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Chapter 1

General introduction and aims of this thesis

Arjen E. de Vries

Heart Failure

Heart failure (HF) can be defined as an abnormality of the cardiac structure or function leading to failure of the heart to deliver oxygen. For clinically purpose, HF can be defined by the inability of the heart to provide sufficient blood flow to meet the body's need. The failure of the pump function of the heart causes a cascade of syndromes, symptoms and complaints. They can include shortness of breath, fatigue and fluid retention in the lung and/or body.[1]

Heart failure is mainly related to people aging but is also a result of lifestyle in industrialized countries which results in myocardial infarction, obesity and hypertension, the three most important contributors for HF. Because of this increasing elderly population and an improved survival after myocardial infarction, the number of patients with HF is increasing. In the Netherlands alone, about 130,000 individuals in the adult population (1%) are diagnosed with HF and it is estimated that in 2025 195,000 (an increase of 50%) people will suffer from HF. The prevalence of HF in individuals older than 70 years is between 20 and 30%.[2,3]

Heart failure is described and characterized as a major health problem and a burden of epidemic proportion. It is also associated with a high re-admission and mortality rate.[4-6] The re-admission rate of patients with HF is between 30-45% within 6 months after their initial admission. Forty percent of the patients that are admitted for HF die or are re-admitted within 1 year. About 50% of the patients will die within 5 years after the diagnosis. Perhaps more important is the strong negative effect that HF has on the quality of life.[7] Moreover, patients with an HF diagnosis tend to have more depressive symptoms than the healthy population, but also in comparison to patients with other chronic diseases.[8,9]

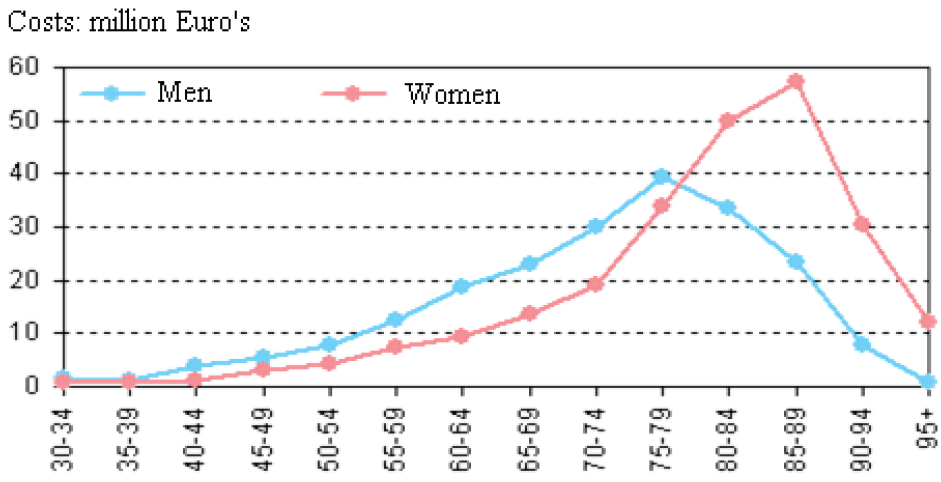

Figure 1: Costs of HF, related to increasing age. Source: RIVM rapport 260401006/2012[2]

HF is not only a burden for patients themselves but also for our society. Due to the prevalence and high re-admission rates, it is associated with a high cost for healthcare.[10,11] In 2008, 0,5% of the total Dutch healthcare budget was spend on HF (€ 500 million). With an estimated prevalence of 195,000 people in 2025 this amount will be about €10 billion.[2] Because HF is mainly an "aging" disease, the costs of HF are growing with an increased older age in the population (Figure 1).

Heart failure management and guideline adherence

In order to reduce the re-admission and mortality rates and improve the quality of life, many interventions and strategies have been developed over the years. One of them is the strong evidence of pharmacological treatment with medication as Angiotensin-inhibitors, Beta-blockers and Aldosterone-antagonists. Another important intervention is the application of disease management programs (DMP's), a multidisciplinary intervention designed to improve quality and cost effectiveness of care of a chronic disease, using a systematic approach and employing multiple treatment modalities.[12,13] Many trials have shown a positive effect of DMP's on the clinical outcome of HF patients as a result of better pharmacological and non-pharmacological care.[14,15] Although the key characteristics of patients who benefits most of a DMP intervention remain unclear,[16] the European Society of Cardiology (ESC) has developed guidelines in which HF DMP's are strongly recommended for all patients with HF.

Guideline adherence

HF disease management care is mainly provided in special HF clinics, characterized by a strong collaboration between HF nurses and cardiologists in a multidisciplinary setting. Nowadays, these HF clinics are considered as "usual care" in several European countries.[17] HF guidelines clearly indicate that patients with systolic HF should be treated with specific medication, targeted to an optimal dosage. Also tailored management of the disease should take place (e.g., lifestyle interventions, education, recognizing signs and symptoms). Nevertheless, translation of these pharmacological and non-pharmacological guidelines into daily practice remains difficult.[18-20] A possible solution to improve guideline adherence is the introduction of health information technology. [21]

Health information technology

Health information (and communication) technology (HIT) includes technology such as electronical patient records, (EPR), computerized clinical decision support systems (CDSS) and telemonitoring. It can support diagnoses, treatment and follow-up of patients, based on guidelines and protocols and facilitate adherence to guidelines.[22] HIT provides several new opportunities in healthcare and has been promoted as having

tremendous promise in improving the efficiency, cost-effectiveness and quality and safety of care.[23] However, the use of HIT is not always successful,[24, 25] and implementation of HIT can easily fail, providing not the success on patient outcome and cost-efficiency as expected or promised. Developers and companies often claim cost-effectiveness and an improved quality of care by using HIT, but in daily practice many HIT applications do not fulfill these claims, leaving healthcare providers disappointed and frustrated. To retrieve maximum benefit of this technology it is important to understand why some HIT-implementations are successful and others are not. A solid implementation and success of HIT, depends on many critical factors such as comprehensive training for users, regular evaluation and clear and measurable outcomes. The importancy of these factors is often underestimated by (future) users and management.[26]

Computer decision support system (CDSS)

CDSSs are able to provide support and decisions and are mainly used to provide software-based healthcare-related advice to assist doctors and nurses in making decisions and developing solutions in complex or non-routine situations.[27] In healthcare, CDSSs are often developed to improve care for patients with chronic conditions, including HF. The most important reason for using CDSSs in patients with chronic conditions is the general belief that, specifically in this area, higher quality of care and reduction of costs in a growing population is achievable. When a CDSS with incorporated guidelines is directly linked to an electronical patient record (EPR), data such as medical history, diagnosis, laboratory and pharmacological treatment can be "read" by the CDSSs, thus interpreting the actual patient data and can give the user advice on how to treat the patient according to the guidelines.

Telemonitoring

Another HIT application is telemonitoring which consist of the remote monitoring of patients, including the use of audio, video, and other telecommunications and electronical information. For HF it includes the measurement, monitoring collecting and transfer of clinical data related to the health status of a patient at home and guides patients in taking action in case of deterioration.[28] Telemonitoring is considered as a promising new intervention for HF patients, and initial studies showed that remote monitoring of HF patients reduced hospitalization and mortality rates.[28-30] However, other studies did not confirm these findings[31,32] or even showed, in contradiction, that monitoring patients at a distance can lead to an increase of re-admissions and hospital visits. This increase of re-admissions and hospital visits could be a result of the "need" of patients and healthcare providers to resolve a problematic situation, even without the presence of signs and/or symptoms.[33] At this time it is unclear which patient with HF will benefit most from the of use of telemonitoring.[34]

Combination of CDSS and telemonitoring in heart failure

Although both HIT applications (CDSS and telemonitoring), can be used to monitor patients, optimize medication (at a distance) and provide structural support and education,[21,35,36] few hospitals have experience using this combination in HF patients. There are few studies on "smart" telemonitoring systems, which are able to give advice on how to treat patients in case of deterioration of HF.[37] This systems can provide advice based on incoming data as weight, heart rate and/or blood pressure and answers on digital questions about HF symptoms. A much more advanced but also complex solution is the combination of telemonitoring with CDSS, incorporated in the patient's own EPR. Now the advice and support are also based on the clinical variables at home such as weight, blood pressure and heart rate, together with the actual medication, medical history and diagnoses, renal function and physical condition. Besides the input of data from the electronic patient record, the data are completed with answers on digital health questions about HF symptoms from patients home situation (Figure 2). All data are transferred by the internet and the CDSS is able to generate a tailored advice, based on actual patient data and the incorporated HF guidelines. An example of the possibilities of this data-flow is the titration of a Beta-blocker at the patient's home, using blood pressure, weight, EKG, symptoms, renal function and other medical information. The healthcare provider is now able to titrate this Beta-blocker to a higher dose, under safe conditions at home, making a visit to the outpatient clinic, solely for titration of medication, unnecessary.

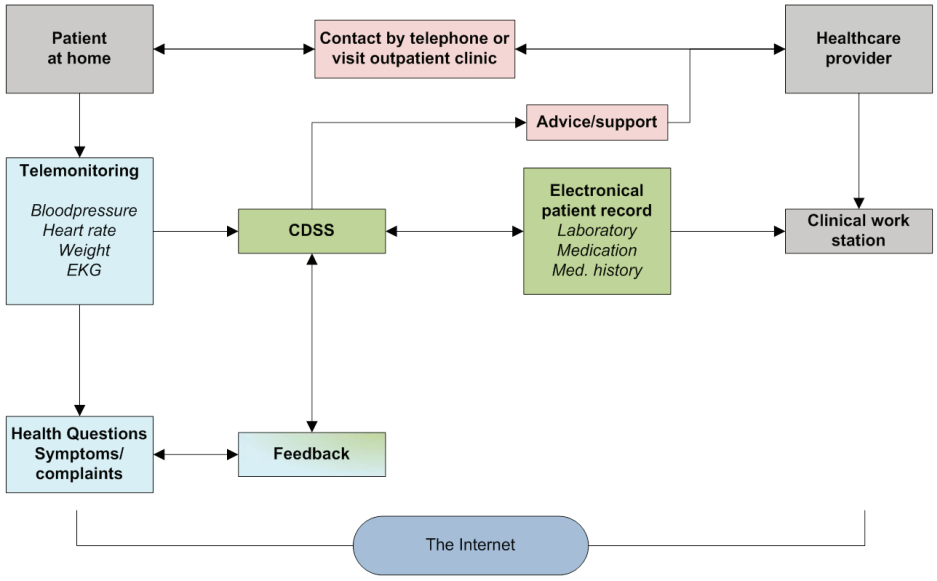

Figure 2: Schematic diagram of dataflow of a telemonitoring system in combination with CDSS functionality for patients with heart failure.

Difficulties in using CDSS for heart failure care

Despite the existing evidence that using CDSS significantly improved clinical outcomes, widespread development, implementation and evaluation in HF clinics is lacking.[38,39] The most important reason for this lack of use seems to be a certain level of mistrust and resistance to CDSS. Another reason is a problematic implementation, consolidation and evaluation.[40-42] These reasons have been described as a barrier for the use of HIT and therefore also for using CDSS in HF,[43,44] although it is unclear to which extent these barriers are present. Another reason for the lack of use is that a full integration of a CDSS into a hospital EPR environment is rather difficult. Finally, it is unclear if using a CDSS in HF disease management care is cost-effective.

Objectives

Although there have been major developments in the treatment of patients with HF in the last decade, more benefits could be achieved with a better and particularly structural application of evidence-based guidelines. A better adherence to guidelines, leading to improvement of outcomes, might be partly achieved by using such HITs as CDSSs and telemonitoring for patients with HF. It is therefore important to understand why and to what extent users in the field of HF experienced barriers in using HIT in their daily practice and to know if there is additional effect on patients' outcomes in using CDSS in combination with telemonitoring in HF. To gain more insight into practical use, consequences, advantages and disadvantages of using CDSS and telemonitoring in HF care, with a focus on user-related expectations, experiences and barriers, the following aims of this thesis are formulated:

1. What are the effects of telemonitoring combined with CDSS on clinical outcomes, adherence to guidelines, cost effectiveness and quality of life.
2. To explore the expectations, experiences, barriers and usability of telemonitoring and CDSS, used by HF nurses and cardiologists in the treatment of HF patients.
3. To gain insight into different HF disease management models (one of which is CDSS-driven) and explore differences in and effects of prescriber adherence of medication.

Study populations

Data for this thesis was collected from Dutch HF clinics, concerning both HF patients and HF nurses and cardiologists. To explore differences in prescriber adherence we used data from the COACH study,[14] DEAL study[45] and the HF outpatient clinic of the Martini Hospital Groningen, Netherlands.

Outline of this thesis

In Chapter 2, a case study on the value of the use of telemonitoring, integrated into an ICT- guided disease management system in direct patient care is described. The outcome and expectations of the health information technology used in this case report was the rationale to design the INTOUCH study,[46] a multicentre randomized trial in the Netherlands (Chapter 3). This study was designed to investigate the effects of telemonitoring in addition to an ICT-guided disease management system, on the quality and efficiency of care of patients after worsening HF, focusing on clinical outcomes, adherence to guidelines, cost effectiveness and quality of life. A substantial part of this ICT-guided disease management system, was CDSS-driven, especially with a focus on prescription of HF medication.

In Chapter 4, we describe and evaluate the primary outcome of the INTOUCH study, a composite endpoint of mortality, HF re-admission and quality of life. Beside this primary outcome we focus on the cost-efficiency of telemonitoring and CDSS.

In Chapters 5, 6 and 7, we provide insights into the actual use of telemonitoring in Dutch HF outpatient clinics and focus on user-related expectations versus experiences of using telemonitoring. We evaluate the practical usability and acceptability of the CDSS used in the INTOUCH study and explore type and number of perceived barriers of HF nurses and cardiologists to using CDSS in the treatment of HF patients.

In Chapter 8, we offer insight into the effect of three different HF disease management models on prescriber adherence of medication. One model focuses solely on education and counseling (COACH), while the other two focus on optimization of medication (DEAL and Martini Hospital). One of these models tried to achieve a better prescriber adherence with the help of a CDSS, the other model with the help of a dedicated physician.

In Chapter 9 of this thesis we will discuss and reflect the major findings of this thesis and give recommendations for clinical practice and future perspectives in relation to the use of telemonitoring and CDSS in HF and their contributions to better guideline adherence.

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Chapter 2

ICT-guided disease management and telemonitoring in heart failure Case report

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Eur J Cardiovasc Nurs. 2012 Dec;11(4):432-8

Abstract

In the last decades, the introduction of information and communication technology in healthcare promised an improved quality of care while reducing work load, and resulting in a more cost effective system. This might be realised by the use of computer guided decision support systems and telemedicine. This case study describes the potential of a computerised disease management system in combination with telemonitoring in the context of heart failure. With the help of a computer guided decision support systems and telemedicine we were able to prevent at least two readmissions for heart failure in a period of 10 months and we gained more insight in patients' behavior with regard to compliance with the heart failure regimen at home. Frequent contact at distance and the on-line availability of physiological and biological measurements at home facilitated patient tailored education and help the patient to react adequately to symptoms of deterioration. Additionally, uptitration of medication was performed without seeing the patient in the outpatient clinic.

Introduction

Heart failure (HF) is not only associated with very high mortality, morbidity and re-admission rate but also with high direct and indirect costs.[1] Readmission rates usually vary between 25% and 50% within 6 months after the first hospitalization for HF and a substantial part of these readmissions occur in the first month after discharge.[2-4] Randomized studies and recent meta analyses suggest that disease management programs and telemonitoring can reduce readmissions for HF or cardiovascular disease by 30%[5-9] and significantly decrease mortality.[10,11]

A disease management program (DMP) is defined as a multidisciplinary intervention, designed to improve quality and cost effectiveness of care of a chronic disease, using a systematic approach and employing multiple treatment modalities.[12] DMP following treatment and lifestyle instructions as recommended by the European Society of Cardiology guidelines,[1] showed to be more effective in improving clinical outcome than other programs.[13] There is also evidence that remote monitoring of HF patients reduces readmission and mortality.[11] With this remote monitoring it is possible to recognize early deterioration and therefore avoid unnecessary readmission, but it can also be used for a more efficient up-titration of HF medication (e.g. ,angiotensin converting enzyme (ACE) inhibitors or beta-blockers). Although studies ar not inconclusive, there is a strong indication that DMP's and telemonitoring are effective, however, these components are not widely implemented. An important issue is not only how to successfully implement DMP and telemonitoring, but moreover how to identify the patient that could benefit from these devices.

This case study describes a patient with severe chronic HF, who was frequently hospitalized for HF. Treatment of this patient is guided by a computerised DMP program structured by the current guidelines with integrated remote monitoring facilities. The potential use, consequences and experienced benefits and barriers of this system will be discussed.

Case report

A 50-year old man visited the cardiologist in August 2004 because of a decrease in exercise capacity and shortness of breath during exercise. Echocardiography showed a large anterior wall defect and a left ventricular ejection fraction (LVEF) of 29%. It subsequently appeared that he had suffered from a large myocardial infarction in March 2004. He was not diagnosed at that moment, due to a lack of symptoms. He was diagnosed with HF, New York Heart Association class (NYHA) class II-III, and referred to the outpatient HF clinic for optimizing medication, education and self management. In May 2005 he received an implantable cardioverter defibrillator and in June 2006 he was on optimal HF medication and discharged from the outpatient HF clinic in a stable condition (NYHA class I; with a LVEF of 32%). Follow-up was performed by the cardiologist.

Table 1: medication and parameters at discharge and at 10 months

	At discharge	At 10 months
Medication		
Carvedilol	3,125 mg twice a day	12,5 mg twice a day
Ramipril	1,25 mg once a day	5 mg twice a day
Hydrochlorothiazide	12,5 mg once a day	12,5 mg once a day
Spironolactone	25 mg once a day	25 mg once a day
Furosemide	40 mg twice a day	40 mg twice a day
Acenocoumarol	conform protocol	conform protocol
Simvastatine	40 mg once a day	40 mg once a day
Weight	85.3 kilogram	84.7 kilogram
Bloodpressure	95/45 mmHg	105/48 mmHg
Urea	6,2 mmol/l	5,7 mmol/l
Creatinine	146 µmol/l	122 µmol/l
Heart rate	72 bpm	64 bpm

In March 2008, he was readmitted to the hospital with acute HF and treated with i.v. diuretics and dobutamine. The most likely explanation for this deterioration of HF was a holiday in Greece where the patient had a high salt and fluid intake. He was in the hospital for sixteen days.

After discharge he was readmitted five times within six months, once with dehydration, the other readmissions for worsening HF. These frequent instabilities were caused by a combination of factors including lack of compliance, symptoms of depression and delay in seeking care when symptoms of deterioration occurred.

The patient was referred to the outpatient HF clinic again, but his situation and frequent readmissions caused an unstable period whereby time after time, he was readmitted to the hospital before he could visit the HF clinic. His last hospitalisation was critical; because of chronic hypotension he suffered of hypoperfusion of the brain, leading to cognitive dysfunction, central cyanoses, and permanent peripheral edema and ascitis. During this hospitalisation, his HF medication was reduced to minimal dosages due to symptomatic hypotension and renal dysfunction. He was diagnosed with terminal end stage HF, (NYHA class IV; LVEF 22%). During hospitalisation, the patient was stabilised and because of the frequent readmissions it was decided to monitor him immediately after discharge with telemonitoring integrated in a computerised DMP. With this system, described further below, we tried to remain a stable situation. The main purpose was to monitor weight and intervene early in case of deterioration, thereby trying to avoid readmission. Another purpose was to try to slowly up-titrate his HF medication at home. At discharge, the patient was classified as NYHA class III. Medication and clinical parameters at discharge and after 10 months are shown in Table 1.

Description of the system

The system consists of a computerised disease management system located in the hospital, together with telemonitoring devices used in the home-setting of the patient measuring weight and blood pressure including a health monitor. With the health monitor, an interactive dialog with the patient is possible. In case of a deviation of predefined ranges of weight and blood pressure, the health monitor will lead the patient systematically through a sequential list of questions on the presence of HF symptoms (Table 2). All data are send to the system in the hospital. With these data, it is possible to adjust therapy to optimal levels, using integrated HF guidelines.

For the up-titration of medication, the system advises based on renal function, blood pressure and heart rate. If the vital signs are within predefined ranges, an advice for the HF nurse is generated to further up-titrate the medication to optimal doses according to the HF guidelines. At the same time, the system will advise to give specific education on HF and the HF regimen to the patient.

