements"*	equal
Wootton et al.[70]	*"There were no significant differences in total costs of care"*	same	*"Benefits from care coordination programmes may take some time to emerge."*	equal
Smith et al.[89]	*"The intervention was costly to implement"*	incurred	*"The intervention was effective"*	increased
Copeland et al.[87]	*The CHF-related costs were higher for the intervention group*	incurred	*"..no differences in clinical outcomes"*	equal
Dar et al.[86]	*"..at little additional cost"*	incurred	*"..produces a similar outcome to usual' specialist care "*	equal
Soran et al.[92]	*"We found that overall medical costs of medicare patients were significantly higher for patients who were randomized to the HFMS argm"*	incurred	*"Our study results suggest that enhanced patient education and follow-up is as successful as a sophisticated home monitoring device"*	equal

Note: arranged by cost change and effect (alphabetically within groups)

DISCUSSION

We presented a review of thirty-two studies reporting on cost-effectiveness of telehealth in chronic disease management of heart failure patients. The studies suggest that telehealth is cost-effective for management of CHF patients. Nineteen studies reported on cost savings, nine on costs being the same during and after the intervention and four on incurred costs. Majority of the retrieved studies (21 of 32) reported on improved outcomes after the intervention, thus supporting the hypothesis that telehealth is more effective than the usual chronic disease management care - and saves costs. However, we performed a qualitative evaluation of the outcomes without analyzing the magnitude of the effects, or costs incurred. The interventions and outcomes in these reviews were diverse and sometimes incomparable. The economic aspect of telehealth was present in all of the studies, but in different forms. The methodological quality was considered to be low.

The results are consistent with other reviews and meta-analysis. Inglis et al.[58] performed a systematic review and found three out of eleven studies reporting on reduction in costs with application of telemonitoring and telephone contact in CHF, while Klersy et al.[57] showed in a meta-analysis of 21 RCTs that management of

CHF patients by telemonitoring is cost saving, mainly because of reduction in number of hospitalizations. They have, in the same light as we, expressed some concerns due to great variety in reviewed studies.

Limitations of the study

Our review has some limitations. First, in respect to assessing the abstracts and full texts we used a double-reading technique and solved disputes by inviting third author to mediate. In the methodological assessment phase, we decided that the main author should assess all of the articles and the second author should assess the random sample of five studies. The overlap of 85% or more was deemed as unbiased. Second, data mining, extraction, and analysis was performed by the main author only and could potentially be flawed. Much of it is subjective and qualitative, and the repeatability debatable. Third limitation is in presenting an overview of the results in absolute rather than relative terms. We sought for a report in change in costs and effects but did not look into the size of the effect. This could potentially bias our judgment as even a slightest improvement in cost-effectiveness was deemed as an “improvement”.

CONCLUSION

Although almost 60% of the reviewed studies showed that telehealth interventions for CHF patients are cost-effective, based on the analysis of the seven studies with low risk of bias, we believe that cost-effectiveness of telehealth in CHF is not ascertained: four studies reported same costs with equal effectiveness,[68,74,88,97] two incurred costs with equal effectiveness,[86,92] and only one on saved costs with increased effectiveness.[67] Thus, we have reached three conclusions.

First, the evidence from the scientific literature is scarce and thus insufficient for our understanding of the economic aspect of implementing telehealth services. More full economic analyses are needed to reach a sound conclusion.

Second, the quality of evidence in the scientific literature is poor. We sought for studies of decent methodological quality to attain unbiased conclusions. To our surprise we were able to retrieve only a handful of papers that could withstand rigorous methodological check.

Third, there is a difficulty in capturing all of the consequences/effects of telehealth intervention. Thus the cost-effectiveness evidence for specific implementations in the field of telehealth is limited. As suggested by some authors,[60] problems with telehealth interventions reside in absence of quality data and appropriate measures. The quality of economic data is especially questionable.

POLICY IMPLICATIONS

We cannot conclude whether telehealth interventions in CHF are cost-effective or cost-ineffective: papers are heterogeneous and of poor methodological quality. Still, there is a political need for strong evidence. A possible short-time solution is to get evidence based on cost-consequence principles. The cost-effectiveness framework for telehealth needs valid cost-effectiveness modelling to assess the full long-term impact of telehealth interventions.

Chapter 3

Cost-Effectiveness Analysis in Telehealth: A Comparison Between Home Telemonitoring, Nurse Telephone Support and Usual Care in Chronic Heart Failure Management

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ABSTRACT

Objectives: To assess the cost-effectiveness of home telemonitoring (HTM) and nurse telephone support (NTS) in comparison to usual care (UC), in management of chronic heart failure (CHF) patients, from a third-party payer's perspective.

Methods: We developed a Markov model with a 20-year time horizon to analyze the cost effectiveness using the original study (Trans-European Network-Home-Care Management System) and various data sources. A probabilistic sensitivity analysis was performed to assess the decision uncertainty in our model.

Results: In the original scenario (which concerned the cost inputs at the time of the original study), HTM and NTS interventions yielded a difference in quality-adjusted life-years (QALYs) gained compared with UC: 2.93 and 3.07, respectively, versus 1.91. An incremental net monetary benefit analysis showed €7,697 and €13,589 in HTM and NTS versus UC at willingness-to-pay (WTP) threshold of €20,000, and €69,100 and €83,100 at a WTP of €80,000, respectively. The incremental cost-effectiveness ratios were €12,479 for HTM versus UC and €8,270 for NTS versus UC. The current scenario (including telenurse cost inputs in NTS) yielded results that were slightly different from those for the original scenario, when comparing all New York Heart Association (NYHA) classes of severity. NTS dominated HTM, compared with UC, in all NYHA classes except NYHA IV.

Conclusion: This modeling study demonstrated that HTM and NTS are viable solutions to support patients with chronic heart failure. NTS is cost-effective in comparison with UC at WTP of € 9000/QALY or higher. Like NTS, HTM improves the survival of patients in all NYHA classes and is cost-effective in comparison with UC at a WTP of € 14,000/QALY or higher.

INTRODUCTION

Cardio vascular disease (CVD) is the number one cause of death in the world – in 2012 17.5 million people died from CVD, representing 31% of all global deaths.[99] Age-related changes in the cardiovascular system – particularly hypertension, coronary artery disease, and valvular heart disease – result in a high prevalence of heart failure.[100] As a result, chronic heart failure (CHF) is becoming an increasing problem globally, imposing "direct costs to healthcare systems and indirect costs on society through morbidity, unpaid care costs, premature mortality and lost productivity".[101]

In the European Union (EU), the rate of mortality from CVD has been declining since the early 1980s, but recently deaths caused by CVD have plateaued in 15 countries.[102] CVD causes 1.9 million deaths in the EU and is estimated to cost the EU economy almost €196 billion a year.[103] Out of the total cost of CVD in the EU, about 54% is accounted for by direct healthcare costs, 24% by productivity losses, and 22% by informal care.[103]

People live longer in the EU,[104] and although mortality from CVD is in decline, there will be an increasing number of patients with heart disease in the future, and this will place a significant burden on the healthcare systems.[105] The use of information communication technologies in the provision of care for patients with heart disease could prove to be a useful strategy for tackling this problem. It is believed that successful management of patients with CHF is dependent on telemonitoring, adherence to treatment, provision of guidelines, and daily communication with patients.[5,106] There have been a number of studies on the clinical effectiveness of telemonitoring systems,[107,108] but few full analyses of the cost-effectiveness of telemonitoring systems for patients with CHF.[109,110]

The biggest telemonitoring trial to date – the Whole System Demonstrator (WSD) – aimed to "examine the costs and cost-effectiveness of telehealth in addition to standard support and treatment, compared with standard support and treatment" in heart failure in the United Kingdom.[109] Participants received telehealth equipment and a monitoring service for 12 months, whereas the control group received usual care (UC) and social care. The authors found that telehealth is associated with lower mortality and reduced emergency admission rates,[56] but "the QALY gain by patients using telehealth in addition to usual care was similar to that for patients receiving usual care only, and total costs associated with the telehealth intervention were higher".[109]

The Trans-European Network-Home-Care Management System (TEN-HMS), another study from the United Kingdom, the Netherlands, and Germany, found the "number of admissions and mortality similar among patients assigned to home telemonitoring (HTM) or nurse telephone support (NTS), but the mean duration of hospital admissions reduced by 6 days (95% confidence interval 1 to 11) with HTM".[5] The interventions were similar to the WSD: HTM consisted of twice-daily patient self-measurement of weight, blood pressure, and heart rate and rhythm with automated devices linked to a cardiology center; NTS consisted of specialist nurses being available to patients by telephone; and UC consisted of care delivered by primary care physicians.[5] Patients assigned to receive UC had "higher one-year mortality (45%) than patients assigned to receive NTS (27%) or HTM (29%) ($p = 0.032$)".[5]

Both the WSD and TEN-HMS trial used versions of a Philips telemonitoring system. The aim of this study was to provide insights into the cost-effectiveness of a telehealth (i.e. telemonitoring) system in the Netherlands. We were interested in knowing whether HTM and NTS are cost-effective strategies in the management of CHF, compared with UC, and whether there is a subgroup of patients with CHF who can benefit the most from telemonitoring.

METHODS

We developed a Markov cohort model to analyze the cost-effectiveness of HTM and NTS for managing patients with CHF, compared with UC. We secured access to original data from the TEN-HMS study. Modeling was necessary for two reasons: 1) the original trial used a short follow-up interval of 240 to 450 days, and so there was a need to extrapolate beyond the endpoints of the trial because CHF is a chronic condition, and 2) the intervention is expected to have an effect on the costs and quality-adjusted life-years (QALYs) after the trial.[111] Besides the TEN-HMS, we concentrated on clinical results and it was necessary to include Dutch healthcare costs to study the cost-effectiveness.

Framing the model

Target population

In this modelling study we deal with a hypothetical cohort of 1000 people with CHF aged 70 years and older, in all New York Heart Association (NYHA) classes of severity.[18] Our chosen population reflects the TEN-HMS database population, that is, patients with CHF older than 70 years of age, of both sexes, and in all four NYHA stages. In the clinical trial, random permuted blocks for each hospital were used to allocate 426 patients to treatment groups by an independent statistical group (Institute for Medical Informatics and Biostatistics, Basel, Switzerland). Patients were assigned randomly to HTM, NTS, and UC in a 2:2:1 ratio. The TEN-HMS study included patients who had recently been admitted to a hospital with worsening heart failure (left ventricular ejection fraction <40%), and we used the characteristic of that population to model our own. A detailed description and the results of the TEN-HMS trial are published elsewhere.[5]

Setting and location

Our model reflects the healthcare situation in the Netherlands, because we were using the EuroQoL five-dimensions questionnaire (EQ5D) weights and costs from the Netherlands.

Study perspective

Because in the Netherlands it is probably the healthcare insurers who will decide on the availability of monitoring support to patients with CHF, in this study we performed the analysis on the basis of the third-party payer's perspective.

Comparators

We were interested in the cost-effectiveness of two interventions, compared with one comparator, in the management of CHF: HTM and NTS compared with UC. We give an outline of how each intervention is commonly delivered.

UC comprises a patient management plan[112] which, upon discharge from hospital, is usually sent by a nurse to the patient's primary care physician, who is asked to implement it. The protocol follows the clinical guidelines. Where the usual organization of care involves the titration of drugs by a specialist nurse, this is encouraged. The patient's status is usually evaluated at a clinic every four months to assess intervention history, symptoms and signs, renal function, and serum electrolytes.

NTS is managed as described for UC except that patients are contacted by telephone each month by a specialist heart failure nurse to assess their symptoms and current medication. The nurse can offer advice to the patient at this time and provide feedback to the primary care provider. Patients can contact the nurse by telephone at any time, either directly or by leaving a message on a telephone-answering machine. Nevertheless, in the event of an out-of-hours emergency, they are expected to contact their primary care doctor or the ambulance service.

Patients on HTM receive the telemonitoring equipment and written instructions on how to use it. A service engineer visits the patient's home to install the equipment, which usually consists of low-profile, electronic weighing scales, an automated sphygmomanometer, and a single-lead electrocardiogram using wrist-band electrodes. Each device contains a short-range radio transmitter that allows it to communicate automatically with a hub connected to the patient's conventional telephone line. The signal is sent automatically to a central web server and then via secure Intranet connections to a workstation at each clinical site. Data are encrypted during transmission to ensure patient confidentiality. Patients are asked to take a set of measurements every day before breakfast and before their evening meal, after emptying their bladder, while wearing light clothing, no shoes, and before taking their next dose of medication. The patient's weight, blood pressure, and heart rate and rhythm are therefore monitored twice daily.

Utilization data

Data gathered in the TEN-HMS study were used for the purposes of cost-effectiveness analysis. We were interested in healthcare resources utilization and tracked time-dependent (per 4 months) and time-independent (average) utilization of the following in each treatment arm: number of telephone calls with the telenurse, plus number of contacts with nurses, general practitioners, specialists, and hospitalists. We also mined and tracked time-dependent and time-independent number of emergency room visits and hospital days.

Time horizon

The time horizon in our model is 20 years. Given that in Framingham Heart Study the median survival after the onset of congestive heart failure, a possible etiology of CHF, was 1.7 years in men and 3.2 years in women,[113] and in view of the predefined age for our hypothetical population, we assume that 20 years is sufficient to analyze the benefits of the interventions, and it can be considered a lifetime horizon. We expect all the patients to be dead at the end of the time horizon, so as to be able to calculate all the life-years (LYs)/QALYs generated in a patient's lifetime.

Discount rate

The costs and effects were discounted by a 4% and 1.5% yearly rate, respectively, according to the Dutch guidelines for pharmacoeconomic evaluation.[114]

Outcomes of the model

The outcomes of the model are life expectancy, QALYs, and expected costs. QALYs are calculated by multiplying the duration of the period in which a patient remains in a health state by the utility values of the same state.[115] The cost per Markov cycle is calculated by multiplying the cost by the volume of services rendered during the period in which the patient remains in that health state and intervention arm (e.g. NYHA IV in HTM). By comparing the three interventions, incremental cost-effectiveness and net monetary benefits can be calculated for HTM versus UC, and for NTS versus UC (also HTM vs. NTS, although we are not interested in this outcome).

Structuring the model

Model and population type

Our modeling approach included a Markov decision model for a hypothetical cohort of 1000 patients in all three intervention arms (HTM, NTS, and UC). The cohort/population was constructed from the original (TEN-HMS) data on patients with CHF for the United Kingdom, the Netherlands, and Germany. We acted as if all those patients had been treated by the healthcare system in the Netherlands, by applying the EQ-5D weights and costs for the Netherlands. This was necessary because the TEN-HMS study was inadequately powered,[5] and if we were to exclude patients from other countries, we would miss the real effect of the interventions. The utility values were derived from the EQ-5D data[116] in the TEN-HMS database.

Model states

The patient enters the model in one of the four states, according to the initial distribution of patients at baseline in the TEN-HMS trial: 19.44% in NYHA I, 43.94% in NYHA II, 29.29% in NYHA III and 7.32% in NYHA IV. The cohort progresses through the states with the passage of time, that is, the progression of the disease. From each of the NYHA states, it is possible for a patient to move to any of the four NYHA states in the next cycle of four months. Death is possible from each of the NYHA states. We were not tracing events that move the patient from one state to another but just the movement between the NYHA states for each of the three strategies compared. The structure of the model is presented in Figure 3.

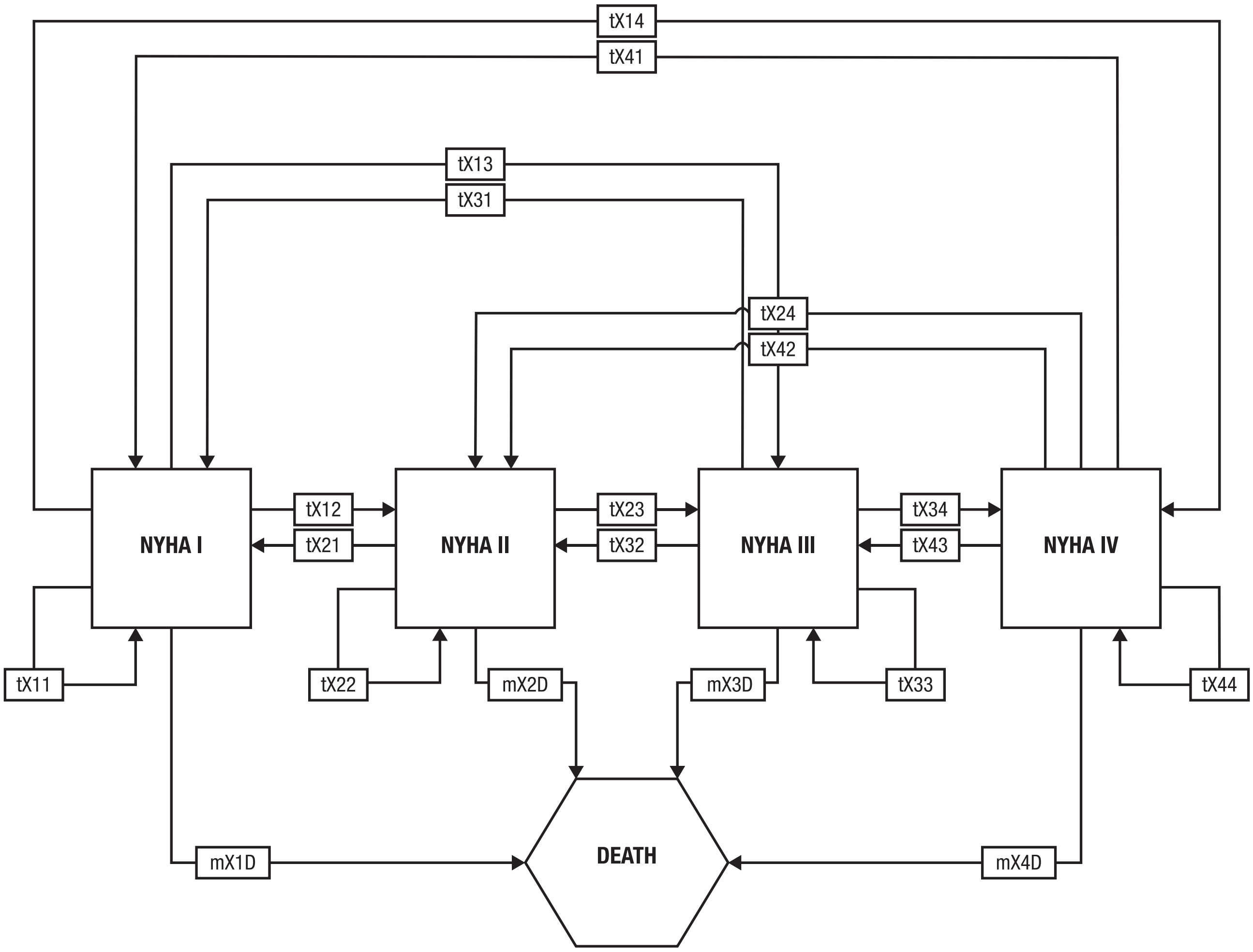

Figure 3. Diagrammatical representation of the model structure, where X is "H" in HTM, "N" in NTS, and "U" in UC. HTM, home telemonitoring; m, mortality; NTS, nurse telephone support; NYHA, New York Heart Association; t, transitional probability; UC, usual care.

Populating the model

Transition probabilities

The transition probabilities between Markov states, which represent patients moving between disease stages, have been constructed from the TEN-HMS database that we acquired from the manufacturer of the telehealth system. We excluded the patients for whom we could not trace the change of the NYHA class and were then left with 396 patients from the total of 426 that took part in the study.[5] The probabilities were constructed by dividing the number of patients who moved to an NYHA class by the total number of patients in an originating class. For instance, the transition probability from NYHA class I to NYHA class II in the HTM intervention arm (0.30159) was constructed by dividing the total number of patients who moved from NYHA class I to NYHA class II (38) by the total number of patients in NYHA I class (126). The transitions were time-independent, that is, not dependent on the time when they happened during the intervention. We assumed that the transition probabilities, which were measured in a limited timeframe of 240 to 450 days in the original study, will continue unaltered for 20 years. See Table 7 for the probabilities used in the deterministic analysis.

Table 7. Transition probabilities in the Markov model.

NYHA	HTM	NTS	UC
I-I	0.60317	0.60504	0.43478
I-II	0.30159	0.27731	0.34783
I-III	0.03968	0.07563	0.06522
I-IV	0.01587	0.02521	0.04348
I-D	0.03968	0.01681	0.10870
II-I	0.17672	0.15311	0.15663
II-II	0.54310	0.55024	0.50602
II-III	0.17241	0.17225	0.20482
II-IV	0.03448	0.03349	0.04819
II-D	0.07328	0.09091	0.08434
III-I	0.07767	0.12500	0.12308
III-II	0.37864	0.34375	0.21538
III-III	0.35922	0.38281	0.35385
III-IV	0.06796	0.07813	0.15385
III-D	0.11650	0.07031	0.15385
IV-I	0.10000	0.12500	0.11765
IV-II	0.10000	0.18750	0.23529
IV-III	0.43333	0.28125	0.35294
IV-IV	0.26667	0.21875	0.17647
IV-D	0.10000	0.18750	0.11765

Note: Stages in the model: I, II, III, and IV.
D, death; HTM, home telemonitoring; NTS, nurse telephone support; NYHA, New York Heart Association; UC, usual care.

Costs, currency, price date, and conversion

We used personnel- and hospital-related costs from the Dutch healthcare costing manual,[117] adjusted for the 2015 rates on the basis of the consumer price index.[118] Details of the cost of the telemonitoring system were acquired from the manufacturer and adjusted in accordance with the market research[119] for set-up, equipment, and service fee per month (see Table 8 for a detailed cost breakdown and Table 10 for treatment specific costs per Markov cycle). The hospitalization costs were assumed to be treatment-arm-independent, but NYHA-class-dependent. The price scenarios – original and current, together with the threshold analysis – were built into the model. No currency conversion was necessary because all costs were expressed in euros.

Table 8. Cost inputs to the Markov model in all three analyses (in euros).

	Original scenario	Contemporary scenario	Threshold analysis
Telemonitoring costs[119]			
Equipment & Service fee (per year)*	800-1500	800-1500	†
Instalment fee (every 5 years)‡	50-150	50-150	50-150
Personnel costs[117]			
Health care			
Nurse (per visit)	20	20	20
GP (per visit)	28	28	28
Specialist (per visit)	64	64	64
Hospitalist (per visit)	64	64	64
Telephone call (tele-visit)	14	14	14
Telehealth nurse (per year)	-	30,000	30,000
Non-healthcare			
Telenurse overhead (per year)	-	10,000	10,000
Hospital-related costs[117]			
Day in a hospital	435	435	435
ER visit	151	151	151

ER, emergency room; GP, general practitioner; HTM, home telemonitoring; NTS, nurse telephone support; UC, usual care.
* Consists of equipment manufacturer fee and medical service provider fee.
‡ Consists of shipment, installation, setup, and patient training fee.
† Varied until breakeven (threshold of the HTM dominance over both NTS and UC can be found in the Results section).

Measurement and valuation of preference-based outcomes

We used the utility values for each NYHA class, independently of the treatment arm, derived from the TEN-HMS database and constructed using the Dutch utility weights (see Table 9). We assumed that the utility values are connected to the severity of the disease, because they have been measured by the EQ-5D, and not the intervention, that is, the treatment arm.

Table 9. Treatment arm-independent and time-independent utility values of the Markov states.

NYHA	Mean	SE
I	0.87976	0.00827
II	0.71178	0.00944
III	0.61405	0.01349
IV	0.49228	0.03032

NYHA, New York Heart Association; SE, standard error.

Analyzing the model

Original scenario analysis

The original scenario considered the assumptions from the time of the TEN-HMS study (2000-2002). The transition probabilities and utilities were estimated from the original data. The costs of NTS in this scenario were blended with other costs, which we adapted for 2015. In our analysis the patients stayed in the intervention arm to which they were assigned; for example, patients in the HTM arm were not removed from telemonitoring if the disease was controlled or the severity reversed. The same applied to patients in the NTS and UC treatment arms. In other words, no crossovers were allowed from one treatment arm to another.

Current scenario and subgroup analyses

We ran a current scenario analysis for all NYHA classes, and three subgroup analyses based on NYHA classes II to IV. The current scenario is a cost scenario in which telehealth nurse costs are added in the NTS treatment arm. This better reflects the reality of a nurse-led heart failure management service today, where salaries with overhead costs and fringe benefits prove to be the largest cost components.[80] We kept the utilities treatment-independent (utilities are NYHA-class-dependent and not treatment-arm-dependent) and the transition probabilities consistent throughout all analyses. The difference between the original and the current scenario therefore lies in telenurse cost inputs (Table 8).

The subgroup analyses were combined with the original and the current scenarios to find information on the cost-effectiveness of HTM and NTS compared with UC in different stages of CHF severity (i.e. NYHA class). The subgroups were NYHA II to IV, NYHA III and IV, and NYHA IV only, where the cohort of 1000 patients was deployed according to the initial probability of group participation, adjusted for the number of NYHA classes. The baseline population distribution was 195 patients in NYHA I, 439 in NYHA II, 293 in NYHA III, and 73 in NYHA IV.

Threshold analysis

The threshold analysis was performed on the current scenario, keeping all the parameters from the scenario constant and varying the costs of telemonitoring in NYHA IV only. The telemonitoring setup costs were kept from the current scenario (deterministic €6.67/Markov cycle, probabilistic interval of €50-150/y, equipment lifetime 5 years, after which it is exchanged for the same fee), whereas equipment and service fees were varied until a minimum value for these costs was found that resulted in HTM having a greater probability of being cost-effective than NTS compared with UC.

Sensitivity analysis

We performed a probabilistic sensitivity analysis (PSA) to assess the decision uncertainty in our model.[120] Each parameter in the model was defined by the distribution according to the nature of the parameter. The polynomial transition probabilities were deconstructed in a Dirichlet matrix using a cumulative gamma function, because each draw was not independent. For the utilities, we used the beta function (which is bound from 0 to 1), and for the personnel- and hospital-related costs we used the gamma function (0 to infinity). The equipment and service fees, together with the installment fee, were parameterized by uniform function. We discerned the uncertainty not around the costs but around the volumes of care, and based it on the standard error.

For the PSA 2500 Monte-Carlo simulations were run, where a value for each parameter was drawn at random from the probability distribution of the model parameters (transition probabilities, costs, and utility values). This led to 2500 estimates in terms of expected costs, QALYs, and life expectancy for HTM, NTS, and UC separately. We plotted the results in a cost-effectiveness plane and LY plane (Figure 7). This procedure informed us of the “spread” of our scenarios and gave us a graphical representation of the uncertainty in our model. We then continued to the incremental analysis of each scenario, that is, the difference between the effects in relationship to the difference in costs, plotted again in the cost-effectiveness plane.

The results were then transferred into the net monetary benefit framework and subsequently converted into the probability of each intervention being cost-effective. Finally, cost-effectiveness acceptability curves were plotted in order to visualize which intervention is cost-effective at each willingness-to-pay (WTP) level: €0 to €80,000/QALY to reflect the healthcare realities in the Netherlands.[121] The model and the analyses were created in MS Excel 2013, whereas the data mining was performed by RStudio 3.0.2.

Assumptions

The main assumption of our cost-effectiveness analysis is that the original data from the TEN-HMS trial reflect the course of a CHF population depending on the intervention group to which a patient was randomly assigned. For instance, in our analysis the background mortality is included in the transition probabilities. In our model, after the first cycle, people can only die because of the probabilities that were estimated in 240 to 450 days of follow-up in the original study.

Also, the clinical trial was run in three European countries (the United Kingdom, the Netherlands, and Germany), although we are modeling for the Dutch decision-making context only.

Other assumptions concern the price of the telemonitoring equipment and the effectiveness of the telemonitoring service. Regarding the prices, in those 20 years of simulation they did not change in any treatment arm—not in HTM, NTS, or UC. This was a modeling assumption to make a 4-month cost contribution to Markov model constant. We based our analysis on the information found via the market research. The prices for the current scenario are based on the information received from the Centre for Telehealth (Hull, UK), where one telehealth nurse manages 200 to 400 patients with CHF.[122] We assumed that four such nurses would be able to deliver the necessary care for our fictitious cohort of 1000 patients in the current scenario and threshold analysis, but not in the original scenario, where they were not introduced. Costs were calculated per patient per Markov state in all three Markov chains.

Table 10. Treatment-specific costs (€) per Markov cycle (4 mo) for all interventions in all scenarios.

Scenario	HTM				NTS				UC			
	NYHA I	**NYHA II**	**NYHA III**	**NYHA IV**	**NYHA I**	**NYHA II**	**NYHA III**	**NYHA IV**	**NYHA I**	**NYHA II**	**NYHA III**	**NYHA IV**
Healthcare utilization												
Nurse	95	143	113	107	69	94	123	70	8	15	5	34
GP	41	48	56	35	42	50	45	60	1	8	3	15
Specialist	7	8	12	25	12	10	13	11	4	7	4	6
Hospitalist	13	10	11	3	15	22	20	17	3	4	1	0
Telephone call (tele-visit)	230	222	251	229	232	238	242	256	64	28	53	176
ER visit	3	5	11	29	6	5	17	27	22	9	13	16
Day in a hospital	954	1234	2500	2934	954	1234	2500	2934	954	1234	2500	2934
Sum*	1460	1815	3210	3652	1444	1797	3216	3668	1147	1418	2802	3455
Original												
Healthcare utilization plus												
Equipment & Service	383	383	383	383	Per cycle per person							
Instalment	7	7	7	7	Per cycle per person (equipment changed for the same fee every 5 y)							
Markov state value	1850	2205	3600	4042	1444	1797	3216	3668	1147	1418	2802	3455
Current												
Healthcare utilization plus												
Equipment & Service	383	383	383	383	Per cycle per person							
Instalment	7	7	7	7	Per cycle per person (equipment changed for the same fee every 5 y)							
Telenurse					53	53	53	53				
Markov state value	1850	2205	3600	4042	1498	1850	3269	3722	1147	1418	2802	3455

Note: The values are rounded to the nearest full number for easier interpretation.
ER, emergency room; GP, general practitioner; HTM, home telemonitoring; NTS, nurse telephone support; NYHA, New York Heart Association; UC, usual care.
*Sum of healthcare utilization costs is adjusted via the consumer price index from 2010 to 2015 prices[118]

RESULTS

Original scenario results

The results of the deterministic analysis of the original scenario show clearly, within the parameters of our model, that both HTM and NTS were cost-effective compared with UC. From a third-party payer's perspective, patients assigned to HTM and NTS incurred higher costs than those treated in UC, but also produced more QALYs (Table 11).

The PSA results show the costs incurred for HTM (€27,468; 95% confidence interval [CI] €19,759–€37,368), NTS (€24,430; 95% CI €17,302–€33,859), and UC (€14,822; 95% CI €9,604–€22,323). Both HTM and NTS yielded more QALYs and LYs compared with UC. The PSA results in HTM show 3.01 QALYs gained (95% CI 2.21–3.99), in NTS 3.15 QALYs gained (95% CI 2.31–4.18), and in UC 1.97 QALYs gained (95% CI 1.34–2.98). The life expectancy results from the PSA show that HTM generated 4.13 Lys (95% CI 3.04–5.47), NTS 4.32 LYs (95% CI 3.19–5.72), and UC 2.84 LYs (95% CI 1.91–4.14).