In case of serious deviated measures at home, together with HF symptoms, the HF nurse will be informed automatically by short message service (SMS) and E-mail. In case of a slight deviation of the predefined ranges without an increase of HF symptoms, the patient receives an automatic generated advice to take action (for example advice about

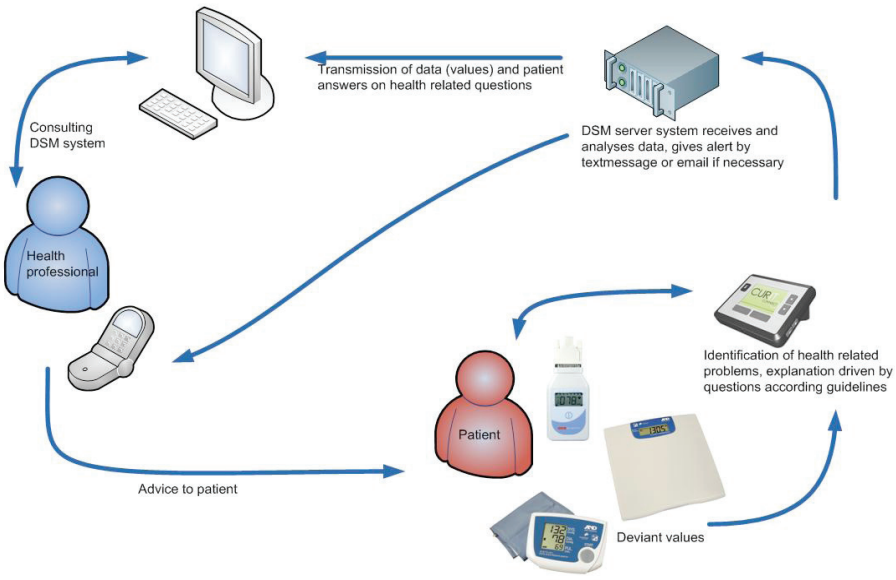

Figure 1: dataflow of the computerised disease management system and remote monitoring

Table 2: Data transfer and handling of deviating values of the computerised disease management system

Alarm type	Specification	Questions health monitor	Answers patient to health monitor	Advise healtmonitor to patient	Advise ICT-DSM to HF nurse	Alarm
Blood pressure (diast.) under lower-limit	95/38	Your blood pressure is low, do you have any complains?	No	Monitor your blood pressure two times the coming 24 our, or more often if any complains	1:Patient is currently using a ACE inhibitor and a beta-blocker. Monitor the blood pressure the coming day's. If any complains: consider lowering medication. 2: check fluid and sodiumbalans	None
Telemonitoring alarm	Low battery weight scale	Your battery of the weight scale is low, replace the battery			The battery of the weight scale is low, monitor if replacement took place	None
Blood pressure (syst.) above upper-limit	115/63	Your blood pressure is higher than normal, do you have any complains?	No	Monitor your blood pressure two times the coming 24 our, or more often if any complains	1: If the patient is in a up-titration period of ACE inhibitor or beta-blocker, check if titration is possible, if not, monitor blood pressure and signs of decompensation	None
Weight above upper-limit (87)	87,5 kg	1:Your weight is more than 2 kilo's above your optimal weight, do you have any complains?	Yes			
		2:Do you suffer from dyspnea?	Yes			
		3:Do you sleep bad at night?	Yes			
		4:Are your ankles swollen?	Yes	Contact will follow in two hours	There are signs of decompensation in combination with complaints,	Alert to SMS and Email
Weight above target (85) but lower than upper limit (87)	86,2 kg	Your weight is more than 1 kilo's above your optimal weight, do you have any complains?	No	Take care of your fluid and sodiumbalans, do not drink more than 1500 ml a day. In case of complaints, contact your HF nurse	Patient weight is above target but lower than upper limit; no complaints	Email
No data received	no data received the last 48 hours	not applicable		not applicable	There is no data received the last 48 hours	Alert to SMS and Email

prescribed fluid restriction and the use of sodium). Advice about medication, derived from the computerised disease management system, after judgment of renal function, blood pressure and/or heart rate, is only given after consultation of the HF nurse. A major difference between a stand-alone telemonitoring system and the system described in this case study, is that the telemonitoring function is integrated into a computerised DMS. It is attached to an incorporated electronic health record and is possible to interpretate and give advice about type and dose of medication, laboratory tests and supplementary examinations. The system is also able to generate alarms for missing data and/or technical problems.

Follow up of the patient after discharge

The patient was discharged with the described system. In addition, the patient visited the HF clinic regularly for comprehensive tailored education on self-care behavior, sodium and fluid restriction and exercise. Psychosocial care for his depressive feelings and his fear for readmission was also an important issue during these visits.

The scheduled visits for follow-up and optimisation of medication were replaced by remote monitor devices at home. The patients' weight at discharge was 85 kg with an allowed variability of 2 kilogram. When his weight exceeded 87 kg, the health monitor generated a set of questions about the presence of HF symptoms. When the patient reported symptoms of dyspnea, sleep disorder and swollen ankles, the health monitor answered that the HF nurse would contact the patient by telephone within two hours. At the same time, an alarm was generated on a mobile phone, whereupon the HF nurse logged in into the computerised disease management system to evaluate the alarm. Based on up to date available data from the electronic health record (renal function) and telemonitoring devices (blood pressure and weight), the system generated the advice to double the dose of diuretics for a period of 3 days, monitor weight and blood pressure more intensively and to contact the patient the next day by telephone (Table 2). During the first initiated contact, within 2 hours after the alarm, the HF nurse assessed patients' compliance and provided additional information on how to manage fluid intake and sodium restricted diet. As a result of these interventions, the weight of the patient reduced to 85 kilogram after 2 days, together with a decrease of dyspnea and ankle swelling. Two months later, there was again an increase of weight in combination with HF symptoms, with the same successful anticipated treatment with temporarily increase of diuretics.

As shown in table 2, the system is able to generate alarms for weight, blood pressure and HF symptoms as reported by the patient in dialog with the health monitor. Beside correcting two periods of decompensation, it was possible with frequent control of blood pressure, heart rate and weight, provided by the telemonitoring devices, to up-titrate the HF medication in the home situation under safe conditions. The electrocardiogram and laboratory tests, needed for the up-titration, were performed in the outpatient clinic, without direct contact with cardiologist or HF nurse. The patient in this case did not visit

the outpatient clinic for medication consults, but the titration of the beta-blocker took place at the patients' home, with the help of the telemonitoring system together with ECG and laboratory tests.

Discussion

This case report concerns a patient with severe HF, treated with a computerised DMP with integrated telemonitoring after a period of frequent readmissions. With this system, it was possible to monitor this patient at home and give advice about taking extra diuretics and lowering fluid intake in an early phase of deterioration. The patient in our case reached a stable phase of HF. Due to the described system, we were able to prevent at least two readmissions for HF in a period of 10 months and we gained more insight in patients' behavior with regard to compliance with the HF regimen at home. Frequently contact by telephone gave us the opportunity to educate the patient and help him to react properly to symptoms of deterioration.

With this type of system it is possible to provide a safe shifting of tasks from the cardiologist to the HF nurses. Even so, we belief that a reduction in costs can be achieved by a decrease of readmission rate and a more efficient up titration of medication at the patients' home without visits to the HF clinic. In case of updated therapeutic guidelines, changes can be incorporated easily into the computerised system and will give the healthcare provider directly advice according the latest consensus texts.

The awareness of devices at home and the knowledge that deviating or missing data provide alarms, had a positive effect on the compliance of the patient. In this case study, the patient integrated the daily measurement into his normal daily life without problems.

Many researchers have described the benefits of telemonitoring for HF patients in general,[10,14,15] however there are also disadvantages of this kind of remote monitoring systems. One often reported problem from a patient's point of view is the permanent presence of "the disease" in the home environment due to the existing devices and daily required measurements. The feeling that the patient cannot leave home without informing the hospital, can also be experienced negatively.

The combination of a computerised disease management system with intergraded telemonitoring is rather new in medical care and certainly not commonly used in daily practice. A potential indolence of patient and healthcare provider in leaving the recognition of signs of deterioration only by the computer can give a false sense of security and should be recognized In addition, healthcare providers might feel reluctant to use these systems, encounter difficulties to work with systems which will "think for them", in contrast to, for example air traffic personnal.[16] An experienced loss of autonomy can be an important factor for resistance of implementation of such systems. Nevertheless, decision support as

a substantial component of a computerised disease management program can be of great help to apply guidelines.[17,18]

Despite the expected opportunities of integrated and combined systems, there is a great lack of experience and evidence for widespread implementation. Therefore it is advisable to further investigate the effects of this type of intergraded systems. It is questionable whether the use of telemonitoring devices is preferable for all HF patients and whether all visits to the HF clinic can be replaced by remote monitoring.

In our opinion, telemonitoring, driven by a computerised DMS, can be a useful supplement to face-to-face contact and a tool to prevent HF related readmissions. It can also be helpful in more efficient uptitration of HF medication, without contact at the HF clinic. However, because of the impact and intrusion in the patient's daily life, the use of telemonitoring must be considered. In this case the patient visits the outpatient clinic for a electrocardiogram and laboratory tests, needed for the up-titration of his medication. In the further development of this model we discovered that these test can perform safe in the own home environment. The challenge, and at the same time the difficulty, is to identify the right category of patients for this kind of monitoring.

It seems recommendable to start with patients in an unstable phase of HF, just after an admission for HF, since many expensive readmissions occur shortly after a HF hospitalisation.4 Therefore, this first vulnerable period seems most appropriate to observe signs of early deterioration in the home situation. It is also possible to use the system to up titrate medication efficiently at home in stable HF patients.[19]

In this case there was no special focus on cost effectiveness, but to examine whether this developed combined model indeed leads to a lower readmission rate for HF, lower costs, higher quality of life and possibly lower mortality, a large randomized trial will be necessary.

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Chapter 3

The value of INnovative ICT guided disease management combined with Telemonitoring in OUtpatient clinics for Chronic Heart failure patients. Design and methodology of the IN TOUCH study

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Abstract

Background

Although the value of telemonitoring in heart failure patients is increasingly studied, little is known about the value of the separate components of telehealth: ICT guided disease management and telemonitoring. The aim of this study is to investigate the value of telemonitoring added to ICT guided disease management (DM) on the quality and efficiency of care in patients with chronic heart failure (CHF) after a hospitalisation.

Methods/Design

The study is divided in two arms; a control arm (DM) and an intervention arm (DM+TM) in 10 hospitals in the Netherlands. In total 220 patients will be included after worsening of CHF (DM: N=90, DM+TM: N=130). Total follow-up will be 9 months. Data will be collected at inclusion and then after 2 weeks, 4.5 and 9 months. The primary endpoint of this study is a composite score of: 1: death from any cause during the follow-up of the study, 2: first readmission for HF and 3: change in quality of life compared to baseline, assessed by the Minnesota Living with Heart failure Questionnaire. The study has started in December 2009 and results are expected in 2012.

Discussion

The IN TOUCH study is the first to investigate the effect of telemonitoring on top of ICT guided DM on the quality and efficiency of care in patients with worsening HF and will use a composite score as its primary endpoint.

Background

Heart failure (HF) is the most common hospital discharge diagnosis in elderly patients.[1] Between the age of 70 and 80 years the incidence of HF is 10 to 20%. HF is associated with high mortality and morbidity, readmission rates and costs.[1] The readmission rates vary between 25% and 50% within 6 months after the first hospitalisation for HF, with a higher readmission rate within the first month after discharge.[2,3] The costs related to HF contribute to 1-2% of all healthcare expenditures and are mainly the result of hospital stay.[4-6] Because of an increasing shortage of resources, HF is a major public health problem and therefore, a more effective and efficient organisation of care for HF patients needs to be reconsidered. A first step in organising treatment and care for patients with chronic HF more efficiently, was the implementation of specialised outpatient HF clinics. In the recent European Society of Cardiology (ESC) guidelines, HF management programmes are strongly recommended for all patients with HF[1] and HF clinics are considered as 'usual care' in several European countries.[7] A widely used way to implement HF management is the use of specific disease management (DM) programs.

DM can be defined as an intervention, designed to manage a chronic disease and to reduce hospital readmissions, using a systematic approach to care and potentially employing multiple treatment modalities.[8] Control and cost effectiveness are substantial components of a DM program. Randomised studies suggest that DM programs can reduce readmissions for HF or cardiovascular disease with 30% [7, 9,10] and significantly decrease mortality rates.[11] Yu et al [12] described that DM for HF patients, as recommended by the ESC guidelines,[1] are effective in reducing hospital readmissions and mortality rate.[13] However, inconsistent findings for readmission and mortality rates have been found, probably due to the variety of components and practical applications of the DM programs.

We recently reported results of the COACH study, a study on the effect of a nurse led DM program on clinical outcome,[14] in which the positive effects of a DM program on readmission were not confirmed, although there was a trend to a reduction of mortality in the intervention groups. The INH study [15] on the effect of DM in HF, showed that a DM program compared to usual care could reduce mortality but not hospitalisation rates. Important components of this program were patient education, optimisation of medical therapy, psychosocial support and an easy access to healthcare. An important aspect for the treatment of HF patients is the prescription of HF related medication at an optimal dose i.e. ACE-inhibitors, beta-blockers, and aldosteronantagonists. The up titration to optimal dosage is an aspect that often takes place at a HF outpatient clinic. However, data from the Euro Heart Failure Survey showed us that guideline adherence for HF medication although improving still is not optimal.[16] In the IMPROVE study, dedicated HF clinics were associated with greater use of cardiac resynchronisation therapy and a better HF

Table 1: In and exclusion criteria IN TOUCH

Inclusion criteria
Worsening HF defined as signs of fluid retention (peripheral oedema / congestion)
needing an increase of the dose of diuretics (i.v. or oral)
Evidence for structural underlying heart disease
Documented reduced left ventricular ejection fraction (LVEF) ≤45%
18 years of age
Patients have to be able to understand content of and willing to provide informed
consent.
Exclusion criteria
History of myocardial infarction in the previous month
Life expectation less than 1 year
Undergone cardiac invasive intervention within the last 6 months (PCI, CABG, HTX, valve replacement, CRT implantation)
A planned procedure for PCI, CABG, HTX, CRT implantation or valve replacement in the following 3 months
Evaluation for heart transplantation prior to or during the study
Weight more than 200 kilogram
The use of telemonitoring devices at home
Haemodialysis

education, but not with better guideline adherence to medication.[17] Health information technology, integrated into a DM program might facilitate adherence to guidelines of health professionals.[18] With new information and communication technology (ICT), healthcare providers can be supported in the diagnosis, treatment and follow up of HF patients by expert computerised systems, based on guidelines and protocols.[19] These systems can be used to optimise medication according to guidelines and provide structural support and education.[20] We were the first to report promising findings on ICT guided DM in terms of higher doses of recommended HF medication and lower readmissions.[21,22] Another promising ICT tool is telemonitoring. Telemonitoring is often used to monitor patients at home and guide patients to take action in case of deterioration, but it also can be used to up-titrate medication according to guidelines at distance.[23] There is support that remote monitoring of patients with HF can reduce hospitalisation and mortality rates,[24,25] however results on clinical outcome and efficacy are inconclusive and limited.[26-28] There are also recent study's that where not successful in their primary endpoints.[29,30] Furthermore, cost-effectiveness of these systems has not been thoroughly evaluated. It can be concluded that the overall effects of telemonitoring are inconclusive. To summarise, due to a growing population of patients with HF and an expected shortage of healthcare providers in the near future, there is a need to seek to more cost effective

and efficient ways of providing optimal care for HF patients, including a better adherence to guidelines. ICT guided DM tools in combination with telemonitoring could be of important value.[31,32] At the same time there is substantional data that the adaptation and implementation of those systems is lacking.[33] The experiences with such a system however are fragmented. User resistance is described as a major obstacle in the adoption of these computerised tools. More insight in user resistance and experienced barriers in using ICT guided DM tools is needed to successfully implementing such tools.[34]

The IN TOUCH study will investigate the effect of telemonitoring in addition to an ICT guided DM system on the quality and efficiency of care for patients after worsening HF. This is the first study investigating a combination of two newly developed ICT interventions in a group of chronic HF patients on clinical outcome, adherence to guidelines, cost effectiveness and quality of life.

This study will add important information to other telemonitoring studies because of its strong commitment to ICT guided DM, the chosen composite endpoint, a strong focus on cost-effectiveness and the investigation of the influence of user aspects as resistance and barriers that accompany the use of modern healthcare related ICT tools.

Methods/Design

Study hypothesis

Telemonitoring added to ICT guided DM improves prognosis and quality of life in patients with HF compared to ICT guided DM alone.

Aim of the study

The primary aim of this study is to assess the effect of telemonitoring on top of an ICT guided DM system in patients after worsening HF on the combined endpoint of death, readmission and quality of life, compared to patients treaded with ICT guided DM alone.

Secondary aims of the study are;

- To assess the effect of telemonitoring in addition to an ICT guided DM system compared to an ICT guided DM alone on the separate components of the combined endpoint (death, readmission and quality of life)
- To determine the cost benefit ratio of ICT guided DM with telemonitoring compared to ICT guided DM alone.

Study design

A multicentre, randomised study in which in total 220 HF patients (NYHA II-IV) will be included. Patients will be randomised to the ICT guided DM (control) arm (N=90) or into the ICT guided DM with telemonitoring (intervention) arm (N=130) (Figure 1).

Study population

All patients admitted to the intensive care/coronary care unit or cardiology ward for HF or visiting the outpatient clinic with worsening HF who need treatment or adjustment of oral or intravenous diuretics, can be included in the study. Other inclusion criteria are; evidence of structural underlying heart disease, left ventricular ejection fraction <45% and age of at least 18 years. Reasons for exclusion are myocardial infarction in the past month, cardiac invasive intervention (percutaneous coronary intervention, coronary arterial bypass, valve replacement, heart transplantation, or cardiac resynchronisation therapy) in the past 6 months or planned in the next 3 months, weight >200 kg, actual haemodialysis and the use of other telemonitoring systems. (Table 1)

Primary endpoint

The primary endpoint of the study is a composite, weighted score consisting of values for mortality, HF readmission and change in quality of life between end of the study and baseline measured with the Minnesota Living with HF Questionnaire (MLHFQ), adapted from the A-HeFT study [35] (Table 2). A readmission for HF is defined as an overnight hospital stay for HF or directly related to HF. The readmissions for HF will be blinded adjudicated by an endpoint committee. When data on quality of life are missing, the worst-case score for that component of the composite endpoint will be used in the analysis.

Secondary endpoints

Secondary endpoints of the study are the separate components of the primary endpoint. Other secondary endpoints are the total number and duration of all hospital admissions, treatment according to the guidelines using the criteria of the Guidelines Adherence Indicator-3,[36] number of visits to the outpatient HF clinic, patient and carer satisfaction, and cost-benefit ratio.

Ethics statement

On March 2009 this study design has became ethical approval (M09.070323) given by the medical ethical commission (MEC) of the medical university of Groningen (UMCG). The study has started (first patient) in December 2009.

Incremental cost-effectiveness ratio (ICER)

Costs

A distinction will be made between intervention costs and resource utilization costs. The intervention costs consist of the costs of the DM system and the costs of the telemonitoring

Table 2: score system for primary endpoint IN TOUCH

End point	**Score**
Death (at any time during study)	-3
Survival to end of study	0
First readmission for heart failure	-1
No readmission for heart failure	0
Change in quality of life at 9 months	
Improvement ≥ 20 units	+2
Improvement by 10 until 19 units	+1
No improvement by -9 until +4 units	0
Worsening by +5 until +9 units	-1
Worsening by ≥ 10 units	-2
Possible score	-6 to +2

devices and will be calculated as a lump-sum over the study's follow-up period. Resource utilisation costs will be estimated by preparing a structured data collection form to collect detailed information regarding scheduled and non-scheduled outpatient clinic visits and hospital admissions (both HF and non-HF related), ward type (e.g. intensive/coronary care unit, cardiology, general internal medicine), and cardiovascular procedures/ operations. In addition, a patient questionnaire will be administered at 4.5 months and 9 months of follow-up to collect complementary data on general practitioner visits, home care utilization, and nursing home admissions. Unit costs will be estimated by using the Dutch guidelines for cost calculations and inflated to current price levels using a general consumer price index. Indirect costs, such as productivity losses, will not be taken into account.

Quality Adjusted Life Years (QALYs)

Preference-based quality of life scores will be obtained by administering the EQ-5D to all patients in both the control group and the two intervention groups at baseline, 4.5 months of follow-up, and 9 months of follow-up. QALYs will subsequently be estimated by calculating the area of the two trapezoids that result from linear extrapolation of the three quality of life scores.

Cost-effectiveness

The balance between costs and effects will be assessed by estimating the incremental cost per QALY gained (ICER) for the intervention group compared with the control group.

Table 3: Questionnaires and medical assessment used in the IN TOUCH

Questionnaires	Baseline	2 weeks	4.5 months	9 months
Minnesota living with heart failure questionnaire (MLHFQ)	•			•
Revised Heart failure Compliance	•			•
Disability Rating Index (VAS)	•			•
Hospital Anxiety and Depression scale (HADS)	•			•
Heart failure self-care behaviour scale(EHFScB)	•			•
Medical technology assessment (MTA)			•	•
EQ-5D	•		•	•
Satisfaction questionnaire for patients and providers				•
Medical assessment				
NYHA score	•	•		•
Echocardiography	•			
ECG	•	•		•
Physical examination	•	•		•
Laboratory tests	•	•		•

The time horizon over which the costs end effects of the different treatment strategies will be compared is equivalent to that observed during the period of the study (i.e. no future projections will be made). Uncertainty surrounding the ICER will be represented through the use of cost-effectiveness acceptability curves, which show, for each possible value of λ (i.e. the societal willingness-to-pay for one additional QALY), the probability that the intervention will be cost-effective.

Randomisation and data collection

Patients can be randomised during admission for HF, and in case of worsening of HF at the outpatient clinic. After confirmation of eligibility and written informed consent, patients will be included into the study. Patients will be randomised into the control or intervention group. Patient characteristics and clinical variables will be collected at baseline, and 2 weeks and 9 months after discharge. Echocardiography, ECG, and laboratory analysis will be performed at baseline during hospitalisation and at the end of the study. Quality of life as part of the primary endpoint, measured with the Minnesota Living with HF Questionnaire, will be collected at baseline and at 9 months. Data about utilisation of resources will be collected prospectively and comprise components of direct costs, i.e. scheduled and non-scheduled outpatient visits and hospital admissions.

Questionnaires about self-care behaviour, anxiety, depression, compliance and medical technology assessment (MTA) will be completed before discharge, and at 4.5 and 9 months (Table 3). Patients should be included preferably as soon as possible but at least within a period of time of 14 days after discharge or after the first visit at the HF clinic with worsening HF.

Control group (ICT guided disease management system without telemonitoring)

Patients in this group receive care guided by an ICT DM system. This system supports DM in a fully automatic way, assisting the HF nurse to optimise pharmacological and non-pharmacological treatment, evaluate treatment and adjust therapy to optimal levels, according to current HF guidelines. The patient will receive tailored education and counselling on the HF regimen, symptom management and improvement of the pharmacological and non pharmacological regimen.

The system mainly works as a computer decision support system. Based on the input of data from physical examination, medical history, questionnaires and nursing assessment, the system provides an advice to healthcare providers according to the actual guidelines, including up titration of HF medication to optimal doses.

Intervention group (ICT guided disease management with telemonitoring)

Patients in the DM with telemonitoring group will be treated with the above described ICT guided DM system in combination with the following integrated telemonitoring devices that will be installed at the patients' home;

- weighing scale; patients will be instructed to weigh daily.
- blood pressure meter; patients will be instructed to measure their blood pressure daily during up titration of medication.
- ECG; patients have to perform an ECG twice a week during up titration of beta-blockers.
- Health monitor; an interactive monitor collects data from the weighing scale, blood pressure meter and ECG device and will respond to the patients' collected data. Data will be directly transmitted to the DM system in the hospital.

In case of a deviation of individualised predefined ranges of weight, blood pressure or heart rhythm, the health monitor will automatically generate supplementary questions directly to the patient to evaluate the actual health situation. This data, measurements and subjective patient information (predefined multiple choice questions about HF symptoms) will be transferred to the computerised DM in the hospital. Furthermore, the health monitor will generate an advice about the non-pharmacological treatment, for example regarding compliance with fluid and sodium restriction. When the data collected by the system deviates from predefined ranges, the HF nurse will be informed automatically by mobile phone and email. In that case, the HF nurse will contact the patient by phone within two hours and further discusses symptoms and treatment. If data are outside any reference range in combination with symptoms of deterioration, patients will receive a message from the health monitor that they will be contacted by the HF nurse.

Sample size calculation

Group sample sizes of 130 patients for the group treated with telemonitoring and ICT guided DM and 90 patients treated with ICT guided DM achieve 80% power to detect superiority for telemonitoring using a one-sided, two-sample t-test. The margin of equivalence is 0.0. The true difference between the means is assumed to be 0.8. The significance level (alpha) of the test is 0.025. The data are drawn from populations with standard deviations of - 2.0 and + 2.0. These figures are based on a publication [37] in which the effect of the combination of isosorbidedinitrate and hydralazin was investigated in patient with HF. In this study a difference of 0.4 was demonstrated regarding the composite endpoint. Using telemonitoring, we expect to find a larger difference especially in the QoL domain. It has to be addressed that no information is currently available regarding the sensitivity of the composite endpoint in a setting of new onset or worsening HF patients.

Statistical analyses

The primary analysis will consist of a comparison of the composite endpoint scores (Table 2) between ICT guided DM in combination with telemonitoring, compared to ICT guided DM without telemonitoring. The test will be performed using a two-sample t-test, and two-sided 95% confidence intervals will be constructed to describe the treatment differences. An analysis of covariance will be used to test for the treatment effect controlling for different baseline characteristics. The results will be analysed using an intention-to-treat analysis including the full set of all randomised patients (primary efficacy population). The primary efficacy population will be analysed at endpoint for composite score. Secondary endpoints involving e.g. individual evaluation of deaths, hospitalisations, and QOL after 9 months will be analysed over the entire course of the study using appropriate methods. Two types of economic analyses will be performed: these include a cost-consequence analysis (CCA) for a disaggregated examination of resource costs and health outcomes associated with the alternative intervention; and cost-effectiveness analysis (CEA) in which the alternative intervention is examined in light of total cost per unit of health outcome. Thus CCA will be performed using the primary outcome of the study as the measure of effectiveness. For this, the annual cost per patient treated to postpone or prevent one patient experiencing a cardiovascular death or hospital admission for worsening HF within the trial will be calculated.[38] For CEA, the incremental cost-effectiveness ratios (ICERs), in terms of cost per life year gained (LYG), will be estimated given that there was a significant increase in survival with DM and telemonitoring. CEA will not be performed in case no reduction will be observed in cardiovascular or all cause mortality. In case of missing data for the composite end point score, the worst-case scenario will be assumed for the primary analyses. Patients lost to follow-up will be assumed to have died (-3) and those without a quality of life measurement will be assigned the worst score (-2).

Study organisation

To include 220 patients in this study, 10 hospitals in the Netherlands are participating in the IN TOUCH study. The first patients are recruited in December 2009; the end of the study is expected to be in September 2012.

Support and monitoring

The study is supported and monitored by the Trial Coordination Centre (TCC), a contract research organisation for clinical trials. Both the quality of the research data and of the intervention will be structurally monitored according to the GCP guidelines and TCC standards (ISO 9000:2001)

Discussion

In the last decades, the introduction of ICT in healthcare promised an improved quality of care while reducing work load, and resulting in a more cost effective system. This might be realised by the use of computer guided decision support systems and telemonitoring.[20,31,32,39,40] The IN TOUCH study is the first to investigate the effect of an ICT guided DM system in combination with telemonitoring in patients with HF. In recent years there has been much research in the field of HF and DM. This has resulted in the implementation of DM programmes in the ESC guidelines.[1] The development of these guidelines has enabled the creation of computer aided decision support programms.[39] In the recent guidelines the application of ICT by DM programs is recommended. Although there has been progression in the development of ICT guided tools and these tools have become practical equipment for enhanced decision making, healthcare providers still experience great barriers in using and implementing them for several, often unclear reasons.[33,34]

Mortality and morbidity are important outcomes in studies in HF patients. Quality of life becomes a more important issue for patients and may be even more important for them than survival or readmissions. Therefore, a composite primary endpoint, including quality of life, mortality and morbidity was chosen for the IN TOUCH study. Another reason for this composite endpoint is that for HF a high standard of care has been established which makes it more difficult to investigate the added effect of new therapeutic options. Beside the statistical advantage of a composite endpoint, the study becomes less costly and results of promising new treatment may occur earlier with this selected design. The strength of this study is the important role of ICT guided DM, telemonitoring, the composite endpoint, including quality of life, a strong focus on cost effectiveness and the emphasis on experienced user resistance and barriers regarding ICT tools in healthcare.

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Chapter 4

The value of telemonitoring and ICT-guided disease management in heart failure: results from the INTOUCH study

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Submitted

Abstract

Aim

It is ambiguous whether telemonitoring reduces hospitalizations and mortality in heart failure (HF) patients and it is unclear whether telemonitoring as an integrated approach with an ICT-guided-disease-management-system (DMS) improves clinical and patient-reported-outcomes or reduces health-care cost.

Methods

The value of Innovative ICT-guided-disease-management combined with Telemonitoring in OUtpatient clinics for Chronic HF patients (IN TOUCH-study) was a multicenter randomized controlled trial; 179 patients were included after worsening HF and in need of extra diuretics. Patients were randomized to ICT-guided-DMS or to ICT-guided-DMS+telemonitoring with a follow-up of nine months. The composite endpoint consists of mortality, HF-readmission and change in health-related quality of life (HR-QoL).

Results

The mean age was 69 years; 72% male; 77% in NYHA III-IV; mean LVEF was 27%. There was a none significant difference in the mean score of the primary composite endpoint which was -0.63 in ICT-guided-DMS versus -0.73 in ICT-guided-DMS+telemonitoring; mean difference 0.1, 95% CI: -0.63 –0.85, p=0.31. All-cause mortality in ICT-guided-DMS was 12% versus 15% in ICT-guided-DMS+telemonitoring (p=0.53). HF-readmission 27% vs 29% p=0.80) and all cause readmission (48% vs 51% p=0.68) was not significant different between respectively the ICT-guided-DMS and ICT-guided-DMS+telemonitoring group. HR-QoL improved in most patients and was equal in both groups. Incremental costs were 1360 euro in favor of ICT-guided-DMS. ICT-guided-DMS+telemonitoring had significantly fewer HF-outpatient-clinic visits (p<0.01).

Conclusion

ICT-guided-DMS with telemonitoring for the management of HF patients did not affect the primary and secondary endpoints. However, we did find a reduction in visits to the HF-outpatient clinic in the ICT-guided-DMS with telemonitoring group. This reflects that telemonitoring is safe to use and can be used in reorganizing HF-care with relatively low costs.

Introduction

Improvements in medical care and an increase in the presence of lifestyle related-risk factors in the general population have resulted in a substantial increase in the prevalence of heart failure (HF).[1] In the Netherlands, the prevalence of HF is predicted to increase to 50% in men and 20% in women between 2007 and 2025.[2] In the elderly, HF is the most frequent cause for all hospital admissions.[3] The costs for patients with HF is also increasing and was 375 million Euro in 2003, of which more than 50% related to costs for hospital admissions. Because of an impending shortage of resources, growing costs due to ageing, more expensive treatments and downwards pressure on healthcare budgets, a thorough review of the care for patients with HF is necessary, stressing the importance of patient-centered care.

Heart failure clinics and disease management

A first step in organizing treatment and care efficiently for patients with chronic HF, started in the 1990ties by implementing specialized HF outpatient clinics, with a strong collaboration between HF nurses and cardiologists[4,5] In these HF outpatient clinics, disease management was introduced, which is a multidisciplinary intervention designed to improve quality and cost effectiveness of care, using a systematic approach and employing multiple treatment modalities.[6,7] Over the last decade, these HF outpatient clinics became 'care as usual' in several European countries.[8] Two randomized studies investigated the effect on quality of care and clinical outcomes in HF clinics in the Netherlands, the Coordinating Study Evaluating Outcomes of Advising and Counseling in HF[9] (COACH) and the Deventer-Alkmaar HF Project[10] (DEAL-HF). Although these two studies have contributed to the quality the of disease management in HF outpatient clinics led by specialized HF nurses, the key characteristics of patients who benefits most from a disease management program remain unclear.[11]

Disease Management System

A Disease Management System (DMS) can be described as a comprehensive coordinated system of preventive, diagnostic, and therapeutic measures intended to provide cost-effective and high quality healthcare for patients who have or are at risk for a specific chronic illness or medical condition.[12,13] A DMS includes the following characteristics: designed for a well-defined patient population; aimed at multidisciplinary collaboration; includes patient education, self-management and prevention modules; uses recognized protocols and guidelines; divides patients in treatment regimes; and is driven by information and communication technology (ICT).[13-15] One of the components of a DMS could be a computer decision support system (CDSS), can facilitate healthcare professionals into optimizing treatment and care for HF patients. Based on predefined patient profiles, treatment options and current patient medical data, the CDSS generate a treatment plan specifically for that particular patient.

Telemonitoring

Pivotal in organizing treatment and care is the monitoring of patients with HF by means of regular outpatient clinic visits or assessments through telephone (tele-homecare) or with telemonitoring. There are many definitions used for telemonitoring but the core principle does not generally differ. A commonly used international definition is 'the remote monitoring of patients, including the use of audio, video, and other telecommunications and electronic information processing technologies to monitor a patient status at a distance.'[16]

In the Netherlands the most used definition is that telemonitoring includes the measurement, monitoring, collecting and transfer of clinical data, concerning the health status of a patient in his or her home environment, due to the use of information and communication technology. Cardiologists and HF nurses in the Netherlands have high expectations of telemonitoring at home and it is expected to improve quality of care, to reduce costs and to improve patients' health-related quality of life through feelings of control and empowerment of the patient.[17] Some studies have shown that remote monitoring of HF patients reduced hospitalization and mortality rates[18-20] however, other studies have not confirmed these findings.[21,22] It is still not clear whether telemonitoring, when delivered as an integrated approach added to an ICT-guided DMS improves clinical and patient reported outcomes or reduces healthcare costs.

The aim of this study is to assess the effect of telemonitoring on top of an ICT-guided DMS in patients after worsening HF on the combined endpoint of death, readmission and quality of life, compared to patients treated with ICT-guided DMS alone.

Methods

IN TOUCH Study

Experiences with disease management systems and telemonitoring are fragmented and solid evidence on the effects are still lacking. In the Netherlands, at the Martini Hospital Groningen, an ICT-guided DMS system gave promising results[23] ,and the outcome of this experience was the rationale for the IN TOUCH study (The value of INnovative ICT guided Disease Management combined with Telemonitoring in OUt patient clinics for Chronic Heart failure patients). This rationale and design have been described and published elsewhere.[24] The IN TOUCH is a multicenter, randomized study designed to investigate the effects and costs of ICT-guided DMS, versus ICT-guided DMS combined with telemonitoring in HF patients on a combined endpoint of mortality, HF readmission and change in health-related quality of life.

Recruitment and procedure

Patients were recruited during a period of 25 months (December 2009 to January 2012) and followed for a fixed period of 9 months. All patients provided written informed consent. Our investigators adhered to the principles outlined in the Declaration of Helsinki. The medical ethics committee approved the protocol and the study was registered in the Dutch trial register (NTR) with the trial ID: NTR1898. Adjustment of the study protocol was performed December 2010 because of the impossibility of recruiting control sites with HF patients. Using telemonitoring for regular care was an exclusion criterion to participate as a control hospital in this study. However, hospitals, pre-recruited as control hospitals were, in the end, not willing to participate in the study with the agreement of not using telemonitoring for their regular HF care during the study period of 2009-2012. For that reason, redesigning the study to a randomized intervention study without a control group was necessary. Another reason for adjustment of the protocol was the low inclusion rate of patients with a (re) admission for HF. In an attempt to improve the inclusion, it was decided to also include patients with deterioration for HF, treated with extra diuretics, visiting the outpatient HF clinic. Adjustment of the protocol was reported and approved by the medical ethics committee and had no consequences for the feasibility of the ongoing study (ABR:NL26271.042.08). The trial was prematurely discontinued after an extended inclusion period of 6 and respectively 3 month due to a poor accrual inclusion rate.

Patient population

All patients were included if they had worsening of HF based on typical signs and symptoms of fluid retention. Patients were either admitted to the intensive care/ coronary care unit or cardiology ward or were visiting the outpatient HF clinic and needed treatment or adjustment with oral or intravenous diuretics. Patients were 18 years of age or older and all had evidence of structural underlying heart disease and documented reduced left ventricular ejection fraction (LVEF) ≤ 45%. Exclusion criteria were a myocardial infarction in the last month, cardiac invasive intervention (percutaneous coronary intervention, coronary arterial bypass, valve replacement, heart transplantation, or cardiac resynchronization therapy) in the past 6 months or planned in the next 3 months, actual hemodialysis, the use of other telemonitoring systems (implanted devices and/or external use) and the inability or unwillingness to give informed consent.

Randomization

All patients were randomized to either receiving care supported by an ICT-guided DMS or receiving care supported by an ICT-guided DMS system with telemonitoring devices at home. Randomization was performed as soon as possible but at least within 2 weeks

after discharge or after the initial visit at the HF outpatient clinic with worsening of HF. The computer-generated randomization scheme used random permuted blocks of 2:1 (original protocol) and 1:1 (adjusted protocol December 2010) stratified by center to ensure balanced assignment of patients to each group in the ten participating centers.

Intervention strategy

Patients in both groups received tailored education and counseling on the HF symptom management regimen and improvement of the nonpharmacological regimen based on protocols and recent HF guidelines[25] For the pharmacological treatment in both groups computer decision support (CDSS) functionality by means of a ICT-guided DMS system was incorporated. Based on the input of data from nursing assessment, physical examination, medical history, laboratory and questionnaires, the system provided advice to healthcare providers according to the actual ESC HF guidelines, including up titration of HF medication to optimal individual doses. Furthermore the CDSS gave advise in treatment options, for example how to react on incoming alerts of deviating values from patients at home by telemonitoring (e.g., increase of diuretics). The intervention group was provided with the same ICT-guided DMS system but also received telemonitoring devices at home. The telemonitoring devices used were a weighing scale, blood pressure equipment, an ECG device and a health monitor. The health monitor was an interactive monitor that generated data from the abovementioned devices and health related questions about the health status of the patient data, which were directly transmitted through the GPRS network to the DMS system located in the hospital. In case of deviation of predefined individual ranges of weight, blood pressure or heart rhythm, the health monitor at home generated supplementary questions to the patient to evaluate the actual health situation. At the same time, the HF nurse was informed automatically by mobile phone and email about any deviation of the health of the patient, according to the study protocol. The HF nurse contacted the patient within two hours and discussed the symptoms and treatment with the patient. Patients allocated to the group with ICT-guided DMS and telemonitoring were only allowed to visit the cardiologist or HF nurse in the case of an absolute need for intervention. The patients in just the ICT-guided DSM intervention followed the normal HF routine of the individual hospitals, like any other HF patient, without limitations on the visits.

Follow-up and data collection

Patients were followed for a 9-month period in which data on hospitalizations and mortality were collected from the medical records. The change in quality of life between baseline and the end of the study was assessed by the Minnesota Living with HF Questionnaire (MLHFQ). The reason of hospital readmission or death and the date of the event were adjudicated by an independent endpoint committee blinded for the

Table 1: score system for primary composite endpoint

End point	Score
Death (at any time during study)	-3
Survival to end of study	0
First readmission for heart failure	-1
No readmission for heart failure	0
Change in quality of life at 9 months	
Improvement ≥ 20 units	+2
Improvement by 10 until 19 units	+1
No improvement by -9 until +4 units	0
Worsening by +5 until +9 units	-1
Worsening by ≥ 10 units	-2
Possible score	-6 to +2

group assignment. For the cost analyses, a distinction was made between intervention costs and resource utilization costs. Data on resource use for both interventions were also collected from medical records and questionnaires on a patient level. The cost of the intervention were defined as the costs of the ICT-guided DMS, the costs of the telemonitoring devices and handling of the alarms (personnel) were calculated as a fixed price over the follow-up period of the study. Resource utilization costs were calculated by collecting data on scheduled and non-scheduled outpatient clinic visits and hospital admissions (HF and non-HF-related). In addition, a patient MTA-questionnaire adapted from the iMTA/TiC-P[26] was administered at 4.5 months and 9 months of follow-up to collect complementary data (e.g., GP, dietician, physiotherapist visits, home care, and nursing home [day care, and admissions]). Unit costs were estimated by using the Dutch guidelines for cost studies[27] and inflated to the price level of 2012 using a general consumer price index (http://www.CBS.nl). The time horizon of the cost analysis was 9 months. Indirect costs, such as productivity losses, were not calculated.

Endpoints

The primary endpoint was a composite weighted score consisting of a value for mortality, HF readmission and change in quality of life between baseline and end-of-study measured with the MLHFQ with a possible range of –6 to +2. An HF readmission was defined as an unplanned overnight hospital stay due to progression of HF or directly related to HF. The scoring system of the primary composite endpoint was adapted from the A-HeFT study[28] (Table 1). In case of missing data for the primary composite endpoint, the worst-

case scenario was used for the analyses. Patients lost at follow-up were assumed to have died (-3), and patients without a quality of life score have been assigned the worst score for that component (-2). Secondary endpoints of the study were the separate components of the primary endpoint (mortality, readmission for HF and change in quality of life). Other major secondary endpoints were the total number and duration of all hospital admissions, number of visits to the outpatient HF clinic and cost analyses.

Sample size

We expected with 80% power to detect superiority for telemonitoring using a one-sided, two-sample t-test, when 130 patients were included in the intervention group with telemonitoring and 90 patients in the ICT-guided DMS group. The true difference between the two groups was assumed to be 0.8 regarding the primary composite endpoint score. The largest difference between the two groups was expected to be observed in the quality of life domain.

Statistical Analysis

All analyses were conducted according to the intention-to-treat principle. Descriptive statistics were used to characterize the study population. Students't-test and Wilcoxon Rank Sum tests for continuous variables and Chi square tests for categorical variables were performed to compare the demographic and clinical characteristics between the two groups. To compare the primary composite endpoint score between the group with ICT-guided DMS with telemonitoring and the group with ICT-guided DMS without telemonitoring a two-sample t-test was performed, and two-sided 95% confidence intervals were constructed to describe the treatment differences. Kaplan Meier curves were constructed for the differences in time to mortality between the two groups. Differences in the number of hospital readmissions were analyzed by a two samples t-test and visits to the outpatient clinics and the differences in length of hospital re-admissions between the two groups where calculated using the Wilcoxon Rank Sum test. Costs per category were calculated by multiplying resource use with the cost per item. Means per group and incremental costs were calculated based on the trial data. Bootstrap simulations (5000 replications of the trial data) were performed to estimate the confidence intervals surrounding the incremental costs (2.5th and 97.5th percentile). All analyses were performed using PASW version 18.0, Excel version 2003 and R version 2.15.1.

Results

During the inclusion period of 25 months in total 179 patients from 10 Dutch hospitals were randomized in the study. Two patients did not fulfill the inclusion criterion of worsening HF and were therefore not part of the analyzed population. In total, 177 HF

patients were analyzed, of which 80 patients were randomized into the ICT-guided DMS intervention and 97 patients to the ICT-guided DMS with telemonitoring intervention. The distribution of included patients between both intervention groups is not equal, due to the forced adjustment of the study protocol (as described under methods) and therefore a change in randomization blocks of patients from 2:1 to 1:1.

Baseline characteristics

Overall the mean age was 69 (± 12) years of age, 72% were male and the mean Left Ventricular Ejection Fraction was 27% (± 9). At the time of admission, most patients were classified in New York Heart Association (NYHA) class III-IV (77%) of which 23% were in NYHA II. Twenty-four (13%) patients were included during their visit to the outpatient HF clinic, the others were included after a admission for HF. Of all 177 analyzed patients, 30% were newly diagnosed with HF (<6 months of date of HF diagnosis). The other patients were diagnosed with HF for an average period of, on average 4.6 years, (ICT-guided DMS) and 5.4 (ICT-DMS+ telemonitoring) years (p=0.35) respectively. Other baseline characteristics of both groups were comparable (Table 2). There were no significant differences between the two groups in the use of HF medication. Total percentages of HF medication prescribed in the group of ICT-guided DMS was: ACE-inhibitor 59%, Beta-blocker 69% and Aldosteron antagonist 58%. For ICT-guided DMS with telemonitoring this was: ACE-inhibitor 60%, Beta-blocker 64%, and Aldosteron antagonist 59%.

Adherence to the intervention

Patients with telemonitoring were instructed to record their weight and blood pressure once a day and an ECG in the case of starting or uptitration of Beta-blockers. Adherence of the patients with telemonitoring (assessed by daily weighing and measuring of blood pressure) was 95% with a range from 87%-99% for the total study period of 9 months.

Outcomes - Primary endpoint

The mean composite endpoint score in the ICT-guided DMS group of –0.63 was not significant different from the endpoint score of -0.73 for the telemonitoring group; mean difference 0.1, 95% CI: -0.63 –0.85, p=0.31 (Table 3). In total 8% of the patients had the worst possible score of –6; 7% of the patients in the ICT-guided DMS group and 9% in the ICT-DMS group with telemonitoring. In total 27% of the patients had the best possible score of +2 of which 23% were in the ICT-guided DMS group and 28 patients (30%) in the ICT-DMS group with telemonitoring, with no statistical differences between the groups.