Incremental net monetary benefits show €7,697 and €13,589 in HTM and NTS versus UC at a WTP threshold of €20,000, and €69,100 and €83,100 at a WTP threshold of €80,000, respectively. The results of the deterministic analysis are presented in Table 11.

The results of the deterministic subgroup analysis show 2.85, 2.96, and 1.88 QALYs generated in HTM, NTS, and UC respectively, for NYHA classes II and above. The PSA results show 2.91 QALYs gained for HTM (95% CI 2.1–3.92), 3.04 QALYs for NTS (95% CI 2.18–4.05), and 1.97 QALYs for UC (95% CI 1.29–2.87). In NYHA class III and above, there were 2.71, 2.92, and 1.77 QALYs generated in HTM, NTS, and UC, respectively. The PSA results show 2.77 QALYs generated for HTM (95% CI 1.95–3.77), 3.0 QALYs for NTS (95% CI 2.19–4.07), and 1.86 QALYs for UC (95% CI 1.22–2.79). In NYHA class IV only, there were 2.68, 2.56, and 1.81 QALYs generated in HTM, NTS, and UC, respectively. The PSA results show 2.73 QALYs generated for HTM (95% CI 1.83–3.76), 2.63 QALYs for NTS (95% CI 1.72–3.71), and 1.89 QALYs for UC (95% CI 1.13–2.81).

Table 11. Discounted cost-effectiveness of HTM and NTS vs. UC for all three scenarios, all with treatment arm-independent hospitalization costs.

Treatment	Original scenario (all NYHA classes)			Contemporary scenario (all NYHA classes)			Contemporary scenario (only NYHA IV class)		
	Costs	QALY	LY	Costs	QALY	LY	Costs	QALY	LY
HTM	€ 27,186	2.93	4.02	€ 27,186	2.93	4.02	€ 27,539	2.68	3.79
NTS	€ 23,995	3.07	4.21	€ 24,604	3.07	4.21	€ 22,449	2.56	3.61
UC	€ 14,414	1.91	2.71	€ 14,414	1.91	2.71	€ 15,407	1.81	2.65
Increment HTM over NTS*	€ 3,190	-0.14	-0.19	€ 2,582	-0.14	-0.19	€ 5,090	0.12	0.18
Increment NTS over UC	€ 9,581	1.16	1.51	€ 10,189	1.16	1.51	€ 7,042	0.75	0.96
Increment HTM over UC	€ 12,771	1.02	1.31	€ 12,771	1.02	1.31	€ 12,131	0.86	1.14

Treatment	Incremental costs/ Incremental QALY	Incremental costs/ Incremental LY	Incremental costs/ Incremental QALY	Incremental costs/ Incremental LY	Incremental costs/ Incremental QALY	Incremental costs/ Incremental LY
HTM vs. NTS	-€ 23,611*	-€ 16.555	-€ 19,109*	-€ 13.398	€ 44,040	€ 27.733
NTS vs. UC	€ 8,270	€ 6.363	€ 8,795	€ 6.767	€ 9,398	€ 7.364
HTM vs. UC	€ 12,479	€ 9.726	€ 12,479	€ 9.726	€ 14,027	€ 10.644

Treatment	Net monetary benefit	Net health benefit	Net monetary benefit	Net health benefit	Net monetary benefit	Net health benefit
WTP: € 20.000						
HTM vs. NTS	-€ 5,892	-0.29462	-€ 5,284	-0.26421	-€ 2,778	-0.13891
NTS vs. UC	€ 13,589	0.67945	€ 12,981	0.64904	€ 7,944	0.39722
HTM vs. UC	€ 7,697	0.38483	€ 7,697	0.38483	€ 5,166	0.25831
WTP: € 80.000						
HTM vs. NTS	-€ 13,999	-0.17499	-€ 13,391	-0.16739	€ 4,156	0.05195
NTS vs. UC	€ 83,100	1.03875	€ 82,491	1.03114	€ 52,903	0.66129
HTM vs. UC	€ 69,100	0.86376	€ 69,100	0.86376	€ 57,059	0.71323

HTM, home telemonitoring; LY, life-year; NTS, nurse telephone support; NYHA, New York Heart Association; QALY, quality-adjusted life-year; UC, usual care; WTP, willingness to pay.
*HTM is dominated by NTS.

Current scenario results

For the full population analysis, that is, NYHA I to IV, the current scenario yielded results slightly different to those from the original scenario (Table 11). For the subgroup analyses NYHA II to IV and NYHA III to IV, the results were similar. Nevertheless, the current scenario analysis revealed the greater cost-effectiveness of HTM versus both NTS and UC in NYHA IV subgroup analysis. The current scenario included the cost of telehealth nurses of €30,000/y (four nurses in the model, one nurse in charge of 250 patients). Patients assigned to HTM and NTS incurred higher costs than those treated in UC, but also gained more QALYs and LYs. The results of the deterministic analysis in all NYHA classes, and in NYHA IV only, are presented in Table 11.

The PSA results show €28,121 for HTM (95% CI €19,269–€38,722), €23,052 for NTS (95% CI €14,782–€33,426), and €16,037 for UC (95% CI €9,490–€24,933). HTM intervention and NTS yielded a difference in QALYs gained, compared with UC. The PSA results show 2.77 (95% CI 1.81–3.81), 2.61 (95% CI 1.72–3.76), and 1.89 (95% CI 1.14–2.89) QALYs in HTM, NTS, and UC, respectively. The probabilistic results for LYs are 3.91 for HTM (95% CI 2.73–5.37), 3.68 for NTS (95% CI 2.42–5.24), and 2.77 for UC (95% CI 1.72–4.18).

Incremental net monetary benefits show €5,166 and €7,944 in HTM and NTS versus UC at a WTP threshold of €20,000, and €57,059 and €52,903 at a WTP threshold of €80,000, respectively.

The threshold analysis for NYHA IV only revealed that €20 to €36.5/mo for telemonitoring equipment and service combined is the monetary value at which HTM starts to have a greater probability of being more cost-effective compared with UC than NTS compared with UC, at a WTP threshold of €20,000 (the setup fee is kept at €50-€100 per 5 years). This represents a sharp decline of €66.7 to €125/mo from the ranges used in the original and the current scenarios (see “Equipment and service annual fee” in Table 8).

Sensitivity analysis results

The results of the PSA suggest that there is a very low probability of HTM being cost-effective when NTS is available for the management of patients with CHF, whereas both HTM and NTS are cost-effective compared with UC at a WTP of € 14,000/QALY or higher. In the NYHA IV subgroup, there is a greater probability of HTM being more cost-effective than UC than there is of NTS being more cost-effective than UC at a WTP of € 40,000/QALY or higher. Please see Figure 4 for the cost-effectiveness acceptability curves for two main scenarios, and an NYHA IV subgroup analysis, and Figure 7 for the results presented in the cost-effectiveness plane.

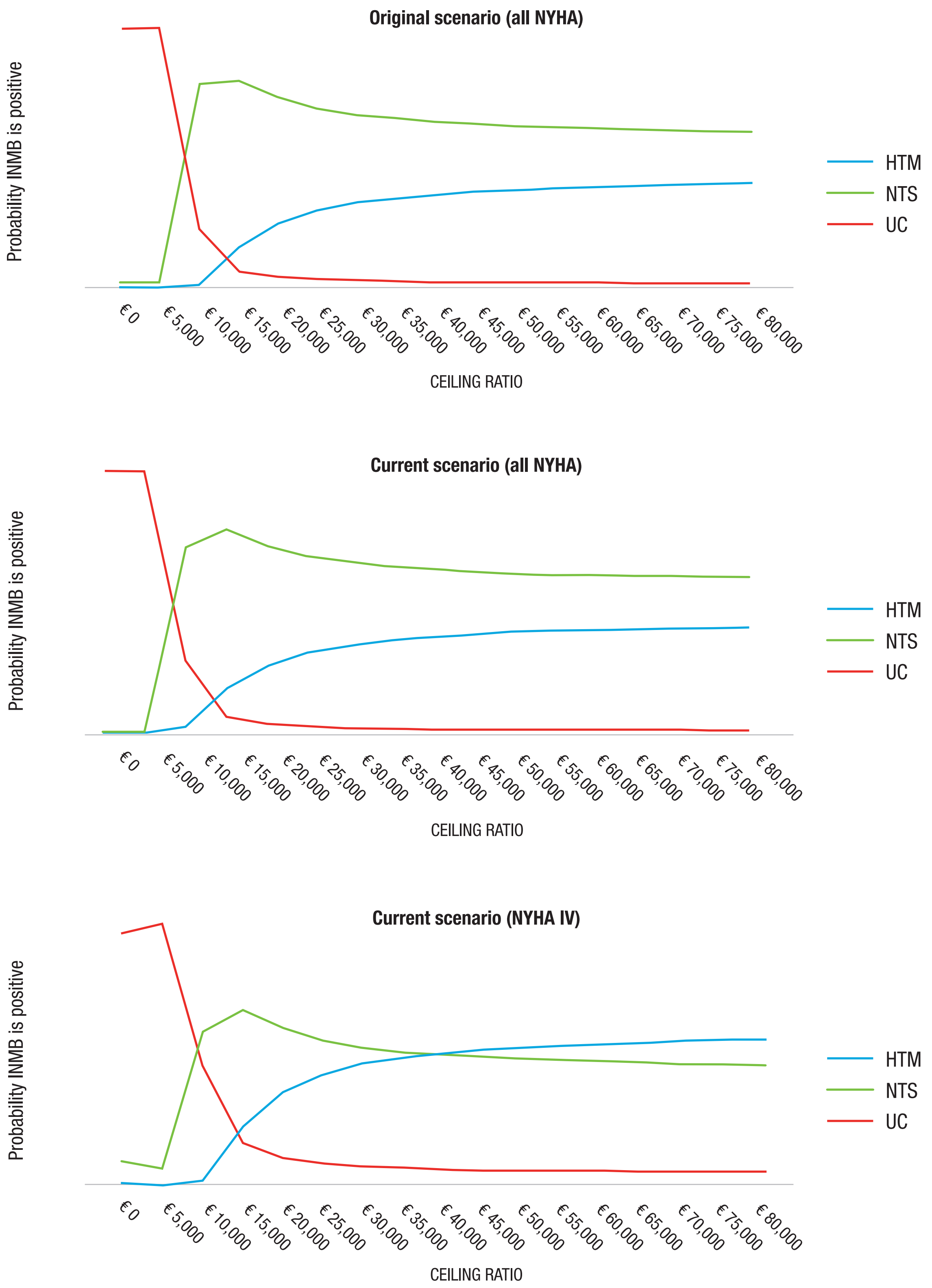

Figure 4. Cost-effectiveness acceptability curves generated from 2500 runs of Monte-Carlo simulation: 1) original scenario for all NYHA classes, 2) current scenario for all NYHA classes, and 3) current scenario for NYHA IV class only, all with treatment arm-independent hospitalization costs. HTM, home telemonitoring; INMB, incremental net monetary benefit; NTS, nurse telephone support; NYHA, New York Heart Association; UC, usual care.

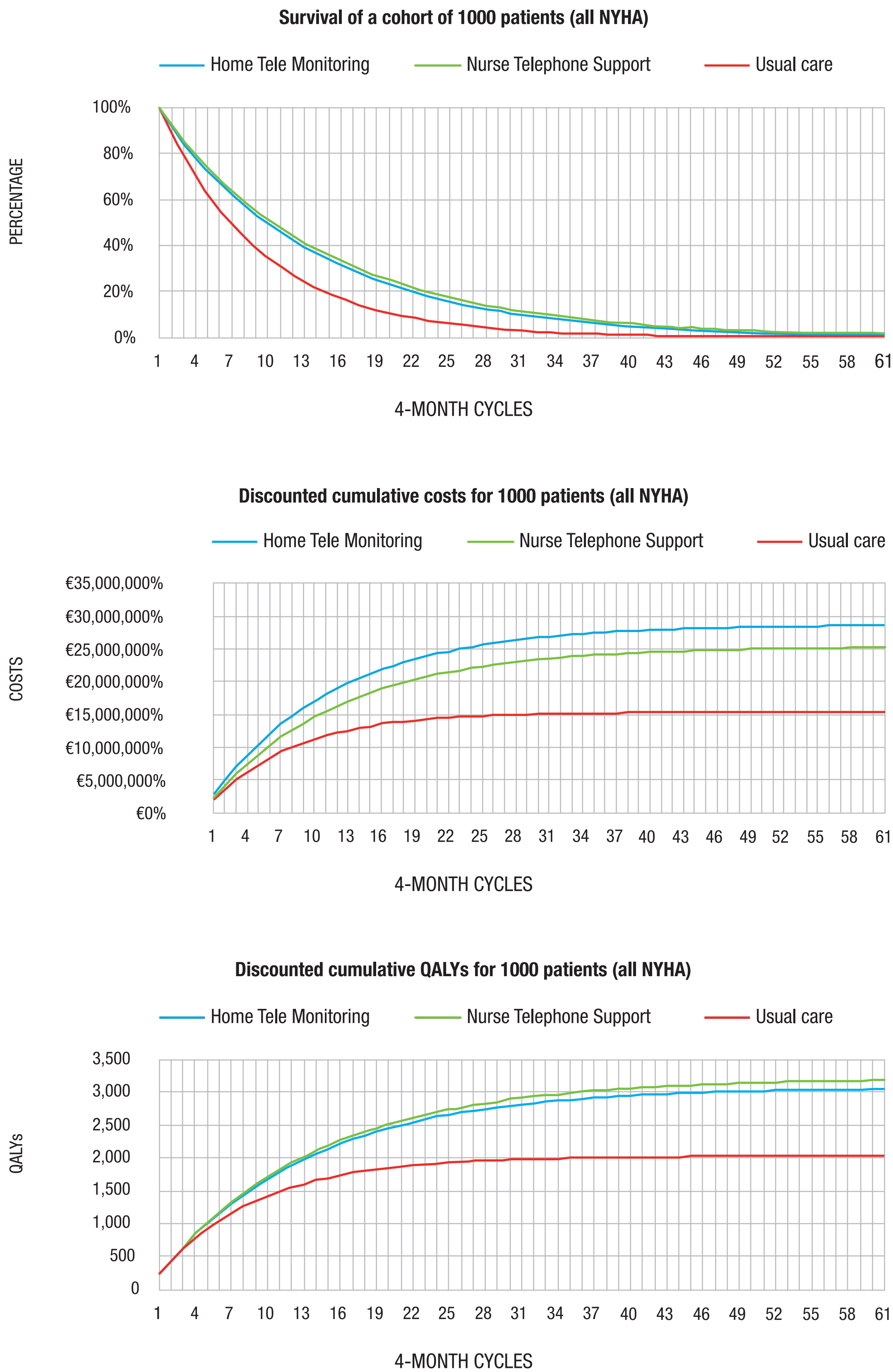

Figure 5. Survival, cumulative discounted costs, and effects for the cohort of 1000 patients: original scenario for all NYHA classes with treatment arm-independent hospitalization costs. NYHA, New York Heart Association; QALY, quality-adjusted life-year.

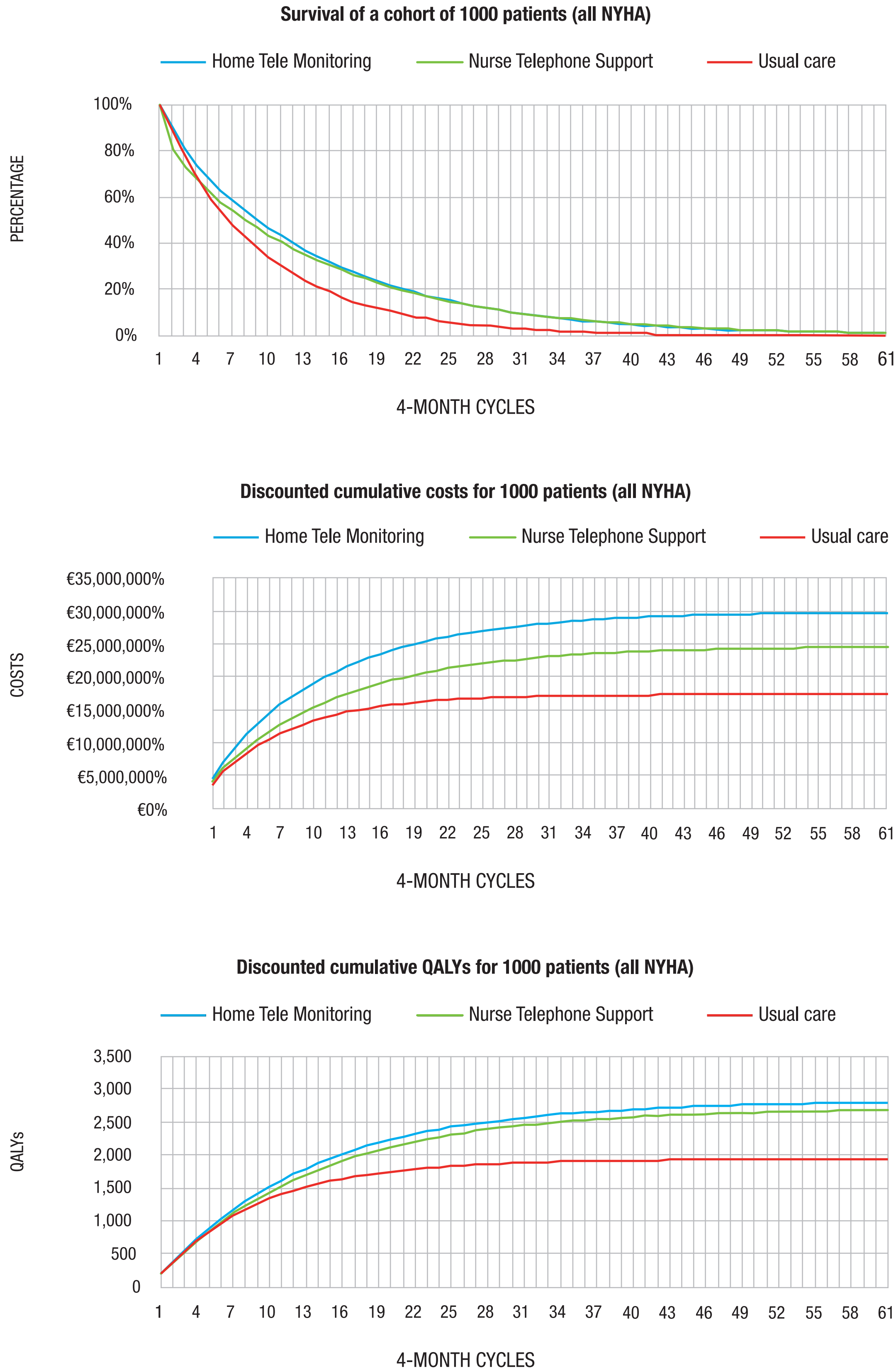

Figure 6. Survival, cumulative discounted costs, and effects for the cohort of 1000 patients: current scenario for only the NYHA IV class with treatment arm-independent hospitalization costs. NYHA, New York Heart Association; QALY, quality-adjusted life-year.

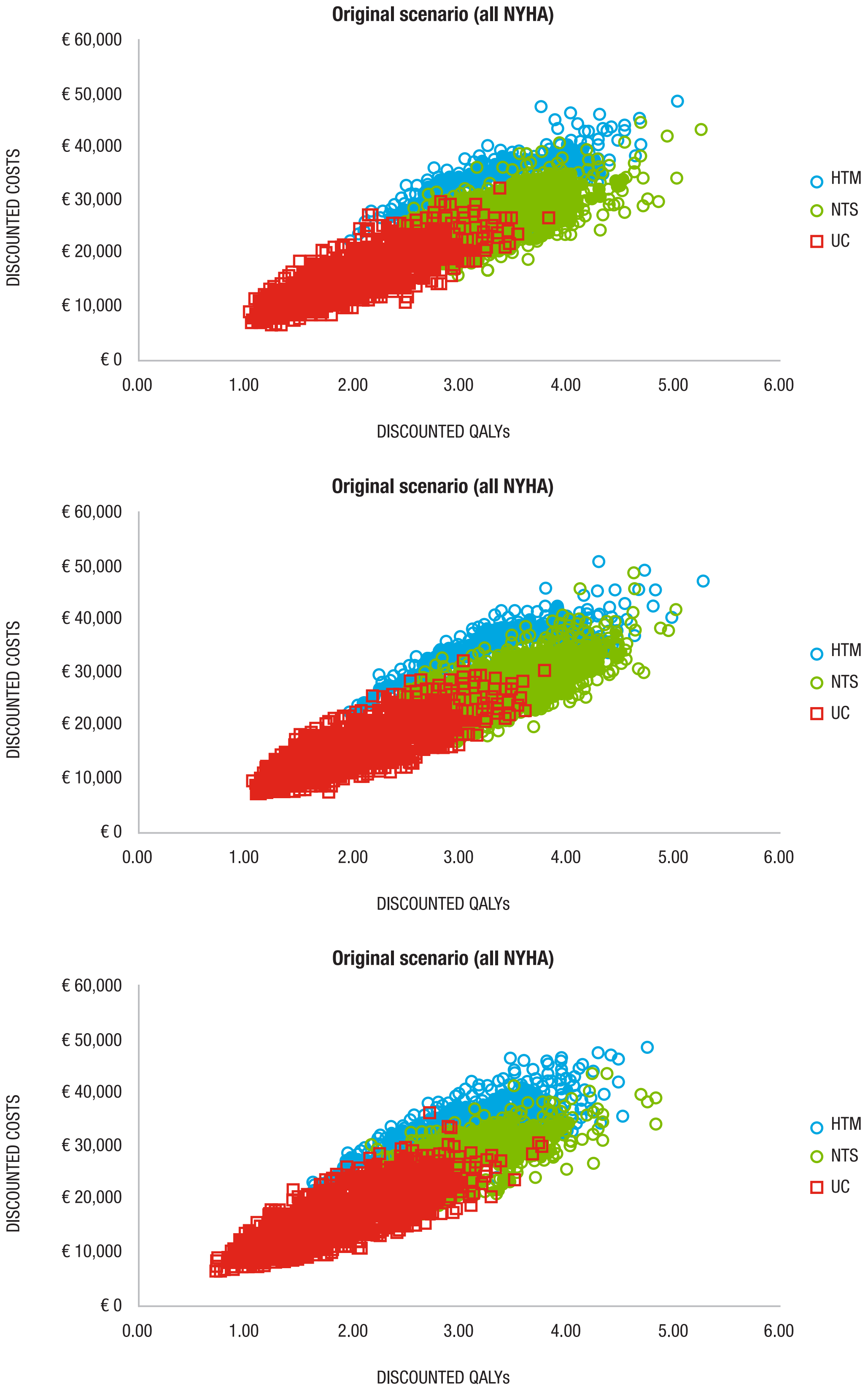

Figure 7. Cost-effectiveness plane, presenting discounted average costs and effects of all three interventions, generated from 2500 runs of Monte-Carlo simulation: 1) original scenario for all NYHA classes, 2) current scenario for all NYHA classes, and 3) current scenario for only the NYHA IV class, all with treatment arm–independent hospitalization costs. HTM, home telemonitoring; NTS, nurse telephone support; NYHA, New York Heart Association; QALY, quality-adjusted life-year; UC, usual care.

DISCUSSION

Study findings and comparisons

Our model demonstrated the cost-effectiveness of both HTM and NTS compared with UC for patients with CHF in various scenarios (Figure 4). It also showed better survival in both HTM and NTS than in UC. In terms of survival, a cohort of patients in HTM, consisting of all NYHA classes of severity, is shown to consistently outperform a similar cohort in UC, although it lags slightly behind a comparable cohort in NTS (Figure 5). In the NYHA IV class, in terms of survival the HTM treatment arm outperforms NTS and UC by some 8.7 years (26 cycles in our model) and generates more QALYs (Figure 6).

The estimates from this model show cost-effectiveness of both HTM and NTS compared with UC in healthcare systems that pay more than €14,000/QALY. Nevertheless, comparing HTM with NTS, HTM is being dominated by NTS in all subgroup analyses except NYHA IV. The incremental cost-effectiveness ratios (ICERs) in the original scenario for all NYHAs are €12,479 for HTM/UC and €8,270 for NTS/UC. In the current scenario the central estimate for the ICER of HTM/UC stays the same and remains below the often-quoted upper limit for the WTP threshold of €20,000/QALY in the Netherlands,[123] whereas it changes to €8,795 for NTS/UC in all NYHA classes. The upper limit of our analysis is set at €80,000/QALY – proposed by the Council for Public Health and Health Care (Raad voor de Volksgezondheid en Zorg) – which is not a fixed threshold but a maximum at the range commonly used in economic evaluations.[123]

We searched for similar modeling studies representing the Netherlands, but without success. We compared our results with those from international studies and found the study from the United States by Smith et al.[89] that ascertained that telephone support is an effective strategy in disease management, with improved survival of patients with NYHA class III/IV symptoms when the ICERs were $67,784 and $95,721/QALY gained, respectively. A major difference with the methods we used was that we created a Markov model with full probabilistic analysis, whereas the authors of this US study used bootstrap resample to generate ICERs. Another Markov modeling study, carried out in the United Kingdom by Thokala et al.[110], compared telemonitoring and structured telephone support with UC, and found HTM to be a cost-effective strategy. Telemonitoring (TM) had an estimated ICER of £11,873 per QALY, whereas 'human-to-human' telephone support (STS HH) had an ICER of £228,035 per QALY. The same study found that "the monthly cost of TM has to be higher than £390 to have an ICER greater than £20,000/QALY against STS HH".[110] The difference in results is significant, possibly because of the different methodologies used or the intervention implementation. A direct comparison of our results with other countries' calculations might be biased because of transferability issues.[124]

The subgroup analysis revealed that HTM is more cost-effective than NTS, compared with UC, in NYHA IV patients, that is, patients with the most severe cases of CHF. The PSA suggests that in countries willing to spend more than €40,000/QALY, HTM should be the first choice for tackling what are usually gravely ill patients who take up a significant amount of healthcare resources. Comparing our results with those of previously published studies, we discovered that a bootstrap analysis from the Netherlands (the Telemonitoring in Heart Failure study) found that telemonitoring is a preferred intervention in patients with CHF in early stages of the disease and at €50,000/QALY or higher.[53]

Limitations, generalizability, and recommendations

As in any modeling exercise, our analysis has limitations, which are governed by data availability and related assumptions. We used 15-year-old data from the TEN-HMS study and derived information about patient satisfaction (i.e. utilities) and utilization of healthcare resources from it. In the meantime, several changes have occurred that have improved the prospects for successful implementation of telehealth: 1) more effective technology, 2) differentiated service offering, and 3) better embedding of telemonitoring technology in daily healthcare practice. The WSD trial reported on all three issues: telehealth being associated with lower mortality and emergency admission rates,[56] each study site having a different supplier and service but not being designed to "investigate the effect of individual service configurations or technologies",[109,125] and the necessity for services of this complexity to "organically evolve, be responsive and adaptable to the local health and social care system, driven by support from front-line staff and management".[126]

Modern telemonitoring systems have significantly surpassed the technology used in the TEN-HMS study 15 years ago, in terms of both effectiveness and patient-related outcomes. Current telemonitoring implementation strategies might use more dynamic offerings. For instance, more recent concepts include a tiered approach for different patient groups or disease severities, with a step-up/step-down possibility. Even with improved accountability of the modern systems, 24/7 availability is not realistic, but we did not model the system downtimes and adverse effects.

Our model does not compute these "complications", and neither does it take into account time dependency. The building block of our Markov model is a 4-month period for which we calculate transitions and cost per QALY per LY contributions that have happened over the whole length of the TEN-HMS trial. Also, our model has not stratified the results by sex or age, and we have not modeled other possible consequences of CHF,[127] nor a competing risk of death (e.g. multimorbidity). The background mortality was included in the model via transition probabilities to the 'death' state. For future research, social characteristics need to be considered in cost-effectiveness analysis given the importance of such factors for health status, access to healthcare, and the uptake of eHealth.

Lack of evidence of the benefits of telemonitoring and telephone support in the long run (improved awareness, disease management skills, behavioral changes, etc.) may mean we have missed the effect of HTM and NTS on the [quality-of-life] weights, as we understand that "the organizational benefits of telecare go beyond finance and capacity"[128(p.6)] and that they may become apparent only in the long run.[129] The telemonitoring equipment and service costs range was chosen on the basis of the market research and is in the medium to medium-high ballpark (i.e. telehealth vs. telecare implantation strategy for telemonitoring). Therefore, the current estimation of the HTM/UC ICER can be considered slightly conservative and biased against telemonitoring.

In addition, the methods applied in the analysis have a number of limitations that need to be considered when assessing its relative generalizability. Firstly, the perspective was that of a third-party payer and not a societal one and, as such, it excluded indirect costs and/or out-of-pocket direct costs incurred by the patient (inclusion of the productivity-related costs would be minimal, considering that the average baseline age for CHF is quite high). Taking these costs into account would likely increase the cost-effectiveness of the HTM and the NTS strategies. We deviated from the pharmacoeconomic guidance, which states that a societal perspective is to be preferred,[114,130] because we were interested in the cost perspective of a healthcare organization trusted with implementation of these technologies in healthcare. Secondly, the data used in our analysis were derived from a single clinical study (which was run at 16 hospital sites), a potential limitation to the generalizability of our findings to other countries or healthcare systems. Also, the TEN-HMS study was inadequately powered to demonstrate a reduction in the risk of an adverse event in the subgroup analysis.[5] The original study considered three countries in Europe, thus making it applicable to the EU in general, but bringing into question its applicability to the US context. Further research should compare patient characteristics and outcomes by location to explore whether any difference emerges from such analysis.

As indicated, technological evolution and new methods of providing telemonitoring have significantly improved the cost-effectiveness of providing these services to a broader range of chronically ill patients. Consequently, we advise governments and other organizations that deal with the implementation of telemonitoring to consider HTM for patients with CHF in NYHA classes II-IV. NTS may also be an alternative, this, however poses challenges in terms of making the necessary levels of staff available, because a larger number of patients need to be supported. Telephone support intervention is to be preferred over UC in healthcare systems that pay €9000/QALY or higher, but this is often difficult to set up because of problems in staffing, training, and logistics.[131] Telemonitoring, on the other hand, is to be preferred for a broad range of acuity levels and not only for the most acute patients. The trade-off between the cost-effectiveness and the potential to manage populations of different sizes will be explored in future research for both HTM and NTS.

CONCLUSION

Our modeling study based on 2002 TEN-HMS data proved that HTM is a cost-effective solution for tackling CHF, but so is NTS. In all scenarios, HTM is cost-effective compared with UC at a WTP of € 14,000/QALY or higher. NTS dominates HTM, compared with UC, in all NYHA classes except NYHA IV. For the most severe cases, that is, NYHA IV patients, the cost-effectiveness horizon shows UC to be the preferred intervention at a WTP of less than €9000/QALY, NTS is to be preferred at a WTP of between €9,000 and €40,000/QALY, and HTM is to be preferred at a WTP threshold of €40,000/QALY or higher.