Table 2: Baseline characteristics of the patients according to the assigned treatment (n=177)

	ICT-guided DSM (n = 80)	ICT-guided DSM plus TM (n = 97)	p-value
Demographics Mean ± sd			
Age (yrs)	69 ± 11	69 ± 12	0.92
Male sex no. (%)	62 (75)	66 (70)	0.47
LVEF %	28 ± 9	27 ± 10	0.65
Duration of diagnosis HF, years	4.6 (5.6)	5.4 (6.5)	0.35
New diagnosis of HF no. (%)	25 (31)	29 (30)	0.64
Etiology			
Ischemic no. (%)	33 (40)	39 (43)	0.96
History of myocardial infarction no. (%)	25 (32)	35 (35)	0.72
Co-morbidities no (%)			
Hypertension no. (%)	29 (35)	26 (28)	0.30
COPD no. (%)	17 (21)	21 (22)	0.67
Atrial fibrillation no. (%)	32 (40)	47 (48)	0.26
Diabetes no (%)			
IDDM	16 (19)	13 (13)	0.89
NIDDM	13 (16)	19 (20)	0.87
Stroke	6 (8)	12 (12)	0.29
Oncology	12 (15)	12 (13)	0.61
Clinical variables			
NYHA (%)			0.90
II	18 (23)	21 (22)	
III	49 (60)	51 (54)	
IV	18 (18)	18 (19)	
Heart rate	84 ± 20	81 ± 19	0.69
Weight (kg)	84 ± 18	81 ± 17	0.26
LBTB no. (%)	16 (19)	31 (33)	0.15
SBP (mmHg)	123 ± 20	117 ± 20	0.09
DBP (mmHg)	74 ± 13	71 ± 11	0.07
Cardiovascular interventions no. (%)			
CABG no. (%)	15 (19)	22 (23)	0.52
PCI no. (%)	13 (16)	18 (19)	0.69
ICD no. (%)	10 (11)	16 (18)	0.24

	ICT-guided DSM (n = 80)	ICT-guided DSM plus TM (n = 97)	p-value
Laboratory			
Hemoglobin, mmol/L	8.4 ± 0.98	8.2 ± 1.16	0.26
Sodium, mmol/L	141 ± 2.95	141 ± 4.2	0.99
Creatinine, µmol/L	138 ± 67.6	140 ± 77.7	0.83
Nt-pro BNP, ng/l (range)	5380 (483-24799)	3646 (591-23800)	0.27
Mean eGFR – ml/min/1.732	66.3 ± 26.6	65.3 ± 29.8	0.90
Medication (total % of use)			
Diuretica	88	87	0.51
ACE-inhibitor	59	60	0.73
Angiotensin renine blocker	27	24	0.15
Beta blocker	69	64	0.75
Aldosteron antagonist	58	59	0.41

Note: DMS = disease management system; TM = telemonitoring; yrs = years; LVEF = left ventricular ejection fraction; HF = heart failure; IDDM = insulin dependent diabetes mellitus; NIDDM = non-insulin dependent diabetes mellitus; NYHA = New York Heart Association; LBTB = Left Bundle Branch Block; SBP = systolic blood pressure; DBP = diastolic blood pressure; CABG = Coronary Artery Bypass Graft; PCI = Percutaneous Coronary Intervention; ICD = internal cardiac defibrillator; NT-pro-BNP = N-terminal prohormone of brain natriuretic peptide; eGFR = estimated globular filtration rate: ACE-inhibitor = Angiotensine Converting Enzyme inhibitor

Outcomes - Secondary endpoints

Mortality

All cause mortality in the ICT-guided DMS group was 12% (n=10) and in the ICT-guided DMS group with telemonitoring 15% (n=14), p=0.53 (Table 3). The analyses of time to death showed a hazard ratio (HR) of 1.28 (95% CI 0.55-2.96, p=0.56). During the 9 months of follow-up, the total number of days lost to death was 156 days with a range of 114 to 206 for the ICT-guided DMS group and 128 days (84-217) for the ICT-guided DMS group with telemonitoring (p=0.52). Kaplan Meier Survival analysis did not show a statistically significant difference between the two interventions (log rank $\chi 2$=0.025, p=0.88).

Readmission for HF

Of all patients, 28% were readmitted for HF at least once during the 9 month follow-up period: 29% (n=24) in the ICT DMS group versus 28% (n=26) in the ICT DMS group with telemonitoring group (p=0.80). (Table 3). The mean number of readmission days for HF was 3.7 (±8.3) in the ICT DMS group versus 4.2 (±9.8) (p=0.80) in the ICT DMS group with telemonitoring.

Table 3: Primary and secondary outcomes: composite endpoint score and the separate components of the composite endpoint

	ICT-guided DSM (n = 80)	ICT-guided DSM plus TM (n = 97)	Difference 95% CI	p-value
Primary endpoint				
Composite endpoint score, mean	-0.63	-0. 73 ±	0.10 (-0.63-0.85)	0.31
Secondary endpoints				
Mortality % (n)	12 (10)	15 (14)	-4 (-14 – 6)	0.53
Re-admission HF % (n)	29 (24)	28 (26)	-2 (-12 - 15)	0.80
Change in quality of life, mean	-14.63	-13.97	-0.66 (-8.68-7.36)	0.87

All cause readmission

In total 48% percent (n=40) of the patients included in the ICT-guided DMS group were admitted to hospital at least once for all-cause reasons with a median of 6.5, IQR 25-75% 4, 6, 21. For the patients using telemonitoring this was 51% (n=48) with a median of 10.5 days, IQR 25-75% 3, 10, 19 (Table 4).

Health-related quality of life

The MLHFQ was similar in the two groups at baseline (49 ± 22 versus 48 ± 21, p=0.20). At 9 months the mean change in score on quality of life was -14.6 units in the ICT DMS group versus -14.0 units in the telemonitoring group; mean difference -0.6, 95% CI: -8.7 -7.4, p=0.87 (Table 3). Most patients had improved quality of life during the 9 month follow-up: in total, 39% (n=51) of patients improved with ≥ 20 units of which 34% was in the ICT-guided DMS group and 44% was in the telemonitoring group. In total 16% (n=21) patients improved between 10 and 19 units. (23% in the ICT DMS group vs 10% in the telemonitoring group). In total 46% did not improve and even had a worse quality of life at the end of the study. In total 24% (n=31) patients had no improvement (-9 to +4) (21% in the ICT DMS group vs 26% in the telemonitoring group) and 17% (n=22) of the patients (18% in the ICT DMS group vs 16% in the telemonitoring group) had worsening quality of life (≥ +5 units). Regarding the physical and emotional sub scores of the MLHFQ, no significant differences were seen between both groups.

Outpatient clinic visits

Patients in the ICT-guided DMS group were supposed to have regular contact with the outpatient HF clinic during the 9 months, in line with the normal follow-up of HF patients in each of the participating hospitals according to the HF ESC guidelines.[29] Patients in the telemonitoring group were not scheduled for regular follow-up during these 9 months, except for worsening of HF that could not be managed at home. The median number

Table 4: Number of patients with hospitalizations, number of hospitalizations and number of outpatient visits

	ICT-guided DSM (n = 80)	ICT-guided DSM plus TM (n = 97)	p-value
Number of patients with hospitalizations % (no.)			
All-cause hospitalization	48 (40)	51 (48)	0.68
Cardiovascular-related hospitalizations	18 (15)	17 (16)	0.86
Heart failure-related hospitalizations	29 (24)	28 (26)	0.80
Number of hospitalizations			
All cause	79	98	
Cardiovascular-related	24	18	
Heart failure-related	37	39	
Number of days readmitted, median			
All- cause	6.5	10.5	0.95
IQR 25-50-75%	4-6-21	3-10-19	
Heart failure-related	8	11.5	0.80
IQR 25-50-75%	5-8-21	5-11-28	
Number of visits to outpatient clinics, median			
All- cause	7	6.5	0.47
IQR 25-50-75%	4-7-12	4-6-9	
Heart failure-related	9	7	0.01
IQR 25-50-75%	5-9-13	5-7-9	

of contacts times with the HF outpatient clinic was 5 for the ICT-guided DMS group versus 2 times for the telemonitoring group (p< 0.01) (Table 4). To any outpatient clinic a median of 6 versus 5 visits was observed (p=0.47) (Table 4).

Cost analysis

Results showed a mean total costs of € 5006 per patient for the ICT-guided DMS group and € 6366 per patient for the telemonitoring group (Table 4). Incremental costs were € 1360 in favor of patients in the ICT-guided DMS group. In this scenario the costs for outpatient visits were €530 for telemonitoring vs. € 603 for the ICT-guided DMS. Hospital admissions were € 3213 for DMS and € 2427 for telemonitoring. In both groups, the highest proportion of costs consisted of costs for admissions to a hospital ward. Costs incurred outside the hospital (GP, dietician, physiotherapist visits, home care and nursing home [day care, and admissions]) amounted to €1152 in the ICT-guided DSM strategy and €1642 in the telemonitoring strategy. The major cost driver in this category was nursing home admissions. The handling of the incoming telemonitoring data (alerts, viewing the ICT-guided DMS, making telephone calls to patients, reporting the action/ intervention and performing follow-up) was estimated at 12 hours for each patient for the total study period, which was calculated to be €364 based on nurses salary. The cost data

Table 5: Bootstrap simulations (5000 replications of the trial data) to estimate the confidence intervals surrounding the incremental costs (2.5th and 97.5th percentile)of the interventions (*software.**software, telemonitoring devices and the handling of incoming data)

	ICT-DMS	ICT-DMS with telemonitoring	Difference	CI 95%
Intervention costs	€37*	€1766**	€1729	constant
Re-admission costs	€3213	€2427	€786	- 2875 +1525
Out-of-hospital care costs	€1152	€1642	€490	-1297 +2880
Outpatient clinic costs	€603	€530	€73	- 261 +110
Total	€5006	€6366	€1360	- 2263 +5221

for hospital admissions were highly skewed due to one patient with an extreme admission duration (126 days of rehabilitation) Therefore, were performed this analyse whereby for this patient the mean of admission duration was replaced with the group mean value.

Post-hoc analysis

In order to examine if patients with lower HF related readmission rates we performed a post-hoc analyses on a group of patients with none or only one readmission for HF (n=161). For the ICT-guided DMS group all cause mortality was 10% (n=8) vs. 13% (n=11) for the telemonitoring group (p=0.60). Readmission for HF was 23% (n=18) vs. 19% (n=16) p=0.50, respectively. The score of change in quality of life in the ICT-guided DMS group was -14.5 vs. 15.1 (p=089).

Discussion

In this study on the effects of ICT-guided DMS compared to ICT-guided DMS with telemonitoring, no additional effect of ICT-guided DMS with telemonitoring were found compared to ICT-guided DMS on the composite endpoint score; all cause mortality, readmission for heart failure and QoL. We expected to find a difference of 0.8, however we found a difference of only 0.1. One of the explanations for the absence of an effect could be that patients in this population (both groups) were relatively "healthy" compared to other HF studies,[30] making a significant or clinical difference for further improvement in outcome rather difficult. Furthermore, only 16 patients had more than 1 readmission for HF (9%), and a relative large group of included patients (30%) was newly diagnosed with HF and therefore did not have a history of frequent re-admissions, Frequent readmissions are known as unfavorable for outcome. The mortality rate was rather low (12%) and almost all patients (96%) received scheduled visits to the HF clinic, indicating that there was no need for acute care because of worsening of HF. Furthermore, although in both groups the QoL increased equally, no differences in the changed score between

baseline and 9 months was seen between the two groups. Moreover, it might be possible that the effect of the intervention was not large enough to be able to discriminate since the differences in treatment modalities was moderate; daily measurements of weight, blood pressure and an EKG in case of titration of Betablocker.

To find an effect for telemonitoring on mortality, readmissions and, quality of life probably requires a more defined and coherent group of patients that could benefit from this new intervention.[31] It seems reasonable to assume that other variables, such as age, socioeconomic demographics like living alone or the severity of the disease in terms of frequent readmissions before starting with telemonitoring might affect the benefit of telemonitoring, perhaps more than we initially calculated and defined in the study protocol.[32] However, previous studies do not show specific profiles of patients are known who could benefit more from telemonitoring, with the exception for patients with depressive symptoms.[31] In post hoc analyses, we could not find specific patient characteristics that played a role in their benefiting from telemonitoring. To find out if patients with more than one readmission influenced the outcome on the primary endpoint negatively, we performed analyses on the group of patients with none or only one re-admission for HF. This analysis did not provide new insight. Recently Richard Wootton, editor of the Journal of Telemedicine and Telecare, propose to focus future telemonitoring studies on patients' characteristics and comparable endpoints, like long term follow-up, quality of life, costs to society, emergency department visits, and days in hospital.[33]

It was set out in the study protocol that for starting and titration of HF medication during the follow-up period in both groups the CDSS functionality in the ICT-guided DMS had to be used. The adherence of using ICT-guided DMS was experienced as difficult, especially regarding the use of the CDSS functionality for up-titrating HF medication, which might be reflected by the relatively low percentage of prescribed ACE-inhibitor use at the end of the follow-up period. Although the percentage of Beta-blockers and Aldosteron antagonists are conform the observed percentages in the EURO Heart survey II study,[34] the percentage of ACE-inhibitors at the end of the study (59% vs. 68%) is much lower than the observed 80%. The main reason for the lack of use of the CDSS was that the usability and acceptability were considered poor, primarily due to organization- and system-related barriers, which are known as major obstacles in applying CDSS in healthcare.[35,36] A known personal-related barrier to use a CDSS is a lack of trust, this was also observed in some participating hospitals where HF nurses were not allowed to titrate medication themselves due to the hesitations of the cardiologists. Finally, the lack of use was also attributed to the fact that the CDSS was not integrated into the existing electronic patient record and therefore caused additional work.

Despite the fact that we could not find a difference in outcome in favor of the telemonitoring group, we did find that telemonitoring and ICT-guided DMS seem

safe to use for HF patients. The number of HF-related visits to the outpatient clinic was substantially lower (partly protocol-driven) compared to patients who did not use telemonitoring, but the outcome in terms of readmission and mortality was similar in both groups. Importantly in this context is the overall patient adherence of using telemonitoring at home which was very high (the telemonitoring devices were used in 95% of cases, according to the protocol). Compared to other studies[21,22] in which patient adherence of using telemonitoring was overall not higher than 30-40%, this clearly indicates that the devices used for this study, in combination with the protocol of daily measurements, were well accepted by patients and therefore suitable to implement regular care.

Practical implications

Taking into consideration the advances and possibilities of telemonitoring and the limited additional costs, an intervention with telemonitoring might be an option for caregivers. This could be in situations where patients do not have direct or difficult access to a HF outpatient clinic (e.g., primary care, long distance to travel, the inability of a patient to visit the HF outpatient clinic) or in case of preventing regular visits to the outpatients clinic just for uptitration of medication or assessment of physical condition. From this same perspective, given the comparability of both interventions in terms of an effect on outcome, a change in standard HF practice, could therefore be based on costs, availability of human recourses, usability and trust of patients and healthcare providers instead of focusing 'only' on reduction of mortality and/or re-admission. Telemonitoring could be a significant tool for re-organizing HF care to be more efficient, a necessity due to the understaffed care of a growing and aging population.

Limitations

Despite an extended inclusion period of 9 months in combination with an adjustment of the study protocol to include patients with a deterioration of HF from the outpatient HF clinic, we were not able to include the number of patients needed as calculated. This could have influenced the outcome in terms of a lack of sample strength. However, the calculated p-values did not show a trend or 'near' significance. In addition there were no numerical differences between both groups indicating that a larger population would not make a difference. Additionally we calculated based on the figures of inclusion and results how many patients would be needed to probably cause an effect (HH). In the design of the study, a cost effectiveness analysis (CEA) and or cost consequence analysis (CCA) was planned. However, since no difference in primary and secondary clinical endpoints was found, the planned analyses were not performed. To account for this, we performed a cost minimization analysis. Finally, we have no information on how many patients were eligible for this study because this was not part of the protocol.

Conclusions

ICT-guided disease management in combination with telemonitoring, used in the follow-up of HF patients, did not affect the primary (composite) endpoint of mortality, HF readmission and quality of life, nor the separated individual outcomes of this composite endpoint. However, we demonstrated that telemonitoring is safe and can reduce visits to the HF outpatient clinic, keeping HF care accessible. Costs however were still Euro 1360,- higher with TM. The adherence of patients in using telemonitoring was very high, indicating that the devices used for this study, in combination with daily measurements, were well accepted by patients and therefore acceptable when implementing regular care.

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Chapter 5

Usability and experiences of a heart failure related computer decision support system

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Submitted

Abstract

Background

Computer decision support systems (CDSS) can contribute to more effective implementation of recommended guidelines and prescription of optimal dosage of heart failure medication. However, a widely spread implementation of CDSS in heart failure (HF) is lacking. The IN TOUCH study, a study on the effect of ICT-guided disease management in HF, incorporated a CDSS to improve guideline adherence of HF medication. During that study, minimal use of the offered CDSS was observed. The objective of our study was to explore the usability and acceptability of the implemented HF CDSS and to gain insight into barriers experienced by HF nurses in using a CDSS to start or up-titrate HF medication.

Methods

A descriptive design was used with both quantitative (SUS questionnaire) and qualitative (interviews) data collection. The system usability scale (SUS) was developed and regularly used to measure the percieved ease-of-use of a CDSS.

Results

In total, 9 HF clinics participated in this study. 27 SUS questionnaires from 27 respondents were received (mean age 46 years). Of the 27 respondents, 15 participated in the interview procedure. The total score on the SUS questionnaire was 48 (SD 16) points. In the interviews, organizational, system-related and personal barriers were found. 60% of respondents admitted not using the CDSS because it was not integrated into the current electronic patient record, and 40% stated that they were not allowed to use it by their supervisor (cardiologist). 47% stated that using the CDSS was too time consuming, was "awkward" and not "user friendly", was not sophisticated enough, and that the advice of the CDSS did not correspond to daily practice. Finally, 27% stated they did not need a CDSS, experienced a lack of trust, or did not have enough knowledge to make appropriate use of it.

Conclusions

The usability of the CDSS was considered very low; the average score on the SUS was 68 points. Acceptance of the CDSS was also low mainly because of organizational, personal, and system-related barriers. The overall impression of the CDSS by respondents was that it needed more development. Therefore it was clear that success, in terms of optimal use of the CDSS related to start and up-titrate of HF medication, was not achieved.

Introduction

The prevalence of heart failure (HF) increases with age and as a result of lifestyle-related risk factors such as myocardial infarction and hypertension. It is associated with a high re-admission and mortality rate.[1] Many interventions have been developed in order to reduce these rates, for example, the structural prescription and usage of HF medication. This evidence-based prescription of medication plays a substantial role in the recent HF guidelines.[2,3] However, healthcare providers still experience difficulties when implementing those guidelines in daily practice, especially in structural prescription and up-titration of HF medication.[4] To encourage a better implementation of the recommended guidelines, computerized clinical decision support systems (CDSSs) as part of a disease management program could be used. These systems can provide advice and support in prescribing the optimal doses of medication.[5] Based on the existing literature, a CDSS can provide software-based healthcare-related advice to assist healthcare providers in making decisions and developing solutions. Using a CDSS can significantly improve clinical outcomes and quality of care.[6-9]

Despite the evidence for the effectiveness of CDSS, widely spread development, implementation, and evaluation of CDSSs in HF clinics are lacking.[10,11] Mistrust and user resistance to CDSSs,[12,13] have been described as major barriers for their implementation and use.[13-16] Other barriers for using a CDSS include the lack of integration of the system into clinical workflow. Working with a CDSS, especially in the beginning, may be considered "too time consuming".[17] In the IN TOUCH study, which was designed to investigate the effects of telemonitoring, in addition to an information and communication (ICT) guided disease management system,[18] a CDSS was incorporated to improve guideline adherence of HF medication (start and up-titration).

During the monitoring visits of the IN TOUCH study (December 2009 to September 2012) and analyses of the first raw data, we observed minimal use of the CDSS functionality. To judge a CDSS useful, it must be effective in many ways.[19] Various factors—human, organizational, technological—will have an influence on the success or failure of the implementation and use of a CDSS.[17] One of the outcome measures in this 'judgment' is the usability and acceptability of a CDSS.[20] For this study, we defined usability as "ease-of-use", ie, the extent to which users found the CDSS easy to use. Ease-of-use is critical for the adoption of a CDSS.[20] We defined acceptability as the extent to which users approved of or accepted the CDSS. To gain more insight into the usability and acceptability of the CDSS offered in the INTOUCH study, our objectives consisted of the following:

1. To explore the usability and acceptability of the HF CDSS.
2. To gain insight into barriers experienced by HF nurses in using a CDSS to start or up-titrate HF medication.

Methods

Description of the system and incorporated CDSS functionality

A descriptive design was used with both quantitative (questionnaire) and qualitative (interviews) data collection. The qualitative data were analyzed according to a directed approach to content analysis.[21]

CDSS

The CDSS that was evaluated was part of CardioConsult HF®, a computerized disease management system specifically developed and built for HF clinics in the Netherlands by Curit BV. For the up-titration of medication, the actual CDSS functionality provides advice based on the HF guidelines, guided by the actual HF medication, renal function, blood pressure, and heart rate of the HF patients. If vital signs (eg, blood pressure, renal function, and heart rate) of the HF patients are within predefined ranges, advice for the HF nurse is generated to start or further up-titrate the medication to an optimal dose. CardioConsult HF® is implemented as a stand-alone application and therefore not integrated into the hospital's own electronic patient record (EPR) environment, except for the interchange between the CDSS and the hospital EPR for renal function, blood pressure, and heart rate, which is needed for the CDSS to advise on medication. Benefits of the CardioConsult HF® are that clinical content can be updated instantly and that the system is able to generate alarms and reminders for missing data.