Chapter 4

Extending the Business-to-Business (B2B) Model Towards a Business-to-Consumer (B2C) Model for Telemonitoring Patients with Chronic Heart Failure

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ABSTRACT

Purpose: The purpose of this study is to describe an alternative approach to telemonitoring patients suffering from Chronic Heart Failure (CHF), i.e. the Business-to-Consumer model (B2C), by extending the current Business-to-Business model (B2B). The B2C model is the one where the customer, in this case the patient, is the payer for the services consumed. We describe and perform an initial evaluation of the extension of the B2B to the B2C model for telemonitoring patients with CHF.

Design/methodology/approach: We explored the problems in implementation of telemonitoring via the B2B model by means of a Root Cause Analysis, including the 5-whys method to help us understand the shortcomings of the B2B approach, and then the 5W1H method to explore whether the B2C is a better strategy. The extension of the model was executed in the Business Model Generation framework. By using qualitative content analysis techniques we supported our argumentation with findings from other studies.

Findings: The B2C model is based on the interplay of four agents – Healthcare Provider, Equipment Manufacturer, Payer/Regulator and Distributor/Promotor – all working together to improve health related outcomes in a jurisdiction. The success of the extended model in telemonitoring CHF hinges on Telemonitoring Center and Telehealth Nurses being repositioned in the out-of-the hospital setting.

Social implications: We believe that penetration of mobile telehealth via the B2C model will allow for greater availability, access and equity in healthcare for patients with CHF.

Originality/value: We introduced a fourth pillar to the existing B2B model (i.e. Distributors and/or Promotors). The B2C model we propose does not exist currently but might allow for scalability, generalizability and transferability of telemonitoring currently unattained with the B2B model.

INTRODUCTION

Population aging is no longer a rich-country phenomenon. In high-income, as well as in middle and low-income countries the populations are getting older, the healthcare workforce is becoming scarce and the cost of care is accounting for an increasing proportion of the Gross Domestic Product.[132,133] At the same time, healthcare delivery is fragmented, uncoordinated and not value-based.[134,135]

The greatest burden of disease globally is attributed to chronic diseases, which are expected to continue to contribute the most disability-adjusted life-years (DALYs) through 2020.[136] Mathers and Loncar[137] further investigated the global burden of disease in the years 2020-2030 and found that there will be no change in rank from the first Global Burden of Disease study,[138] with ischemic heart disease topping the list of the leading causes of death in high-, middle-, and low-income countries (15.8%, 14.4%, and 13.4% of total deaths, respectively). Ischemic heart disease is "the principal etiology of heart failure in the Western world".[139]

Many patients suffering from chronic diseases are not sufficiently empowered to manage their own disease, they rarely have means to track the disease progression, and their understanding of the disease is vague.[140] Moreover, the majority of chronic patients are suffering from multimorbidity, i.e. two or more chronic diseases.[141–143]

Telemonitoring has the potential to support timely detection and slower disease progression in chronic heart failure.[144] Inglis[145] defined telemonitoring as "the transmission of physiologic data, such as an electrocardiogram (ECG), blood pressure, weight, respiratory rate, and other information, such as self-care, education, lifestyle modification and medicine administration, using… technology like broadband, satellite, wireless or Bluetooth".

Today, telemonitoring is mostly implemented via a Business-to-Business model (B2B), usually involving cooperation between a healthcare organization and an equipment manufacturer.[146] A business model describes "the rationale of how an organization creates, delivers and captures value".[147] The B2B model in electronic communication has its advantages: 24/7 availability, breaking geographical barriers, selling in batches, organization-wide implementation and elimination of the "middleman".[148] However, the key challenges of the current model are well documented too: staffing, project management, provision of support, technology, partnerships, funding and strategy.[149]

It has been difficult for telemonitoring introduced via a B2B model to become mainstream, as it seems not to flourish after the pilot testing phase.[150] A broad deployment of patient-centric solutions is hampered by barriers, both external, like market forces, and internal, like the medical technology companies' impotencies.[151] The successful model of implementation will have to satisfy the Triple Aim criteria: 1) improve the experience of care, 2) improve the health of patients, and 3) reduce costs.[152]

Our analysis concerns patients with chronic heart failure (CHF) because of the severity of the disease and its universality. Based on the Framingham Heart Study, 30-day mortality for these patients is around 10%, 1-year mortality is 20-30%, and 5-year mortality is 45-60%.[153] In 1928 the New York Heart Association (NYHA) established a chronic heart failure classification that is now used worldwide,[18] and has divided the patients into four groups according to the severity of the disease expressed in physical limitations and shortness of breath. As CHF is a highly lethal disease, patients need help and encouragement to adhere to the medical regime.[154,155]

Our objective is to describe a new model for the implementation of telemonitoring, i.e. the Business-to-Consumer model (B2C), by extending the current B2B model. B2C model in healthcare is enabled by digital technologies, and the advent of internet, where the customer (i.e. the patient) is the payer for the services consumed. We are keen on exploring whether extending the B2B model to B2C can “support citizens’ and patients’ health and well-being in the home and on the move ... and enable a virtual healthcare continuum” on an unprecedented scale,[156] and if there is a difference to be expected in the speed and scale of implementation of telemonitoring for CHF patients via the extended business model.

METHODS

Extending the Business-to-Business model (B2B) in telemonitoring of patients with chronic heart failure took three steps: 1) a Root Cause Analysis of problems in implementation of telemonitoring via B2B, 2) possible improvements via the B2C approach, and 3) the creation of the extended business model.

In the Root Cause Analysis[157] section we first applied the 5-whys method in order to understand the shortcomings of the B2B model in telemonitoring of patients with chronic heart failure, and then the 5-whys-1-how (5W1H) method for exploring whether the B2C might be a better strategy. The 5-whys technique is used to explore the cause and effect relationship[158] while the 5W1H technique is used to understand the context of the problem, and is called the Kipling Method because those six questions – Who?, What?, Where?, When?, Why? and How? – are immortalized in a Rudyard Kipling poem published in Just So Stories in 1902.[159] We selected and consulted scientific literature, brainstormed on these questions, and took a devil’s advocate perspective to each of the five answers.

The model itself was crafted according to the Business Model Generation framework.[147,160] We employed this methodology as a proven one in various companies for generating innovative business models.[161] It consists of nine building blocks: Customer Segments, Value Propositions, Channels, Customer Relationships, Revenue Streams, Key Resources, Key Activities, Key Partnerships, and Cost Structure.

We supported our analysis with papers published in peer reviewed journals, covering multiple countries, and where possible in the form of reviews and meta-analyses. We searched for publications in English, since 2000, and in some exceptional cases from the 1990s. In addition, we used online resources of business literature from the same period (including ideas and concepts from various consultancies, companies, and magazines). As we are presenting a viewpoint article, we tried to support our argumentation with findings from other authors. We opted for a convenience sample of papers[162] instead of a more systematic selection. Convenience sampling is a non-probability technique that uses sources because of their accessibility, which introduces bias. We looked for papers that support and oppose our perspective and included both, if found. We used qualitative content analysis techniques for systematization of ideas from other authors, in order to allow for categorization and quantification of presented concepts.[163] We worked with prior formulated, theoretically derived categories of 5-whys and 5W1H methods, where the qualitative step of the analysis consisted of a methodically "controlled assignment of the category to a passage of text".[163]

RESULTS

Root cause analysis

Shortcomings of the B2B approach

Here we list the barriers of the B2B model to the implementation of telemonitoring. We start from the finding that the prevailing business model is not optimal for telemonitoring of CHF patients[9] and investigate further the barriers reported in the literature.

The biggest trial in telehealth to date, the Whole System Demonstrator (WSD), which was carried out in three regions in the United Kingdom, lists the following barriers to participation and adoption of telemonitoring: "requirements for technical competence and operation of equipment; threats to identity, independence and self-care; expectations and experiences of disruption to services".[164] If the business model is based on the telemedicine service where equipment is being paid for, which was the case in the WSD, the problems obviously relate to technical and privacy issues.

Willemse et al.[150] list the following three barriers for telemedicine in Belgium: 1) financial constraints, 2) incomplete transmural coordination, cooperation and digital communication and 3) telemonitoring not being integrated in routine care. On the financial constraint side, the authors postulate lack of equipment (devices were not provided after the pilot phase) and no financial remuneration foreseen for the follow up of telemonitoring. In terms of coordination, cooperation and communication problems they list issues such as industrial partners offering different platforms for data storage; follow-up and coordination only performed in the own organization; no integration of telemonitoring data in patient records; transmural data sharing was not carried out; regular healthcare providers often did not participate. In terms of integration with routine care, telemonitoring was considered to require an additional effort in the pilot projects.[150]

Coye et al.[9(p129)] examined in greater depth the overview of barriers to the implementation of remote patient telemonitoring. On financial constraints they state that "financial models and assumptions needed to calculate costs and return on investment do not exist". Without detailed calculations of direct and indirect costs, be it healthcare or non-healthcare, no sustainable innovation can be successfully introduced. They continue: "perhaps most difficult of all – there are few models of implementation by individual physicians, large medical groups, or healthcare delivery systems to draw upon".[9] Continuing to ask why? will eventually lead us to the 'principal barriers' to innovation in chronic care: the (poor) effects of benefit design and reimbursement mechanisms.[10,165,166]

Medicare/Medicaid, a US national social insurance, "reimburses for telehealth services when the originating site (where the patient is) is in a Health Professional Shortage Area (HPSA) or in a county that is outside of any Metropolitan Statistical Area (MSA), defined by HRSA and the Census Bureau, respectively".[167] Medicare will reimburse for face-to-face interactions, store-and-forward applications (e.g. remote ECG application) but there is no single accepted reimbursement standard for private payers. The American Telemedicine Association conducted a national online survey of private payer reimbursement in 2012 and found "that private payers have administrative rules regarding telehealth reimbursement that are barriers to services and reimbursement, and that some providers would benefit from being better informed about billing and coding for telehealth services and how to advocate for telehealth services reimbursement".[168]. In conclusion, Antoniotti et al.[168]. list the major reasons for not billing for services delivered via telemedicine: no Medicaid reimbursement (33%), major payers do not pay (32.4%), practice in urban area (19.3%), services are bundled through contracts (17.4%), could not get support from my organization (4.7%), too risky for penalties for fraud and abuse (4.7%), and other (43.9%).

Improvements via the B2C approach

Extending the B2B model towards the B2C model concerns the improvements in the following aspects: cost-effectiveness (i.e. health for money), modus and timing of introduction, education and self-management.

One of the impediments to wider uptake of telemonitoring is its business model[169] while the other is its cost-effectiveness.[170]. The evidence that telemonitoring saves costs while improving outcomes is still debated in the literature,[57,171,172] while the optimal business model is yet to be found. Telemonitoring is currently introduced via the not easily scalable B2B approach, and literature does not examine other modalities of implementation or their cost-effectiveness.[169,173,174] Addressing the cost-effectiveness barriers as well as market and consumer barriers (regulations, ease of use, technology, access and coverage, promotion etc.) can lead to scalability.

Telemonitoring of chronic/multimorbid patients today is a time-bound activity. Patients usually stay with the B2B telemonitoring service anywhere from one to eighteen months,[175] whereas they could continue to use the B2C model for the duration of the disease (i.e. lifetime, as they are paying for the service themselves). An inability to properly manage CHF usually lands those patients in the emergency room (ER) and this significantly shortens their life prospects.[176] Having access to the telemonitoring service at all times can be highly beneficial to CHF patients as telemonitoring has been shown to reduce mortality, hospital readmission and bed occupancy, even at short intervention and follow-up intervals.[27]

CHF patients should ideally be approached after an adverse health event (e.g. heart failure, mild infarct, stroke). That is a time when patients are most aware of their health problems and need to actively participate in the hospital discharge process.[177] Currently patients are recruited to clinical studies involving B2B telemedicine systems months after the onset of the disease. In the B2C model patients can be informed about the existence of the service at the point of departure from the healthcare system, or via public health channels (e.g. mass media campaigns). The B2C telemonitoring service should be available at all times to patients in a given jurisdiction.

Patient education is of importance to guarantee adherence. The self-management component of CHF programs (physical activity, drug adherence, diet, etc.) has "a positive effect, although not always significant, on reduction of numbers of all-cause hospital readmitted patients … decrease in mortality and increasing quality of life".[178] The educational component of the system allows for empowerment of patients, while the monitoring component helps with early detection of disease worsening. In most B2B cases the education is offered by a nurse – in person or via the telephone and rarely via the device [175]. This prevents patients from revisiting the message and impedes learning. In the B2C model education is always at hand, which should promote learning and behavioral change.

One of the main problems in telemonitoring is scalability,[179] which comes with regulatory issues. The European Commission has indicated in the e-Commerce Directive that "for business-to-business (professional-to-professional) telemedicine services, such as teleradiology, the country of origin principle applies: the service offered by the professional must comply with the rules of the Member State of establishment. In the case of business-to-consumer activities (which might be relevant to telemonitoring services) the contractual obligations are exempted from the country of origin principle: the service might need to comply with the rules of the recipient's country".[180] This indicates that the telemonitoring provider should be based in the EU jurisdiction most favorable to eHealth and provide services to other member states via the internal market clause.[181] Using mass media to reach consumers, combined with referrals by physicians and pharmacists, might be a way to enroll patients in their thousands without establishing a physical presence in the jurisdiction (as is necessary with B2B today). Thus Business-to-Consumer (B2C) telemonitoring might pave the way to population-wide health monitoring either within or between countries.

The B2C telemonitoring service can be introduced initially as an increment of the B2B model. The B2B model is currently used by technology providers to implement their products in high-income countries. In the US, for example, after the adoption of the "meaningful use of IT in healthcare" initiative, Congress invested billions of dollars in infrastructure building to support three goals: improve quality of care, reduce costs, and increase access and coverage.[182] Previous investments in B2B telemonitoring can help with the transition to B2C as systems have been deployed already, and the research findings are available too.[183] The rapid evolution of mobile health apps will be the promotor of B2C telemonitoring and will encourage patients to "accept greater responsibility for their own healthcare either individually or with their healthcare navigators".[183(p185)]

Paré et al.[184(p274)] found out that: "home telemonitoring of chronic diseases seems to be a promising patient management approach that produces accurate and reliable data, empowers patients, influences their attitudes and behaviors, and potentially improves their medical conditions". However, there is inconclusive evidence of the clinical effectiveness and cost-effectiveness of telemonitoring for CHF patients.[170,185,186] While business model and cost-effectiveness are considered to be major barriers to further implementation of telemonitoring in chronic disease management, the enablers are to be found in duration of the intervention, modus and timing of introduction, education, and self-management (Table 12). Extending the B2B model towards B2C might be a way to tackle all those major deficiencies in the telemonitoring service today.

Table 12. Summary table of the barriers and enablers in CHF telemonitoring.

B2B Barriers	B2C Enablers
1) Technical - Requirements for technical competence and operation of equipment, 2) Personal - Threats to identity, independence and self-care, 3) Organizational - incomplete transmural coordination, cooperation and digital communication, and 4) Financial - poor effects of benefit design and reimbursement mechanisms	1) Effectiveness – Addressing regulations, ease of use, technology, access and coverage, can lead to scalability, 2) Modus and timing - The service is available at all times, for a lifetime, 3) Education - always at hand, which should promote learning and behavioral change, 4) Self-management - Better health outcomes.

BUSINESS MODEL GENERATION

Next, we describe in detail the Business-to-Consumer (B2C) model. We believe that its success hinges on two entities – the Telemonitoring center and Telehealth nurses – being repositioned in the out-of-the hospital setting. We depict the position of the two in the Business Model Canvas.[187] The canvas allows for improved clarity and understanding of this value proposition. Figure 8 presents the extended business model based on the findings generated by the two preceding steps - a Root Cause Analysis of problems in implementation of telemonitoring via B2B, and possible improvements via the B2C approach.

Key Partners

MONITORING & WELLNESS
1) Strategic alliance between payer/regulator and distributor/promotor,
2) Cooperation between healthcare provider and equipment manufacturer,
3) Joint venture between equipment manufacturer and distributor/promotor and
4) Buyer-supplier relationship between insurer/regulator and healthcare provider

Key Activities

MONITORING
1) Production – Creating the app
2) Problem solving – Care coordination and bidirectional communication, and
3) Platform/Network - 24/7 unobtrusive telemonitoring

WELLNESS
1) Production – Creating the app
2) Problem solving – Wellness tracking and support

Key Resources

MONITORING
1) Physical - Telemonitoring center,
2) Financial - initial investment in the venture
3) Intellectual - IP and algorithms, and
4) Human - Telehealth nurses

WELLNESS
1) Physical - Telemonitoring center,
2) Financial - initial investment in the venture,
3) Intellectual - IP and algorithms

Value Propositions

MONITORING
24/7 unobtrusive personalized telemonitoring (disease monitoring, education, serious games and communities) with biweekly calls from a personal care coordinator (telehealth nurse)

WELLNESS
Wellness tracking (disease tracking, education, serious games and communities)

Customer Relationships

MONITORING
1) Dedicated personal assistance,
2) Automated alerts and messages, and
3) Communities

WELLNESS
1) Automated alerts and messages, and
2) Communities

Channels

MONITORING & WELLNESS
1) Distribution of the app/service via the established app stores,
2) Communication with patients via telecom operators

Customer Segments

MONITORING
1) CHF patient after an adverse event,
2) Tech savvy with smartphone and mobile internet, and
3) Able to pay for the service

WELLNESS
1) Older than 55 years and at cardiovascular risk,
2) Tech savvy with smartphone and mobile internet, and
3) Able to use the service

Cost Structure

MONITORING
1) Telemonitoring equipment
2) Telecommunication charges
3) Salaries
4) Overhead

WELLNESS
1) Backend charges
2) Telecommunication charges

Revenue Stream(s)

MONITORING
Subscription based (premium model)

WELLNESS
Free (freemium model)

Figure 8. The B2C model of telemonitoring CHF expressed in the Business Model Canvas (adapted from Osterwalder et al.[147]).

Customer segments

At the very beginning of the business model generation, we need to understand for whom is the value created? There are several types of Customer Segments: Mass Market, Niche Market, Segmented, Diversified or Multi-sided Platform.[147] Cambridge University Press[188] explains that "product … designed for the mass market is intended to be bought by as many people as possible, not just by people with a lot of money or a special interest", and market segment is defined as "a group of possible customers who are similar in their needs, age, education, etc.". This model concerns CHF patients, as CHF contributes the most to mortality from chronic diseases in the world,[155] making this is a segmented market.

The newly crafted business model caters for the specific customer segment, i.e. CHF patients with a certain severity of the disease expressed in the New York Heart Association (NYHA) framework.[18] It is too early to say which class of patients – NYHA class I to IV – can benefit the most from B2C telemonitoring, or whether it is a cost-effective intervention. For the time-being we will consider all NYHA class patients as possible customers. The criteria for the customers are: 1) CHF patient after an adverse event such as a heart attack or stroke for the monitoring track, and/or older than 55 years for the wellness track, 2) tech savvy with smartphone and mobile internet, and 3) able to pay for the service. In the US 17% of the daily mobile internet users older than 55 years purchased a service or a product via smartphone, and have on average 5.7 paid apps on their devices.[189] Thus the value propositions, distribution channels, and customer relationships need to be tailored to the specific requirements of this customer segment.

Value proposition(s)

A Value Proposition "creates value for a Customer Segment through a distinct mix of elements catering to that segment's needs".[147] The same authors define values as quantitative (e.g. price, speed of service) and qualitative (e.g. design, customer experience). What value can be delivered to the identified customers via the B2C model? Several, from the following categories: Newness, Performance, Customization, Getting the Job Done, Design, Brand/Status, Cost Reduction, Risk Reduction, Accessibility and Convenience/Usability.[147]

The key success factors, in terms of customer needs – effectiveness, costs, accessibility, ease of use, credibility – correspond to the value-added characteristics of the B2C model. The duration of intervention, the modus and time of introduction, education and self-management, the effectiveness in terms of better healthcare outcomes, are all important improvement points for B2B, and at the same time value propositions for B2C telemonitoring. The B2C value proposition is inspired by Triple Aim[152]improving the health of populations, and reducing per capita costs of health care. Preconditions for this include the enrollment of an identified population, a commitment to universality for its members, and the existence of an organization (an "integrator" and specified for telemonitoring of patients with CHF from a consumer's perspective. As such, the key success factors of the B2C model address different aims: Care (e.g. accessibility, ease of use, credibility), Health, and Costs (e.g. cost reduction, effectiveness, scalability).

An example of the B2C telemonitoring service that we will use in this business model generation exercise concerns a 24/7 unobtrusive personalized telemonitoring service (monitoring, education, games, and communities) with biweekly calls from a personal care coordination, or for a wider audience of 55+ years a wellness tracking app (disease tracking, education, games and communities). Personalized monitoring entails algorithm pushing nudges, content, education, and scripted interactions to the patient according to the signal reads from the monitoring devices. Personal care coordinator is a dedicated telenurse that monitors the patient via a dashboard, and acts as the "health coach" (supports the patients throughout their patient journey). The personalization on the patient side is driven by the severity of the disease, therapy adherence, willingness to pay, motivation, etc.

In the event of an emergency, or during the night when the patient is not supervised by a real person, the clever algorithm flags the situation and logs an automatic call with an emergency service on behalf of the patient.[190] The telemonitoring service should not be mistaken for an emergency service.

Currently, telemonitoring can be provided via several platforms (e.g. smart and mobile devices, TV, telephone) but is executed in a one-size-fits-all fashion. Each patient is unique, and the customization of the service is a crucial part of the value proposition in the B2C approach. This can be done via smart algorithms using educational content, surveys, information provision, games, etc. – all personal and engaging. Patients are happy when care is tailored to them personally and/or to their individual needs.[191]

The brand power is crucial to service uptake. Aaker[192] provided a framework for assessing brand equity with four dimensions: brand's perceived quality, brand awareness, brand associations, and brand loyalty. Patients might not be comfortable with IT companies monitoring their health, nor allow "one's biometric indicators [to] be constantly measured, analyzed and displayed publicly on Facebook or Twitter",[193] but the recently introduced ResearchKit from Apple proves that things are beginning to change – smartphones will track one's health status, and even one's genetic information – and thousands of people have signed up for this already.[194] An established player in the healthcare domain with a strong brand has a fair shot at monitoring wider populations. In this way, the adoption of a new technology can be accelerated.[195]

B2C value proposition features cost reduction, risk reduction, accessibility, and convenience/usability. It has a similar proposition to B2B, where customers essentially buy "peace of mind", but with more convenience as the service runs on a personal device and is considered 'device-agnostic'. It also reduces costs for the customer, as there is no need to install the equipment or to run updates. There is no 'downtime risk' as the service is hosted in the cloud – the top 10 cloud services have downtime of less than 0.14% [196]. Convenience is assured by unobtrusive telemonitoring, via third party devices, and seamless connection via a backend, over mobile internet. This value proposition allows accessibility to a first-class healthcare service, which is assured even in the areas where such medical service was previously unheard of. According to the International Telecommunication Union[197] there are almost 3 billion internet users, two-thirds of them in the developing world, and the number of mobile-broadband subscriptions reached 2.3 billion globally. Smartphones and mobile internet are prerequisites for enjoying 24/7 coverage and medical service via the B2C telemonitoring model. With accessibility comes scalability, a necessary but not sufficient condition.

Channels

Channels are crucial in reaching a designated Customer Segment. Osterwalder and Pigneur[147] distinguish between direct channels (e.g. sales force, web sales) and indirect channels (e.g. own stores, partner stores, wholesaler), as well as between owned channels and partner channels. Finding the right mix is important for successfully bringing the value proposition to the market.

The focus of the B2C model lies on locking-in the customers with a superb value proposition, by establishing a relationship with the personal health coach (i.e. telehealth nurse) rather than on owning the channels for marketing or distribution. The B2C model in telemonitoring should rely on distribution of the app/service via the established (app)stores, while the communication with patients should be executed in a secure and controlled manner via telecom operators.[198,199]

This is a departure from the historical channel for telemonitoring, i.e. hospitals. Several factors that hamper wider deployment of telemonitoring if executed within the hospital setting, i.e. lack of funding, motivation and cooperation between the hospital and the GP,[150] can be eradicated by new ways of healthcare delivery. B2C utilizes new channels and customer relationships in order to raise awareness of and extend the reach of telemonitoring.

Customer relationships

Osterwalder and Pigneur[147] distinguish between several categories of Customer Relationships, which may coexist in a provider's relationship with a particular Customer Segment: Personal Assistance, Dedicated Personal Assistance, Self-service, Automated Services, Communities, and/or Co-creation.

CHF patients can establish three types of relationships via the B2C model: dedicated, automated and community-based, depending on the choice of the service model, premium monitoring service or freemium wellness service.

Patients who pay, or are sponsored to enroll in the telemonitoring service, can receive dedicated personal assistance from a telehealth nurse (i.e. bimonthly calls and check-ups). Suter et al.[200(p87)] find that "during ... assessment calls, telehealth nurses often provide education regarding cause and effect relationships between personal health behaviors and obtained physiological results, serving to reinforce prior teaching regarding disease self-monitoring and self-management", thus unequivocally supporting the crucial role played by telehealth nurses in telemonitoring. Patients/customers who download the app for free, and are on the wellness track, can have automated services (e.g. education, games, and reminders). Both segments should enjoy communities, i.e. online forums for exchange of experiences and information in a similar fashion to PatientsLikeMe[201].

Revenue streams

Revenue Streams represent the cash a company generates for each Customer Segment.[147] We believe that the strongest motivation for patients with chronic diseases, the value proposition one is willing to pay for, is "peace of mind" – knowing that someone is looking after you at all times.

Bradford et al.[202] investigated the willingness to pay for telemedicine and found that 30-50% of hypertensive patients are willing to pay at least $20 per month, while for the CHF patient this number was even higher. Qureshi et al.[203] found that "the majority of those choosing telemedicine (95%) were also willing to pay a median of $25 (5 to 500 dollars) out of pocket", while Seto[204] found that 55% of heart failure patients were willing to pay $20, and 19% were willing to pay $40. In a more recent poll of 2019 customers, the result showed that the majority (62%) thinks that a telehealth visit should cost less than an in-person visit, which currently costs $82 for first-time patients.[205] These payments can be a part of two different types of revenue streams: transactional revenues, i.e. one-off payments, and/or recurring revenues.

The B2C approach for telemonitoring chronic diseases revolves around subscription. The app/service can be free for the wellness track (freemium service with videos, education, and tracking of disease progression) and subscription based for the monitoring track (premium service consisting of telemonitoring, coaching, contact with telehealth nurses, and coordination of care).

Key resources

Resources allow an enterprise to create and offer a value proposition, reach markets, maintain relationships with customer segments, and earn revenues.[147] Key resources in this venture are physical (telemonitoring center), financial (initial investment in the venture), intellectual (IP and algorithms), and human (telehealth nurses). We will explore the crucial two, without which it would be impossible to extend the B2B model towards B2C. Telehealth centers are a new organization of healthcare services for the digital age, ready to handle the complexity of the care-coordination process in telemonitoring, while telehealth nurses are specially trained providers of those services.

Telehealth nurses

Telehealth nurses are seen as "health-quarterbacks" in charge of organizing and implementing care protocols for chronic/multimorbid patients.[206] Their role is in care-coordination between the patient, the physician, the pharmacist, and the informal caregiver. It should be noted that a proper relationship between the patient and the telehealth nurse should be established and maintained, to prevent confusion for the patient about who is in charge of their wellbeing in the complexity of healthcare.[207] Effective chronic care management is based on interaction between the healthcare professionals and the patient's social support network.[208] The patient allows and introduces one or more informal caregivers into the care-coordination chain, while the telehealth nurse manages the stakeholders. This is all possible with the current state of technology.

The telehealth nurse provides a personalized care to patients enrolled in the telemonitoring service. On average, he/she contacts the patient every two weeks, for a 10-minute check-up. This is adequate time for a quick conversation, as patients usually get only 10-15 minutes with their physician once every three months.[209,210] This allows one nurse to monitor and communicate with approximately 50 patients a day, or a maximum of 500 patients per month (with one monthly contact one nurse would be able to monitor almost 1000 patients). This is somewhat similar to the existing telemonitoring service in Hull, UK, where one telemonitoring nurse oversees 200-400 CHF patients.[211] Telehealth nurses could be trained in order to reach the efficiency level needed to maintain the cost-effectiveness of the B2C model.

Telemonitoring center

The B2C model introduces another entity to healthcare – a telemonitoring center – in order to provide 24/7 digital monitoring on smartphones (or a mobile device of the user's choice). The telemonitoring center is a physical entity that hosts telehealth nurses and the equipment, and performs two functions: telemonitoring and communication with patients. The monitoring part is automatic/algorithmic and runs in the background, while the communication between the telehealth nurse, the patient, and the care team occurs during working hours.

The monitoring service proposed here should personalize the experience for each patient. For patients that have an older set of measuring devices (e.g. weight scale, blood pressure cuff, ECG recorder, pulse oximeter) the measurements should be entered into the app manually. This is usually tedious and error prone, but with the new automated equipment that connects via telephone or internet the transfer of the measurements is automatic and unobtrusive.[144] The B2C model is device-agnostic as not to restrict the telemonitoring service to device manufacturer silos, and because peripheral measuring devices might soon be commoditized.[212]

The communication system can be built on top of various unifying communication platforms, which allow for video calls, voice calls, instant messaging and presence.[213] This can be supplemented with email and an SMS/MMS service for sending pictures and educational materials. The Health Insurance Portability and Accountability Act of 1996 (US) demands that telemonitoring networks take precautions in order to prevent third parties from intercepting health-related data.[214] There are many existing systems which are HIPAA compliant (i.e. full support of privacy issues) and can be readily deployed around the globe to ensure secure communication with patients.

Key activities

Key Activities are required in order to create and offer a Value Proposition, to reach markets, maintain Customer Relationships, and earn revenues.[147] Key Activities can be categorized into: Production, Problem solving, and Platform/Network.

The monitoring service can reuse the design, algorithms and functions of the established B2B telemonitoring platforms (i.e. physical systems) but adapt them to the B2C context (i.e. cloud services), in order to achieve scale and reach. This represents a departure from a product-oriented to a service-oriented approach. By introducing electronic distributors/promotors into healthcare delivery, the problem of population-wide healthcare coverage for chronic/multimorbid patients can be solved at regional, community, and individual levels.[215] Recently one of the major insurers in the US, UnitedHealth, widened telehealth coverage to millions of Americans, finally removing one of the last obstacles to scale.[216]

Evolving the B2B model to seize this opportunity means introducing a new ‘platform’ into healthcare (i.e. the telemonitoring center) that performs key activities: 24/7 unobtrusive telemonitoring of patients with chronic diseases (CHF in this case), bidirectional communication with patients, and care coordination by telehealth nurses.

Key partnerships

Key Partnerships describe the network of suppliers and partners that make the business model work.[147] In order to take telemonitoring out of the hospital setting and into the telemonitoring center where customers can purchase a telemonitoring solution on their own, there needs to be governance and awareness, in addition to providers of healthcare and equipment manufacturers.