Data collection

System Usability Scale (SUS)

To measure the usability ("ease-of-use") of the CDSS, we used the System Usability Scale (SUS).[22] While SUS was intended to measure only the perceived ease-of-use as a dependent variable (a single dimension), recent research shows that it provides a global measure of system usability and subscales of usability and learnability. The usability of a CDSS is multilevel in principle. It provides not only insight into the characteristics of a CDSS, but also to individual familiarity with the CDSS. The SUS was developed by International Business Machines (IBM) and has been used in more than 500 evaluations of usability of health information technology.[22] It has proven to be a reliable and valid instrument for measuring system usability. The SUS is a 10-item questionnaire with 5 response options ranging from 1 ("strongly disagree") to 5 ("strongly agree"). The average SUS score from all 500 studies is 68 points.[22] Items 4 and 10 of the questionnaire provide the learnability dimension, and the other 8 items provide the usability dimension. In our study, Cronbach's alpha was .80 for the total scale. Cronbach's alpha for the subscales learnability was .65 and for usability .82.

Interviews

To describe the specific barriers for the minimal use of the CDSS function to start or up-titrate HF medication by HF nurses, semi-structured interviews were conducted and analyzed using content analyses.[21] Nurses working in the 9 HF clinics in the IN TOUCH study who considered themselves as having the most experience with working with the CDSS were invited to participate and received written and verbal information. Those who were willing to participate in the interview procedure were approached by telephone by an interviewer who was independent of the study. Before the start of the interview, participants were further instructed about the procedure and anonymity. The interview guide, which was completed in approximately 15 minutes, included the following three questions: 1) "Can you tell or explain why you barely used or did not use the CDSS functionality of the offered system?", 2) "In your opinion, what should change or should happen to result in more frequent usage of the system, specifically for starting or up-titrating medication?", and 3) "Do you have any further questions or comments regarding the previous two questions?" Additional questions (e.g. "Can you give an example?", "Can you explain?", "Can you elaborate?") were asked to encourage participants to elaborate on their thoughts and responses.

Analysis

The quantitative data were analyzed using descriptive statistics. Data were presented by mean and SD or as percentages in the case of categorical data. Qualitative data on specific barriers for barely using or not using the CDSS were presented by describing, per category, the number of respondents that reported that specific barrier. Furthermore, the two most relevant reported barriers per category were presented. Statistical analyses were performed using PASW version 18.0 and ATLAS.ti version 7 for Windows.

The complete interviews were recorded on tape and transcribed according to the verbatim method. Data were scored and categorized into system-related, organization-related, and person-related barriers by 2 independent observers. These three categories were predefined and formulated on a practical and a theoretical concept,[12,17] based on the assumption that the assessed barriers for not using the CDSS could be categorized into one of these three categories. Respondents were not informed beforehand about these three predefined categories. All text from the audio tape that was recorded and transcribed verbatim was coded using the predetermined categories whenever possible. Text that could not be coded into one of the three categories was coded with another label, called "other barrier". In case of inconsistency in categorizing data into the three different categories by the 2 independent observers, a third observer was consulted. After this procedure, the tapes were erased; as a result, data could not be linked to respondent or clinic characteristics afterwards, in order to ensure anonymity.

To control for the results of the observers and to obtain possibly new constructs and/

Table 1: Summary of baseline characteristics (N = 27)

Characteristic (SD)		
Age (mean), years	46	(10)
Female gender (%)	96	
Years of experience in current position (mean)	8	(4)
Working hours per week with HF patients (mean)	26	(8)
Experience with computers (years)	18	(5)
Email	15	(3)
Internet	14	(3)

or information, ATLAS.ti 7 software was used. This qualitative or nominal statistical software, designed for coding and analyzing qualitative data, did not give new insights other than what we already obtained as a result of the independent observers from the verbatim interviews.

Results

In total, 27 SUS questionnaires were sent out to the HF nurses of the 9 HF clinics in the Netherlands who participated in the IN TOUCH study, with a total response rate of 100%. Of the 27 participants, 15 regarded themselves as eligible for participating in the interview because they considered themselves as "most experienced" in working with the CDSS during the 9-month study period. All 15 respondents were willing to participate in the interviews, resulting in a 100% response.

Basic characteristics of the sample

The 27 respondents had a mean age of 46 (SD 10) and all were female. The mean years of work experience in the current position was 8 (SD 4) years, and the respondents worked with HF patients for an average of 26 (SD 8) hours a week. The mean experience in years of working with computers was 18 (SD 5) years. Respondents reported having at least 14 (SD 3) years of experiences using email and Internet (Table 1).

SUS

The total mean score of all 27 respondents on the SUS questionnaire (all 10 items) was 48 points (SD 16) (Figure 1). The score of the subscale learnability was 5.6 (SD 1.5), with a theoretical range from 2 to 10 points, indicating a neutral opinion on the learnability of the CDSS. For the scores of the individual SUS questions, refer to Table 2.

Table 2: The 10 items the SUS questionnaire (N = 27; 5 response options ranging from 1(strongly disagree) to 5 (strongly agree)

SUS items	Mean	SD
1. I think that I would like to use this system frequently.	2.1	1.1
2. I found the system unnecessarily complex.	3.5	1.1
3. I thought the system was easy to use.	2.6	1.1
4. I think that I would need the support of a technical person to be able to use this system.	1.9	0.9
5. I found the various functions in this system were well integrated.	2.6	0.9
6. I thought there was too much inconsistency in this system.	3.1	0.9
7. I would imagine that most people would learn to use this system very quickly.	3.0	1
8. I found the system very cumbersome to use.	2.5	1.1
9. I felt very confident using the system.	2.8	1.1
10. I needed to learn a lot of things before I could get going with this system.	2.4	0.9

Interviews

The various types of reported barriers were categorized into three predefined categories: organizational, system, and personal. The categories are known to influence the acceptability of a CDSS. To assess barriers related to the use of the CDSS, we first asked respondents: "Can you tell or explain why you barely used or did not use the CDSS functionality of the offered system?

Organization-related barriers

Fourteen of the 15 participants reported that not using the offered CDSS was directly related to the organization of their work. The average number of the quoted organization-related barriers was two. The reported barriers were: "the CDSS was not integrated into the existing EPR (Electronic Patient Record)" (n = 9), "no permission, or unwillingness to use the CDSS by the cardiologist" (n = 6), "the CDSS does not match the routine of our organization" (n = 3), "we use a different protocol for up-titration of medication" (n = 2), and "in the case of actually purchasing the system, it is too expensive" (n = 1).

System-related barriers

Of the 15 participants, 12 reported one or more system-related barriers for not using the offered CDSS. The average number of the quoted system-related barriers was two. The reported barriers of the participants were: "using the CDSS is too time consuming" (n = 7), "medication advice from the CDSS does not correspond with daily practice" (n = 7), "I find it awkward to use" (n = 7), "I find it not sophisticated enough" (n = 7), "the CDSS is inflexible" (n = 4), "it is not user-friendly" (n = 4), "the CDSS does not have any additional value" (n = 3), and "occurrence of system errors" (n = 1).

Person-related barriers

In total, 8 of the interviewed participants reported that not using the CDSS was person related. The average number of the quoted person-related barriers was one. Specifically, 4 participants reported that they had "enough knowledge and experience"' themselves and therefore did not find it necessary to use the CDSS to up-titrate medication, regardless of the added value of the system. Other barriers were "lack of trust in the CDSS" (n = 2), and "not enough knowledge to use the CDSS" (n = 2). "Negative previous experience with the system", "dislike of the system", and "lack of routine in using the system" were barriers that were reported by 1 respondent. Furthermore, 2 respondents reported that their patients were already on optimal medication. In summary, Table 3 presents the two most reported barriers per category.

The second question in the interviews was: "What should change or should happen to result in more frequent usage of the system, specifically for starting or up-titrating medication?"

The majority of the responders pointed out that the barriers (organization- and system-related) would have to change for them to overcome their resistance to working with the offered CDSS. The most frequent desired change was a full integration of the CDSS into their own hospital environment (EPR), a further development of the system to provide more sophisticated functionality, such as reminders and alerts, and an adequate up-to-date medication protocol that corresponds to daily practice. There was no recommended change regarding the barriers experienced in the person-related category.

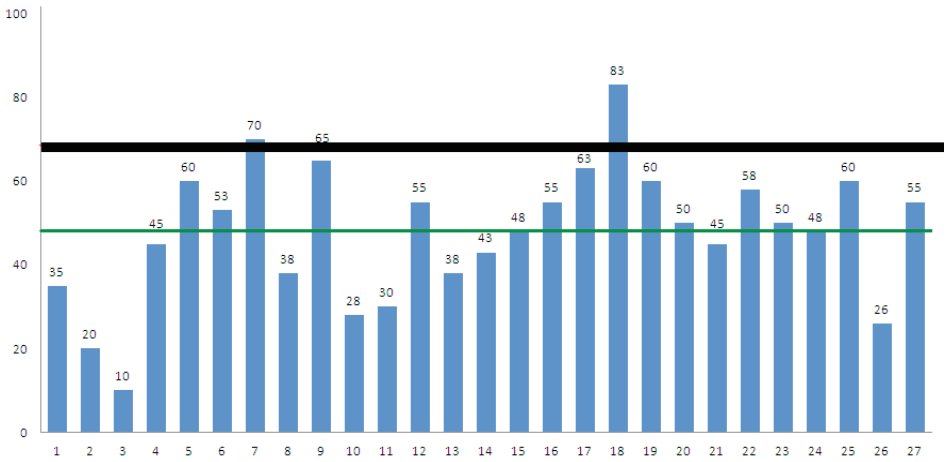

Figure 1: All individual total SUS scores and mean scores (thin line = 48 points; the fat line = 68 points and indicates the average score of the 500 control studies).

Table 3: The most reported barriers for not using the CDSS per construct

System related	**% (n)**
"using the CDSS is too time consuming"	47 (7)
"medication advice from the CDSS does not correspond with daily practice"	
"I find it awkward to use"	
"I find it not sophisticated enough"	
Organization related	
"the CDSS was not integrated into the existing EPR"	60 (9)
"no permission or unwillingness to use the CDSS by the cardiologist"	40 (6)
Person related	
"I have enough skills myself, therefore I find it not necessary to use the CDSS"	27 (4)
"lack of trust in the CDSS"	
"not enough knowledge to use the CDSS""	13 (2)

Discussion

One of the motivating factors for executing this study was the observed lack of use of the CDSS during the IN TOUCH study. Specifically, the functionality for starting and up-titration of HF medication was barely used. This is an interesting but also remarkable observation because the use of the medication titration module was a compulsory part of the IN TOUCH study protocol and because it was introduced primarily to help the HF nurses in applying a better guideline adherence to HF medication, as shown in earlier studies.[5,6] It is extraordinary that even a strict study protocol for using the intentional "helpful" software tool did not lead to a higher usage in the group of nurses of the IN TOUCH study.

Principal findings

The users of the CDSS in this study qualified the overall usability or ease-of-use of the CDSS as low (48 points). Results of 500 earlier studies using the SUS questionnaire to measure the usability of a software tool[22] showed that an SUS score below 68 points can be considered as "below average".

Furthermore, the acceptability of the CDSS was considered poor. Earlier research has shown that organizational, system-related, and human factors (ie, person-related factors) are frequently identified as the main cause of the failure of health information technology (HIT) implementations and that these factors are significant barriers in the acceptability of a system.[12] The results of these earlier studies are similar to the findings of our study; participants quoted organization-, system-, and person-related barriers as reasons for not using CDSS.

Barriers regarding acceptability

Our results showed that the lack of integration of the system within the hospital EPR environment was the most frequently cited organization-related barrier for not using the CDSS. Another important barrier for not using the CDSS was a lack of cooperation and unwillingness to work with the CDSS by the cardiologists involved. Approximately half of the nurse participants indicated that they were willing to start and up-titrate medication with the CDSS, but they were not allowed by the cardiologists in charge of the HF clinics to titrate medication with the help of the CDSS. Because we did not interview the cardiologists, we cannot elaborate clearly on this statement by the nurses. However, it is possible that the perception of a loss of experienced autonomy, unwillingness to rely on a computer-guided protocol, and a lack of trust in the offered CDSS might play a role.[12,23] In this context, we also observed that users stated that the CDSS did not fit into the usual routine of their organization due to a different protocol for up-titration of HF medication. Not developing clinic-specific protocols that reflect the actual procedure in daily practice is a known obstacle for the introduction and use of HIT.[24,25]

The four most frequently named system-related barriers were mainly caused by the "immaturity" of the tested CDSS, ie, it was still too rudimentary. This clearly indicates that there is much more to be developed for this specific CDSS in the field of both general (eg, layout) and professional HF functionality (eg, medication protocols). The "time consuming" and "awkward" nature of the CDSS are two of the four most quoted (system-related) barriers. The system was also described as "inflexible" and "incomplete" because a number of treatment protocols were missing. The reason "not sophisticated enough" is directed at a lack of sufficient alerts and reminders.

Regarding person-related barriers, several nurses indicated that they had personal barriers for not using the CDSS effectively. This is particularly evident in the case of users who classified themselves as "not having sufficient skills for properly titrating". Others stated that they did not need a CDSS for titration and were very capable themselves of optimizing medication without the help of a CDSS. However, recent research on optimal medication in HF shows that a substantial number of HF patients do not receive optimal medication.[26,27]

To interpret the results of this study appropriately, it is important to address a number of factors that may have caused this lack of usage of the CDSS and consequently the outcome of this study. First, despite the CDSS being offered in the IN TOUCH study, it is known that HF nurses in the Netherlands do not have much experience in working with CDSSs. Second, this CDSS was specifically introduced and used within the framework of the IN TOUCH study, and due to a low inclusion ratio, experiences and routine in working with the CDSS in daily practice remained low. Third, because the CDSS was introduced as a research tool, integration in the hospital EPR was not possible and the system should be considered as a "stand-alone" program. Stand-alone programs are often designed and desired for "personal additional value" and therefore have limited technical

support across hospitals. A significant drawback of these additional stand-alone, patient-related programs is the storage of various data sources into different systems. Double registrations are experienced as ineffective and characterized by low user acceptability and result in an increase in errors. The participating hospitals were permitted to use this CDSS for other HF patients outside the study, but this rarely happened. We conclude, therefore, that the users experienced little pleasure and/or benefit in working with the CDSS. It is obvious that if a new software tool is used, it will be judged critically on complexity and/or time saving and routine.[28]

Limitations

In this study, we assessed the usability and acceptability of only one CDSS in a specific, limited group of users. The generalizability of this study, therefore, may be questionable. However, the outcome is quite similar to that of other studies.

Implications and future research

It is important to understand why users classify a system as lacking "ease-of-use" or rate it low in "acceptability"; these practical experiences provide useful information on how to implement CDSS in daily practice and to develop and improve the system to a higher level or generation. In a recent review, Gagnon et al[17] pointed out a number of interventions and strategies that could potentially overcome this HIT implementation failure. The most important factors for a successful adoption were: training for users varying from general instruction to intensive training, the usage of "super users", a realistic perception of the benefits of the innovation (e.g., the possibilities of a CDSS, but maybe even more important, the impossibilities of a CDSS). "Ease-of-use" was the second most cited facilitator for a successful adoption. Interestingly, sociodemographic characteristics such as age, gender, experience, etc., were seldom considered as HIT adoption factors. Because the results of our study are, in principle, comparable with studies in other domains, it is therefore reasonable to assume that these interventions and strategies could improve the usability and acceptability of an HF CDSS as investigated in our study.

An often cited principle for successful usage of health information technology in this context is "KISS", meaning "Keep It Simple Stupid" (or more kindly, "Keep It Short and Simple"). This principle was used in the 1970s when computer programmers preferred to avoid large, time-consuming, and complex computer programs. These days, the "KISS" philosophy is still popular and used to introduce simple, easy-to-use, and understandable new technology in healthcare.[29] To help the introduction of health information technology and so the usage of CDSSs, it is important, aside from further technical development of CDSS, to focus in further research not only on successful implementation strategies but also on the barriers encountered, in order to find the most effective way of using CDSSs.

Conclusions

The main conclusion of this study is that the usability and the acceptability of the offered CDSS in HF clinics were considered poor, mainly due to organization- and system-related barriers. These findings were largely attributed to the "immaturity" of the CDSS itself and the fact that the CDSS was not integrated into the existing EPR environment.

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Chapter 6

Expectations versus experiences of telemonitoring: survey among heart failure clinics

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Abstract

Background

Although telemonitoring is increasingly used in heart failure care, data on expectations, experiences, and organizational implications concerning telemonitoring are rarely addressed, and the optimal profile of patients who can benefit from telemonitoring has yet to be defined. Our objective was to assess the actual status of use of telemonitoring and to describe the expectations, experiences, and organizational aspects involved in working with telemonitoring in heart failure in the Netherlands.

Methods

In collaboration with the Netherlands Organization for Applied Scientific Research (TNO), a 19-item survey was sent to all heart failure clinics in the Netherlands.

Results

In total, 31 out of 86 (36%) heart failure clinics were using telemonitoring and 12 heart failure clinics (14%) planned to use telemonitoring within one year. The number of heart failure patients receiving telemonitoring generally varied between 10 and 50; although in two clinics more than 75 patients used telemonitoring. The main goals for using telemonitoring are "monitoring physical condition", "monitoring signs of deterioration" (n=39, 91%), "monitoring treatment" (n=32, 74%), "adjusting medication" (n=24, 56%), and "educating patients" (n=33, 77%). Most patients using telemonitoring were in the New York Heart Association (NYHA) functional classes II (n=19, 61%) and III (n=27, 87%) and were offered the use of the telemonitoring system "as long as needed" or without a time limit. However, the expectations of the use of telemonitoring were not met after implementation. Eight of the 11 items about expectations versus experiences were significantly decreased (P<.001). Health care professionals experienced the most changes related to the use of telemonitoring in their work, in particular with respect to "keeping up with current development" (before 7.2, after 6.8, P= .15), "being innovative" (before 7.0, after 6.1, P= .003), and "better guideline adherence" (before 6.3, after 5.3, P= .005). Strikingly, 20 out of 31 heart failure clinics stated that they were considering using a different telemonitoring system than the system used at the time.

Conclusion

One third of all heart failure clinics surveyed were using telemonitoring as part of their care without any transparent, predefined criteria of user requirements. Prior expectations of telemonitoring were not reflected in actual experiences, possibly leading to disappointment.

Introduction

Telemonitoring in heart failure care is used to monitor patients' symptoms at home and to guide patients in taking action in case of deterioration. Telemonitoring is considered a promising new intervention for heart failure patients, and a study on the use, perceptions, and experiences has been published recently.[1,2] However, current evidence regarding the effectiveness of telemonitoring in the care of heart failure patients is conflicting.[3] There are many definitions used for telemonitoring, but the core principle does not generally differ. A commonly used international definition is "the remote monitoring of patients, including the use of audio, video, and other telecommunications and electronic information processing technologies to monitor patient status at a distance".[4] In the Netherlands, the most used definition is that telemonitoring includes the measurement, monitoring, collecting, and transfer of clinical data concerning the health status of a patient in his or her home environment, using information and communication technology. Initial studies showed that remote monitoring of heart failure patients reduced hospitalization and mortality rates.[5-8] However, recent studies performed on a larger scale did not confirm these findings.[9,10] Questions remain regarding the optimal patient profile for using telemonitoring, the technical aspects of the telemonitoring systems, the intensity and frequency of providing data, and the cost-effectiveness of the various telemonitoring systems used.[11,12] Furthermore, expectations and consequences of telemonitoring for the organization of care, logistic processes, and the work of health care providers are rarely studied, and thus unclear. However, these aspects of telemonitoring are vital for the consideration and acceptance of these systems in future practice.[13]

Despite the inconclusive evidence for the use of telemonitoring in heart failure, telemonitoring is considered to be a promising development,[7] and there are increasing efforts to introduce telemonitoring in outpatient heart failure clinics. In some countries, including the Netherlands, health care insurance companies reimburse telemonitoring for heart failure patients. The present study was designed to assess the perspectives and expectations for both heart failure nurses and cardiologists working in a heart failure team with telemonitoring.

To this end, the following research questions were posed: 1) What are the perceptions and expectations of cardiologists and heart failure nurses with respect to the implementation of telemonitoring in heart failure patients? and 2) What are their experiences with the implementation of telemonitoring? In this study, we did not focus on possible differences between heart failure nurses and cardiologist in their perceptions of working with telemonitoring.

Methods

Participants

Participants in the study consisted of cardiologists and heart failure nurses working in heart failure outpatient clinics in the Netherlands. Out of all 118 Dutch heart failure clinics, 109 clinics received a questionnaire in March 2011, addressed to the cardiologists and heart failure nurses working in the heart failure outpatient clinic. Nine heart failure clinics were excluded and did not receive a questionnaire due to their participation in the IN TOUCH study, a study evaluating the added value of information and communication technology-guided disease management combined with telemonitoring for heart failure patients.[14] Participants were requested to return the questionnaire within 12 weeks. We sent out two reminders.

Instrument

In collaboration with the Netherlands Organization for Applied Scientific Research (TNO), a 19-item questionnaire on telemonitoring was specifically developed for this study, based on the two research questions. For this questionnaire we defined telemonitoring as: "The remote, Internet-based monitoring and mentoring of heart failure patients on weight, blood pressure, heart rate, and signs and symptoms that disclose the actual condition of the heart failure patient. The devices are used by the patients in their own home environment and the generated data are transferred by the Internet". The use of telemonitoring by means of telephone, telephone support, telephone follow-up, or by means of implantable devices was not included in this study because our focus was to investigate expectations and experiences of using telemonitoring devices that required an active user interaction (eg, direct handling of deviated values, generated alerts, and complaints). The technology and handling for users between implanted devices and external devices, such as weight scales and/or blood pressure measurements, are essentially different. Based on the research questions, items for the questionnaire were developed with the input of 10 cardiologists and 10 heart failure nurses, resulting in a questionnaire consisting of 3 domains: 1) availability of telemonitoring, 2) experiences with telemonitoring, and 3) organization of telemonitoring. The questionnaire consisted of both multiple choice and "agree/disagree" questions. For data regarding the motivation for and importance of using telemonitoring, as well as the experiences with using telemonitoring, we asked respondents to rate 11 items on a 10-point scale. On this scale, 0 counted as "not important"' and 10 as "very important".

These 11 items were based on practical considerations related to the start-up of telemonitoring. Aside from addressing the practical considerations of health care workers in our study, these same 11 items are frequently used by sales representatives to convince future users of the added value of working with telemonitoring. The 11 different items could be combined into 3 groups: 1) direct patient care (better self-management,

improving quality of care, and reduction of (re) admission); 2) telemonitoring system–related aspects (current development, innovation, and better guideline adherence); and 3) organizational aspects (treating more patients, fulfilling hospital policy, reducing workload, lowering heart failure related costs, and fulfilling health care insurance policy).

Validation Process of the Questionnaire

To test the questionnaire, a group of 30 pilot responders, representing the future research population, completed the questionnaire. Internal consistency (Cronbach alpha) of the questionnaire in the current sample was .85. This parameter measures the reliability of the scale. A set of questionnaire items with a reliability of .70 or higher is considered acceptable. Face validity (10 cardiologists, 10 heart failure nurses) was assessed by analyzing the feedback received on the total questionnaire.

Statistical Analysis

Descriptive statistics were used to present the data. For some parts of the analysis, we subdivided the respondents into current telemonitoring users (n=31) and intended telemonitoring users (n=12), because some research questions are related to actual experiences of working with telemonitoring and other are more exploratory (eg, which patients do you think are suitable for applying telemonitoring?). Paired samples t tests were used to examine possible differences between expectations of and experiences with using telemonitoring. Analyses were performed using PASW, version 18.0 for Windows.

Results

Basic Characteristics of the Study Population

Of the 109 heart failure clinics who received a survey, 86 clinics responded (79%). Their responses were included in the analysis. Respondents had a mean age of 48 ± 8 years, and 68% were female. The mean years of work experience in the current position was 14 ± 9 years, and the respondents worked with heart failure patients for an average of 19 ± 10 hours a week. Of the 86 responding clinics, 31 reported using telemonitoring in their current patient care (36 %), and 12 clinics (14%) planned to use telemonitoring within one year. Further analysis was therefore restricted to the clinics that actually used telemonitoring and those that planned to use telemonitoring within one year (total n=43).

Availability of Telemonitoring

The three systems most frequently used for telemonitoring were commercially available systems (Motiva, Health Buddy, and IPT Telemedicine),[15-17] and one clinic had developed its own telemonitoring system. The systems used in this study are generally similar to each other based on functionality. They transfer measurements generated at home and

Table 1: characteristics of the commercial available telemonitoring systems used in this study

	Motiva [27]	Health Buddy [28]	IPT-Telemedicine [29]
Monitoring			
Blood pressure	yes	yes	yes
Weight	yes	yes	yes
Heart frequency	yes	yes	yes
Electrocardiography	no	yes	yes
Questions			
Symptoms	yes	yes	yes
Knowledge heart failure	yes	yes	yes
Change of behavior	yes	yes	yes
Informing of patient about			
Symptoms	yes	yes	yes
Knowledge about heart failure	yes	yes	yes
Change of behavior	yes	yes	yes
Communication			
Datacenter	yes	yes	yes
Medical service Center	yes	no	yes
Direct feedback true application to patient	yes, through television	yes	yes
Direct feedback of healthcare provider to patient	yes, by phone	yes, by phone	yes, by phone
Continue feedback to healthcare provider	yes, through software on desktop	yes, through software on desktop	yes, through portal
Alerts in case of deviation of predefined measurements	yes, through software on desktop	yes, risk profile's (low-middle-high)	yes, through portal
Patient requirements			
Ability to read	yes	yes	yes
Active input	yes	yes	yes
Cognitive functional	yes	yes	yes
Manual	extensive	simple	simple
Television	yes	no	no

Source: Inventarisatie eHealthNu Expertgroep Hartfalen 2010; authors: TNO Kwaliteit van Leven, Ton Rövekamp, Pim Valentijn). For specific product information see references 27-29.

answers to questions to a health care environment via the Internet. The Health Buddy system differs, however, because it transfers the data directly to the health care provider instead of a data center. This means that the heart failure nurses are directly responsible for the handling of data and measurements. However, the consequence of directly receiving data and measurements is the need for a 24/7 shift of health care providers.

Table 2: Availability and use of telemonitoring (TM) system by actual users (n=31) and planned users (n=12)

TM systems	Actually used system (31 clinics)	System of choice in case of a new decision (31 clinics)	No current user but expecting to make a choice within 1 year (12 clinics)
Health Buddy	7 (28%)	2 (8%)	-
Motiva	14 (46%)	4 (12%)	5 (42%)
IPT Telemedicine	6 (15%)	2 (6%)	-
Other systems	4 (11%)	3 (10%)	2 (16%)
No choice yet	-	4 (12%)	2 (16%)
Unsure	-	16 (52%)	3 (26%)

The feedback from the health care provider to the patient in all three systems is given by telephone. For the specific characteristics of the commercially available systems used in this study,[18] see Table 1.

The clinics that intended to use telemonitoring within a year mostly reported (42%, n=5) that they planned to use the Motiva system (Table 2). The number of patients using telemonitoring in a clinic varied between 10 and 50, but in two clinics more than 75 patients used telemonitoring.

The following main goals for implementing telemonitoring were reported: "monitoring physical condition", "monitoring signs of deterioration" (91%, n=39), "monitoring treatment" (74%, n=32), "adjusting medication" (56%, n=24), and "educating patients" (77%, n=33) (see Table 3). Beside these goals, most clinics also used this as a practical reason to start telemonitoring.

Experience With Telemonitoring

Patient Profile

The criteria for using telemonitoring for a specific patient were reported to be based on "needing education" (68 %, n=29), "increasing self management" (63%, n=27), "having complaints of heart failure symptoms" (60%, n=26), and "being (re) admitted due to heart failure" (60%, n=26). See Table 4.

Respondents from 8 clinics reported that the current use or amount of medication were reasons for using telemonitoring. The majority of respondents (85%, n=36) stated that the New York Heart Association (NYHA) functional class was not a reason to start telemonitoring (see Table 5).

In order to determine the best course of therapy, heart failure professionals assess the stage of heart failure according to the New York Heart Association (NYHA) functional classification system (see Table 6). This classification system relates symptoms to everyday

Table 3: General descriptive data of heart failure centers using (31) and plan to use (12) telemonitoring (TM)

Number of patients in TM care	**N= 31 clinics**
None	2 (6%)
0-10	5 (16%)
10-20	8 (26%)
20-50	11 (35%)
50-75	3 (11%)
>75	2 (6%)
Main goal of using TM (31 + 12 clinics, more answers possible)	**N= 43 clinics**
Monitoring physical conditioning, signs of deterioration	39 (91%)
Monitoring and adjustment of treatment	32 (74%)
Titration of medication	24 (56%)
Patient education	33 (77%)
Other goals	3 (7%)
Duration of applying TM in patient care	**N= 31 clinics**
Between 3 and 6 months	6 (19%)
Between 6 and 12 months	6 (19%)
No limit	9 (30%)
As long as necessary	10 (32%)

activities and the patient's quality of life. The NYHA class is not a determined factor for the application of telemonitoring according to the guidelines.

Nevertheless, patients in NYHA class II and III were most often reported to be enrolled for telemonitoring, whereas no patients in NYHA class I used telemonitoring. In total, 15% of patients in NYHA class IV used telemonitoring.

Length of Time of Telemonitoring

Most respondents stated that they monitor their patients with telemonitoring "as long as needed" or without a time limit. Six clinics noted a maximum time period for using telemonitoring per patient between 3 and 6 months respectively. In response to the question on whether clinics (n=43) could estimate which of the total percentage of all patients in heart failure care were suitable for telemonitoring, the mean percentage was 10%.

Telemonitoring System

Fifteen of the 31 clinics that actually used telemonitoring stated that if a new selection process were to be put in place, they would choose a different system compared to the

Table 4: Criteria for applying telemonitoring (TM) in heart failure (HF) patients, more answers possible

Criteria for applying TM	N= 43 clinics
Education	29 (68%)
Patient management	27 (63%)
HF Re-admission	26 (60%)
Complaints HF symptoms	26 (60%)
Based on actual NYHA class	13 (30%)
Medication status	8 (19%)
Different	2 (4%)

Table 5: NYHA class in telemonitoring (NYHA: New York Heart Association classification for heart failure), more answers possible

Actually NYHA class of patients currently using telemonitoring	N= 31 clinics
NYHA I	0 (0%)
NYHA II	19 (61%)
NYHA III	27 (87%)
NYHA IV	5 (15%)
Which NYHA class in your patient population is suitable for applying telemonitoring?	**N= 43 clinics**
NYHA I	3 (6%)
NYHA II	14 (32%)
NYHA III	18 (41%)
NYHA IV	10 (23%)
Is the NYHA class decisive for applying telemonitoring?	**N= 43 clinics**
Yes	6 (15%)
No	36 (85%)

Table 6: NYHA: New York Heart Association classification for heart failure

Class	Patient symptoms
Class I (Mild)	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea (shortness of breath).
Class II (Mild)	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation, or dyspnea.
Class III (Moderate)	Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation, or dyspnea.
Class IV (Severe)	Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.

system they currently used. Sixteen clinics indicated that they were not sure which system they would choose (see Table 2). Of the 31 clinics, 14 reported that they were satisfied with their current telemonitoring system. The other 16 clinics took a neutral stance, and one user reported to be dissatisfied with the telemonitoring equipment.

Expectations Versus Experienced Outcomes

In Figure 1, the expectations of applying telemonitoring are compared with the experienced outcomes after implementation of telemonitoring. The combined 3 groups of aspects of working with telemonitoring (direct patient-related care, telemonitoring system aspects, and organizational aspects) and 10 of the 11 separate items showed that the actual experiences did not meet the prior expectations. The results showed that users had high expectations of the benefits of using telemonitoring, in particular with respect to direct patient-care aspects (mean 7.4).

Expectations of the system-related aspects (mean 6.8) and organizational aspects (mean 6.0) were also high. However, these high expectations of the use of telemonitoring were not reflected in the actual experiences after implementation. The largest difference was

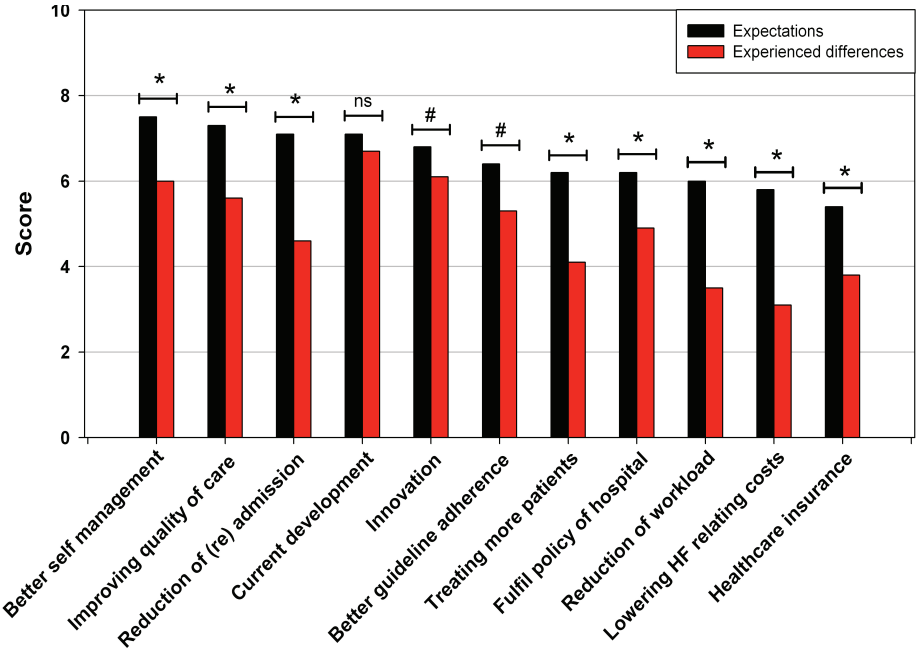

Figure 1: Expectations of applying telemonitoring and experienced differences after applying telemonitoring (31 clinics) y-axis: 0='not important', 10 = 'very important'. * =P<.0001, # innovation = P.003, # better guideline adherence = P.005, ns (non-significant)=P.146 (paired sample T-test).

found in the group of organizational aspects (reduction of workload score, 5.9 versus 3.5, P<.001) and lowering heart failure–related costs, score 5.8 versus 3.2, P<.001). The aspect "keeping up with current developments" was the only one in which a reduction was not significant (score, 7.2 versus 6.8, P=.15).

Organizing and Financing Telemonitoring

A total of 12 clinics (39%) reported to be in a "start-up" period; whereas the other 19 clinics stated that they had fully integrated telemonitoring in their daily care routine. Rules and protocols on the implementation of the system and responsibility for incoming data were available in 70% of the clinics. Protocols on the acceptable length of time between the moment of incoming patient data and the response of the caregiver (response-reaction time) were available in 60% of the clinics. With respect to financing, 54% of telemonitoring systems were financed by health care insurance companies, 13% by project financing, and 7% by the hospital itself or the cardiology department. The other 26% of the clinics did not give insight into their financing of telemonitoring.

Discussion

The most prominent result of our study was that, although the respondents had high perceptions and expectations of working with telemonitoring, these were not positively reflected in the actual experiences.

The trade-offs directly related to the telemonitoring system were most often addressed, but important trade-offs of telemonitoring concerning direct patient care and organizational aspects were only briefly mentioned or not reported at all. A striking finding is that the majority of responding heart failure clinics stated they were considering the use of a different system than the system currently used. Furthermore, aspects of direct patient care (like monitoring and education) were reported as main goals for implementing telemonitoring.

The dominant criteria for using telemonitoring for a specific patient included "education", "heart failure (re) admission", and "complaints of heart failure symptoms". Thirty percent of the respondents mentioned that the actual NYHA class is a criterion for applying telemonitoring, but at the same time only 15% stated that the NYHA class was decisive for applying telemonitoring. In actual practice, the majority of the patients showed to be in NYHA class II and III. Finally, although 1 out of 10 patients was suitable for telemonitoring, the actual number of patients using telemonitoring was limited in general and the duration of the use of telemonitoring unknown. Despite the increased introduction and use of telemonitoring in heart failure, there has been little research regarding user-related aspects of working with telemonitoring. Therefore, it is unknown to what extent expectations, experiences, and possible difficulties in the implementation

process of telemonitoring are present in health care providers working with telemonitoring. In this first study to focus specifically on the application of telemonitoring in heart failure clinics, we showed that heart failure clinics have high expectations of patient care, system, and organizational outcomes of working with telemonitoring.

In an earlier study on the expectations of telemonitoring of caregivers in nursing homes, Chang et al[19] reported that respondents expected the benefits of improved efficiency and quality of care, reduction of medical costs, and a reduced workload. However, experiences of telemonitoring were not measured in the study of Chang et al. Although the evidence for the use of telemonitoring in heart failure patients is still growing,[5-8] gaps in knowledge about the use of telemonitoring in heart failure remain.[3,20,21] These gaps in knowledge are mainly caused by the absence of data on adequate patient profiling and the overall cost-effectiveness of telemonitoring.

Despite the presence of conflicting evidence on the usefulness of telemonitoring for heart failure and the lack of data regarding the implementation of telemonitoring, the consequences for health care providers, and the logistic processes in daily practice, more than one-third of all heart failure clinics in the Netherlands have implemented this new technology for some of their heart failure patients. This indicates that health care providers have high expectations of working with telemonitoring and are even willing to start working with telemonitoring in the absence of guidelines, protocols, and solid evidence for its usefulness. The use of telemonitoring, however, is still in its infancy, and many clinics are still searching for a way to provide telemonitoring efficiently and effectively. A similar experience was reported with respect to the selection processes for electronic patient records and other technology tools in health care.[22-24] Users were either extremely positive or negative about their system, and this had a "wait-and-see" effect on potential future users. Negative experiences were reflected in the fact that some users were considering looking for a different system than the system currently used. The need for a different system seems to be primarily driven by the practical usage of the system, which falls short of expectations. Our findings indicate that the actual functionalities of the telemonitoring system itself are of great importance to the respondents. Hence, it is questionable if the feeling of overall disappointment is indeed the result of a failing telemonitoring system or is due to a lack of efficient organization around the implementation of telemonitoring systems.

For future success it is very important to create an efficient organization around a system.[13] In the case of telemonitoring, this means that a system should be integrated in a heart failure clinic in which heart failure nurses[11,25] have a coordinating role and have insight in all aspects of patient care (eg, health care professionals involved, situation at home). Within this setting, the heart failure nurse can take appropriate action on the data received from the telemonitoring system.[26,27] Furthermore, additional training is required in which insight and understanding of receiving data, data handling, evaluating expectations, and effect monitoring are vital.[28]

Our data showed that in 61% of the heart failure clinics that actually worked with telemonitoring, it was used only in small cohorts with numbers of 10 to 50 patients. Although this concerns only a limited number of patients, it is important to realize that monitoring 50 heart failure patients (next to the treatment of other heart failure patients) might cause a substantial amount of additional work with respect to logistic adjustment, training on using the system, and the development of protocols on data handling, response time, and treatment. We could therefore predict that implementing telemonitoring will not automatically decrease workload.

In this first study on user-related aspects of telemonitoring, we demonstrated that the optimal use of telemonitoring remains a challenge. The main finding of our research is that a substantial difference exists between prior expectations of telemonitoring and the actual use of telemonitoring in daily practice. The focus on, for instance, optimizing medication by using telemonitoring, however, has been shown to be a promising and cost-effective future application.[29,30] While the use of telemonitoring is still in its infancy, it is important to learn from current experiences, even if it currently concerns only a limited number of telemonitoring systems and patients. Ongoing studies such as the IN TOUCH trial[14] in the Netherlands should provide more evidence about cost-effectiveness and the effects of telemonitoring in combination with different types of disease management in heart failure.

A finding that has to be specifically addressed is that most of the respondents indicated that telemonitoring will be applied as long as needed or can even be used indefinitely. This approach should be critically evaluated. First, it might not be the most cost effective in terms of using equipment and staff. Most intervention studies on the use of telemonitoring were short in follow-up, and therefore there are no data available that support the choice for (life) long use of telemonitoring. Second, ethical issues can be raised about whether or not patients would benefit from lifelong monitoring, regardless of the burden on their personal lives. Other notable findings were that 85% of the respondents indicated that the NYHA functional class was not decisive for the application of telemonitoring and that most patients who received telemonitoring were in NYHA functional classes II and III. Although the optimal patient profile for successful use of telemonitoring has not yet been described, it can be expected that specifically patients with severe and more unstable heart failure are suitable for telemonitoring and would benefit in terms of preventing re-admissions. Considering this, it is remarkable that in daily practice telemonitoring is increasingly used for patient education and for optimizing medication in patients with less severe heart failure.

Limitations

For this study, we used a self-developed questionnaire that was not designed to test the feasibility of a telemonitoring system, but rather to examine both the general

considerations and reasons for applying telemonitoring in Dutch heart failure clinics, as well as the organizational aspects these systems address. In this study, we did not focus on possible differences in the perception of working with telemonitoring of heart failure nurses and cardiologists, because the main goal of this study was to explore the expectations and experiences of a heart failure team working with telemonitoring. However, one might predict that the comments of the two separate groups would relate to their characteristics. Although we are aware of the limitations of asking about experiences with telemonitoring retrospectively, the design of this study could not correct for this. To account for this limitation, we have focused in the discussion on the learning aspects of the experiences instead of giving clear-cut conclusions.

Conclusion

This representative study (86 of 109 surveyed Dutch heart failure clinics) showed that one- third of heart failure clinics were using or planned to use telemonitoring as part of their care, albeit in a limited number of patients only. Our survey also showed that telemonitoring is not a success story yet. Respondents did not experience a decreased workload while working with telemonitoring, and prior expectations of introducing telemonitoring were not reflected in actual experiences, possibly leading to disappointment. Criteria for both the optimal duration period of using the telemonitoring system and the targeted patient groups were not established, and the choice for a telemonitoring system seemed to be made on the specifications of the system itself, rather than on organizational issues such as protocols or education of staff. All the suppliers of telemonitoring devices observed in this study provide the services of generating and transferring data from a home environment to a health care environment. Telemonitoring is not a "one size fits all" solution. From a patient point of view[9,10] and supported by the recent European Society of Cardiology heart failure guidelines (2012), we conclude that the optimal profile of patients who might benefit from telemonitoring needs to be further explored. Long-term experiences are necessary to discover the most effective use of telemonitoring in terms of reduction of mortality, re-admissions, and improvement of quality of life.

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Chapter 7

Perceived barriers of heart failure nurses and cardiologists in using clinical decision support systems in the treatment of heart failure patients

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Abstract

Background

Clinical Decision Support Systems (CDSSs) can support guideline adherence in heart failure (HF) patients. However, the use of CDSSs is limited and barriers in working with CDSSs have been described as a major obstacle. It is unknown if barriers to CDSSs are present and differ between HF nurses and cardiologists. Therefore the aims of this study are; 1. Explore the type and number of perceived barriers of HF nurses and cardiologists to use a CDSS in the treatment of HF patients. 2. Explore possible differences in perceived barriers between two groups. 3. Assess the relevance and influence of knowledge management (KM) on Responsibility/Trust (R&T) and Barriers/Threats (B&T).

Methods

A questionnaire was developed including; B&T, R&T, and KM. For analyses, descriptive techniques, 2-tailed Pearson correlation tests, and multiple regression analyses were performed.

Results

The response- rate of 220 questionnaires was 74%. Barriers were found for cardiologists and HF nurses in all the constructs. Sixty-five percent did not want to be dependent on a CDSS. Nevertheless thirty-six percent of HF nurses and 50% of cardiologists stated that a CDSS can optimize HF medication. No relationship between constructs and age; gender; years of work experience; general computer experience and email/internet were observed. In the group of HF nurses a positive correlation (r .33, P<.01) between years of using the internet and R&T was found. In both groups KM was associated with the constructs B&T (B=.55, P=<.01) and R&T (B=.50, P=<.01).