Governments aim to improve the performance of their healthcare systems[217] and rely on hospitals and national licensing authorities to provide services and to regulate the healthcare market. Out of 58 counties in the world that currently have Universal Healthcare Coverage[218] there are developed countries where the government is the payer and the regulator (e.g. Canada where the government pays for 70% of healthcare expenses) and countries where these roles are separated (e.g. the Netherlands). Governance, consisting of payers and regulators, is one of the four pillars that “hold” the B2C model.

People are usually made aware of the existence and availability of the telemonitoring service by physicians or public health authorities, but here we are advocating for a new route – informing customers directly via mass media. Targeted mass media campaigns are often used to inform patients about specific health issues or to promote desired behavior – for instance, to increase the uptake of screening, vaccination or healthy nutrition,[219] but rarely to inform these people about the availability of certain healthcare services in a jurisdiction. The extension of the B2B model towards B2C mainly involves the introduction of mass media, as a new type of channel for delivering healthcare services. Media, consisting of distributors and promotors, represents another important pillar of the B2C model.

Regarding partnerships, the new business model can create the strategic alliance between non-competitors – payer/regulator and distributor/promotor – working together to raise awareness and improve the management of chronic diseases in their jurisdiction. It also can create a buyer-supplier relationship between healthcare provider and payer/regulator, as public bodies might want to procure telemonitoring for certain groups of citizens. On the other end, a joint venture between equipment manufacturer and distributor/promotor can be expected as the B2C model relies heavily on informing the customers/patients about the availability of the service in their jurisdiction. Finally, cooperation – a strategic partnership between competitors – can be established between equipment manufacturer and healthcare provider as they both compete for the same customer/patient in the B2C model.

With the introduction of the B2C model for telemonitoring chronic or multimorbid patients a new way of delivering healthcare services will be achieved. Chronic patients will be “shared” between home telemonitoring (remote management) and traditional in-hospital services, while today Accountable Care Organizations (ACOs) are trying to introduce nurse telephone support and telemonitoring in an attempt to avoid readmission penalties.[220] This will take place as a symbiosis between the four sectors: healthcare, industry, government, and media. Figure 9 depicts the four building-blocks of the B2C model and their relationship with one another in a healthcare system where the payer and the regulator are the same body, i.e. the government.

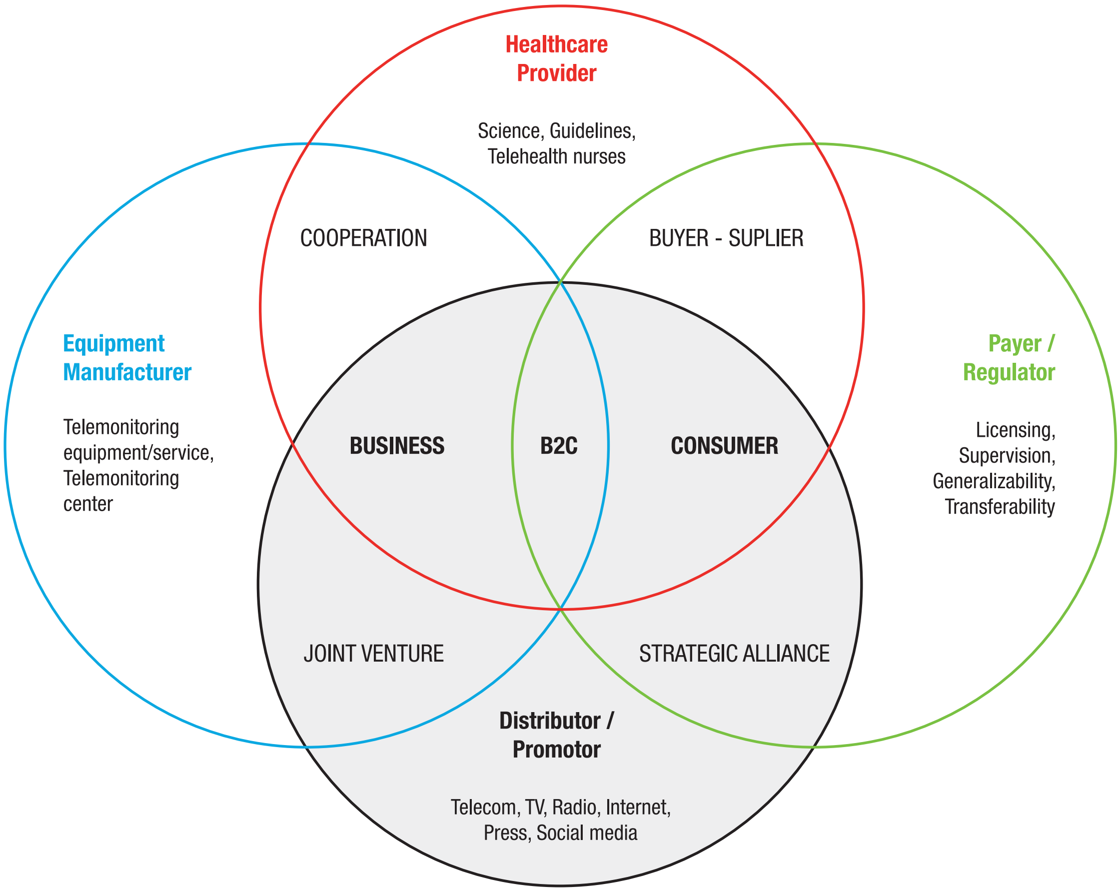

Figure 9. Key partnerships in B2C telemonitoring of patients with chronic diseases in a healthcare system where government is the payer and the regulator.

Cost structure

Costing is particularly important in delivering this value proposition to chronic or multimorbid patients. Creating and delivering value, maintaining customer relationships, and generating revenue all incur costs.[147] The costs can be fixed or variable, and the business can be cost-driven or value-driven. We believe B2C telemonitoring is value driven because it focuses on value creation for chronic or multimorbid patients, i.e. 24/7 unobtrusive monitoring, peace of mind, coordination of care, creation of communities, education, and help with self-management.

DISCUSSION

The extension of the B2B business model into the B2C model for telemonitoring CHF presented here proposes a synergy between equipment manufacturers, healthcare providers, payers and regulators, distributors and promotors in order to achieve population-wide telemonitoring. It calls for the establishment of a telemonitoring center in an out-of-hospital setting, staffed by telehealth nurses, for reasons of effectiveness and efficacy. In this way telemonitoring can enable care to be provided in various settings (e.g. at home, work, on the move), instead of having patients seek care in hospitals and care organizations. The B2C model connects the business side with the consumer side of telemedicine, as shown in Figure 9. It is our belief that extending the B2B model toward the B2C will increase the speed and scale of adoption of this technology in chronic disease management.

We presented our analysis in the Business Model Canvas by Osterwalder and Pigneur[147] because of the methodological strength it embodies – a mediation between the idea and the customer [221]. The advantage of the canvas is in recognizing the key importance of the value proposition to the end customer of the B2C model – the patient. The limitation is in absence of a strategy portrait, and the relationship of the business model with a possible strategy. Teece[222] theorized that the two are connected, where strategy follows business modelling. Thus, we tried to present possible strategic partnerships in Figure 9.

Coye et al.[9] compiled an overview of the early business models for chronic disease management and found that all of the previous operations were B2B and have proven unsuccessful in bringing telemonitoring to the masses. In these organizations the patients, i.e. the consumers, were not able to procure the service on their own. Evidently, in the beginning scalability, generalizability and transferability were trumped by implementation problems.

As with most products and services in healthcare, the B2B model is designed with a primary focus on providers. Telehealth projects executed via the B2B approach focus on how to improve product qualities so they fulfill physicians' requirements, resulting in an inability to identify important patient and treatment needs. However, the B2C model breaks away from the traditional consideration of providers as key buyers and shifts the attention to patients themselves, recognizing their vital need for convenience, accessibility, and customized education. The B2C model capitalizes on the proliferation of smartphone devices, tablets and the rapid rise of the internet, and offers the solutions directly to patients, while breaking down the barriers created by intermediate functions.

The B2C model bears similarities to the Blue Ocean Strategy approach. Challenging an industry's conventional wisdom about which buyer group to target can lead to value innovation – i.e. the creation of innovative value to unlock new demand.[223] According to Kim and Mauborgne[223] one approach to create a new uncontested market and satisfy demand from a previously overlooked set of buyers is to look across buyer groups. Since the B2C model shifts the perception in terms of the primary buyer group from providers to patients, and offers the latter group additional critical products/service attributes that unlock value, it bears many similarities to a blue ocean strategy.

However, the concept of value is not without problem in healthcare. Welfare economists still follow an influential concept by Harsanyi[224(p55)] that "in deciding what is good and what is bad for a given individual, the ultimate criterion can only be his own wants and his own preferences". In healthcare value is not expressed only as a personal preference for an outcome, but more typically as a "triple aim"[152]: health gain, improving patient's satisfaction with care, and/or reducing per capita cost of care. The B2C model would most likely not improve health, but deliver on other two types of value.

The B2C approach might also solve the transferability and generalizability issues in telemonitoring, explored in the Model for Assessment of Telemedicine,[225] by controlling for differences in demography and disease (telemonitoring works in the same way for different age and disease-severity groups), availability of healthcare resources (telemonitoring is available in a whole jurisdiction, irrespective of geography), variation in clinical practice (telemonitoring introduces the same standards of care), alignment of incentives to healthcare professionals and institutions (telemonitoring centers are outside the hospital setting), uniformity of costs and prices (the fee for a telemonitoring service is the same for everyone).

Three key characteristics of a good business model are alignment, self-reinforcement, and robustness.[226] The B2C model in telemonitoring of patients with CHF is aligned with the goals of all four stakeholders and represents a middle ground between the business needs and the consumer needs. It is self-reinforcing because allowing patients to procure a telemonitoring service at their own request will help achieve the "triple aim" in healthcare[152] by improving the patient's experience of care, improving the health of populations, and reducing per capita cost of care. It will increase revenues and innovation in industry, help governments to fight chronic diseases while controlling the budget, and allow media to educate and lock-in customers.

This business model can sustain its effectiveness over a long period by fending off the threat of imitation, as it is difficult to replicate the established telemonitoring center in a jurisdiction, and holdup as customers cannot exercise their bargaining power due to the interplay of stakeholders. In addition, it helps to avoid slack, as organizational complacency is not to be expected, and substitution, as new products can reduce the customer's perceived value of this service, but the stakeholders can and should come up with new services themselves.[226]

Our analysis is not without flaws or potential bias. We assessed theoretical strengths, the potential usefulness and the success of extending the B2B model in telemonitoring of chronic diseases. We based our analysis on the convenience sample of published articles.[162] Potential weaknesses of the B2C model still remain to be identified. As we are not aware of similar studies or business models, convergence validation has not been assessed.[227]

Future research should provide an in-depth assessment of the business model described, and a financial analysis of a fictitious venture that runs on the model presented here. Business modeling, like economic evaluation, should indeed be iterative and maximize the efficiency of R&D in health technology assessment.[228] There needs to be, in a similar fashion to early health technology assessment,[229] an 'early business model assessment'.

The telemonitoring domain is increasingly being democratized and the proliferation of health gadgets will bring a myriad of new telemonitoring apps and services. The WHO Global Observatory for eHealth[230(p17)] ascertains that "mHealth can revolutionize health outcomes, providing virtually anyone with a mobile phone with medical expertise and knowledge in real-time". We recommend that decision makers, industry leaders, healthcare professionals, media moguls, and patients consider new modalities of healthcare delivery via technology, at a distance.

CONCLUSION

Telemonitoring is nowadays ubiquitous and cheap, mainly due to the penetration of mobile devices, but the established business models are restricting the speed and scale of the adoption of telemonitoring. We looked into the evolution of the provider-oriented approach (B2B) into a service-oriented approach (B2C). The cornerstone of the strategy is the value innovation, i.e. the strategic move that creates value for the market, while simultaneously reducing or eliminating features or services that are less valued by the current or future market. The market for the B2B telemonitoring consists of hospitals, while in the B2C model it consists of patients themselves.

In this study we presented the extended model – B2C – for the telemonitoring of chronic heart failure, which takes into account the healthcare continuum and supports patients' health and well-being at home and on the move. This is achieved by taking the telemonitoring service out of the hospital setting and into a new entity – the telemonitoring center – and by introducing a fourth pillar to the existing B2B model – distributors and/or promotors. Hence, the patient becomes the customer of the telemonitoring service and the B2C model is born. With this maneuver a difference is to be expected in the speed and scale of implementation of telemonitoring for chronic/multimorbid patients. We believe that the B2C model, in combination with B2B, is key to population-wide telemonitoring in the 21st century.

Chapter 5

Assessment of a Business-to-Consumer (B2C) Model for Telemonitoring Patients with Chronic Heart Failure

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ABSTRACT

Introduction: The purpose of this study is to assess the Business-to-Consumer (B2C) model for telemonitoring patients with Chronic Heart Failure (CHF) by analyzing the value it creates, both for organizations or ventures that provide telemonitoring services based on it, and for society.

Methods: The business model assessment was based on the following categories: caveats, venture type, six-factor alignment, strategic market assessment, financial viability, valuation analysis, sustainability, societal impact, and technology assessment. The venture valuation was performed for three jurisdictions (countries) – Singapore, the Netherlands and the United States – in order to show the opportunities in a small, medium-sized and large country (i.e. population).

Results: The business model assessment revealed that B2C telemonitoring is viable and profitable in the Innovating in Healthcare Framework. Analysis of the ecosystem revealed an average-to-excellent fit with the six factors. The structure and financing fit was average, public policy and technology alignment was good, while consumer alignment and accountability fit was deemed excellent. The financial prognosis revealed that the venture is viable and profitable in Singapore and the Netherlands but not in the United States due to relatively high salary inputs.

Conclusion: The B2C model in telemonitoring CHF potentially creates value for patients, shareholders of the service provider, and society. However, the validity of the results could be improved, for instance by using a peer-reviewed framework, a systematic literature search, case-based cost/efficiency inputs, and varied scenario inputs.

INTRODUCTION

Populations globally are aging, chronic diseases are becoming more prevalent and healthcare budgets are strained. Telehealth, i.e. telecommunication technologies used in healthcare, are emerging rapidly to help cope with the ever-increasing number of people suffering from chronic diseases. In the current healthcare climate, where a quarter of countries worldwide have a telehealth policy in place,[55] the dominant financial strategy is based on reimbursement schemes. This is also referred to as the Business-To-Business model (B2B). However, there are many barriers to the uptake of telehealth under the B2B model.[231]

In a previous publication we designed a Business-to-Consumer (B2C) model for telemonitoring patients with Chronic Heart Failure (CHF), by extending the existing B2B model. In order for CHF patients to have access to this service, healthcare providers, equipment manufacturers, regulators/payers, and promoters/distributors must come together via the establishment of a telemonitoring center in a jurisdiction. The B2B model needs to be extended toward the B2C to create synergies between these players in the healthcare ecosystem. However, it is not known if this model creates value for the proposed venture and society.

The venture is based on patient-driven demand for telemonitoring of cardio-vascular disease in the future. The targeted customer is: 1) a person aged 55+ at risk of or suffering from CHF, 2) with smartphone and mobile internet, and 3) able to procure the service and the telemonitoring devices. Care coordination is performed by telemonitoring nurses based in a telemonitoring center. A physician, pharmacist, and informal caregiver are included in the care process, and each stakeholder can set up and invite other stakeholders to join the care-coordination team. The patient is still a part of the healthcare system, which pays for the physician time and service, but is able to receive telemonitoring service irrespective of the spacetime restrictions (e.g. on the road, during the weekend). The procurement of the drugs, and the reimbursement for healthcare system utilization, goes via the regular pharmacies and insurance companies/ national health systems. Figure 10 describes the flow of data, voice communication, money, and medication between stakeholders.

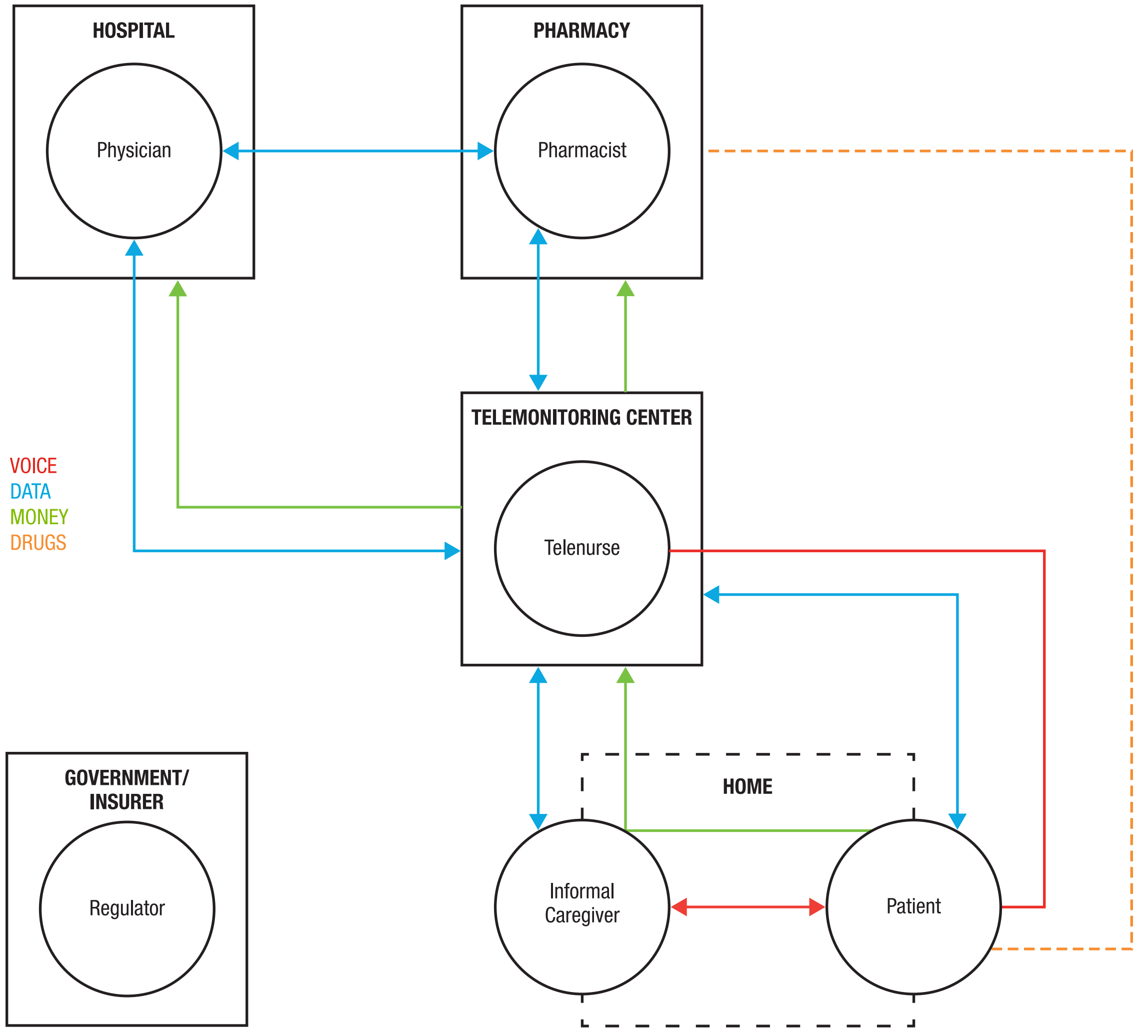

Figure 10. Individual and institutional communication in the B2C model for telemonitoring patients with chronic heart failure. Telenurse occupies the central role in the B2C telemonitoring model, and coordinates the care between the physician, pharmacist, patient, and informal caregiver, from the telemonitoring centre. The flow of voice communication (red line), data (blue line), reimbursement (green line), and drugs (orange line) can be unidirectional or bidirectional. It is represented by arrows between the agents or their respective institutions. The B2C telemonitoring decouples the patient and the informal caregiver from receiving care in the home. The payer in the B2C model is the patient, thus the government plays a role of the regulator only.

From an execution perspective, B2C telemonitoring involves: 1) informing patients via the media that the telemonitoring service exists, 2) patients and other stakeholders downloading the app, 3) patients registering and paying the installation charge and monthly fee, 4) connection of the peripheral monitoring devices, 5) technical assistance to resolve any installation issues, and 6) a telemonitoring nurse making an initial call to the patient. Figure 11 presents the Care Experience Flow Map[232] with the estimated number of minutes each action requires.

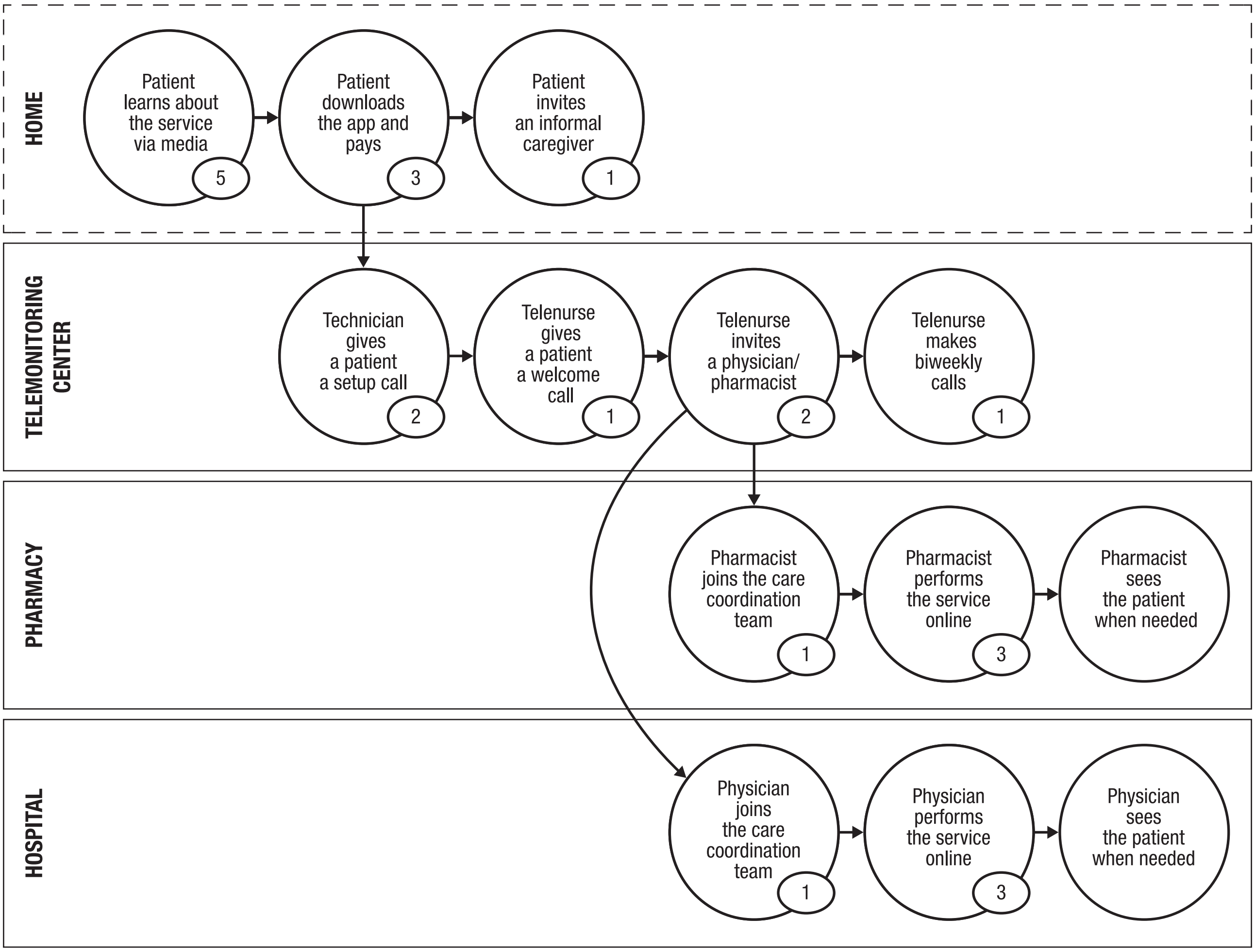

Figure 11. Care Experience Flow Map of the B2C model for telemonitoring patients with chronic heart failure (time in minutes). The map shows the experience of the patient on the B2C telemonitoring service, with a flow from one state to another, and time in minutes spent in each state. The flow is segmented according to the institution of care. The map shows what the experience of exchange in the B2C telemonitoring is, and is not exhaustive. Adapted from Patient and Family Centered Care Innovation Center of UPMC[232]

The aim of this study is to assess the B2C model in telemonitoring patients with CHF by analyzing the potential value it creates for 1) organizations or ventures that provide telemonitoring services based on this model, and 2) society. Our hypothesis is that B2C telemonitoring is well aligned with current healthcare structures, financing possibilities, public policy, technology availability, and consumer demands.

METHODS

We used a non-peer-reviewed method 'Innovating in Healthcare Framework' to assess the B2C model for telemonitoring CHF.[233] We searched the literature in order to inform both the non-financial part of the assessment and the financial calculations (i.e. the MS Excel model creation). We took a critical look at our assessment by discussing caveats and limitations.

Literature search

Both peer-reviewed and non-reviewed sources were taken into account. Scientific literature in English from 2010 onwards was searched. NHS Evidence, TRIP Database, Cochrane Library, PubMed, Medline, EMBASE, CINAHL, Web of Science, and Scopus were searched for 'telemonitoring', 'costs', 'financial', 'CHF', and combinations thereof. Business literature, such as Harvard Business Review, and reports from respected consulting firms were searched for the same terms. Our intention was not to do the systematic literature search, but to inform the assessment. We opted for a convenience approach, selecting literature based on ease of availability,[162] and did not use exclusion criteria. A.G. performed the search and the selection.

The framework

The Innovating in Healthcare Framework[233] is divided into three parts, consisting of ten main elements: 1) caveats – "Life is not literature", "Basic is beautiful", and "Beware of true believers", 2) venture type, 3) six-factor alignment – structure, financing, public policy, technology, consumers, and accountability, 4) strategic market assessment, 5) financial viability – breakeven and market share analysis, 6) valuation analysis, 7) sustainability – revenues, costs, management, and technology, 8) managerial assessment (not performed due to early stages of venture ideation), 9) societal impact, and 10) technology assessment. See Additional file 1 for detailed framework structure, at https://doi.org/10.1186/s12911-017-0541-2

The three distinctly different types of healthcare innovation

Healthcare ventures can be consumer-focused, technology-based, or integrators.[233] Consumer-focused ventures involve patients/consumers in their own care. Technology-based ventures rely on scientific advances to provide new treatments and cures, while the integrators rely on "horizontal and/or vertical integration to achieve healthcare efficiency and quality benefits".[233] Understanding the type is important for assessing the business model, how it fits with the six factors, and which cost items should go into the financial analysis.

Six-factor alignment: Is the idea viable?

The six factors that most critically influence innovation in healthcare are: 1) structure, 2) the nature of financing, 3) public policy, 4) technology, 5) consumers, and 6) accountability.[234] Structure deals with the established organizations and their power dynamics in the healthcare market. Financing considers reimbursement policies and available sources of capital. Public policy promotes activities in a society, or creates distortions in the market which can work against innovation. Technology is necessary in order to provide new ways of treatment, but is by no means sufficient. Consumers are the players in the market, usually time stressed, not empowered or satisfied with the care offering. Finally, accountability is key to the long-term success of a venture, be it toward the customers or the shareholders. It is imperative to understand the interconnections between these components in order to succeed in the healthcare market.

A.G., R.K. and H.V. graded the B2C model according to its fit with the six factors. No blinded scoring was performed, nor inter-rater variation assessed. We used a 4-point Likert-type scale[235] to assess the fit by consensus. The scale ranges from non-existent, poor and good to excellent.

Business model elements: How to make it happen

In the third part of the assessment we analyzed market size, competitive strategy used, and the venture's financial viability. The calculations were performed in 2016 US dollars. Personnel costs were converted from Singaporean dollars (SG) and euros (NL) to US dollars (July 2016). Non-personnel costs and volumes were expressed in US dollars and assumed to be equal in all three countries.

The breakeven analysis considered the number of patients needed for profits to surpass costs. If the venture is not able to reach the breakeven point (easily), it is not viable. Breakeven analysis is an important tool for profit planning.[236] It is also referred to as 'cost-volume profit analysis', and describes the volume of patients needed for the service to generate a profit.

The final step of the analysis involves assessing venture sustainability, managerial aspects (not performed in this publication due to early stage ideation phase), societal impact and technology-related risks.[233]

Financial calculations

The venture valuation was performed for legal jurisdictions, i.e. countries – Singapore, the Netherlands and the United States – in order to portray the opportunity in a small, medium-sized and large country (i.e. population). These countries were chosen because smartphone penetration there is among the highest in the world – Singapore 88%, The Netherlands 76%, and the US 57%.[237] Also, the state of telehealth in these countries is among the most advanced, and thus favorable for implementation of telemonitoring technology via the new business model. Singapore 's healthcare system ranks among the best and most efficient in the world, e.g. 2nd for healthcare outcomes by The Economist Intelligence Unit Healthcare.[238] The same report puts The Netherlands in 6th place for spending on healthcare but 17th for outcomes, while the United States is first for spending but 32nd for health outcomes.[238] The financial model was created in MS Excel 2013, with 5-year projections based on the historical data retrieved by the literature searches.

The fictitious B2C telemonitoring venture provides a 10-min consultation with a telenurse every fortnight, which is similar to the Centre for Telehealth, University of Hull, where one telenurse provides a 15-20-min consultation once per month. Advanced telehealth systems can support more than 250 patients per nurse,[239] but we conservatively based our calculations on one telenurse taking care of 200 patients. The technician makes a 20-min call once a year (at set-up and for yearly maintenance) and is able to service 250 patients per month. There is one manager per 30 staff members. Holidays, sick leave, maternity leave, and personnel churn is accounted for as spare capacity of 15%.

Cosentino[239] acknowledges that "determining clinical staffing requirements and nurse-to-telehealth patient ratio is one of the most important operating cost factors", and proposes $27/ month for a program that employs one full-time telehealth nurse per 200 patients. The literature search yielded the willingness-to-pay for telehealth services in general,[202–205] and the calculations were based on the following input: a one-off annual charge of $50 plus monthly subscription of $25 USD ($275 per year, for 11 months) for the service. The median salaries were reported per country on Payscale (www.payscale.com) and converted to US dollars. Table 13 lists all the inputs to the financial analysis.

Table 13. Inputs to the financial assessment of the B2C telemonitoring of chronic heart failure (in US dollars).

Items	Inputs
Sign-up/maintenance fee (per year)	$50
Subscription fee (per month)	$25
Support technician (IT) remuneration in Singapore (per year)	$21,162
Support technician (IT) remuneration in The Netherlands (per year)	$26,999
Support technician (IT) remuneration in the USA (per year)	$41,606
Registered nurse remuneration in Singapore (per year)	$26,889
Registered nurse remuneration in The Netherlands (per year)	$24,102
Registered nurse remuneration in the USA (per year)	$58,371
Operation manger remuneration in Singapore (per year)	$48,629
Operation manger remuneration in The Netherlands (per year)	$58,200
Operation manger remuneration in the USA (per year)	$60,572
Office rent (per employee, per month)	$600
Office supplies (per employee, per year)	$200
Call-center services (per agent, per month)	$50
Back-end services (per month)	$189
App development (per year)	$750,000
Video education (52 videos per year)	$250,000
Mass-media promotion (per addressable market member)	$1.00
Cost to Acquire a Loyal User (CALU)	$2.51

Remuneration consisting of salary, bonus, profit sharing and commission (*Source*: www.payscale.com)
Cost per Loyal User Index: April 2016 (*Source*: www.fiksu.com)

RESULTS

The business model assessment of a fictitious venture for telemonitoring patients with CHF is based on the following categories: venture type, six-factor alignment, strategic market assessment, financial viability, valuation analysis, sustainability, societal impact, and technology assessment. The caveats will be considered in the discussion.