Conclusions

Both cardiologists and HF-nurses perceived barriers in working with a CDSS in all of the examined constructs. KM has a strong positive correlation with perceived barriers, indicating that increasing knowledge about CDSSs can decrease their barriers.

Introduction

With a growing elderly population and improved survival after myocardial infarction, the number of patients with heart failure (HF) is increasing. HF is associated with a high re-admission and mortality rate.[1] In order to reduce these rates, many strategies have been developed over the years. The structural application of disease management programs is one such important strategy, and proven to be an important contributor.[2-5] Disease management programs can be effective in improving the outcomes of HF patients and are therefore advised in recent HF guidelines.[5,6] Since the introduction of those guidelines for both pharmacological and non-pharmacological treatment of HF patients, more patients have been treated with evidence based medication,[7-9] and clinical outcomes of fewer cardiovascular hospitalizations have been observed.[10] However, healthcare providers still experience difficulties when implementing those guidelines in daily practice.[11] The ESC HF pilot survey[12] showed that the rate of prescribed medication that adheres to the guidelines is satisfactory, but the number of patients that receive the optimal dose of ACE-inhibitors, beta blockers, and aldosteron antagonists nevertheless still remains suboptimal. To improve guideline adherence, clinical decision support systems (CDSSs) could, for instance provide advice and support in prescribing the optimal doses of medication,[13] help with managing the complex care process of HF patients, and improve guideline implementation.[14] There are many definitions of a CDSS[15] but the core principle remains the same throughout. Based on the literature, a CDSS can be said to provide software-based healthcare-related advice to assist doctors and nurses in making decisions and developing solutions, and is often used in complex or non-routine situations.

There is evidence that when using a CDSS, the performance of healthcare providers on clinical outcomes in general improves the quality of care significantly.[14,16-18] Despite this evidence for the effectiveness of CDSS, a widespread development, evaluation and implementation of CDSSs, especially in HF clinics, is lacking.[19,20] One of the reasons for this underutilization seems to be a certain level of mistrust or user resistance to CDSSs,[21,22] which has been described as a major barrier for implementing and using CDSSs.[22-25]

Theoretical background

In general, barriers to guideline adherence consist of a lack of awareness, a lack of agreement or perceived self-efficacy to change, minimal outcome expectancy, and inertia associated with a lack of faith in existing treatment practices.[26] For this study a practical working definition of barriers was defined as: "a barrier is the HF healthcare worker's perception or estimation of the level of (objectively or subjectively) experienced obstacles". This indicates that a (perceived) barrier is the result of a complex mental process, in which earlier experiences, beliefs, social environment, and education influence the number of experienced barriers, both in facilitators and in perceived barriers.

Varonen et al.[21] identified potential barriers and facilitators of general physicians to using CDSSs such as earlier experience with dysfunctional computer systems, potential harms to the doctor-patient relationship, unclear responsibilities, threats to clinicians' autonomy, and extra workload due to excessive reminders. Poor computer skills can also be a barrier to the implementation of a CDSS.[27] The next generation of healthcare providers, however might bring with them a higher level of computer literacy, thus possibly helping the implementation of a CDSS.

Knowledge of a CDSS and the management of knowledge itself[28] (i.e., understanding the underlying process of dataflow, the establishment of decisions made by a CDSS, and the assessment of the value of automatically conducted advices by self-generated data input) have been described in earlier research as strong influencers (positive facilitators), for reducing barriers. At this moment however there is limited knowledge about the type and number of barriers experienced in working with CDSSs by healthcare providers caring for HF patients. The justification for our study is that CDSSs are increasingly considered to be very effective instruments for improving guideline implementation.[14,29,30] Therefore we decided to perform this study to increase knowledge about barriers to the adaption of CDSSs.

The aims of the present study are:

1: To explore the type and number of perceived barriers of HF nurses and cardiologists to using a CDSS in the treatment of HF patients.

2: To explore possible differences in perceived barriers between two groups of respondents (cardiologists / HF nurses).

3: To explore whether characteristics such as age, gender, education, profession and computer skills are related to the number of perceived barriers.

4: To assess the relevance and influence of Knowledge Management on Responsibility/ Trust (R&T) and Barriers/Threats (B&T).

Methods

Development of the questionnaire

The term "barrier" is often used as an umbrella term for covering a whole range of differently and subjectively perceived concepts. This heterogeneity makes it difficult to actually measure a barrier itself. Previously described barriers have been classified in five constructs; trust, responsibilities, threats, resistance, and knowledge management. These constructs were used as indicators of perceived barriers in our study. Since no valid instruments have been developed to measure barriers concerning CDSSs in the domain of HF, a questionnaire based on earlier findings of Varonen[21] Leslie,[27] Short,[22] and

Table 1: Definition of constructs

Construct	Definition
Responsibility	The extent to which the user can take accountability for their (professional) actions and its consequences for the (professional) actions by others.
Trust	The expectation of the user that the offered CDSS is doing what is promised and that you can rely on it.
Barrier	A user objectively or subjectively experienced obstacles to the use of a CDSS
Threat	Feeling of doom combined with an experience of threats or danger that is associated with the offered CDSS.
Knowledge management	The structured, continuous process of developing, sharing, learning, and applying knowledge.

Toth-Pal[23] was developed. In all of these studies, the reported barriers met the criteria of the aforementioned constructs, (i.e., trust, responsibilities, threats, resistance, and knowledge management). In this study, the various items to be used in the five constructs were first defined (Table 1), and later reduced by means of interviews and pilot-testing with pilot responders (10 cardiologists and 20 HF nurses) to a set of item groups. The final questionnaire consists of 49 items, focusing on perceived barriers using a 5-point Likert type rating scale. (Table 5, questions of perceived barriers on CDSS questionnaire).

Validation process of the questionnaire

To test the questionnaire, a group of 30 pilot responders, representing the future research population, completed the questionnaire. Face validity was assessed by analyzing the feedback received on the total questionnaire.

As a result of the pilot, and based on remarks of the pilot responders, the original two constructs, 'responsibility' and 'trust' could be pooled together to form one scale (Responsibility and Trust; R&T). The items belonging to the original constructs 'threats' and 'resistance', could similarly be grouped together in a single scale, named Barriers and Threats (B&T). The items of the fifth construct formed the scale of Knowledge Management (KM). Since a lower score on each separate item (1 = totally agree to 5 = totally disagree), indicates more knowledge, a lower score on this construct also indicates more knowledge about a CDSS. After all responders filled in the questionnaire (N=162), reliability of the questionnaire in terms of Cronbach's alpha was .85 for the total scale. This parameter measures the reliability of the scale. A set of questionnaire items with a reliability of .70 or higher is considered to be acceptable. Cronbach's alpha for the subscales ranged from .67 to .79. To identify possibly non-observed variables, or new combinations of variables which could indicate another new construct, a factor analysis was performed. However, no new insights for combining items differently were found. The factor analysis thus supported the decision to combine the original five constructs into three (new) main constructs.

Statistical analyses

Descriptive statistics were used to characterize the study population (mean and SD) and to describe the results of the 49 questions. To examine a possible correlation between characteristics of the respondents and the three constructs, 'R&T', 'B&T', and 'KM', 2-tailed Pearson correlation tests were used. To assess an association of R&T and B&T with KM and the effect of four other theoretically relevant variables (age, years of experiences in current position, years of experience in working with computers, and the use of telemonitoring), multiple regression analyses were performed using the "Forward" selection method.[31] All analyses were conducted for both the whole group and the separate healthcare providers (cardiologists, HF nurses). Missing values (3%) in the questionnaires were corrected by replacing them with mean values per construct. Statistical analyses were performed using PASW version 18.0 for Windows.

Results

Study population

In March 2011, 220 questionnaires were sent out to all 110 HF clinics in the Netherlands. Because most HF teams consisted of one cardiologist and two HF nurses we can estimate that there are approximately 110 HF dedicated cardiologists and 220 HF nurses (distribution 1/3-2/3) in the Netherlands. The questionnaire was addressed to the cardiologists and HF nurses working as a team in a HF outpatient clinic. Participants were requested to return the questionnaire within 12 weeks, and two reminders were sent out. In June 2011 the response period ended, bringing the total response-rate to 74% (total 162 questionnaires, 36 questionnaires from cardiologists; = 32% of the 110 estimated HF dedicated cardiologists and 126 questionnaires from HF nurses; = 57% of the 220 estimated HF nurses). Compared to the responders, the non-responders were equally divided among working region and in professional position. All baseline characteristics of the study population had a normal distribution; there were no extreme outliers (Table II). Thirty-five percent of the responders had experience in working with telemonitoring systems.

Basic characteristics of the study population (Table 2)

Respondents had a mean age of 48 ± 8 year, and 68% ± 45 were female. Of the respondents, 22% were cardiologists and 78% were HF nurses. The mean years of work experience in the current position was 14 ± 9 years, and the respondents worked with HF patients for an average of 19 ± 10 hours a week. The mean experience in years of working with computers was 17 ± 6 years. Cardiologists have more experiences in years of working with computers in general ($p = 0.01$) as in more complex computer routine as working with operating systems ($p = 0.02$) and working with software applications

Table 2: Summary of Baseline Characteristics Perceived Barriers in CDSS (N=162)

	Cardiologist		**HF nurse**		**Total**	
	(N=36)	**SD**	**(N=126)**	**SD**	**(N=162)**	**SD**
Characteristic						
Age (mean),y	50	8	47	9	48	8
Female sex (%)	9(25)	45	102(82)	36	111(68)	45
Work region						
North	9		27		36	
Middle	13		45		58	
South	12		53		65	
Education						
University	34		5		39	
Master			40		40	
Applied science			86		86	
Years of experience in current position (mean)	16	9	6	3	8	6
Working hours per week with HF patients (mean)	11	10	21	8	19	10
Experience with computers (y)	19	7	16	5	17	6
Operating systems	16	7	13	5	14	6
Software applications	16	6	12	5	13	6
Programming language						
Email	13	5	13	4	13	5
Internet	13	4	13	4	13	5
Use of telemonitoring systems (%)	49		32		35	

($p = <0.01$). No differences were found between cardiologists and HF nurses regarding the use of email and the internet (p=ns). Respondents reported no experience with programming language, but did have 13 years of experiences using email and the internet. It is known from earlier experiences and field research that specific CDSS systems for HF in the Netherlands are seldom used. However, one third of the total respondents had experience in using telemonitoring. (Table 2) Because most of the telemonitoring systems that are used in the Netherlands have some CDSS functionality incorporated (e.g. advice to take action based on incoming alerts) it seems justified to assume that 30% of the responders have more or less experiences in using CDSS and therefore responded to the questionnaire based on practical experiences. For the score of all respondents and the separate scores of cardiologist and HF nurses we refer to Table 5. All single items of the CDSS questionnaire were normally distributed.

Responsibility and trust (R&T)

Towards more barriers; sixty-five percent of the respondents indicated they believe that a CDSS can make mistakes. The "clinical expertise" of the healthcare provider was rated as more important and not easily replaced by a computer. The human factor in interpreting clinical patient data and making decisions on treatments was estimated as more important than an advice from a CDSS (98%). Ninety percent stated that advices of a CDSS should always be checked. Seventy-nine percent stated that they are responsible for the treatment of "their" patients and not a CDSS. Sixty-five percent of the respondents stated that they did not want to depend on a CDSS and 50% reported that they still felt responsible for an advice given by a CDSS. Forty-nine percent of the respondents stated that they always checked an advice given by a CDSS and 87% stated that they will always check how a CDSS generates an advice.

Towards less barriers; most respondents stated that a CDSS can give useful advice about the treatment they should implement (80%). Thirty-five percent reported that in their opinion a CDSS is able to assess patient data, and 18% of the respondents reported that they would easily heed to an advice given by a CDSS.

Barriers and threats (B&T)

Towards more barriers; one third (32%) reported that advice given by a CDSS complicates the treatment process. Also, one third (30%) stated that if they have to adapt advices of a CDSS this would costs them time. Sixty-five percent was uncertain about whether advices of a CDSS would improve their care.

Nearly 75% of the respondents were uncertain about the time it will take to work with a CDSS during their patient contact. Twenty percent found it confusing that a CDSS gives advice about their treatment, and 70% were uncertain whether such an advice should be adapted or not. More than 80% of the respondents did not know whether a CDSS especially designed for HF patients would be convenient. Seventy percent stated that they would always notice if deviations or shortcomings in data, such as laboratory tests, physical examinations, and medication appear or are present. Forty-nine percent of the respondents asserted that the development of a CDSS is still in its infancy, and 25% indicated that they need complementary computer skills to work in a satisfactory way with a CDSS. Seventy percent were not sure or disagreed that following a treatment advice given by a CDSS has no influence on whether or not the patient takes a doctor or a nurse seriously. Thirty-nine percent reported that a "normal/standard" patient record provides sufficient information. Ninety percent disagreed with the statement that anyone can treat a HF patient with the help of a CDSS.

Towards less barriers; sixty-two percent of the respondents reported that advice of a CDSS on how to treat a HF patient is a welcome supplement to their own expertise, whereas another 30% reported that a CDSS that works with guidelines can be adapted

Table 3: Differences found in response to a selection of the questions between HF nurses (HF) and cardiologists (cardio).

	% agree			% not agree		
	HF	cardio	diff.	HF	cardio	diff.
Knowledge management						
A CDSS gives me useful information about the treatment.	68	43	26	0	3	3
A warning from a CDSS about the course of treatment is very welcome.	36	62	26	21	6	15
I can determine the optimal dose of heart failure medication much faster with the help of a CDSS.	36	50	14	21	12	9
Responsibility and Trust (R&T)						
The treatment I prescribe to my patients could depend on a CDSS.	36	65	29	23	27	4
A CDSS can give advice about the treatment I should implement.	81	67	14	6	6	0.2
The Healthcare Inspectorate should stimulate the use of a CDSS that can provide treatment advice.	21	18	4	18	32	14
Barriers and Tread (B&T)						
When I use a computer during patient contacts, this does not influence my relationship with the patient.	45	32	13	29	55	26
A CDSS could play a dominant role during a consultation.	20	9	11	38	53	15
A CDSS reduces my work load.	10	0	10	37	49	12
The application of guidelines by a CDSS is still in its infancy.	36	64	28	2	0	2
A CDSS that works with guidelines can be adapted quickly.	27	44	17	2	10	8

quickly. A total of 46% of the respondents stated that the use of a CDSS will not influence the relationship with their patients and 55% stated that a CDSS supplements their independency as a HF care expert.

Knowledge management (KM)

Towards less barriers; sixty percent of the respondents declared that a CDSS can give advice about treatment and gives insight in the treatment process of a HF patient and thus has additional value for the treatment. Fifty percent stated that a CDSS especially designed for HF has added value for their work, and 50% believed that it can give useful information about the treatment. Eighty percent proclaimed that information supplied

by a CDSS adds (additional) value to their own knowledge of treating HF patients. Fifty percent reported that a CDSS makes it easy to use HF guidelines and that it can update protocols, and sixty percent reported that they could learn from a CDSS. The respondents stated that their ability to apply guidelines improved and they felt positive about a warning or alert given by a CDSS about the course of the treatment. Forty percent reported that with the help of a CDSS they are better able to adjust optimal dosages of medication. Sixty-five percent were of the opinion that other healthcare providers involved in care for HF patients should all work with the same CDSS system.

Towards more barriers; Twenty percent stated that they are not better able to adjust optimal dosages of medication with the help of an CDSS. Another 10% stated that a CDSS that provides advice about treating heart failure gives no insight into their treatment process.

Differences between cardiologists and HF nurses (Table 3)

In the descriptive analyses of the constructs, differences were found between the groups of respondents (cardiologists versus HF nurses). In the 2-tailed Pearson correlation tests of the total group, no significant correlation between age, gender, years of work experience, general computer experience or experience with operating systems, computer programs, and email/internet within the three constructs (B&T, R&T and KM) were found for the total group. This means that there is no significant relation between the baseline characteristics and B&T, R&T, and KM. The most prominent differences with respect to the three constructs are described in Table III. In the subgroup of HF nurses there was a significant positive correlation between years of using the internet ($r= .33$, $P<0.01$), years of using email ($r= .23$, $P<0.05$), and years of computer experience ($r= .29$, $P<0.01$) in relation to R&T. There was also a positive correlation between years of computer experience and the construct KM ($r= .22$, $P<0.05$).

In the multiple regression analyses the variables age, years of experience in current function, years of experience in working with computers, the use of telemonitoring, and the construct of KM itself were tested on their possible association with B&T and R&T (Table IV). These variables were chosen for their relevance and strong presence in the baseline characteristics. Only KM had a strong, independent association with the constructs B&T ($B= .55$, $P=<.01$) and R&T ($B=.50$, $P=<.01$). Respondents who reported that they were currently using telemonitoring systems tended to experience less B&T ($B= -.13$, $P=.06$) In summery we found that warnings, alerts, and advices given by a CDSS to enable better guideline adherence seem to be less adopted by the group of HF nurses.

Cardiologists find the use of a CDSS a negative interfering source in their patient contact and are not convinced of reduction in work but are in comparison to HF nurses more aware of the value of a CDSS in terms of medication adherence. In the group of HF

Table 4: Multi variate regression analyses; association of B&T and R&T with independent variables (all respondents)

Barriers and Threats (B&T)				
		95% CI		
	B (SE)	Lower	Upper	P-value
Age	-.02 (.05)	-.10	.07	.74
Knowledge management	.55 (.09)	.57	.92	<.01
Years of experience in current function	.09 (.06)	-.05	.19	.24
Years of experience in working with computers	-.03 (.06)	-.14	.09	.63
Use of telemonitoring	-.13 (.05)	-2.08	.06	.06

Responsibility and Trust (R&T)				
		95% CI		
	B (SE)	Lower	Upper	P-value
Age	-.01 (.04)	-.09	.08	.91
Knowledge management	.50 (.09)	.46	.82	<.01
Years of experience in current function	.11 (.06)	-.03	.20	.16
Years of experience in working with computers	-.03 (.06)	-.09	.14	.65
Use of telemonitoring	-.09 (.53)	-1.70	.40	.23

nurses, a significant positive correlation between variables related to computer experience and the examined construct (R&T and KM) were found, which indicate reduced barriers towards CDSS.

Discussion

In this first study to examine the number of perceived barriers on working with a CDSSs by cardiologists and nurses, we found a substantial number of perceived barriers in using a CDSS in two of the three constructs (R&T and B&T). The results of the construct KM in general showed that most respondents do see the added value of a CDSS in terms of learning, being better informed about the treatment, and a possibly better guideline adherence. Our study explored whether demographic factors, education, and/or computer experience are related to the number of perceived barriers in using a CDSS. Insight into and understanding of these barriers is important because the implementation of CDSSs in HF care can play a significant role in optimizing the management of HF medication according to the guidelines.