Venture type

The B2C model shifts the focus in telemonitoring away from technology (i.e. product focus) to the consumer (i.e. service focus). The plan is to build the venture on the foundations of an established telemonitoring business by extending the B2B model towards the B2C. Although the model uses a strong technology base, i.e. the back-end with patient stratification and data analysis systems, the focus is clearly on engaging patients and involving them directly in their care via measurements, education and targeted communication. The distribution channels for the service provision are digital – mobile communication networks with internet access – and the point-of-care are smartphones. Thus, the distribution channels are curtailing hospitals, and the service can be run on a regional or national level. These are all hallmarks of a consumer-facing venture.

Six-factors alignment

The analysis of the six factors critical to a B2C telemonitoring service for CHF patients is presented in Figure 12.

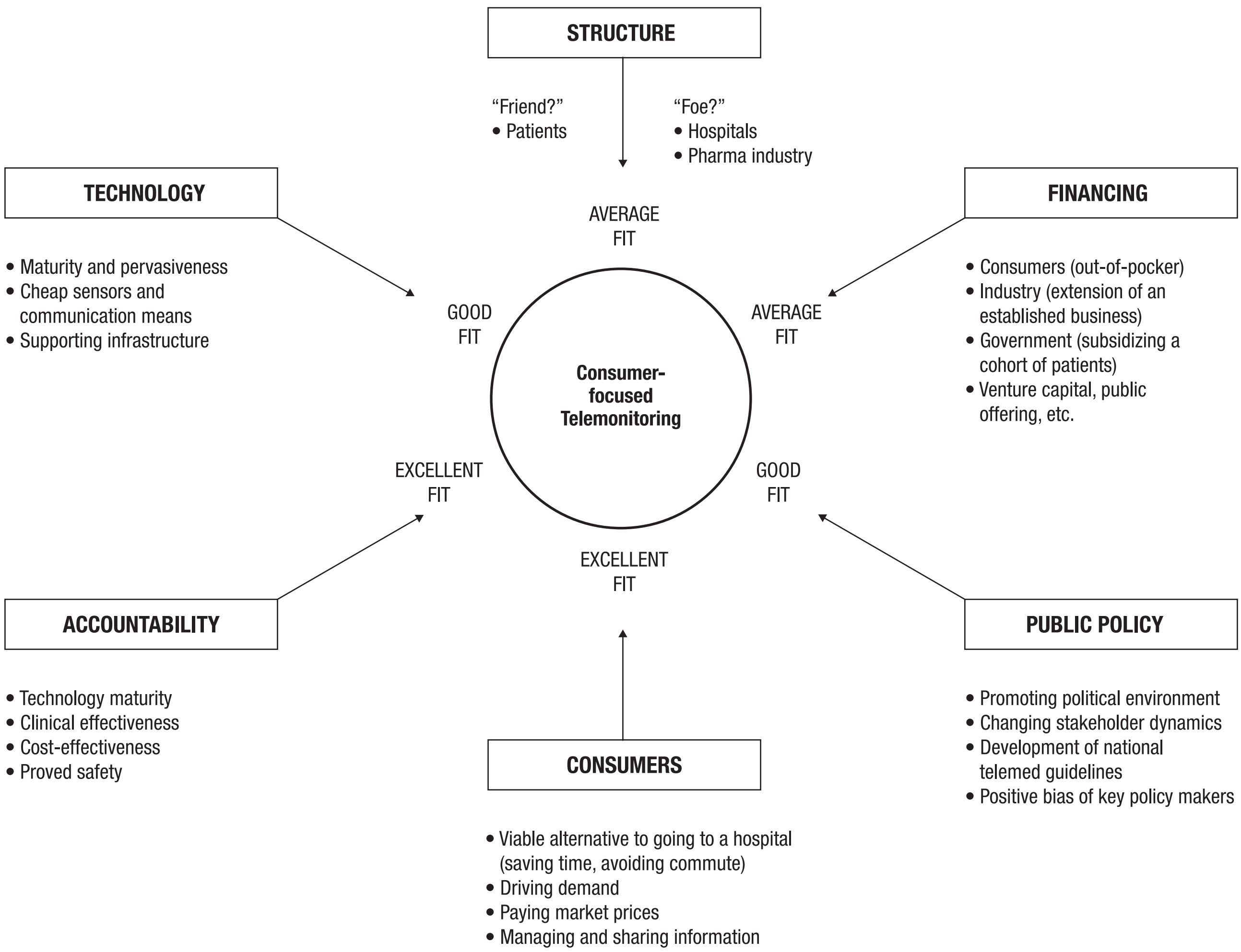

Figure 12. Six factors relevant to the B2C telemonitoring service for chronic heart failure patients. The Six factors analysis shows the relevant factors for implementation of B2C telemonitoring and the driving forces behind each factor. The list is not exhaustive. Adapted from HBS Case No. 313–070, Rev. 2014 (Boston: Harvard Business School Publishing[240])

Structure: 'Average'

There are potential "friends" and "foes" in the contemporary healthcare system, looking to help or attack the innovator.[233,241] The structural components for a telemonitoring venture are already present, but some are part of the healthcare organizations willing to preserve the status quo. The "friends" of this venture are the patients, and additional parties affected by a patient's worsened or prevented heart failure exacerbation, including employers and insurance companies, as well as drug manufacturers given sub-optimal levels of medication adherence for which closer management may lead to increased use. The "foes" would be the hospitals and the healthcare systems operating in the fee-for-service mode, that includes conventional management of outpatient care in which patients show up for billable appointments (not at a hospital); however, with improved care, no billable service would be needed. The structure for the B2C telemonitoring is deemed average – all parts are in existence but need a skillful rearrangement so that all stakeholders remain “on board” (especially the physicians).

Financing: ‘Average’

B2C telemonitoring allows patients to compare and contrast the service offering with other market alternatives, as they pay ‘out of their own pocket’. This guarantees the market price in a given jurisdiction over time. In contrast, in the B2B model the insurance pays hospitals for the telemonitoring service and the equipment physicians and nurses use. The telemonitoring equipment is given to patients by the providers, and taken back after a certain period of time. The B2C model therefore removes the true bottleneck in implementation of telemonitoring – reimbursement.[242] The financing of a B2C telemonitoring venture does not rule out other sources of capital – e.g. venture capital, government subsidies, public offering, and loans.

Public policy alignment: ‘Good’

The following four variables influence public policy: political environment, stakeholder dynamics, regulatory and legislative process dynamics, and biases of key policy makers.[233] The political environment can help promote B2C telemonitoring as it takes the pressure off governments to provide healthcare services. It also reduces the need to train more healthcare staff to care for the rising number of patients with chronic diseases. This can, however, disrupt the current stakeholder dynamics, with some physicians viewing automatic telemonitoring as a threat to their jobs. B2C telemonitoring allows less expensive workers, i.e. telenurses, to take over the mundane part of the care process, while physicians remain in charge of a patient’s therapy. Regulatory dynamics can change over time, but for the time being national telemedicine guidelines have been developed, e.g. in Singapore.[243] In 2004 the United States administration established a dedicated office to promote the use of information technology in healthcare, allowing all Americans to have access to electronic health information.[244] This has resulted in a dramatic increase in funding for health IT, mainly spent on EMR systems, but it could also help the implementation of telemonitoring.

Technology alignment: ‘Good’

Technology innovators face two main problems: knowing when to invest in the technology, and who the competitors are.[233] Early telemonitoring solutions did not catch on, because technology was not mature enough and the ‘healthcare ecosystem’ was not ready. But today the information-communication channels are available, the mobile devices are pervasive, and the push toward consumer-driven healthcare is real. Technology solutions compete not only with each other but also with other services and solutions in the healthcare ecosystem. Telemonitoring CHF can, and should, reduce the consumption of drugs, making the pharma industry a contender. Competition can also occur between outpatient clinics which used to manage chronic disease patients and the telemonitoring venture. Another source of conflict is data privacy and data ownership. ICT companies, governments, patients’ protection organizations all compete for data ownership, and have conflicting agendas. But as we assess the timing and the ecosystem for implementation of B2C telemonitoring, we believe that today there is a good alignment.

Consumer alignment: ‘Excellent’

There are two important trends in healthcare: empowerment, and lack of leisure time.[233] Patients now use the internet to search for information about their disease.[245] In Singapore and the Netherlands 25% and 21% respectively of the daily mobile internet users older than 55 years purchased a service or a product via smartphone.[189] Consumers of healthcare services in the United States spent $34 billion dollars of their own money on Complementary and Alternative Medicine (CAM) in 2007, while making 354.2 million visits to practitioners of CAM.[246] Consumers might recognize telemonitoring as a viable way of managing their condition, besides going to a physician.[184] Statistics from the OECD[248] show that on average per person each year 1788 h were worked in the United States and 1421 in the Netherlands (Singapore was not included). This data shows that leisure time is squeezed and that patients can benefit from not spending time going to see a physician or sitting in a waiting room. The B2C model helps patients engage with a healthcare system on their own terms, when and where they want, gaining ‘peace of mind’ along the way, and thus the consumer alignment is deemed excellent.

Accountability: ‘Excellent’

Nowadays telemonitoring is safe and reliable[184] thanks to sensor and communication maturity. The research and development needed for a B2C telemonitoring service to deliver on its promise lies in the domain of ICT, patent protection and legal frameworks. The accountability toward the stakeholders is assured as several studies have proven that telemonitoring is: 1) effective, helping the industry with the implementation of the early systems,[81,249] 2) safe, helping the healthcare providers to accept the new ways of working,[250,251] and 3) cost-effective, helping governments/insurers with reimbursement for the new technology.[53,110] Overall, the accountability of the B2C telemonitoring can be evaluated as excellent.

Strategic market assessment

There is limited evidence of the prevalence of CHF in Asia, but the range is 1.26 - 6.7%.[252] We used the lower bound of 1.25%, and in Singapore that amounts to 62,500 patients in a population of approximately 5 million. With a smartphone penetration of 88% in the population,[253] the highest in the world, Singapore is the obvious choice for a B2C telemonitoring pilot. In the age group 55+ some 62% of people have a smartphone, so most CHF patients are potential users of telemonitoring services.

Assuming the same estimated prevalence of CHF as in the general population – the market in the Netherlands represents 1.25% of an estimated population of 17 million – i.e. some 212,500 people. The Consumer Barometer and The Connected Consumer Survey 2014/2015[254] show that 50% of the 55+ age group in the Netherlands use a smartphone. Again, with the rise in smartphone penetration in this age segment it is to be expected that the majority of potential CHF patients can be considered potential users of the telemonitoring service.

The same survey[254] shows that in the United States the smartphone penetration in the age group 55+ is 28%, while 71% use either a smartphone or a basic mobile phone. The CHF prevalence of 1.25% in approximately 320 million citizens amounts to 4 million people. The market opportunity in the United States is evidently big, but the challenge to provide the service is equally big, as the population is geographically dispersed and not homogeneous.

Financial viability

A literature search yielded the willingness-to-pay for telemonitoring services. American Well[205] conducted a survey in telehealth in the United States, and found that 64% of people would see a physician over video, but 62% think it should cost less than the current $82 for first-time patients. Qureshi et al.[203] found that “the majority of those choosing telemedicine (95%) were also willing to pay a median of $25 (5 to 500 dollars) out-of-pocket”. Bradford et al.[202] found that 30-50% of hypertensive patients were willing to pay at least $20 per month (CHF patients were willing to pay even more), while Seto[204] found that 55% of heart-failure patients were willing to pay $20, and 19% were willing to pay $40.

Breakeven analysis

The breakeven volume of customers (i.e. CHF patients) in Singapore is 9877 and in The Netherlands it is 9451. That is 15.8% of the total CHF population in Singapore, and 4.45% in The Netherlands (based on 1.25% prevalence rate). The service is not viable in the United States due to scenario inputs (i.e. high median salaries), and does not break even. The total expenses, consisting of personnel and non-personnel expenses, are not offset by the fees collected in the United States.

Market share analysis

In the period from 1st June 2014 to 31st May 2015 there were 4085 admissions due to Heart Failure in Singapore (all hospitals and all wards combined), with each admission costing around $1500 SGD in Ward C (app. $1100 USD) and around $6000 SGD in Wards B1 and A (app. $4400 USD).[255] As Singapore ages, these figures are likely to increase. Given that the total number of CHF patients in Singapore is estimated at 62,500, with 4085 (6.54%) being hospitalized, and the number of patients needed to break even is 9877 (15.8%), this venture seems viable and able to grow the market share. The calculations for the Netherlands are even more favorable due to the low percentage of patients needed to break even. However, due to the increased complexity of the service provision, factors should be applied to calculations in order to address the scalability and transferability issues (logistics, legal issues, care coordination, recruitment and training of nurses, customer acquisition, and media coverage).

Valuation analysis

Here we present the valuation analysis (i.e. terminal value plus annual cash flows), to help us understand the business valuation after five years in Singapore, the Netherlands and the United States. The calculations assume a market share of 100% in the first two years (dropping to 55% in the sixth year) due to the ‘first mover advantage’, the competitive strategy used. The same percentage in a proportionately bigger country is proportionately harder to attain. However, for the comparability of the analyses all calculations assume a fixed market share per year and are presented at the same three levels of expected return on funds invested: 50%, 25% and 15% per year (Table 14). See Additional file 2 for detailed calculations, online at: https://doi.org/10.1186/s12911-017-0541-2

Table 14. Valuation of the B2C telemonitoring venture in the fifth year (in million US dollars).

Country	Discount	Annual Cash Flow (Profit/Loss)	Present Value of Annual Cash Flow	Present Value of All Annual Cash Flows	Present Value of Terminal Value[a]	Total Present Value[b]
Singapore	50% annually	3.13	0.41	1.51	4.13	5.64
	25% annually	3.13	1.03	3.15	10.27	13.41
	15% annually	3.13	1.56	4.42	15.58	20.00
Netherlands	50% annually	10.76	1.42	6.06	14.17	20.23
	25% annually	10.76	3.53	12.12	35.27	47.39
	15% annually	10.76	5.35	16.80	53.51	70.31
USA	50% annually	-94.76	0	0	0	0
	25% annually	-94.76	0	0	0	0
	15% annually	-94.76	0	0	0	0

[a]Terminal value calculated as x10 annual cash flow in the fifth year.
[b]Sums not matching due to rounding.

From Table 14 we see that the B2C telemonitoring model is not only viable but also valuable. Given that the Singapore population is relatively small (roughly 5 million) and the target disease is of low prevalence (1.25%), the B2C model allows for a financially healthy venture valued at around $20 million US dollars (at 15% return annually), with around $3 million USD cash flow in the fifth year. The valuation of a similar venture in The Netherlands, which is a medium-sized country in terms of population (roughly 17 million) with the same disease prevalence (1.25%), comes to more than $70 million US dollars (at 15% return annually) with an annual cash flow of more than $10 million USD in the fifth year. In the United States, which has the largest population of the three (roughly 320 million), the same disease prevalence and the same non-personnel input cost, the venture is not viable.

Sustainability

Furthermore, we explore the sustainability of the B2C telemonitoring from four perspectives: revenues, costs, management, and technology.

Revenue sustainability

The lifetime customer value of a CHF patients is low, due to the nature of the illness and its progression. In the case of a regular churn – the median survival after one year in CHF patients in the Framingham study was 57% for men and 64% for women[113] – a feasible customer acquisition strategy would aim at creating critical mass to ensure breakeven volumes and generate profit. Demand for these types of services, and for telehealth in general, will likely increase in the future as the population ages,[256] adding to revenue sustainability.

Cost sustainability

In the B2C venture the biggest cost contribution is from the nurses' salaries, followed by the salaries of the technicians and the managers. The non-personnel costs of the digital services will remain the same or drop in the future. The marginal cost of acquiring a new user might not equal zero, as this cost is a function of marketing and sales operations, but the cost of adding a new user to the system is obviously sufficiently low to be assumed zero.[257] Furthermore, we believe the telemonitoring equipment (i.e. sensors) will become commoditized in the future and costs will only be incurred for running the service (the B2C model in telemonitoring is device-agnostic). Frost & Sullivan[119] predict a decrease in telemonitoring equipment prices and an increase in telemonitoring service fees, with increased demand for telemonitoring via telehealth or telecare services in the future. The costs, from the provider perspective, will thus be tied to service management and not device manufacture.

Management sustainability

The management of chronic diseases is increasingly being seen as the job of registered nurses (RNs). In telemonitoring "the most frequent activity by the nurses was reporting information to the primary care provider (17%), followed by providing lifestyle information to the patient related to diabetes mellitus and hypertension (e.g., diet, smoking cessation, foot care [14%], and social contact with the patient [14%])".[258] At the beginning of the century, it was expected that the shortage of nurses in the United States would continue until 2020.[259] The employment projections for 2012-2022 released by the Bureau of Labour Statistic[260] in December 2013 confirm this, and the RN workforce is expected to grow from 2.71 million in 2012 to 3.24 million in 2022. This shortage in supply of (tele)nurses will reflect negatively on the scalability of this telemonitoring venture in the short run.

Technology sustainability

The main factor affecting sustainable provision of the service is not the telemonitoring technology but the inability to make the shift from a myriad of small-scale pilots to large-scale deployment, and the integration with contemporary healthcare systems.[261] In the near future, the smartphone manufacturers (or telecom operators) might initiate their own monitoring service. The production of devices and sensors might be commoditized, pushing the device manufacturers toward the service business. The sustainability of the technology is tied to successful implementation in the healthcare system, which in turn will feed another development cycle. This indeed is a 'virtuous cycle' between technology development and service provision.

Societal impact

Telemonitoring solutions for heart failure help patients to better self-manage their condition, and provide peace of mind for both patients and caregivers.[262] Because the B2C model relies on payments from service users (i.e. patients), while the public healthcare sector derives the benefit, in terms of prevented hospitalizations and ER visits, this venture has a positive impact on society. It allows patients the freedom to consume healthcare services when and where they want, governments to rationalize common funds and facilities, industry to generate profits via business-model innovation, and telecoms to extend operations into healthcare. The combination of the B2C and the B2B model can be further extended to B2G as governments might subsidize a cohort of their most severe CHF patients. Thus, this is a truly 'do good – do well' venture – it does good for patients and society and performs well for shareholders.

Technological risk assessment

The technology chain consists of: 1) various sensors and devices that connect to a smartphone via Bluetooth connection, 2) a smartphone connected to the internet via Wi-Fi or mobile data, and 3) a back-end consisting of servers hosting patient data and various types of telemonitoring software. We expect sensors to become cheap, or even commoditized, smartphones to become ubiquitous, and services via internet to become available to most patients in the future. Table 15 lists issues and gives a risk assessment for B2C telemonitoring.

Table 15. Checklist for evaluating new healthcare technologies in the B2C telemonitoring of chronic heart failure.

Issues	Assessment[a]	Explanation
1. Understanding the Black Box	Small risk	Telemonitoring (i.e. measuring and transmitting physiological signals) consists of two parts – the algorithms aiding the nurses in reviewing the physiological data coming from the patients, and the telecommunication technologies – both with widely understood scientific mechanisms.
2. Depth of research	Medium risk	There is a substantial amount of research on the clinical effectiveness of heart failure monitoring, with promising results, but not so much on cost-effectiveness. The available meta analyses show improved survival and better outcomes with telemonitoring, at same or higher costs.
3. Downside risks	Small risk	Telemonitoring does not interfere with bodily functions. The care is provided by registered telemonitoring nurses while cure is administered by doctors and pharmacists.
4. Financial considerations:		
• *Market acceptability to medical personnel?*	Medium risk	Telemonitoring technology is not excessively innovative or disruptive to the healthcare process. The business model (B2C) is an extension of the existing one (B2B), and the novelty revolves about logistics and operations.
• *Are technologies financially beneficial to adopters?*	Small risk	A chronically ill person will spend approximately 1-2% of their average monthly income on a telemonitoring service. There is no risk in “over-spending” and no financial risk for the patient but the payment-borne-by-consumers model demands high attractiveness of the service to customers.
• *Creation of “turf warfare” among different physician specialties?*	Medium risk	As B2C telemonitoring is directed toward the patients/consumers it is opening/creating a market and not encroaching on existing “turf”. However, telemonitoring centres can be seen by hospitals as competitors rather than complementary organizations.
• *Requirement for new types of medical personnel?*	Medium risk	There is risk associated with the creation of a telemonitoring centre staffed by telemonitoring nurses in any jurisdiction. Creating the site, drafting and training personnel is risky.
• *Do technologies fit existing coverage, coding, and payment regulations?*	Medium risk	With such a large population of heart-failure patients in the world today, the regulation is slowly turning to full coverage and payment for telemonitoring.
• *Do technologies create a product and/or customer pipeline?*	Small risk	More advanced monitoring systems and packages tailored to individual patients (or other chronic patients) can be introduced later by adding new customer “pipelines”.
• *Market size and ease of penetration*	Small risk	The market is not very large in Singapore and is therefore easier to penetrate. The US or EU markets are bigger but harder to penetrate. In terms of disease prevalence, the global market for telemonitoring CHF is similar to the general population, i.e. 1-2%.
5. Regulatory issues: Seriousness of Problem	High risk	The FDA in the US has started to look over the medical app market and it is likely that clearance will be needed (likely other jurisdictions will require regulatory oversight). At the moment this risk can be averted by carefully making associations with existing healthcare organizations.
6. Potential competition from other technologies	High risk	There’s not much protection in telemonitoring apart from the algorithmic core, resulting in fierce market competition if new players enter the field. However, a telemonitoring centre is a huge deterrent to any party wanting to go with a purely device/service-based business model.
7. Likelihood of obtaining a patent	Small risk	Patents have been granted on the technologies involved in telemonitoring, on algorithms and software. The business processes and the business model cannot be patented.
8. Production considerations	Small risk	The development of the software/app will have to follow regulatory guidelines. However, once in place and clear of production issues, the service can be easily upgraded and distributed.

Adapted from HBS Case No. 313-070, Rev. 2014 (Boston: Harvard Business School Publishing[240])
[a]Assessment scale: small risk, medium risk, high risk

DISCUSSION

The objective of this study was to assess the potential societal and corporate value of B2C telemonitoring for CHF patients. In doing the analyses we used the Innovating in Healthcare framework as described under Methods, and the Results were presented according to the elements of the framework. The six-factor fit was found to be average for Structure and Financing, good for Public Policy and Technology, and excellent for Consumers and Accountability (Figure 12). The venture created on the basis of the B2C model is viable and profitable for the chosen parameters, in Singapore and The Netherlands, but not in the United States (Table 14).

The healthcare providers – physicians, nurses and pharmacists – are part of the existing healthcare structures that are burdened with waste and inefficiency.[263] Patients go to see their physicians when they can, instead of when they should. In the United States, in 2012, 82.1% of adults contacted a healthcare professional – totaling 1.2 billion visits to physician practices, hospital outpatient and emergency departments.[264] Some of these visits can be prevented with B2C telemonitoring. The analysis revealed that "friends" of this venture would be patients and informal caregivers, employers and insurance companies, as well as drug manufacturers. The "foes" would be the hospitals and the healthcare systems that still operate in the fee-for-service mode.

Weinhold et al.[261] ascertain that "telemonitoring is one of the most promising concepts in enabling patients' self-management, relocating medical services and improving equity in access to high-quality care". However, the same authors say the major problem with telemonitoring today is not the technology, but the inability to move from small-scale pilots to population-wide deployment. This is due to the restrictive business model of the implementation where hospitals are in charge of the service organization and provision. Extending the B2B model in telehealth to B2C model solves for this bottleneck.

In the EU the predominant way of providing telehealth services is via third parties – home-healthcare agencies or specialized hospitals – in essence the B2B model.[265] The B2C model envisions telemonitoring centers as separate entities, which host technology and nurses, and provide the service in a whole jurisdiction. Via this model, consumers are in charge of the service they consume, the data they produce, and the information they share. Consumer-driven healthcare is expected to become the norm in the twenty-first century, but there are problems, as shown in The Netherlands and Switzerland.[266]

The business model is one of the impediments to wider adaptation of telemonitoring, while financing is another. In the healthcare sector revenues and capital are acquired in a different way than in most other industries.[233] In the developed world the reimbursement in healthcare usually goes via a third party – insurers or government – where the user does not pay, and the payer does not use the good or service.[233] The patients know very little about the cost of the treatment, and the prices can be determined by providers in a 'non-market' way. With B2C telemonitoring the patients are aware of prices and can control costs.

The healthcare sector is heavily regulated by the government, as the government is the biggest purchaser.[233] From the government perspective, there is more incentive to protect and overregulate than to face public outcry if a drug or a treatment proves to be harmful.[233] The B2C telemonitoring needs all four stakeholders – creators, providers, distributors, and payers – to work together in order to succeed in a jurisdiction. This is a complex problem, although public policy favors telehealth as it saves costs and improves health-related outcomes.[267]

Understanding the innovation type, the market size, the competitive strategy and the valuation of a venture is not enough. In addition to all of this, the impact of the venture on society should be positive. B2C telemonitoring is an example where all stakeholders are accountable and benefit from innovation – customers benefit from the service when they need it, healthcare benefits from the reduced burden and improved effectiveness, industry benefits from the creation of innovative businesses, and governments benefit from reduced expenditure while citizens enjoy the best possible care.

Thus, extending the B2B model toward B2C could be the next step in health services integration[268] because the B2C model in telemonitoring CHF patients supports:

1. Clinical Integration: the nurse makes sure that the cardiologist only gets involved in complex cases. The patient communicates with the nurse who makes sure others are informed about the status of the patient and interventions, if necessary;
2. Service Integration: the patient receives care at home and does not meet the nurse or the cardiologist at the hospital;
3. Financial Integration: the B2C model applies a monthly rate instead of the current fee-for-service payment structure. As such, it supports financial integration. However, for true financial integration additional changes within the system are required.

Kannampallil et al.[269] proposed a theoretical lens for studying complexity in healthcare based on the degrees of interrelatedness of system components. Functional decomposition is proposed as a mechanism for studying the subcomponents and their interrelatedness. In the B2C model (Figures 10 and 11) data, voice, money and drugs are continuously exchanged. In this framework we would position the B2C model in the NW part of the graph: low number of components, but high degree of interrelatedness.

Limitations

The main limitation of our study is that we used a non-peer-reviewed method,[233] and did not investigate the validity of the six-factor qualification fit. Notwithstanding the Framework not being subject to peer-review in the scientific literature, it was found in this study that the framework is easily applicable in the field of telehealth. Another major concern is the non-systematic search of the literature, and opting for a convenience sample. In the financial analysis we assumed that an equal percentage of market share can be achieved in all three geographies, that the churn of patients on the service will not be extreme due to death or withdrawal, and that patients will be able to spend approximately 1–2% of their net monthly income on the service. The analysis excluded the cost of the telemonitoring devices that the patients would need to procure. The efficiency estimates were taken over from literature and an interview with one telehealth provider (Hull, UK), while the cost of non-personnel expenses was arbitrary. We performed a scenario analysis, without a sensitivity analysis on the level of individual variables. Also, the same group of authors that created the model took part in the assessment, which might have introduced bias.

CONCLUSION

The business model assessment revealed that B2C telemonitoring creates value for customers (patients), shareholders of the service provider, and society. The analysis of the healthcare ecosystem where this innovation could be implemented – Singapore, The Netherlands, or the United States – shows potentially a good-to-excellent fit of the model with the Six Factors. The financial analysis indicates that the venture is profitable, except in the United States, according to the chosen input parameters.

Chapter 6

Care Coordination in Business-to-Business (B2B) and Business-to-Consumer (B2C) Model for Telemonitoring Patients with Chronic Diseases

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ABSTRACT

Introduction: For telemonitoring to support care coordination, a sound business model is conditional. The aim of this study is to explore the systemic and economic differences in care coordination via business-to-business and business-to-consumer models of telemonitoring patients with chronic diseases.

Methods: We performed a literature search in order to design the business-to-business and business-to-consumer telemonitoring models, and to assess the design elements and themes by applying the activity system theory, and describe the transaction costs in each model. The design elements are content, structure, and governance, while the design themes are novelty, lock-in, complementarities, and efficiency. In the transaction cost analysis, we looked into all the elements of a transaction in both models.

Results: Care coordination in the business-to-business model is designed to be organized between the places of activity, rather than the participants in the activity. The design of the business-to-business model creates a firm lock-in but for a limited time. In the business-to-consumer model, the interdependencies are to be found between the persons in the care process and not between the places of care. The differences between the models were found in both the design elements and the design themes.

Discussion: Care coordination in the business-to-business and business-to-consumer models for telemonitoring chronic diseases differs in principle in terms of design elements and design themes. Based on the theoretical models, the transaction costs could potentially be lower in the business-to-consumer model than in the business-to-business, which could be a promoting economic principle for the implementation of telemonitoring.

INTRODUCTION

Telemedicine and telemonitoring systems have profoundly changed the way in which care is provided to patients with chronic diseases. The value that different telemedicine and telemonitoring systems can deliver is closely related to a business model, which structures the provision of the care service mediated by the technological architectures. Given that chronic diseases are the main cause of disability and loss of quality of life in the 21st century – where ischemic heart disease, cerebrovascular disease, lower respiratory infections, lower back and neck pain, and chronic obstructive pulmonary disease are responsible for the biggest burden of disease globally[270] - it is important to properly assess how different telemedicine and telemonitoring business models impact upon healthcare provision where chronic diseases are concerned. This is even more relevant since chronic diseases are no longer seen as diseases of affluence or diseases of the elderly. They are becoming more prevalent in developing countries and among the working population,[271] and will be the major reason for the loss of public good in this century.[272]

So far health technology assessment efforts have focused on cost-effectiveness of telemedicine, overlooking the business model and stakeholder dynamic in chronic disease management. The cost analyses have not gone further than identification of utilization from the payer or societal perspective, completely ignoring the transaction costs in an implementation model. Care coordination via telemedicine is intimately tied to a business model which promotes or hinders wider implementation via interdependencies of the activity system. There is, therefore, a global need for an effective and efficient way to organize activities around the management of people who are at risk or have been diagnosed with a chronic disease.

Chronic disease management and care coordination

The current care provision is inadequate to address the challenges of an aging population.[273] Chronic disease management has proposed new concepts of care coordination and integration as strategies for dealing in a more efficient and cost-effective manner with the complexity of chronic diseases and multimorbidity.[42] Chronic disease management provides managerial solutions to organize and coordinate the different components involved in the care of chronic disease patients pursuing a patient-centric approach.[42] To achieve these goals, and to ensure continuity of care and co-ordination between different health care services providers, an integrated care approach is needed.[274] Given the diversity and complexity of the activities involved in chronic disease care provision, many different care coordination solutions have been proposed.

Schultz and McDonald[275] identified 57 different definitions of care coordination, distilling them into coordination efforts aiming at organizing patient care activities between two or more participants (including the patient) in order to support and enhance the delivery of the appropriate health care services; and into the coordination of information exchanges among healthcare personnel, and all the other resources required to deliver the expected care services. The coordination logics underpinning the two major clusters identified by Schultz and McDonald in the analysis of key concepts of care coordination clearly differ. However, they do overlap and have unclear boundaries, and are used interchangeably[276] when the design and management of new coordination mechanisms is undertaken. This is also evident in the design of telemedicine and telemonitoring systems aiming at supporting chronic care provision.

Telemonitoring, business models, and costs

Telemedicine and telemonitoring are often referred to as "solutions" for delivering high-value care to a patient with a particular condition, in a particular location. Sood et al.[277] analyzed 104 peer-reviewed definitions of telemedicine, distilling them into an e-health branch of services for delivery of healthcare and education from one geographical location to another. The World Health Organization[61] provides a more comprehensive definition of telemedicine as "the delivery of healthcare service, where distance is a critical factor, by all healthcare professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of healthcare providers, all in the interest of advancing the health of individuals and their communities."

Home telemonitoring, a part of telemedicine, in turn is defined as an automated transmission of patient's health status data from a home to the respective healthcare setting.[184]

Telemedicine and telemonitoring can therefore offer great support for the provision of effective healthcare services, minimizing the costs of the services in many different configurations of healthcare and optimizing the use of the resources needed to provide these services. The successful implementation of telemedicine and telemonitoring is challenging since it is not easy to overcome the misfit between the patient's needs and the care model in place, which hampers the effective deployment of these healthcare solutions in the first place. Moreover, the different value chain configurations of the business models used to support telemedicine and telemonitoring solutions affect the value generated by the chosen solution.[278]

A widely used definition of a business model by Chesbrough and Rosenbloom[279] is: "a blueprint for how a network of organizations cooperates in creating and capturing value from technological innovation". Zott and Amit[280] argue that the business model also introduces the company's bargaining power, i.e. the ability to negotiate the price and the value it can derive from its activity.

Telemonitoring is predominantly introduced via the business-to-business (B2B) model.[281] B2B is a strategy where one business makes a commercial transaction with another, e.g. a telemonitoring equipment manufacturer with a hospital. In many instances B2B telemonitoring has not gone further than the pilot testing,[150] possibly due to reimbursement strategies, implementation issues, and/or economic principles. In the B2B model, the technical and legislative costs prevent the implementation of a full-scale long-term project due to high transaction costs.[282] Transaction costs are costs incurred in the selling and buying process. They are divided into search and information costs, bargaining and decision costs, and policing and enforcement costs.[283] Different business models differ in terms of the transaction costs generated for the agents of exchange, and implementation is only possible when investment does not exceed the costs incurred. Hence, new business models for implementation of telemedicine and telemonitoring in the management of chronic diseases should be considered.

The alternative to the B2B model is the business-to-consumer (B2C) model. B2C is a strategy where a business makes a commercial transaction with the end customer, e.g. a telemonitoring center with a patient.

The activities performed in the B2C model for telemonitoring patients with chronic diseases are different, as are the stakeholders, the structure and the governance. The new model allows care to be administered to patients whenever and wherever they need it. It remains to be seen to what extent the B2C model has an effect on the transaction costs. A business model which leverages the supply chain of healthcare services but lowers the transaction costs in the exchange in the healthcare market has yet to be found.[282]

Theoretical framework

An activity system describes the set of activities that a company performs in order to capture value, and is characterized by interdependencies between its suppliers and customers.[280] An activity of a company can be explained as “the engagement of human, physical and/or capital resources of any party to a business model (the focal firm, end customers, vendors, etc.) to serve a specific purpose toward the fulfillment of the overall objective”.[280]

We employ the activity theory[284] to assess the design elements and the design themes in telemonitoring patients with chronic diseases via ‘the NICE model’.[280] The NICE model suggests that the value generated by an activity system is characterized by different design themes that consist of alternative configuration of systems’ design elements. The design elements of an activity system consist of content, structure, and governance. The design themes are novelty, lock-in, complementarities, and efficiency. These two sets of design parameters capture the purposeful, firm-centric design of the activity systems.[280] The framework provides an insight by a) giving business model design a language, concepts, and tools; b) highlighting business model design as a key managerial/entrepreneurial task; and c) emphasizing system-level design over partial optimization.[280]

The central concept of the activity system theory is interdependencies, which provides insights into processes that enable a company’s activities to evolve, even if the market in which the company is competing changes.[285] The interdependencies across activities are chosen by managers in order to better position and integrate a company in the environment in which it operates. The architecture of the activity system defines the possible interactions between the suppliers, the company, and the customers and is the source of the competitive advantage in the ecosystem in which it operates. The activity system cannot easily be changed without repercussions on the interdependencies created. Such an architecture, i.e. a network, is in fact a business model.[286]

Complementary to the activity system theory is the transaction costs theory.[287] Transaction costs theory looks into the efficiency dimension of an exchange process. The theory claims that different factors (uncertainty, bounded rationality, opportunistic behavior, and small numbers) impact upon the way in which organizations coordinate exchanges and indeed activities. These costs unfold in three different phases of an exchange: search, negotiation, and enforcement.[288] The phases of the transaction unfold as activities in the activity theory.

The analysis of the impact of transaction costs on the activities underpinning telemonitoring in the B2B setting, currently predominant in telemonitoring implementation, and in the B2C, was chosen to compare the effectiveness of the two different business models.

There are several cycles of activities that add up to the transaction costs total [289]:

1. Search costs – incurred when agents spend time looking for opportunities for an exchange (in the healthcare domain the exchange of a healthcare service/ product for money);
2. Negotiation costs – the costs associated with negotiating the terms of this exchange;
3. Enforcement costs – the costs associated with enforcing the agreement to exchange.

Transaction costs are seen as the costs incurred by running imperfect systems.[290] The elementary unit of analysis in this theory is the exchange between at least two individuals.[289] If all participants in an economic exchange were to have the same information, the transaction costs would be nonexistent. Healthcare is full of these kinds of imperfections because the knowledge is protected by the people who have it, either by means of a license to practice or a license to establish a practice.

Activity theory is potentially useful in portraying the interdependences in different telemonitoring systems. The transaction costs analysis of those interdependences might allow identification of the most efficient and effective telemonitoring configurations, and help mangers and engineers to design more efficient and effective chronic care solutions.

Study aim

The aim of this study is, first, to create the B2B and B2C care models and, second, to explore the differences in care coordination and transaction costs between these models for telemonitoring patients with chronic diseases. Our hypothesis is that, due to the different activity systems, the transaction costs in the B2C model for telemonitoring chronic diseases are lower than in the B2B model. The transaction costs are taken as a proxy for model efficiency.

METHODS

We performed a literature synthesis in order to inform the B2B and B2C telemonitoring case creation, to assess the design elements and themes by applying the activity system theory, and to estimate the transactions costs in each case.

Literature search and analysis

The literature synthesis was performed via Google Scholar, where papers in English from 2000 onward were retrieved. We searched for the following terms (in various combinations): B2B, B2C, case, model, design, telemonitoring, telemedicine, telehealth. We opted for a convenience sample,[162] without exclusion criterion. We looked for case studies and conference papers with design elements of telemonitoring systems, in order to design our own. The input was interpreted in the B2B and B2C model for telemonitoring. As such, the literature analysis can be described as a directed content analysis approach.[291] The literature was searched for and gathered by the first author, while all authors were involved in the analysis.

Cases creation

We created two telemonitoring cases for two business models - B2B and B2C - involving all the actors identified by the literature search. We also incorporated the design elements found in the literature – monitoring, modules, mediators, and actors-devices relationships. Then we applied the research design approach proposed by Griffioen[173]. Griffioen used the activity system theory in the sustainable business model design for heart failure home telemonitoring opportunities in Western Europe and created a transaction mapping tool to communicate roles and transaction relations. We created a similar map, with a set of actors and a relational context looking at modules and relationships in B2B and B2C model of telemonitoring. Individuals (actors) are represented by a circle (patient, informal caregiver, care coordinator, social worker, registered nurse, physician, pharmacist, and telenurse) while institutions (stages) are represented by squares (home, hospital, pharmacy, and telemonitoring center). The relations are described in terms of voice, data, money, and drug exchange. The activity system mapping was followed by the transaction costs exploration for both models, B2B and B2C, and the discussion on the impact of the business model on the implementation possibilities of the two alternative applications.

RESULTS

Literature review inputs

In total 22 papers were retrieved by the literature search. Seven papers were included in the analysis (three conference papers, two case studies, and two journal articles) while others were omitted as they did not contain useful design elements. The diagrams from the publications that were included were used to create the B2B and B2C telemonitoring cases.

The main finding from this limited number of sources was that companies are developing new markets through the B2C models,[292] while in the B2B models they are trying to replicate and support the existing organizational structure.[293] From the eICU case[146], we replicated the remote monitoring part, both in the B2B and B2C setting, while from the mobile multimedia medical system design and implementation case[294] we considered four modules necessary for system to operate: information desk, patient's portal, video outpatient service, and electronic medical information module. From the document-based service platform for telemedicine[295], we replicated the 'mediator' which in our version of the B2C case is a Telemonitoring Center. From the telemedicine market case[296] we considered the actors-devices relationship, and from the COPD24 case[297] architectures of the business cases, i.e. the B2B and B2C case. The literature inputs to the B2B and B2C telemonitoring cases are presented in Table 16.

Table 16. Literature inputs to the telemonitoring cases.

Author(s)	Year	Type of study	Study objective	Main findings
Herzlinger et al.[146]	2014	Case Study	"Would the advent of global payment models and ACOs create sufficient demand for a telemedicine offering covering the care continuum, from hospitals to the home? This was the decision facing Royal Philips Electronics (Philips), the Netherlands-based producer of lighting, consumer electronics, and health care products, in 2012."	"In the eICU model, patients in hospital ICUs were monitored using bedside devices, which transmitted patient data to a remote station from which clinicians monitored and directed care as needed. The model aimed to improve care quality by enabling early interventions and reducing adverse events, and to cut costs by allowing clinicians to care for a larger number of patients. Building on this and other offerings in its portfolio, including numerous home care devices, Philips could extend this model to create an integrated remote monitoring offering managed through a centralized clinician-staffed station."
Kung et al.[294]	2006	Qualitative Research	"This study describes in detail the system design principles and implementation considerations for mobile telemedicine systems. The system effectiveness and limitations for practical system deployment and usage are described based on the technical and managerial analysis."	"The M3 system can also be used in a hospital's B2B or B2C's customer relationship management frameworks. A hospital can trace the patient's situation online at any time, and provide information on healthcare to the patient (B2C) as well as share information and experience with other hospitals (B2B). This approach can improve the quality of the medical treatment given by a hospital and its medical professionals, and thus increase the loyalty of a patient to the hospital."
Lähteenmäki et al.[295]	2008	Conference Paper	"In this paper, we present a generic service platform, which is applicable in a wide range of telemedicine applications and in other areas involving the need for confidential information exchange."	"The pilot hosted by the Tampere Heart Centre showed that a cardiac consultation service is useful even without full integration with the EPR. Both the Heart Centre cardiologists and the physicians of the remote units considered the benefits of the consultation service to be high. In the consultation cases, cardiology diagnostics and medication could be refined and guidance for patient logistics was provided. The physicians considered it feasible to use a commercial consultation service when available."
Pels et al.[296]	2011	Case Study	"BioScience (BS) is an Argentine company, which develops and commercializes innovative diagnosis equipment since 1995. The BM is a device which sends vital signals (from a patient with a chronic disease) through the mobile phone to a recipient's cell phone (doctor and/or relative). Three market segments, the alternative value propositions and the suggested go-to-markets for each of them are suggested."	"BS realized that contrary to the neurological market, where it was crucial to be in a clinical network, in the telemedicine market, it was fundamental to be associated with telecommunication companies. BS needed the telcos as they had the infrastructure necessary to offer the service. Alternatively, telcos saw telemedicine as an additional high-value application they could offer. BS had already signed an alliance with Telefonica Argentina. The agreement followed the industry practice (such as ringtones) in which the 30 per cent of the profit would go to BS, and the 70 per cent remaining to Telefonica Argentina."
Shevchenko.[293]	2004	Qualitative Research	"The goal of this paper is to outline important trend(s) in the advancement of this rapidly growing area of economy, i.e. the transformation of e-market, and to provide recommendations regarding feasible structure of emerging integrated industrial production/ distribution chains, which could be useful for businesses."	"Like e-market place, i.e. B2C eHub, which has its conventional analogue in supermarket, the B2B eHub can be considered as web-based extension of a conventional enterprise, namely as a sort of 'virtual' implementation of a large corporation with specialized departments spread over the territory, e.g. city, region or country."
Wac and Hausheer.[297]	2011	Conference Paper	"The goal of our COPD24 scenario is to demonstrate and validate the precise conditions to be fulfilled from a healthcare perspective, as well as derive requirements for Future Internet (PI) technologies for subsequent deployment of self-management and tele-monitoring/treatment services for COPD patients."	"Two main alternatives can be distinguished in terms of potential business cases for the COPD24 service. The COPD patient can either have a Business-to-Consumer (B2C) relationship directly with the COPD24 application provider, or with the mobile network operator. In the former case, the COPD24 application provider takes care of establishing SLAs with all involved mobile network operators, denoted as Business-to-Business (B2B) relationships. Optionally, a user may have an additional business relationship with its (home) mobile network operator. In the latter case, the mobile network operator is the only entity in B2C relation with the patient, while the mobile network operator's B2B relationship with COPD24 application provider is transparent to the patient."
Wen and Tan.[292]	2003	Conference Paper	"More specifically, hospitals and health provider organizations tend to use static websites that supply information, but have not made major investments in interactive technologies to engage patients and healthcare consumers more actively. In this paper, we survey a number of key participants in the e-health marketplace and the technologies that these players have employed to date."	"Pharmaceutical companies are developing new markets through B2C e-commerce sites. Vendors such as Merck are also able to reduce their marketing costs by reaching more consumers (both patients and physicians) for less cost with e-health offerings. The third approach is remote medical management via the telephone or electronic communication. Chronic disease is particularly suitable for remote management, especially when there is continuity between the patient and service provider."

Telemonitoring cases

In the B2B model (Figure 13) ICT is used for communication between the patient and the telehealth team, which consists of a care coordinator, a physician, a social worker, a pharmacist and a registered nurse – all based in a hospital. This model of healthcare delivery is also referred to as 'hospital-to-home' telemedicine.[146] During the multidisciplinary rounds, each patient is assessed according to their physiological signals, which are transmitted by the telemonitoring devices, and according to their personal goals/motivation. Via interactive dashboards, the team can easily spot a patient whose condition is deteriorating and who therefore needs more help. They help discharged patients by caring for them in an out-patient setting via technology. In the B2B operation this is usually via some sort of eHub – "a virtual implementation by a large corporation with specialized departments spread over the territory, e.g. city, region or country".[293]

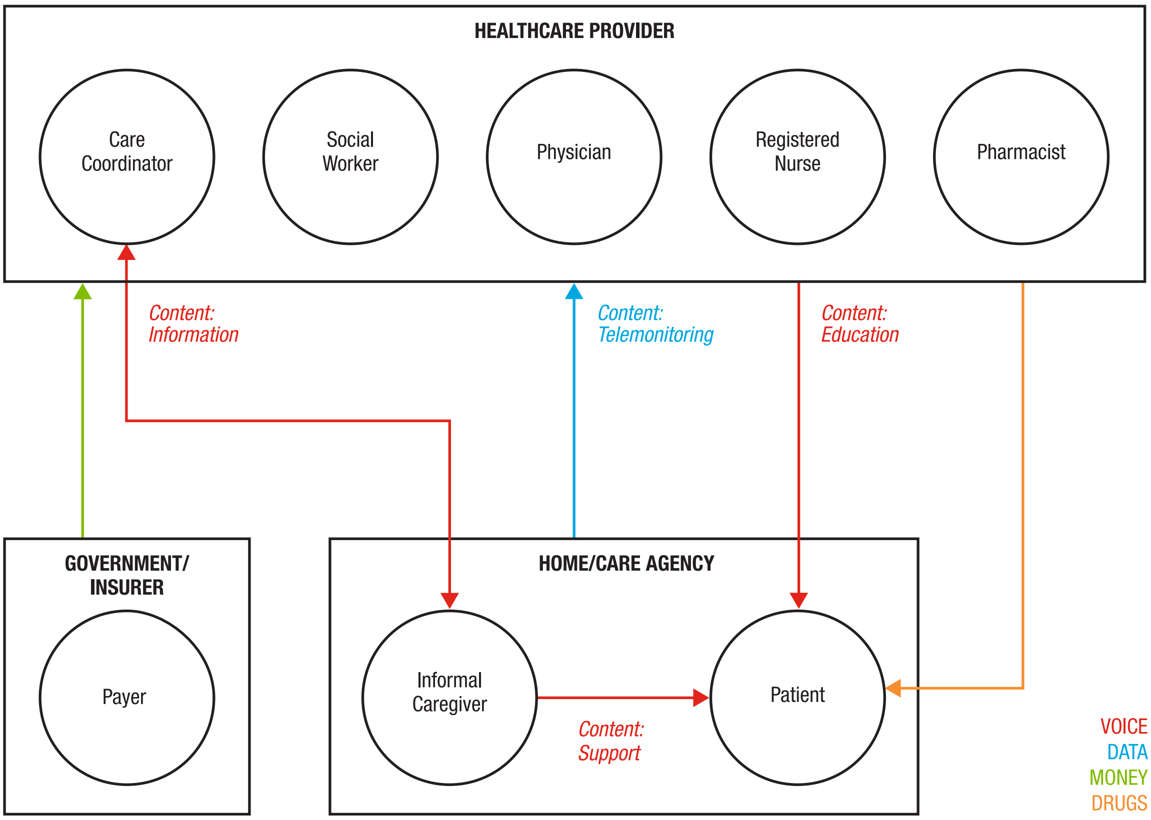

Figure 13. Individual and institutional communication in the B2B model for telemonitoring patients with chronic diseases.

In the B2C model (Figure 14) the communication takes place between a telemonitoring nurse, based in a telemonitoring center (in our design), and the rest of the stakeholders (including the patient) in their respective organizations.[292] The telemonitoring nurse monitors the physiological data daily, aided by smart algorithms. This nurse places a call to the patient every fortnight in order to assess their therapy adherence, emotional state and – if the patient is chronically ill – their wellbeing. Telenurses act as healthcare navigators, helping patients with the complexities of both the healthcare system and the disease and, as personal health coaches, they provide a helping hand to patients and informal caregivers. In this respect, the B2C model is a mixture of a high-touch and high-tech approach in chronic disease management. The dashed lines in Figure 14 represent possible scenarios that go beyond the one we created for the purpose of this assessment: 1) a reimbursement by government/ insurer to a patient directly, 2) a payment by government/ insurer to telemonitoring center for a cohort of patients, and 3) a payment by informal caregiver to telemonitoring center. In the literature, we also found scenarios where drugs are sent from a pharmacy to a patient via post.

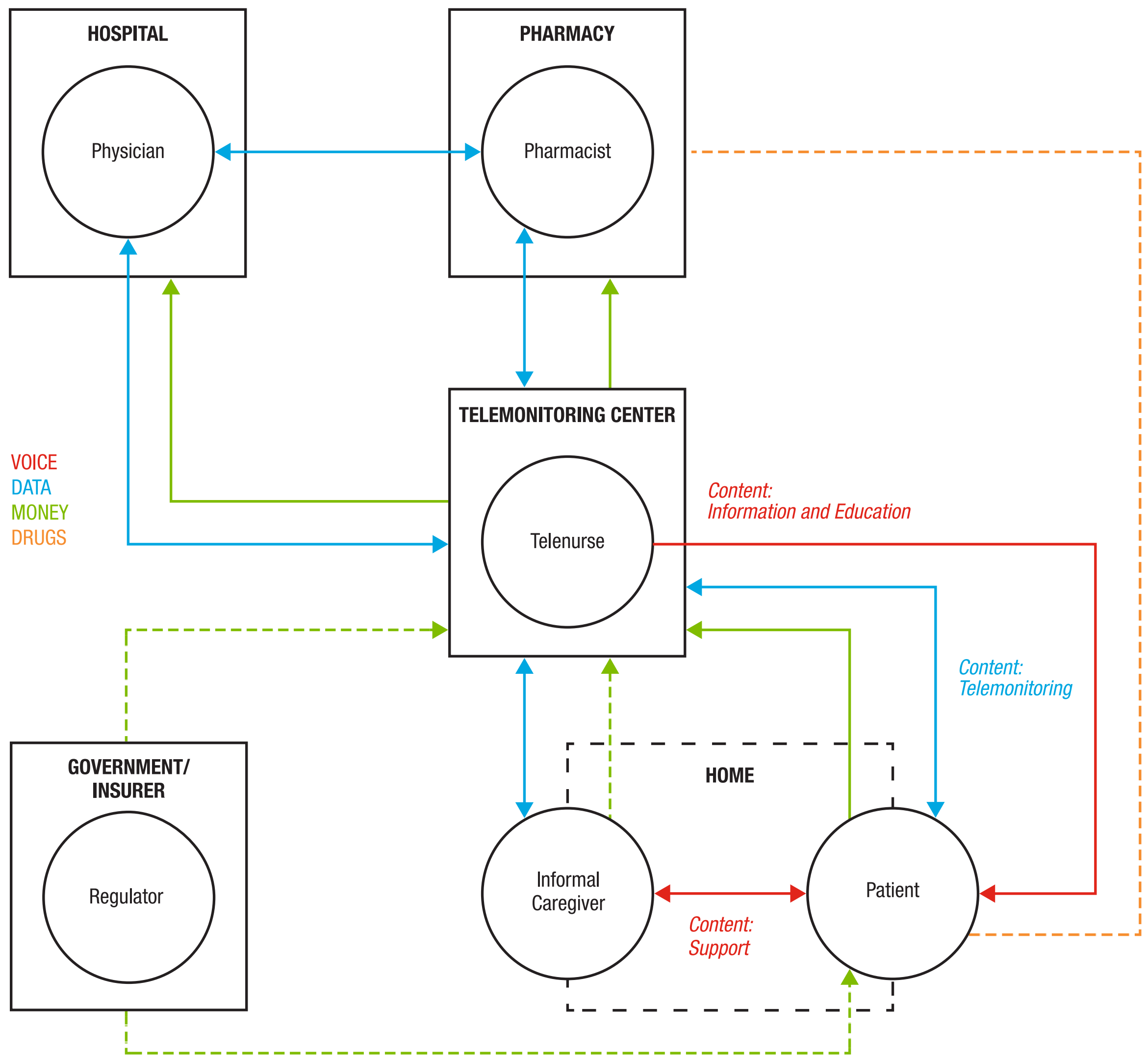

Figure 14. Individual and institutional communication in the B2C model for telemonitoring patients with chronic diseases (a version with government payments to the patient and/or telemonitoring centre).

In the cases, we designed monitoring (in both the B2B and the B2C model) to take place via a smartphone connected to an array of devices, depending on the severity of the disease (blood pressure meter, weighing scale, medication dispenser, etc.). The patient either has a direct relationship with the telehealth provider or with a hospital/service network/care organization.[297] The telemonitoring team uses the care coordination tool (i.e. a series of interactive dashboards that unify the signals and readings from different patients) connected to a document-based service platform (i.e. electronic patient record) to follow the progress of the disease.[295] A telemonitoring platform allows the team to analyze the root cause of the events (e.g. hospitalization) in order to prevent or avoid them, and to amend therapy. The outcomes are constantly measured and reassessed for both the patients and the program. The gathering of the data is unobtrusive and continuous, i.e. runs in the background of the care coordination processes. All the participants in the care process have access to the monitoring data and the disease progression charts. Patients can follow an exercise program with remote monitoring and coaching via a mobile multimedia medical system.[294]

Customization of the telemonitoring service, via smart algorithms using educational content, surveys, information provision, games, etc., is a crucial part of the value creation in the B2C approach. The value proposition in this case is delivered via telecom operators. Value in the B2C model is captured by cost and risk reduction, and increase in convenience and usability. It has a similar proposition to B2B, where customers essentially buy ‘peace of mind’, but with more convenience as the service runs on a personal device and is considered ‘device-agnostic’.

Care coordination in B2B and B2C telemonitoring

The care coordination in the B2B case (Figure 13) is organized between the places of activity, rather than between the participants in the activity. The activity performed via voice communication is intermittent patient support, while the data gathering and analysis runs continuously in the background. The telehealth team meets in a physical location (i.e. hospital) and communicates with other physical locations (i.e. home) where the other two participants are present – the patient and the informal caregiver. The care coordinators are needed in both physical locations – the care coordinator in the hospital and the informal caregiver in the home. This adds a layer of complexity to the care process, and subsequently increases costs. The principal interdependencies in this activity system are location based – all participants in the care process, except the patient, are “exchangeable”, while the locations are “fixed”.

The care coordination in the B2C case (Figure 14) is organized between the players in the activity system, and rarely between the places. The patient in this system is able to receive care on the move and at home. In the B2C business model a telemonitoring nurse is a central character and, just like a personal health coach, manages the players and the resources in the care continuum. This reduces costs as there is no need to coordinate staff at both locations. The interdependencies lie between the persons in the care process (the telenurse, the informal caregiver, and the patients), and not between the places of care. The institutional interdependencies are digitized and automated – via data transfer, digital prescriptions, and access to interactive dashboards – which enables all players to have timely and accurate information at hand.

Activity system and transaction costs in B2B and B2C telemonitoring

The design elements and the design themes differ in the B2B and the B2C activity system for telemonitoring patients with chronic diseases. The content is the same in both cases, but the structure (i.e. hospital vs. telemonitoring center) and the governance differ. In the B2B case the hospital providing the service is also responsible for the governance and operation of the service (together with the equipment manufacturer), while in the B2C case the official governing body of the jurisdiction should be in charge (or, in the absence of a competent body, an international healthcare organization). This is necessary due to the legal, ethical, and socioeconomic factors associated with telecare.[298] Thus, the novelty of the B2C case lies in the structure and governance. Also, the customer (i.e. patient) in the B2C case is not locked in, and can opt out from the service at any time. This helps with the continuity of the service. And, finally, the complementarities in the two cases differ. In the B2B case community services (via the social worker and care coordinator) generate value for the patient, while clinical trials generate value for the hospitals and the equipment manufacturer. In the B2C model there are different complementarities, e.g. monitoring comorbidities benefiting the patient, population monitoring benefiting the government, and big-data gathering benefiting the equipment manufacturer. The design elements and themes of both the B2B and the B2C activity system frameworks are presented in Table 17, where the transaction costs are explored in the efficiency domain.

Table 17. Assessment of the B2B and B2C models for telemonitoring chronic diseases in the activity system framework.

Design		B2B	B2C
Elements			
Content	*What* activities should be performed?	Telemonitoring, education and patient support.	Telemonitoring, education and patient support.
Structure	*How* should they be linked and sequenced?	The care coordination takes place between the telehealth team in the hospital and the team at home (i.e. between a hospital and a home). The team meets in a specific location at a specific time, reviews the patient's data, and engages in an audio/video conversation with the patient and a personal health coach at home.	The care coordination takes place between the members of the care team (i.e. telemonitoring nurse, informal caregiver and patient) via voice communication and with the institutions it takes place via data sharing (i.e. telemonitoring center, hospital and pharmacy). Voice communication takes place every fortnight while data is shared continuously.
Governance	*Who* should perform them, and *Where?*	Hospital and technology partner (i.e. equipment manufacturer). The governance takes place in a clinical setting by licensed practitioners, while the equipment manufacturer is responsible for the system mainte-nance and data protection.	International and national governing bodies. In a jurisdiction where a government acts as an insurer it should perform licensing and supervision. In other geographies an international telehealth organization should provide governance.
Themes			
Novelty	Adopt *innovative* content, structure or governance	Innovative content, old structure and governance.	Innovative content, structure and governance.
Lock-In	Build in elements to *retain business model stakeholders, e.g., customers*	Customers/patients are locked in by the installation of the equipment in their home.	Customers/patients are not locked in, and can opt out of the service at any time.
Complementarities	*Bundle activities* to generate more value	Community services generate value for the patient. Clinical trials generate value for the hospitals and the equipment manufacturer.	Monitoring comorbidities generates value for the patient. Population monitoring generates value for the government. Big data generates value for the equipment manufacturer.
Efficiency	Reorganize activities to reduce transaction costs	High search, negotiation, and enforcement costs.	Medium search costs, and low negotiation and enforcement costs

B2B: business-to-business; B2C: business-to-consumer.
Source: Adopted from Zott et al.[280]

The transaction costs of the B2B case are relatively high. Customers (patients) spend considerable time/resources in searching for the telemonitoring provider (vie their physician) and understanding the disease-related implications of the program. Patients have to negotiate the eligibility in terms of the severity of the disease, location, and ongoing costs.[299] In the end, patients need to enforce the contract either by installing/deinstalling the equipment in their home or by negotiating with the provider and insurance company to keep it after the trial has ended.[299]

In the B2C case, the expected reduction in search costs is due to easier access to information via the Internet (or mass media), the reduction in negotiation costs thanks to an app-store-based contract (predefined and only “a click away”), and the reduction in enforcement costs due to the ease of downloading the mobile app and joining the service, or deleting it (i.e. opting out). Patients can act freely in the marketplace because they are paying for the service, and this is promoting consumer-driven services in healthcare. The negotiating costs are virtually zero in the B2C case, as they are with all app-based services and contracts. The enforcement costs for telemonitoring chronic diseases are also close to zero, as the B2C model of digital service distribution puts the power into the hands of consumers (i.e. they can opt out at any time).

DISCUSSION

We explored the activity system in the B2B and B2C telemonitoring applications for patients with chronic diseases, with the aim of understanding the care coordination and the economic principles that govern the effectiveness in both business models. We believe there are principal differences in several design elements (structure and governance) and themes (novelty, lock-in, complementarities, and efficiency), with lower transaction costs in the B2C model due to the lower search, negotiation and enforcement costs. The business models of B2B and B2C telemonitoring, and the value propositions, are reviewed elsewhere in Chen et al.[278] and Acheampong and Vimarlund[169], but the activity systems are not.

In the B2B model the activity system is organized around the places while the governance of the system lies with hospitals (the true customers) and equipment manufacturers. The B2C model revolves around the players whose actions should be overseen by a government or insurer. The asymmetry of information, the structures, and the competences might give hospitals power over other agents in the healthcare market, namely patients (customers) and equipment manufacturers (suppliers). Patients have no say in procurement, and thus the demand for the B2B telemonitoring remains weak.

The B2B model creates a firmer lock-in than B2C, but for a limited time (e.g. until supported by insurance payments). On the other hand, patients can stay with the B2C telemonitoring service while transitioning to another healthcare provider/insurer, which ensures a long-term commitment. The B2C model also allows patients to procure the telemonitoring service at market prices, assuring a more equitable healthcare exchange.

There is some intrinsic uncertainty in relations between the agents in the marketplace that exist for long periods of time, such that agents in the exchange can exhibit undesirable behavior, i.e. opportunistic behavior.[300] This opportunistic behavior means that an agent acts in their own interest, at the expense of all other agents.[282] There are two applicable opportunistic behaviors[301]: opportunism due to the fact that an agent’s behavior is not visible, and opportunism due to the specific nature of the assets. The former is applicable to the B2C model (and can lead to moral hazard), while the latter is applicable to the B2B model of telemonitoring (the asset cannot be easily redeployed, and the participants in the exchange are bound to each other). The need to protect the parties from opportunistic behavior justifies the existence of governance structures.[302] Beside national and international governing bodies, markets and hierarchies are proposed as alternative ways of governing these transactions.[289]

Pelletier-Fleury et al.[282] used transaction cost economics as a conceptual framework for the analysis of barriers to the diffusion of telemedicine. They found that “the introduction of telemedicine shifts the costs associated with agents’ opportunism from patients to healthcare suppliers themselves”.[282] These costs prevent the wider implementation of telemedicine and telemonitoring. Pelletier-Fleury et al. [282] provide a solution for reducing the transaction costs associated with behavioral factors (bounded rationality and opportunism), and environmental factors (uncertainty and asset specificity) by creating an institutional arrangement associated with the healthcare transactions. Due to the high specificity of the telemedicine asset, and institutional uncertainty, they advocate the integration of transactions in a unified structure. We take their research one step further, by applying the same reasoning for telemonitoring chronic diseases in the B2B case (via hospitals), but also in the B2C case (via a telemonitoring center).

From this theoretical exercise, it would appear that the B2C model has advantages over the B2B model in the implementation of telemonitoring, such as supply chain optimization (with five instead of seven people involved in care coordination), low negotiation and enforcement costs, and long-term outlook. The communication between players is expected to be more efficient than between places. The patient is decoupled from interactions with hospitals and pharmacies, enabling healthcare services to be provided irrespective of the location of the agents. This not only potentially improves implementation of telemonitoring via the B2C model, but also ensures easier access to healthcare.

Transaction cost theory posits that “the optimum organizational structure is one that achieves economic efficiency by minimizing the costs of exchange”.[303] The costs are often a result of the imperfections in possession of information, by participants in the market, and the value that agents place on the exchange. The patient can be seen as an agent willing to invest in resources to mitigate these imperfections. However, the investment needed to do so is substantial, and in many cases detrimental to the effort. This is certainly true for the B2B model, where transaction costs are high but might not be true for the B2C. Even if a patient makes a “wrong” decision and incurs switching costs in the B2C model, they still might be smaller in absolute terms than transaction costs of the B2B model. This might be a promoting economic principle for B2C telemonitoring.

North[304] proposed a theoretical framework for the measurement of transaction costs, i.e. the calculation of the value of all aspects of the good or service involved in a transaction. Measurement, being his first factor in his take on transaction costs, is related to his third, ideological attitudes and perceptions. They encapsulate each individual’s set of values, which influence one’s interpretation of the world. In a B2C model, consumers have to search and compare multiple sources of information, depending on how many suppliers partake in the market, with unknown quality compared to the information they receive from a provider such as a hospital or physician in the B2B model. By eliciting ideological values and perceptions, it is permissible that a person will find more value or quality in information given in the B2B model, via hospitals/physicians, than in the B2C model. However, the ease of finding information and the costs will remain the same, and they are in our opinion lower in the B2C model. The value of information, in respect to transaction costs but also cost-effectiveness in B2B and B2C telemonitoring of chronic diseases, is yet to be determined, and so is the expected value of perfect information, i.e. the price one should pay to get rid of uncertainty in one's decision making.[305]

Our analysis was not without limitations. The literature search was performed by one author (ASG) while all authors were involved in the data analysis. For the literature review, a convenience sample was used. The creation of the telemonitoring cases was based on the sample of peer-reviewed and non-peer-reviewed sources (journal articles, conference papers, and case studies). The assessment of the design elements and themes of the activity system in both models was not impartial. The same is true for the assessment of the transaction costs in the efficiency domain. However, we believe that, given the aim of this study, the strategy applied was suitable to conceptually design the B2B and B2C cases and to explore the potential value of two business models in a descriptive and interpretative manner. Future research should test our models, for example by collecting empirical data from different sites where telemonitoring is applied to support care coordination.

Telemonitoring is commonly introduced to chronic disease patients via the B2B model and is implemented via arrangements between equipment manufacturers and care providers—homecare agencies, delivery systems, and health plans.[9] This takes agency away from patients and burdens them heavily with search, negotiation, and enforcement costs. It renders the B2B model inefficient in comparison to the B2C model, because of the high exchange costs, which could explain the anemic uptake of telemonitoring so far and the suboptimal coordination of care.

The activity system perspective allowed us to see the complexities of care coordination in chronic disease management via innovation in the business model. The transaction costs framework was a useful way of considering the efficiency of introducing information systems to healthcare. The B2B and B2C cases created for telemonitoring chronic diseases principally differ in design elements (structure and governance) and design themes (novelty, lock-in, complementarities, and efficiency). In the B2B model, we believe the search costs are high, negotiation costs even higher (if possible), and enforcement costs the highest. In the B2C model the situations is completely the opposite—transaction costs are small in search, smaller in negotiation, and virtually zero in enforcement. Thus, implementation of telemonitoring for chronic diseases via the B2C model can potentially free up financial resources, which can either be used to support a greater number of people with the same technology or can be invested in new treatments and therapies.

Chapter 7

Value of Information Analysis in Telehealth for Chronic Heart Failure Management

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ABSTRACT

Introduction: Value of Information (VOI) analysis provides information on opportunity cost of a decision in healthcare by estimating the cost of reducing parametric uncertainty and quantifying the value of generating additional evidence. This study is an application of the VOI methodology to the problem of choosing between Home Telemonitoring (HTM) and Nurse telephone Support (NTS) over Usual Care (UC) in Chronic Heart Failure (CHF) management in the Netherlands.

Methods: The expected value of perfect information (EVPI) and expected value of perfect information for parameters (EVPPI) analyses were based on an informal threshold of €20K/QALY. These VOI-analyses were applied to a probabilistic Markov model comparing the 20-year costs and effects in three interventions. The EVPPI explored the value of decision uncertainty caused by the following group of parameters: treatment-specific transition probabilities between New York Heart Association (NYHA) defined disease states, utilities associated with the disease states, number of hospitalizations (including ER visits), health state specific costs (resource utilization), and the distribution of patients per NYHA group. We performed the analysis for two population sizes in the Netherlands - patients in all NYHA classes of severity, and patients in NYHA IV class only.

Results: The population EVPI for an effective population of 2,841,567 CHF-patients in All NYHA classes of severity, over the next 20 years (model's time horizon) is more than €4.5B, implying that further research is highly cost-effective. In the NYHA IV only-analysis, for the effective population of 208,003 patients over next 20 years, the population EVPI at the same informal threshold of €20K/QALY is approx. €590M. The EVPPI analysis showed that the only relevant group of parameters that contribute to the overall decision uncertainty are transition probabilities, in both All NYHA and NYHA IV analyses, and that future research should be on the disease progression.

Conclusion: Results of our VOI exercise show that the cost of uncertainty regarding the decision on reimbursement of HTM and NTS interventions for CHF patients is high in the Netherlands, and that future research is necessary, mainly on the transition probabilities.

INTRODUCTION

Economic evaluation, or cost-effectiveness analysis, resorts to modeling in order to analyze costs and outcomes of technology implementation in healthcare, synthesize different types of data, and extrapolate short term trial results to longer term. Historically those analytical models were deterministic only, but due to irrelevance of p-values and inference in medical decision making,[306] the probabilistic models were developed and the Probabilistic Sensitivity Analysis (PSA) emerged to represent parameter uncertainty. PSA is executed by assigning each uncertain input parameter in the analysis a plausible distribution, and sampling each input parameter from their assigned distributions simultaneously.[120,307] The incremental PSA results can be presented in cost-effectiveness planes, where the incremental result of each simulation iteration in the PSA is plotted, and the "cloud" of results would be interpreted together with relevant Willingness-to-Pay (WTP) thresholds to give an estimate of the probability of being cost-effective and the associated uncertainty around the incremental cost and effect results. Those PSA results for different thresholds were then represented by cost-effectiveness acceptability curves (CEACs)[308] and cost-effectiveness frontiers.[309] However, the CEACs although being useful in understanding the cost-effectiveness of alternative interventions did not provide help with where the uncertainty of the decision originated from. Thus, the Value of Information (VOI) analysis gained traction in economic evaluation in healthcare.[310–312]

VOI analysis provides information on opportunity cost of a decision in healthcare.[313] In the cost-effectiveness analysis the preferred scenario is the one with the maximum expected net benefit of the intervention, either Net Monetary Benefit (NMB), which is the costs borne by the therapy, or Net Health Benefit (NHB), usually expressed in Quality Adjusted Life Years (QALYs). Expected net benefit is defined as the mean of the net benefits across all model iterations.[314] VOI is a Bayesian analytical framework which concerns itself with identification and adoption of the alternative with the maximum expected net benefit and recognizes that such decisions are surrounded by uncertainty which cannot be expressed via p-values.[314] The uncertainty about the alternatives results in wrong decision being made, with opportunity costs. The expected cost of the wrong decision is based on the probability that the wrong decision will be made, and the size of the loss with the wrong decision. Expected Value of Perfect Information (EVPI) analysis is useful because CEAC provides only the probability of being cost-effective and EVPI determines sort of expected cost of uncertainty, which is determined jointly by the probability that a decision based on existing information will be wrong and the consequences of a wrong decision. The Expected Value of Partially Perfect Information (EVPPI) analysis pinpoints a parameter which contributes to the parametric uncertainty most. Thus, the VOI informs decision makers how large the cost of a wrong decision is and whether it is cost-effective to conduct further research on model parameters to lower the uncertainty in the decision-making process.[311]

In 2012, 17.5 million people died from Cardio Vascular Diseases (CVDs), representing 31% of all global deaths.[99] Chronic heart failure is one of the most prevalent CVDs, caused by age related changes in the cardiovascular system.[100] Telehealth solutions are proposed to tackle the challenge for health care systems of an increasing number of CHF patients.[315,316] There were numerous studies in effectiveness of telehealth interventions in CHF management,[94,317–321] a few studies on cost-effectiveness,[109,110] but not much was researched on the topic of VOI in CHF management via telehealth interventions. Given the burden of this disease and the uncertainty of the results of these studies, the value of forgone benefit is expected to be extremely large.

Previously, we conducted a cost-effectiveness analysis, using a cohort-level Markov model, comparing Home Telemonitoring (HTM) and Nurse Telephone Support (NTS) with Usual Care (UC) in CHF management in the Netherlands.[322] Amongst other data sources, our model was based on the clinical trial results from The Trans-European Network — Home-Care Management System (TEN–HMS) study [5]. The results from the CEA showed that both interventions are cost-effective in comparison to UC, considering the cost-effectiveness thresholds used by the decision makers in the Netherlands. The objective of this study is to determine the value of resolving parametric uncertainty inherent in the current evidence and identifying the impact of key parameters of the model - transition probabilities, utility generated, number of hospitalizations, utilization of resources, and the distribution of patients per NYHA class - on the overall model parameter uncertainty. Thus, our study is an application of the VOI methodology to the problem of choosing between HTM and NTS over UC in CHF management in the Netherlands.

METHODS

The Markov model

Structure of the model

The VOI analysis was applied to a probabilistic Markov model comparing the 20-year costs and effects in three interventions (i.e. HTM, NTS, and UC). Details of the model have been published previously.[322] In brief, CHF patients were classified into four disease states of increasing severity based on ability to walk and take care of themselves according to the New York Heart Association (NYHA) guidelines.[18] In prespecified time intervals of 4 months (i.e., Markov cycles), patients could stay in the same state, transition between disease states (from one NYHA class to any other class, e.g. from NYHA III to NYHA I, II, or IV class) or die. Resource use and costs were assigned to disease states, and these disease state-specific costs and resource use estimates were assumed the same for each treatment arm. Primary outcome of the model was the cost per QALY over a period of 20 years, which corresponds to a life-time horizon since the mean age of a patient in TEN-HMS study was 68 years in UC and 67 in HTM and NTS groups CHF is a severely progressive disease - survival in Framingham Heart Study subjects was 1.7 years in men and 3.2 years in women[113] – thus all patients were expected to end-up in the death state at the end of the model's time-horizon.

Model input parameters

Probabilistic input parameters of the model included transition probabilities between disease states, utilities associated with the disease states, number of hospitalizations (with and without ER visits), costs associated with the disease states (resource utilization including specialist/ general practitioner/ nurse contacts), and initial distribution of patients per NYHA group. Uncertainty around these parameters was considered simultaneously and each parameter was sampled from the corresponding distribution, independently. We sampled the transition probabilities between disease states from Dirichlet distribution,[323] and used beta distribution for sampling utilities, and uniform distribution for sampling the installment/equipment and service fee for HTM. Second-order Monte Carlo simulations (i.e. considering parameter uncertainty) were undertaken in which values were randomly drawn from these distributions.

We performed the VOI-analysis for two population sizes in the Netherlands - patients in all NYHA classes of severity, and patients in NYHA IV class only. Fixed model parameters included discount rates for costs and effects (4% and 1.5% respectively). The all-NYHA-model starts with 19% of the patients in NYHA I class, 44% in NYHA II, 29% in NYHA III, and 8% in NYHA IV, as seen in the TEN-HMS study. Transition probabilities between NYHA disease states were based on the total number of transitions observed in the TEN-HMS clinical trial data, until the follow-up period of the trial. After the trial follow-up, same transition probabilities were assumed. Besides structural uncertainty of the model, there is an inherent uncertainty related to data imputation and how transition probabilities are estimated due to the missing data in the TEN-HMS database (due to stopping or missing entries). The mortality risk in each disease state was estimated by calculating the transition probability to death state from the observed deaths in the TEN-HMS trial. Resource use was estimated from TEN-HMS trial data and unit costs (price level 2010) were obtained from the Dutch cost guideline[324] and updated to 2017 prices. Utility values per disease state were based on the EQ5D-3L data from the TEN-HMS study, calculated by the Dutch utility weights.

In addition to the cost-effectiveness analysis,[322] for the VOI-analyses, we modelled the increase in prevalence and incidence of CHF patients in the Netherlands according to the projections from the Dutch National Institute for Public Health and the Environment.[325] They estimated that approximately 1% of the adult Dutch population suffered from heart failure in 2012, i.e.130,000 individuals, and that because of population aging the number of heart failure patients will increase to 195,000 individuals by 2025. The increment per year was thus estimated at 5,000 individuals, which we extrapolated till the end of our time-horizon in the model, starting with 160,000 individuals in 2018 to 255,000 in 2037. The effective population over 20 years was 2,841,567 (total number 4,150,000 discounted by 4%) in All NYHA classes of disease severity. For the number of NYHA IV patients we consulted the initial distribution of patients in the TEN-HMS trial (7.32%) and applied to the simulation. The effective population over 20 years In NYHA IV class only analysis was 208,003 individuals.

The value of information analysis

We run two analyses, for all NYHA patients, and for NYHA IV only patients, continuing the cost-effectiveness analyses from our previous work. Three factors determine the VOI[313]:

1. How cost-effective the technology appears given current or prior information;
2. The uncertainty surrounding cost-effectiveness (i.e. the distribution of the prior mean incremental net-benefit); and
3. Consequences of decision error based on current information.

Expected value of perfect information

The expected value of perfect information is “equal to the net benefit of the optimal strategy given perfect information minus the net benefit of the strategy that would be adopted given current information, averaged over all model iterations”.[314] In other words, the overall EVPI is calculated as the average of the maximum net benefits with a perfect information, minus the maximum of the average expected net benefits across all treatment strategies with current information. The EVPI is thus the expected value of eliminating all parametric uncertainty surrounding the decision. In our case, the expected value of a parameter is obtained by taking the mean value of that parameter over 1,000 simulations, for more than 150 parameters in the model simultaneously. The EVPI analysis was performed using a one level sampling algorithm, for an individual patient (Individual EVPI) as explained in Table 18. After the individual EVPI is calculated, the population level EVPI (Population EVPI) can be also derived, which is the expected opportunity loss for the whole population that is to benefit from a particular technology of interest if a wrong decision is made due to parameter uncertainty. In order to assess this, we need to understand the lifetime of the technology (in our model it is 20 years, although we are aware that there will be new generations of devices and services with improved effectiveness), the period over which information about the decision will be useful (till the end-of-life in our case), and the estimates of incidence over this period. The Population EVPI was calculated as:

Population EVPI= EVPI per person SUM(from t=1 to T) I_t/(1+d)^t*

I_t: incidence in period t, d: discount rate, and T is the number of time periods where the research would be useful.

Table 18. Single loop Monte-Carlo scheme for computing overall individual EVPI.

1. Sample a value from the distribution of the uncertain parameters.
2. Evaluate the net benefit for each decision option using the parameter values generated in step 1.
3. Repeat steps 1 to 2 for N samples, e.g., N=10,000, and store the estimates of the net benefit function for each decision option. This represents the probabilistic analysis sample.
4. Calculate the expected, i.e., average, net benefit across all N samples for each decision option.
5. Choose the maximum of the expected net benefit in step 4 and store. This represents the expected net benefit under current knowledge.
6. Calculate the maximum net benefit of the decision options for each of the N samples generated in step 3.
7. Calculate the average of the N maximum net benefits generated in step 6. This represents the expected net benefit when uncertainty is resolved with perfect information.
8. Calculate the EVPI as the difference between the expected net benefit when uncertainty is resolved with perfect information (step 7) and the expected net benefit under current knowledge (step 5).

Source: adapted from Briggs et al.[313] and Oostenbrink et al.[314]

Expected value of partially perfect information

After exploring if potential further research on cost-effectiveness of HTM and NTS vs UC is cost-effective, i.e. EVPI is positive, we were interested in an indication of what type of additional evidence would be most valuable. The value of reducing the uncertainty surroundin a specific type of parameters of the model was found using a similar approach to the EVPI analysis. The expected value of perfect information for a parameter is the difference between the expected value with perfect and current information about that parameter.[313] Due to computational reasons we approached EVPPI analysis by conducting it first on a small number of groups of parameters. We grouped the cost-effectiveness model parameters into: 1) transition probabilities, 2) utilities, 3) hospitalizations and ER visits, 4) utilization of resources via nurse, General Practitioner (GP), medical specialist, and hospitalist contact or telephone call, and 5) initial distribution of patients per NYHA group. The grouping was performed according to parameter nature, reflecting a possible future study design method to inform the model.[314] It is important to note that EVPPI for all group of parameters do not add to overall EVPPI.

EVPPI was executed using a two-level sampling algorithm in which multiple simulations were performed for different values of the parameter of interest.[310] The two-level sampling algorithm uses two nested levels of Monte Carlo sampling over the plausible ranges for both the parameter(s) of interest, and the remaining uncertain parameters. The two-level sampling algorithm that we have applied is outlined in Table 19.

Table 19. Sampling algorithm for the calculation of EVPPI with double loop (inner loop of size J and outer loop of size K).

1. Sample a value from the distribution of the target parameter(s) of interest.
2. Sample a value from the distribution of the remaining ('complementary') uncertain parameters, conditional on the value of the target parameter(s) sampled in step 1. If the target and complementary parameters are independent, then the sample for this step can be drawn from the prior distribution of the complementary parameters.
3. Evaluate the net benefit function for each decision option using the parameter values generated in steps 1 and 2.
4. Hold the parameter value in step 1 constant and repeat steps 2 to 3 for J samples. Store the estimates of the net benefit function for each decision option (step 3). This represents the inner loop of simulation, conditional on the value of the target parameter(s) of interest.
5. Calculate the expected, i.e., average, net benefit across all J samples for each decision option in step 4 and store.
6. Repeat steps 1 to 5 for K values from the distribution of the target parameter(s) of interest (step 1) and store the output from step 5 conditional on each new value. This represents the outer loop of simulation.
7. Calculate the expected net benefit across all K samples of the output loop stored in step 6 for each decision option, i.e., the average across the inner loop means.
8. Choose the maximum of the expected net benefit in step 7 and store. This represents the expected net benefit under current knowledge about the target parameter(s) of interest.
9. Calculate the maximum net benefit of the decision options for each of the K samples of the output stored in step 6, i.e., the maximum net benefit of the inner loop means.
10. Calculate the average of the K maximum net benefit values generated in step 9. This represents the expected net benefit when uncertainty is resolved with perfect information about the target parameter(s) of interest.
11. Calculate the EVPPI as the difference between the expected net benefit when uncertainty is resolved with perfect information (step 10) and the expected net benefit under current knowledge (step 8).

Source: adapted from Briggs et al.[313] and Oostenbrink et al.[314]

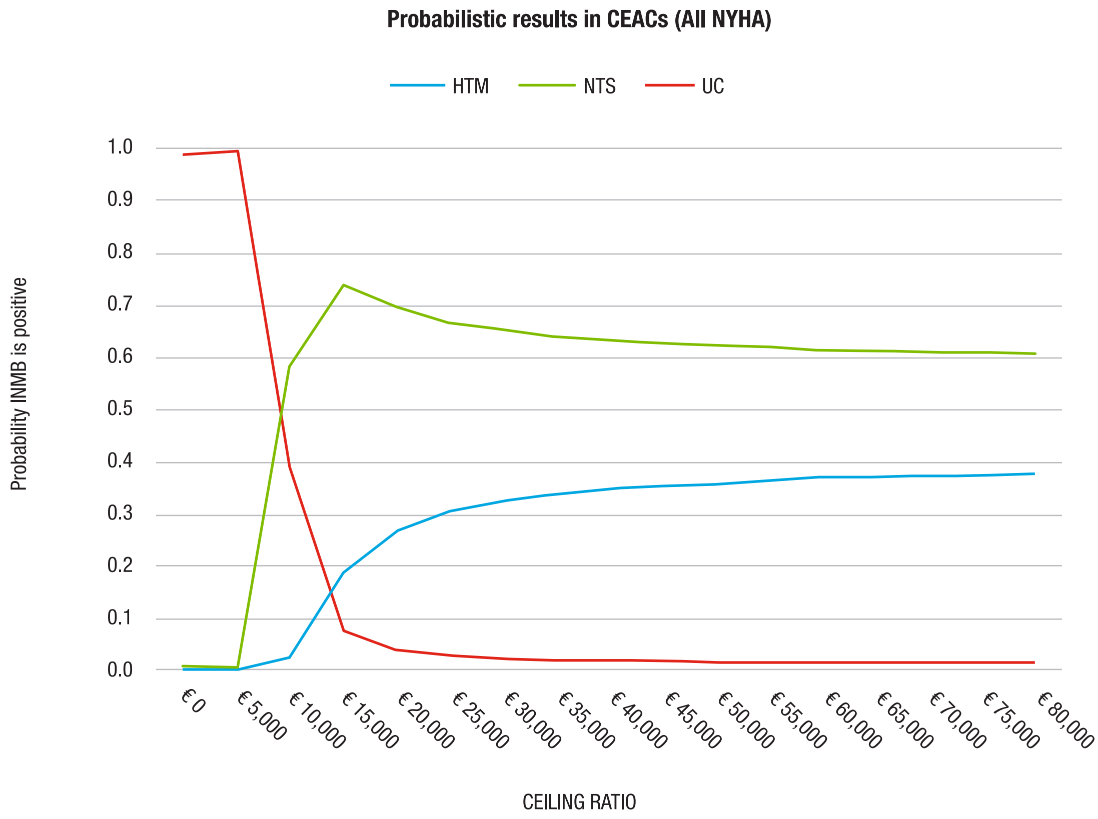
The double-loop algorithm above requires substantial computations, however it is necessary, since it does not depend on linearity assumptions as proposed in other single-loop approaches (e.g. SAVI). This proves to be handy for models where the relationship between the parameters and the expected cost and outcomes is not linear, as it is in Markov models.[313] The inner and outer loop iteration sizes (J and K) were determined iteratively, starting from simulation iteration size of 1,000 for both inner and outer loops, and they were increased until the EVPPI results did not change significantly. In all of the group parameter EVPPI calculations, both inner and outer loop iteration sizes were smaller than or equal to 2,500. All analyses were performed in Excel in Microsoft Office 2016.

RESULTS

Cost-effectiveness

For all patients (All NYHA) the probability of HTM being cost-effective in comparison to NTS and UC increases as the WTP for additional health (i.e. QALY) or the threshold for cost-effectiveness increases (since the effectiveness difference is in favor of HTM), as shown in Figure 15a. The probability that the HTM is the most cost-effective becomes higher than the probability that UC is the most cost-effective from WTP of approx. €14K and higher. There is no scenario where HTM is cost effective in comparison to NTS, in all NYHA classes of patients combined (HTM is not a "part" of the cost-effectiveness frontier).

In the subgroup analysis (NYHA IV), HTM is cost-effective in comparison to UC (and NTS) at WTP higher than approx. €40K/QALY. The CE horizon shows that UC should be preferred at approximately €9K/QALY and less, NTS from €9K to €40K, and HTM at higher WTP (Figure 15b).



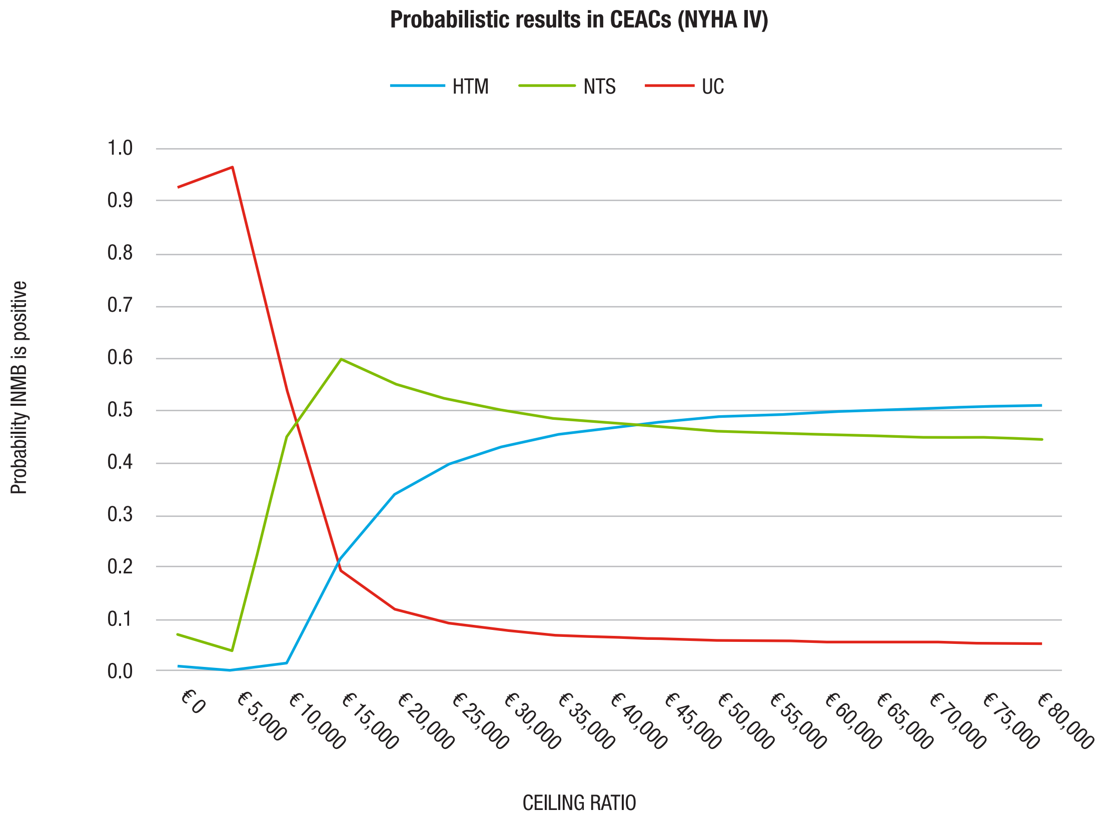


Figure 15. Cost-effectiveness acceptability curves in a) All NYHA and b) NYHA IV analyses.

Individual EVPI

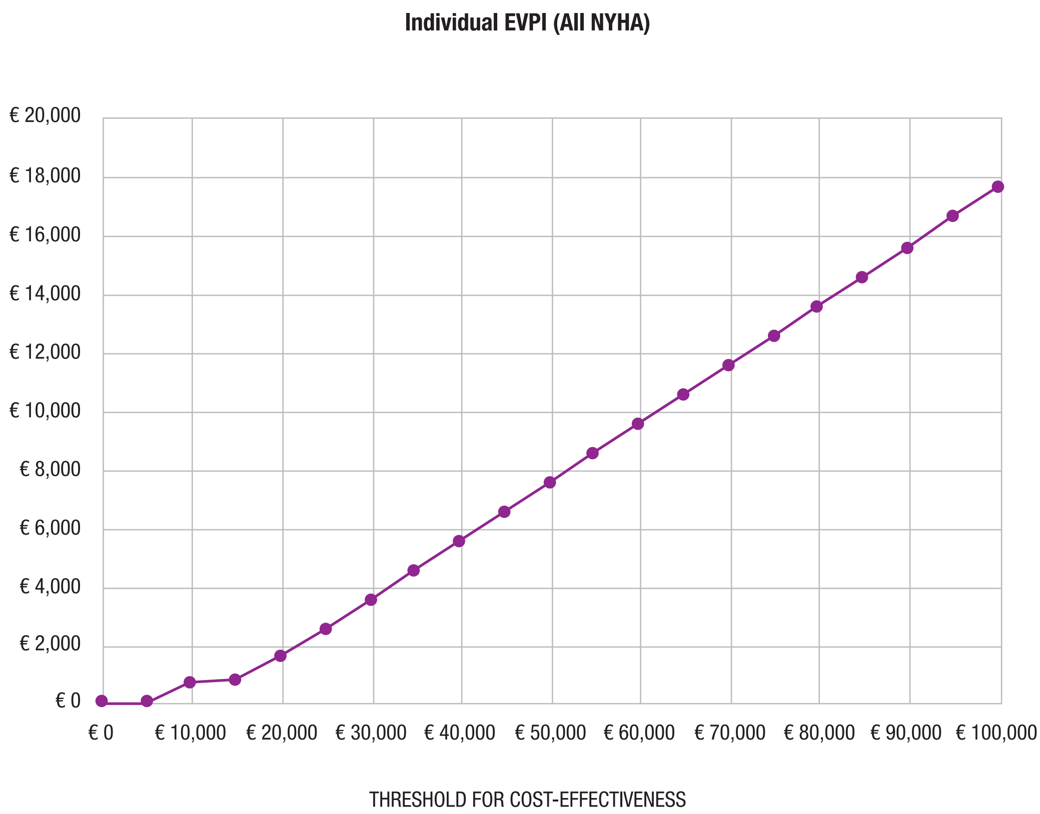
The shape of the EVPI curve in Figure 16a is a representation of the average of the maximum net benefits with a perfect information, minus the maximum of the average expected net benefits across HTM, NTS, and UC. In All NYHA analysis there is a peak, i.e. a change in the slope of the EVPI curve, around the threshold values equal to the ICERs of each of the alternatives – NTS vs UC ICER €7,262 and HTM vs UC ICER €9,816. The decision uncertainty 5seams to linearly increase with the increase of the WTP because the probability of being cost-effective of the technologies compared with UC (HMT and NTS) seems to “plateau” in the Figure 15a. The CEACs do not “meet each other” at the high WTP thresholds, due to the fact that probability of one of the technology options becoming the most cost-effective does not converge to 1 for higher WTP. Thus, the probability and the consequences of error raise, tending to increase EVPI, with increased WTP.

In NYHA IV analysis, the technology options on the CEAC frontier change in two points (Figure 15b), which is reflected by two “peaks” in Figure 16b – at €10K and €45K/QALY. Here as well, the EVPI increase with WTP just as in All NYHA class analysis.

Population EVPI

For our effective population of 2,841,567 patients in All NYHA stages of disease severity in the Netherlands, Figure 17a illustrates the Population EVPI over the next 20 years. If the cost for managing this population exceeds the expected costs of additional research, then it is potentially cost-effective to conduct further research on decision uncertainty. For example, the Netherlands pays €20K/QALY in management of CHF, and the Population EVPI at this WTP is more than €4.5B, implying that further research is highly cost-effective as opportunity costs are enormous. At lower values of the threshold, e.g. in the jurisdictions that pay only €5K/QALY, for the same population size the opportunity costs are slightly above €10M, and the new technology (i.e. HTM and NTS) should be rejected based on current evidence, and further research is required to support this decision, because the returns from further research cannot offset the costs.

In NYHA IV analysis, for the effective population of 208,003 patients over next 20 years, the Population EVPI at WTP of €20K/QALY is approx. €590M. Given the severity and prognosis of this disease stage, the authorities could potentially be willing to pay more per QALY generated, which will increase both the Population EVPI, but also the uncertainty of the decision to adopt HTM and NTS in the management of these patients.



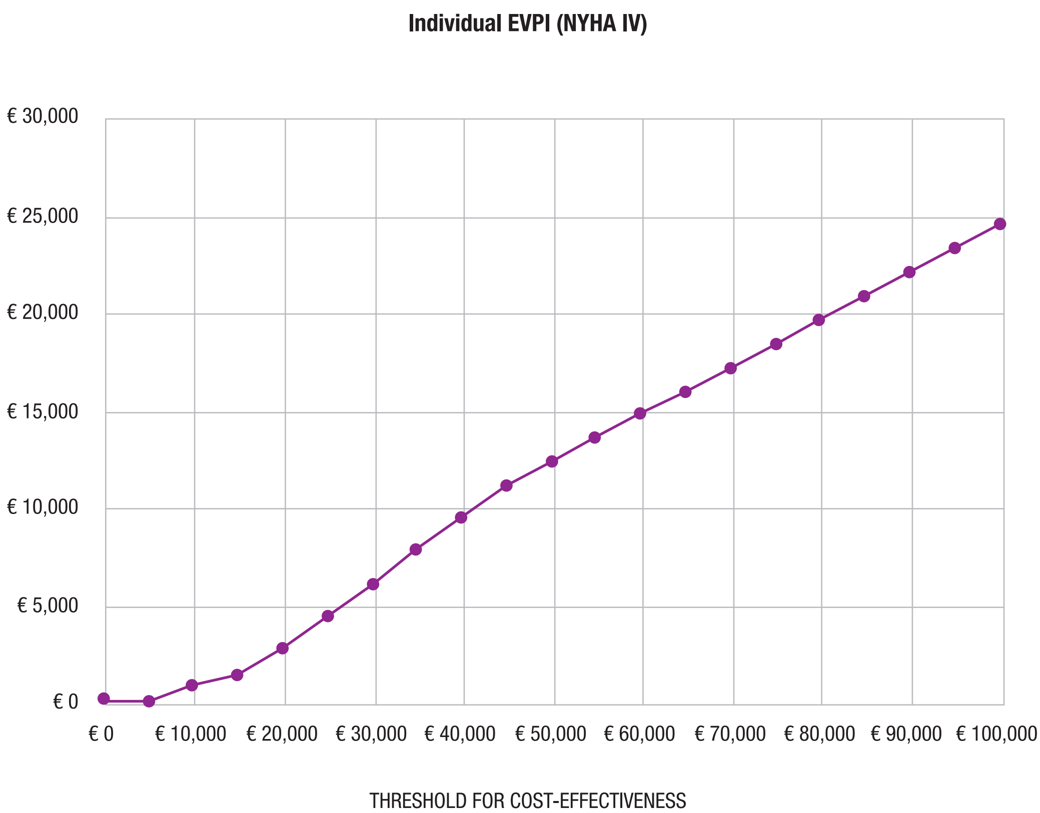
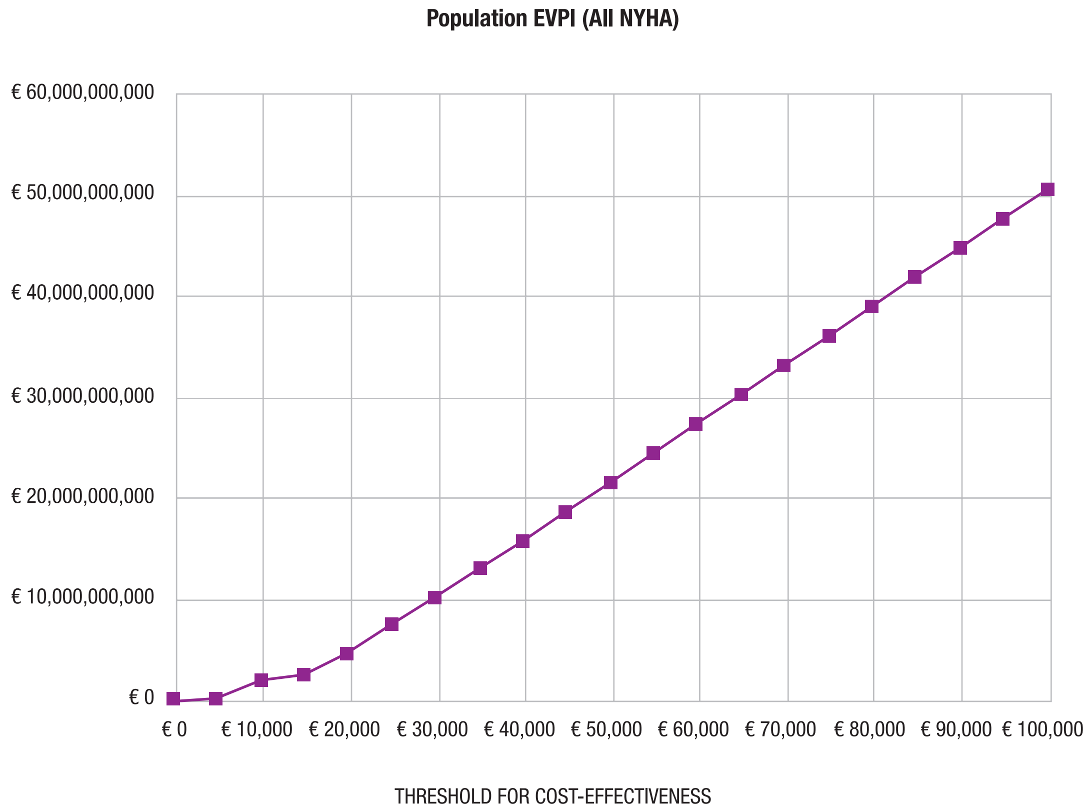


Figure 16. Individual expected value of perfect information in a) All NYHA and b) NYHA IV analyses.



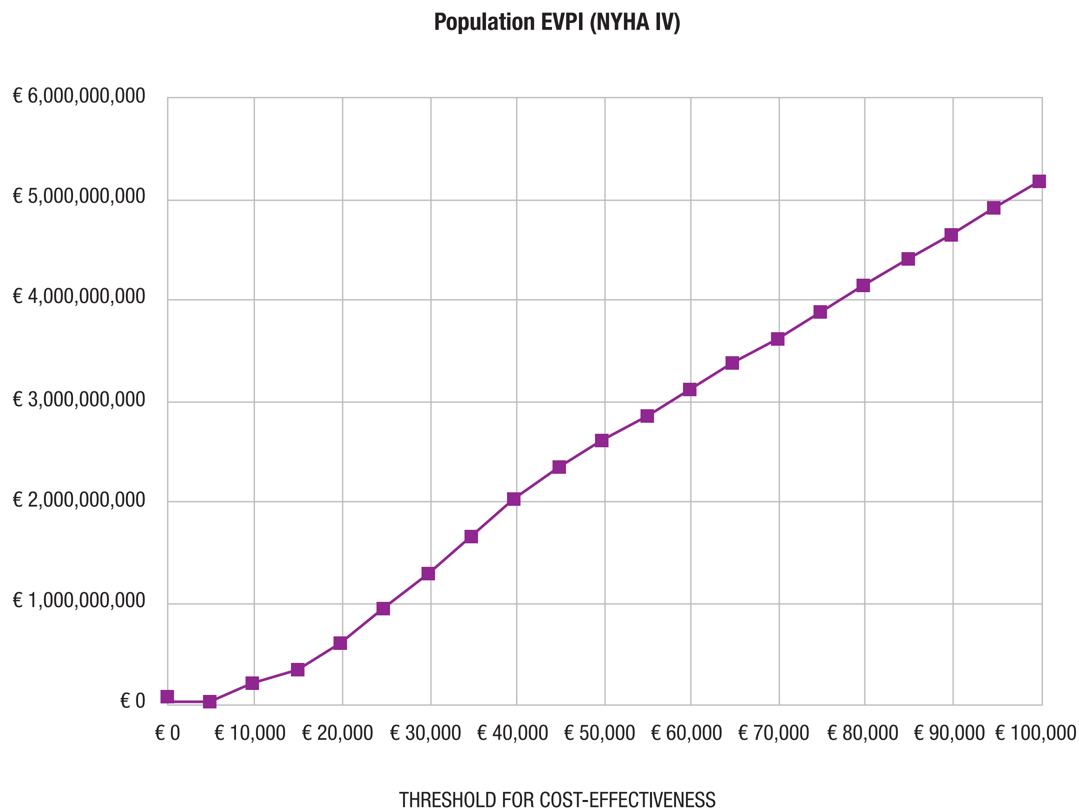


Figure 17. Population expected value of perfect information in a) All NYHA and b) NYHA IV analyses.

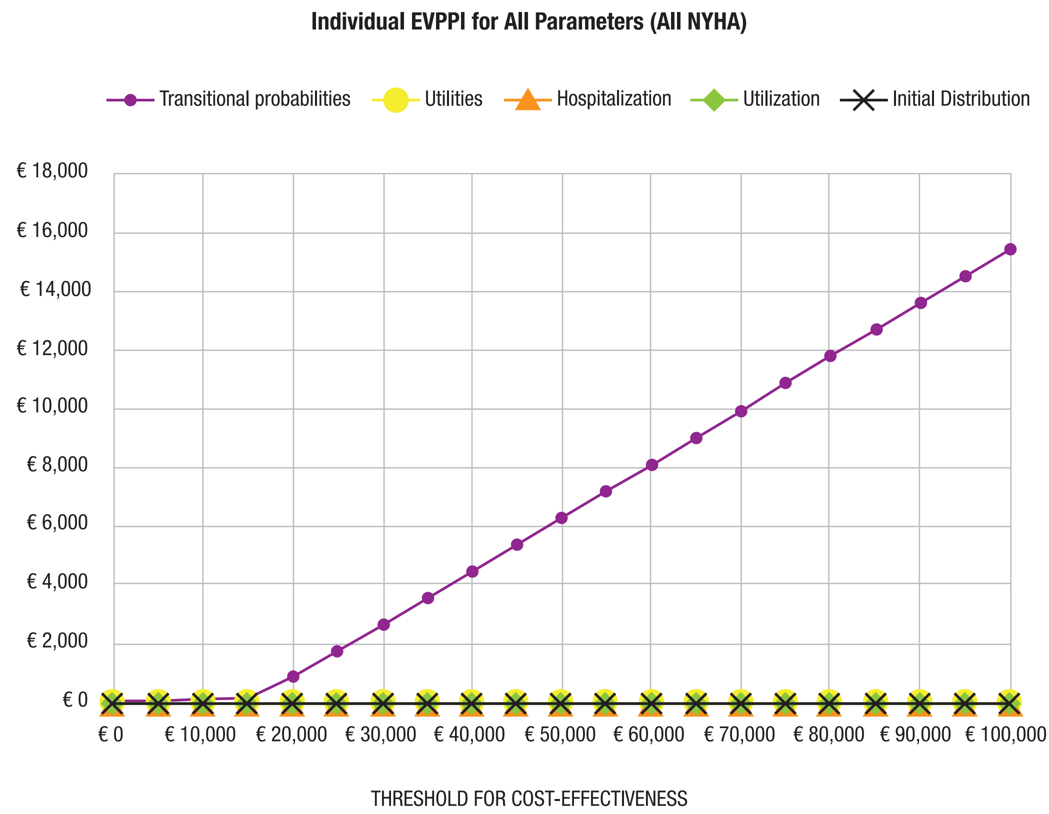
Individual EVPPI

Figure 18a shows the EVPPI for all groups of parameters in the model for one CHF patient (separate simulations were run, no correlation between sampled inputs) – transition probabilities, utilities, hospitalizations, and resource utilization (plus initial distribution of patients in All NYHA analysis). The results show that all decision uncertainty is attributable to uncertainties in transition probabilities, in All NYHA classes combined. The decision uncertainty increases linearly with the increase in WTP, which means that additional research on transition probabilities for HTM and NTS in CHF management is cost-effective and needed. However, the EVPPI for utilities, hospitalization, utilization, and initial distribution is zero at all WTPs, thus resolving parametric uncertainty from these parameters does not seem to add any value or reduce decision uncertainty in All NYHA classes combined.

In the NYHA IV analysis, there are again two “peaks” (at €10K and €45K/QALY) for transition probabilities, corresponding to the technology change on the CEAC frontier, with even higher net monetary benefit value than in All NYHA for given WTP values (approx. €10K in NYHA IV vs approx. €5K in All NYHA) indicating that uncertainty around transitions from and to NYHA IV group drive the overall uncertainty around transition probabilities in our model. The peaks at €10K can barely be seen in Figure 18 due to the scale of the y-axis. For utilities, hospitalizations, and resource use we observe nonzero EVPPI values from WTP higher than €40K, having a hunch at €45K and increasing in a linear fashion after €60K. In the WTP band from 0 to €95K, EVPPI are always less than or equal to €500 (Figure 18b).

Population EVPPI

Figure 19a presents the Population EVPPI results where simulations for all six groups of parameters are to be found in one graph (again, separate simulations were run) for a population of 2,841,567 patients. It is evident that future research should focus on transition probabilities, i.e. disease progression in both HTM and NTS interventions in management of CHF. It seems that at the WTP threshold of €20K/QALY the expected value of partially perfect information for a future (20 years) CHF population in the Netherlands is approx. €2.5B. For a population in All NYHA classes there is no gain in understanding the uncertainty around other parameters except transition probabilities in our model. The opportunity loss for the future (20 years) population of NYHA IV CHF patients in the Netherlands at €20K/QALY is approx. €4.8M, and slowly rises with increase of WTP (Figure 19b).



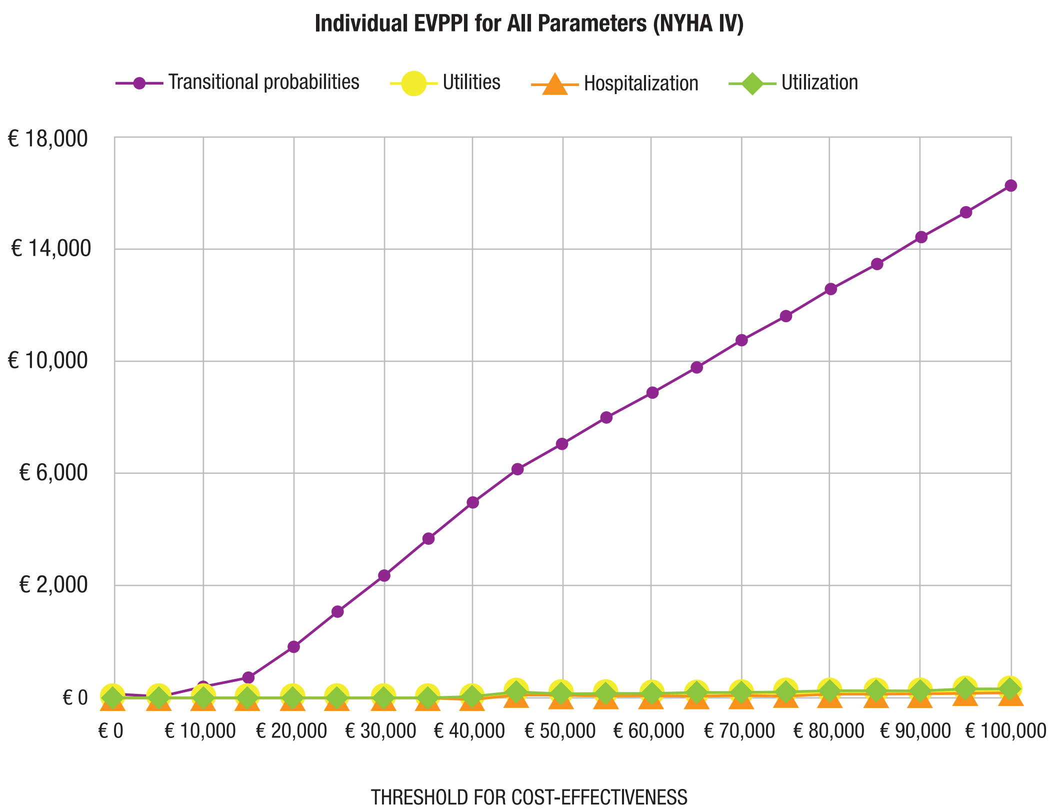
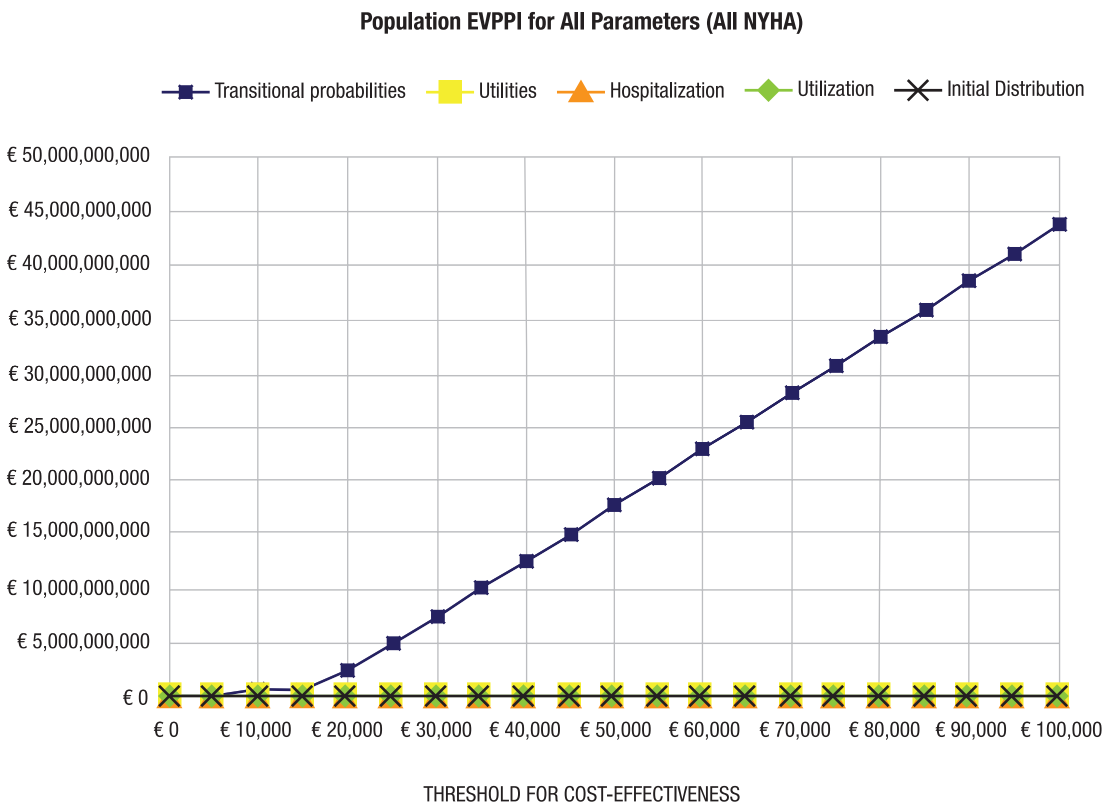


Figure 18. Individual expected value of partially perfect information for all parameters in a) All NYHA and b) NYHA IV analyses.



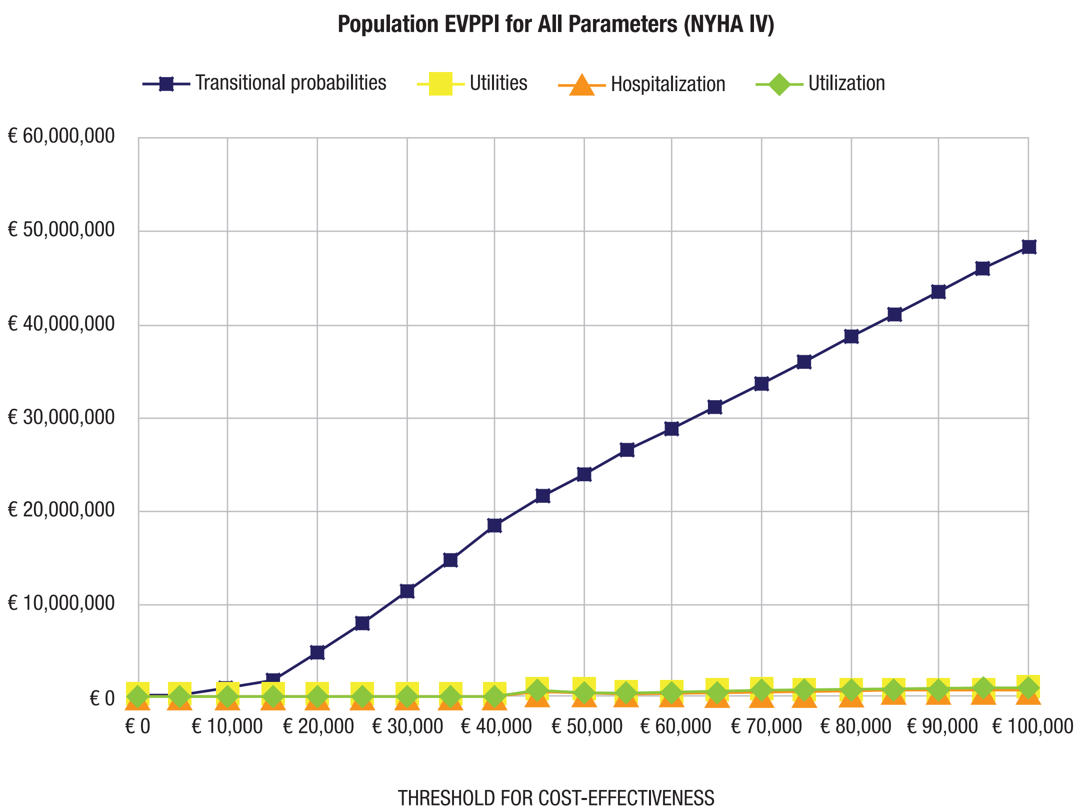


Figure 19. Population expected value of partially perfect information for all parameters in a) All NYHA and b) NYHA IV analyses.

DISCUSSION

In this modelling study, we were interested in knowing the decision uncertainty of adopting HTM or NTS in CHF management in the Netherlands. The decision to implement new technologies will always be uncertain, and that uncertainty is conditional on the cost-effectiveness of new technologies. If the decision based on current information is "wrong" there will be consequences in terms of opportunity loss, i.e. monetary and health benefits forgone. The opportunity loss can be calculated from the estimates of probability and cost of error. This is the expected cost of uncertainty. In other words, "the expected cost of uncertainty can be interpreted as the expected value of perfect information, as perfect information can eliminate the possibility of making the wrong decision".[313]

VOI analysis provides insights into the maximum that authorities should pay for further research (i.e. EVPI). EVPI is possibly the best measure of uncertainty surrounding a particular decision in CEA.[326] However, both EVPI and EVPPI do not include methodological and structural uncertainty, only the parameter uncertainty. Methodological uncertainty arises when "there are different normative views about what constitutes the correct approach for optimum decision making",[327] e.g. discount rates or time horizon in the analysis.[120] It also includes the perspective taken (e.g. provider, payer, societal), how health gains are valued, e.g. via preference-based or non-preference based methods,[328] types of disease outcomes (e.g., survival, health loss, costs),[327] and the macro economic consequences.[329] Methodological uncertainty is best dealt with by creating a reference case, i.e. the explicit list of methodological choices for model creation, so to allow for comparability between the choices authorities are presented with.[330] On the other hand, structural uncertainty refers to "uncertainty about the extent to which structural features of the model adequately capture the relevant characteristics of the disease and intervention being investigated".[327] It includes decisions regarding what disease stages and transition possibilities to include in the model, how transition probabilities are derived, how missing data were dealt with, and if this transition is time independent (like in our Markov model), or dynamic (changes over time).[331] Structural uncertainty can be accounted for via e.g. model averaging approach.[332] Finally parameter uncertainty refers to "uncertainty about the value for each parameter within the model, with respect to its true value".[120,313,333] In this research, we are only concerned with parameter uncertainty, and what is the maximum value at which they can resolve, thus what is the EVPI.

Results of the Individual EVPI analysis (Figure 16) show that where there is more uncertainty (i.e. greater variance in incremental net-benefit), the probability of error will increase and expected opportunity loss and EVPI will be higher. This is because the variance of net monetary benefits increases with the increase of WTP threshold, and as we compare three options (i.e. HTM, NTS, and UC) the variability and uncertainty are greater than when comparing two alternatives. When the threshold for cost-effectiveness is low, the technology is not expected to be cost-effective and additional information is unlikely to change that decision (EVPI is low). In case of All NYHA and NYHA IV the EVPI increases with the threshold because the decision uncertainty (probability of error) increases and the consequences of decision error (opportunity loss) are valued more highly.

For the Population EVPI (Figure 17), i.e. the expected perfect information for the total number of patients that can benefit from HTM and NTS, the value of information is expressed over the model time horizon (20 years). As telehealth technology will not last that long, we added replacement costs every 5 years. However, we expect the effectiveness of both HTM and NTS to remain over the next two decades, or even increase. Thus, our effectiveness estimation can be considered conservative. The EVPI associated with future patients is discounted at a rate of 4% and runs in billions of euros for CHF patients in the Netherlands. The population EVPI can be the first step in identifying whether future research is cost-effective, and which research venues are worthwhile.[313]

With our modelling exercise we have found that the future research on uncertainty surrounding implementation of HTM and NTS is cost-effective. We were then interested in knowing what additional evidence would be most valuable in reducing decision uncertainty. After all, the VOI analysis performed here was based on a fairly old data originating from the clinical trial (TEN-HMS) that took place between January 2000 and July 2002. The value of reducing uncertainty of particular parameters in our model was established using a similar approach to the EVPI analysis. The Individual EVPPI was found by "taking the maximum expected net-benefit given perfect information only about the parameter(s) of interest (calculating expected net benefits over all the other uncertain parameters in the model) and then calculating the mean of all the possible values of the parameters of interest".[313] The EVPPI analysis showed that the only group of parameters that have a substantial impact on the decision uncertainty are transition probabilities, in both All NYHA and NYHA IV analyses, and that the future research should concern disease progression. The optimal research designs to apply would be randomized control trials, or prospective and retrospective studies. In NYHA IV analysis some uncertainty was found for utilities, number of hospitalizations, and resource use at WTP thresholds higher than €45K.

Limitations of our study were plentiful. In the model there is a substantial amount of structural uncertainty, especially in terms of how transition probabilities are derived, assumptions on time dependence and data imputation. Also, utility and resource use costs are state-dependent and not time/treatment-dependent. The assumptions from the original modelling study remained[322] and were supplemented with the new ones: a) presuming that the HTM and NTS will have the same costs and effectiveness over the next 20 years, b) the increase of CHF population in the Netherlands by 5,000 each years for the next 20 years, c) applying the 4% discount rate, d) grouping the parameters assuming independence. Individual parameters when considered in isolation might not resolve at maximum values, to have an impact on the NMBs, but when grouped together they might resolve in such a way to have a significant impact on differences in net benefits and change the decision. EVPPI for individual parameter can be zero, but if grouped there is a possibility to have a substantial impact,[313] and thus our grouping (according to possible future methods for evidence gathering) is biased. There is also a possibility of correlation between the parameters, and grouping will preserve the correlation structure, if done properly. If the correlation exists, there is a possibility that the EVPPI for the group of parameters will be greater than the EVPI of the same group, or even the EVPI for the decision itself,[313] which was our case with transition probabilities. To remedy this situation, we run 2,500 simulations for this parameter group, and 1,000 for all others. We left the Expected Value of Sample Information (EVSI), the continuation of the VOI analysis for calculation of optimum sample size and allocation rates in randomized clinical trials,[310] for future research.

We were not able to find comparable studies on VOI in CHF management via telehealth in the Netherlands, but we did find on COPD in the Netherlands[314] and obesity in Switzerland[334]. Ramos et al.[335] performed a

CEA with VOI for angiotensin inhibitors in CHF patients in the Netherlands, while McKenna performed two systematic reviews and economic analyses, on aldosterone antagonists[336] and external counterpulsation[337] in heart failure management. In our CEA[322] we compared our results with the results from Thokala et al.[110], the HTM and NTS trial and cost effectiveness analysis executed in the UK context. For their effective population of 54,779 HF patients the EVPI per patient at £20K/QALY was £826 while population EVPI at this threshold was £45,247,202.[338] Comparing VOI results is difficult, given the previously discussed methodological, structural, and parametric differences.

Decision to adopt HTM and NTS in management of CHF in the Netherlands ultimately relies on cost-effectiveness of those technologies, uncertainty (variability of NMBs) surrounding cost-effectiveness, and cost of the decision error. The authorities must reach a decision if further research is warranted, or the current evidence is “good enough” for reimbursement of these technologies. Claxton et al.[339] argue that in addition to approval or rejection, the authorities should also consider “only in research” or “approval with research”. The benefits of immediate access might exceed the value of future research, and the decision should not be solely based on expected net benefit.[340] Immediate approval can provide an incentive to a manufacturer, consequently lowering cost of technology, and thus improving cost-effectiveness of HTM and NTS. Rejecting a promising technology in healthcare based on cost-effectiveness prevents us from learning about its performance. That is why decision making in reimbursement of medical devices is so difficult and should also consider learning curve effects, incremental device innovation, investment and irrecoverable costs, and dynamic pricing.[341]

Our research shows that the decision uncertainty in adopting HTM and NTS in CHF management in the Netherlands lies predominantly with the transition probabilities (i.e. the change of a NYHA class in a Markov cycle), and more effort should be given to understanding the dynamics of the disease progression. Results of our modelling exercise show that the cost of uncertainty for All NYHA patients in the Netherlands in the next 20 years amounts to €4.5B at WTP of €20K/QALY. This renders future research in telehealth for the management of CHF in the Netherlands cost-effective, and the return-on-investment substantial.

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