It is generally known that optimizing medication management in HF patients reduces readmission and mortality rates. The respondents of this study were both highly

Table 5: 49-items of the Perceived Barriers on CDSS questionnaire and scores in mean, SD and percentage agree, disagree and neutral of cardiologist, HF nurses and all respondents. Constructs; R&T (responsibility and trust) B&T (barriers and threats) KM (knowledge management)

			Cardiologists N=36				HF nurses N=126				All respondents N=162			
	Questions of the perceived barriers on CDSS questionnaire	**Construct**	**Mean±SD**	**agree (%)**	**neutral (%)**	**disagree (%)**	**Mean±SD**	**agree (%)**	**neutral (%)**	**disagree (%)**	**Mean±SD**	**agree (%)**	**neutral (%)**	**disagree (%)**
1	A CDSS that gave me advice about how to treat heart failure would be a great help.	R&T	2.6± .9	49	34	14	2.7±.8	35	46	15	2.7±.8	41	44	15
2	Computers cannot make mistakes.	R&T	3.5±1	23	17	60	3.6±.9	15	18	66	3.6±1	17	18	65
3	When I use a computer during patient contacts, this does not influence my relationship with the patient.	B&T	3.3±1	31	14	54	2.9±.9	42	22	28	2.9±1	46	22	36
4	My clinical expertise could be replaced by a computer.	R&T	4.6±.5	0	0	100	4.4±.6	2	2	96	4.5±.6	13	1	97
5	When I follow the treatment advice given by a CDSS, my patient takes me just as seriously as always.	B&T	2.9±.7	29	53	18	2.9±.8	30	46	22	2.9±.8	31	49	20
6	It is not necessary to check the advice given by a CDSS.	R&T	4.1±.9	9	3	89	4.1±.6	2	6	90	4.1±.7	4	6	90
7	The advice given by a CDSS is easy to follow.	R&T	2.9±.5	18	76	6	2.9±.5	19	69	12	2.9±.5	18	72	10
8	I readily adopt the advice given by a CDSS.	R&T	3.2±.7	15	59	26	3.2±.5	5	66	29	3.2±.6	7	65	28
9	A CDSS that supports me does not undermine my independence as a health care provider.	B&T	2.6±.9	56	23	20	2.5±.5	58	27	13	2.5±.8	60	26	14
10	The treatment I prescribe to my patients could depend on a CDSS.	R&T	2.8±.9	64	29	26	2.9±.7	36	40	22	2.9±.8	36	39	25
11	A CDSS could play a dominant role during a consultation.	B&T	3.5±.7	9	38	53	3.2±.8	20	42	38	3.3±.8	17	42	41
12	A CDSS reduces my work load.	B&T	3.5±.6	0	51	48	3.3±.7	10	53	37	3.4±.7	7	54	39
13	A CDSS that provides advice about treating heart failure gives me insight into my treatment process.	KM	2.6±.7	53	34	12	2.5±.6	56	35	8	2.5±.7	57	35	9

			Cardiologists N=36				HF nurses N=126				All respondents N=162			
	Questions of the perceived barriers on CDSS questionnaire	**Construct**	**Mean±SD**	**agree (%)**	**neutral (%)**	**disagree (%)**	**Mean±SD**	**agree (%)**	**neutral (%)**	**disagree (%)**	**Mean±SD**	**agree (%)**	**neutral (%)**	**disagree (%)**
14	A CDSS that can advise me about how to treat my patients is a welcome supplement.	B&T	2.3±.4	65	35	0	2.4±.6	62	33	5	2.4±.6	63	33	4
15	As a health care provider, I am responsible for the treatment I provide.	R&T	4.6±.4	100	0	0	4.5±.5	97	2	1	4.5±.6	97	2	1
16	A CDSS specifically for heart failure would have added value for the way I do my job.	KM	2.5±.5	45	54	0	2.5±.5	54	43	3	2.5±.6	52	47	2
17	A CDSS that gives treatment advice only complicates the treatment process.	B&T	2.8±.6	12	54	33	2.7±.6	20	57	22	2.8±.6	32	57	11
18	The Healthcare Inspectorate should stimulate a CDSS that can provide treatment advice.	R&T	3.3±.9	18	50	32	2.9±.6	21	61	18	3.0±.7	20	59	21
19	I do not want to be dependent on the manufacturers of a CDSS that gives me advice on how to treat patients.	R&T	3.7±.7	67	24	9	3.6±.7	64	29	7.2	3.6±.8	65	28	8
20	I am able to feel responsible for advice given by a CDSS.	R&T	2.7±.8	46	29	23	2.6±.5	51	35	13	2.6±.8	51	34	15
21	During consultations, the patient file provides ample information.	B&T	3.0±.9	32	38	29	3.1±.8	41	28	31	3.1±.9	39	31	31
22	A CDSS can give advice about the treatment I should implement.	R&T	2.3±.7	67	26	6	2.4±.5	81	14	6	2.3±.6	78	17	6
23	I always have to assess the advice of a CDSS.	R&T	4.3±.8	89	9	3	4.2±.5	95	3	2	4.2±.6	94	4	2
24	A CDSS gives me useful information about the treatment.	KM	2.5±.7	42	54	3	2.3±.4	68	32	0	2.4±.6	62	37	1

			Cardiologists N=36				HF nurses N=126				All respondents N=162			
	Questions of the perceived barriers on CDSS questionnaire	**Construct**	**Mean±SD**	**agree (%)**	**neutral (%)**	**disagree (%)**	**Mean±SD**	**agree (%)**	**neutral (%)**	**disagree (%)**	**Mean±SD**	**agree (%)**	**neutral (%)**	**disagree (%)**
25	A CDSS that works with guidelines can be adapted quickly.	B&T	2.7±.7	44	47	9	2.7±.5	27	71	2	2.7±.6	30	66	3
26	Information from a CDSS about treatment can supplement my own knowledge.	KM	2.2±.6	83	14	3	2.2±.5	81	15	3	2.2±.5	81	16	3
27	A CDSS makes it easy to keep heart failure guidelines and protocols up to date.	KM	2.5±.7	57	34	9	2.4±.5	58	41	1	2.4±.6	58	40	2
28	A CDSS is able to assess patient data.	R&T	2.9±.8	39	45	15	2.8±.7	35	49	16	2.8±.7	36	48	16
29	A CDSS can indicate treatment priorities.	R&T	2.7±.8	50	29	20	2.7±.7	43	47	10	2.7±.7	44	44	12
30	Adapting the advice of a CDSS costs me extra time.	B&T	3.4±.8	41	53	6	3.3±.6	32	62	6	3.3±.6	33	61	6
31	I can learn from a CDSS.	KM	2.4±.6	65	29	6	2.3±.5	65	34	1	2.4±.6	65	33	2
32	Patient care improves with a CDSS.	B&T	2.9±.7	26	66	9	2.7±.5	32	64	4	2.8±.6	30	65	5
33	A CDSS can help me apply guidelines.	KM	2.3±.6	67	29	3	2.3±.5	69	31	0	2.3±.5	63	31	1
34	A CDSS supplements my independence as a heart failure care expert.	B&T	2.7±.8	47	38	15	2.4±.6	60	34	6	2.5±.7	55	36	8
35	A CDSS that gives advice about treatment is dependent on other systems.	KM	3.6±.6	62	27	6	3.9±.6	74	25	1	3.8±.7	71	27	2
36	Anyone can treat a heart failure patient with the help of a CDSS.	B&T	1.7±.7	3	9	89	1.6±.6	0	80	92	1.6±.7	1	9	91
37	Using a CDSS during a patient contact takes too much time.	B&T	3.1±.5	18	73	9	3.0±.5	11	76	13	3.0±.5	13	75	12

			Cardiologists N=36				HF nurses N=126				All respondents N=162			
	Questions of the perceived barriers on CDSS questionnaire	**Construct**	**Mean±SD**	**agree (%)**	**neutral (%)**	**disagree (%)**	**Mean±SD**	**agree (%)**	**neutral (%)**	**disagree (%)**	**Mean±SD**	**agree (%)**	**neutral (%)**	**disagree (%)**
38	A CDSS that gives advice is confusing.	B&T	3.0±.8	29	38	32	2.9±.7	17	54	29	2.9±.7	20	51	29
39	Advice from a CDSS must always be adapted.	B&T	2.9±.6	12	64	24	3.0±.5	13	73	14	3.0±.6	13	71	16
40	If guidelines are included in a CDSS, I will always be up to date.	R&T	2.7±.9	54	29	17	2.6±.6	50	43	7	2.6±.7	51	40	9
41	A CDSS specifically designed for heart failure is easy to use.	B&T	3.0±.5	15	73	12	2.9±.4	11	84	4	2.9±.4	12	82	6
42	A warning from a CDSS about the course of treatment is very welcome.	KM	2.4±.7	62	32	6	2.4±.6	36	43	21	2.4±.6	62	34	4
43	I can determine the optimal dose of heart failure medication much faster with the help of a CDSS.	KM	2.7±.7	50	38	12	2.8±.8	36	43	21	2.8±.8	39	43	19
44	A CDSS can provide me with supplementary treatment information.	KM	2.3±.7	76	18	6	2.2±.5	80	17	2	2.2±.5	79	18	3
45	I must always be able to check how a CDSS arrives at the treatment advice.	R&T	4.2±.5	91	9	0	3.9±.5	85	13	2	4.0±.6	86	12	1
46	I always notice abnormal diagnostic values immediately during treatment.	B&T	3.5±.9	60	23	17	3.7±.7	71	23	6	3.7±.8	68	23	8
47	The application of guidelines by a CDSS is still in its infancy.	B&T	4.0±.8	64	36	0	3.4±.6	35	62	2	3.5±.7	41	57	2
48	You need additional computer skills to use a CDSS.	B&T	3.0±.8	29	47	23	3.0±.7	23	54	24	3.0±.7	24	52	23
49	Other care providers involved with my patient would have to work in the same system as me.	KM	2.3±.7	62	32	6	2.1±.7	69	30	1	2.2±.7	67	31	2

experienced in working with HF patients, and in working with computers, email, the internet, and software programs. However, contrary to results reported in earlier studies,[21,27] in the subgroup of cardiologists (N=36) no correlation was shown between age; gender; experiences in working with computers, programs, and software on perceived barriers. The often heard presumption that "working with computers" positively influences the capability to work with CDSSs and hence causes fewer barriers was therefore not proven for the group of cardiologists in this study. This is an important finding because previous results from other studies suggest that there might be a relationship between poor computer skills, age, and computer literacy in physicians, which in turn might facilitate or hinder the implementation of CDSSs. However, in the subgroup of HF nurses (N=126) different types of experience in working with computers strongly influenced the number of perceived barriers, in particular with respect to responsibility and trust (R&T). More experience in working with computers was related to higher scores on R&T and therefore to a lower number of perceived barriers. This dissimilarity between cardiologists and HF nurses might be explained by differences in professional position and the amount of autonomy and/or final responsibility in treatment decisions. It is imaginable that HF nurses experience more support from a CDSS as a 'helper' in making important treatment decisions instead of experiencing a loss of autonomy.

Interestingly, a high percentage of respondents who already worked with telemonitoring were found. This could have influenced the number of perceived barriers, because the telemonitoring systems used in the Netherlands have CDSS functionality incorporated (e.g. advice to take action based on incoming alerts). Beside these experiences in working with CDSS's, working with this new technology probably indicates a certain preference for technology. For this reason we corrected by using telemonitoring as a covariate in the multivariate regression analyses. However, no significant relation between the constructs and the use of telemonitoring itself was found. It is remarkable that when a CDSS is less informative and instead gives more direct and stringent advice (alerts, warnings, and request for additional information), respondents seem to have more hesitations or reserves towards a CDSS. This is interesting because this functionality in particular marks the main difference between 'regular' software and a CDSS. A possible explanation for this finding could be that this specific functionality of a CDSS is seen as causing a loss of professional autonomy.

In general, the barriers to the adaptation of a CDSS are similar in both the groups of HF nurses and the group of cardiologists, although some differences were found between the two groups. It is difficult to interpretate these differences because the scores on the constructs towards a greater or lesser number of barriers fluctuated as much in the group of HF nurses as in the group of cardiologists. However, warnings, alerts, and advices given by a CDSS to enable better guideline adherence seem to be less adopted by the group of HF nurses. This could be a result of who is actually performing the HF care in daily practice. A perceived feeling of lost autonomy can therefore be more present in the

young profession of HF nursing.

There were some known prejudices about CDSSs found in this study. We have seen statements confirmed or reject such as 'CDSS is still in its infancy', 'CDSS can reduce my workload', and 'CDSS can play a dominant role during a consult'. These are important factors to consider when introducing and implementing a CDSS in daily HF practice. These prejudices or presumptions can be seen as barriers and are associated with a lower adoption level of a CDSS, and can therefore possibly result in a decrease of adherence to guidelines. The construct Knowledge Management itself was, as expected, not a barrier and was associated with the constructs B&T and R&T. This indicates that a higher level of knowledge in understanding the underlying mechanism of a CDSS leads to a decrease in barriers. This is understandable, because comprehension of how a CDSS works gives a more realistic view of the possibilities and impossibilities of a CDSS. The fact that a CDSS is not a magic black box, but will only generate advice by means of predefined formulas and data provided by the HF professionals themselves, will give more attention to the system's capabilities. This could prevent disillusions and lead to a more positive attitude towards CDSSs.

Limitations

This study has some potential limitations. First of all, we are aware of the disadvantages of using data based on self-reports. Unfortunately, in the Netherlands we do not have a long history of experience in working with CDSSs in the field of HF. Second, the following two questions were central when developing the questionnaire: 'Did we identify the right constructs and independent variables to measure the strength of perceived barriers', and 'Are the constructs representative enough to determine the perceived barriers'? In our pilot we found that four of the five defined constructs (responsibility with trust, and barriers with threats), are strongly aligned to each other and exist in a continuum as it were. Because of this continuum, it was difficult to measure these constructs separately. Combining these related constructs therefore seemed a logical and explainable action. Finally, although the overall response rate of this questionnaire was more than reasonable (74%) and the distribution is in line with the distribution of HF- dedicated cardiologists and HF nurses working in the Netherlands, the actual response of the cardiologists was 36 questionnaires, making the sample of cardiologist rather small with consequently effect for the power of the study. The identified constructs used in this research were based on the available literature on barriers to the adoption of CDSSs. Therefore, we believe that we have sufficient reasons to acknowledge that the identified constructs indeed give information on barriers to using CDSS, although further research should be conducted to give more insights in this specific field.

Conclusion

The first and second aim of our study was to explore the type and number of perceived barriers of cardiologist and HF nurses in using a CDSS in the treatment of HF patients. This study showed that HF nurses and cardiologists working in HF clinics in the Netherlands - while taking into account differences between the groups - indeed have substantial perceived barriers in all three examined constructs when working with a CDSS. The third aim was to explore whether characteristics such as age, gender, and experience in working with computers influenced the strength of the perceived barrier. In the group of cardiologists this was not the case. However, in the group of HF nurses, experience in working with computers and with email and the internet, had a strong effect on B&T and R&T.

These are therefore factors that should be taken into consideration, as described in earlier studies. Our fourth aim was to assess the influence of Knowledge Management on R&T and B&T. Knowledge Management has a strong, significant association with perceived barriers, indicating that users who find the CDSS useful experienced less percieved barriers and that suggests that increasing knowledge will decrease barriers. Teaching future users about the underlying mechanism behind CDSSs can probably decrease the strength and number of perceived barriers. Though it is important to highlight the possibilities of a CDSS, it is perhaps even more important to discuss the impossibilities of a CDSS so as to adequately manage the expectations and presumptions of users about this kind of software support. In spite of the presumption that telemonitoring devices are 'smart devices' and require a higher level of computer literacy, no significant association between the use of telemonitoring and a decrease in barriers to the use of CDSSs was found.

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Chapter 8

Prescriber adherence of pharmacotherapy in heart failure disease management models

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Abstract

Background

Despite clear guidelines, patients often do not receive maximum doses of heart failure (HF) medication. Disease management programs (DMPs) are known to increase guideline driven prescriber adherence, but it is not known what differences exist in prescriber adherence between programs. Objective: 1: To explore the differences in prescriber adherence of three different HF-DMPs. 2: Explore if the severity of HF is related to the (sub)- maximum dose of HF medication in the three DMPs. 3: To explore possible differences in all cause mortality between the three HF DMP models.

Methods

Data from the Martini Hospital (MZH, computer-based decision support driven), the COACH study (nurse led basic and intensive patient education), and the DEAL study (an HF nurse with a dedicated HF physician) was used. Total percentages and (sub)-maximum dosage (75%-100% of the target dose) of angiotensin- converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARB), combined ACE and ARB, beta-blockers and Aldosterone antagonists were assessed. Multivariate logistic regression analyses were used to assess differences in prescriber adherence between the three DMP models and to analyze any relation to severity of HF. To gain insight in all-cause mortality and account for differences between the three groups we used propensity score analyses.

Results

Data from 1564 patients were analyzed (426 MZH, 898 COACH, 240 DEAL). The total percentages of the maximum dose of prescribed HF medication, except for Aldosterone antagonists stayed below 50%. There is a significant relationship between variables associated with the severity of HF and the maximum dose of HF medication. The (sub)-maximum dose of prescribed medication (75 and 100% of the target dose) was significant higher in patients in the DEAL group and MZH group compared to the COACH DMP group for ACE, the combination of ACE and ARB, and beta-blockers and for Aldosteron in the COACH group versus the MZH. For the (sub)-maximum dose of ARB no differences were found between the three groups. The survival of patients in the MZH and the intervention group of DEAL were both higher when compared with the patients of the COACH and the control group of DEAL patients.

Conclusion

The results showed that less than 50% of all patients received the maximum dosage HF medication as advised by guidelines, with the exception of Aldosteron blockers, even in DMPs that have medication uptitration as a specific component of DMP.

Variables that are an indicator of the severity of HF are related to the (sub)-maximum dose of prescribed HF medication. Adjusted for these variables, this study showed that HF DMPs that have a focus on optimization of medication significantly more often prescribe (sub)-maximum dosages of medication compared to a DMP that is focused on counseling. It is reasonable to assume that a higher prescriber adherence of medication results in better outcome in terms of survival.

Introduction

With a growing elderly population and improved survival after myocardial infarction, the prevalence of heart failure (HF) is increasing. HF is associated with high mortality and re-admission rates.[1] In order to manage the burden of HF, disease management programs (DMPs) are implemented.[2-5] DMPs can improve the outcomes of HF patients[6] and are recommended in the recent HF European Society of Cardiology (ESC) guidelines (Class I recommendation, Level of evidence A).[7] In these guidelines, a set of HF management components is recommended, such as optimization of HF medication, targeting to the maximum dosage. The ESC developed clear guidelines of starting up and up-titrating drug therapy in daily practice, and the HF pilot survey showed that adherence to these guidelines is satisfactory. However the number of patients who receive maximum doses of Angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARB), beta blockers and Aldosterone antagonists still remains suboptimal.[8,9] Barriers related to optimal guideline adherence include deficits in knowledge, skills and attitude of healthcare providers.[10-13] A possible helpful tool to overcoming these barriers is the use of a computer decision support system (CDSS).[14-17] Through repeatable alerts to start the right medication and reminders for up-titration under safe and controlled conditions, a CDSS can help in achieving a better prescriber adherence, resulting in a higher dose of evidence-based HF medication.[18,19] For the definition of prescriber adherence, we have adopted the description used by the National Institute for Health and Clinical Excellence (NICE) 2009 clinical guidelines:[20] "The extent of which the prescriber's action matches the agreed recommendations".

With respect to practical implications this indicates that the dosage of HF medication (ACE-inhibitor, ARB, beta blocker and Aldosterone antagonist) should be uptitrated to the recommended target dosage as pointed out in the HF guidelines. In these ESC HF guidelines, optimizing medical therapy is described as an important component of HF DMP programs.

In the Netherlands at least three HF DMP models have been used; The first is a model in which a combination with a CDSS in standard HF care is used in an HF outpatient clinic of the Martini Hospital (MZH) in the Netherlands.[21,22] The effects of this model were not studied until recent involvement in a clinical trial.[23] The second model is the DMP used in the COACH study.[24] COACH was designed to explore a possible difference between HF care provided by cardiologists, compared to two levels of an intensive nurse-led HF DMP. Data from this trial showed that this model was not effective in reducing the primary endpoint of time to first HF readmission and all cause mortality. The third model is the DEAL model, which tested the effects of collaboration between an HF nurse and a dedicated HF physician compared to standard medical care. The primary outcome in the DEAL was a reduction of hospitalization for HF and/or all-cause mortality and an improved functional NYHA class and quality of life. This model had a strong focus on guideline prescriber adherence, and one important outcome in this study was a

significantly higher dose of prescribed HF medication in the intervention group.[25] Since optimal HF medication therapy is directly related to a better outcome, we aimed to gain more insight into the possible beneficial effects in terms of clinical outcome of these three different HF DMPs in relation to the extent of prescriber adherence.

The aims of the present analysis therefore are (1) to explore differences in prescriber adherence of HF medication (ACE-inhibitors, ARB, beta-blocker and Aldosterone antagonist) in total percentages and (sub) maximum doses of medication in three different HF DMPs: a CDSS-driven intervention (MZH), a nurse-led basic and intensive patient education (COACH), and an HF nurse and physician-directed model (DEAL); (2) to explore the relationship between severity of HF and the maximum dose of HF medication in the three different HF DMPs; (3) to explore possible differences in all-cause mortality between the three HF DMP.

Methods

Patient data from the Martini Hospital's HF outpatient clinic in Groningen, from the COACH study (Coordinating study evaluating Outcomes of Advising and Counseling in Heart Failure) and from the DEAL HF study (Deventer-Alkmaar HF project) were pooled in this analysis. Details on the design of the COACH and DEAL study and the CDSS model used at the MZH have been published elsewhere.[14,25,26] Patients with systolic HF (LVEF <45) were followed for a period of 12, respectively 18 months in the three different DMPs and included in this analysis. For this study, we consider the maximum dose of medication (100% of the target dose) as the highest adherence. However, since the HF guidelines are based on medication trials such as MERIT,[27] SOLVD[28] and RALES[29] and the majority of patients in these studies received 75% of the target dose, with significantly positive effects on mortality and readmission outcomes, we also consider 75% of the target dose as optimal adherence to the guidelines and clinical relevant. Therefore we observed the total percentages of HF medication (e.g. the number of patients that use a beta-blocker) and the maximum and sub-maximum target dosage (100% and 75%) of the separate HF medications in individual patients prescribed.

We observed this for the HF medications; ACE-inhibitor, ARB, combined use of ACE and ARB, beta blocker and Aldosterone antagonist. Although the ESC HF 2001 guidelines recommended that 50 mg of Aldosterone antagonist was indicated for patients in NYHA class III/IV, we adhered to 25 mg as the maximum dose because first, the DEAL study started in 2000 and in that specific period, 25 mg Aldosterone antagonist was set as the maximum dose, and second in the 2001-2005 HF guideline, Aldosterone antagonists were also frequently prescribed as an additive diuretic, besides being intervention therapy in the renin angiotensin Aldosterone (RAAS) system. Because there is no maximum or "optimum" dose for diuretics and the use or dose of diuretics is not related to a better outcome, we present only the total percentages of diuretics in the descriptive analyses.

To calculate the percentages of prescribed doses of medication in quartiles at the end of the DM program, we assumed that patients who were on 100% of the target dose also were on the at least 75%, 50% and 25% of the target dose criteria. Patients who were on the at least 75% criterion of the target dose also were on the at least 50% criterion and 25% of the target dose criterion.

Intervention models

Martini Hospital (MZH)

Martini Hospital's DMP[14,21] consists of a CDSS that included patient records and data collected during standard care. For this study, we collected data from a theoretically ascertained baseline and 18 months of follow-up (similar to the period in which patients in the COACH were included. i.e., October 2002 to August 2006). Permission to access this hospital record was granted by the local Ethics Committee (M12.112063). Although written informed consent was not necessary for use of the MZH group data according to the local Ethics Committee, we asked the 429 patients if they had any objection to our use of their files. Three patients did not give their permission and were therefore excluded from m this analysis.

HF patients with a reduced ejection fraction and NYHA functional class II- IV were referred to the HF DMP after admission for HF or a visit to the outpatient clinic, within a 4 week period. The treatment, both pharmacological and non-pharmacological were controlled by and integrated into a CDSS, based on the ESC HF guidelines. The software for this CDSS was specifically developed for the treatment of patients with HF and uses algorithms for starting and up-titrating HF medication to maximum tolerated dosage. The CDSS is linked to the hospital laboratory and electrocardiography database to provide the titration algorithms with the necessary data. History and actual use of medication was introduced manually into the CDSS, due to a lack of integration of the pharmacological database. The treatment and number of visits are structured through automatically generated advice from the CDSS. Patients' education and development of self-management are important issues, but there is a strong focus on optimization of HF medication. This model is defined by the users as an "ICT-guided medical-nursing" model, with no interference of a cardiologist in the pharmacological treatment of HF. However, in the case of a new (or other cardiovascular) diagnosis, persistent complaints or the need for supervision, consultation by a cardiologist was optional. If the HF medication was optimal and patients were aware of signs and symptoms of deterioration and know how to respond adequately, they were discharged from the HF outpatient clinic and referred to regular follow-up by the cardiologist. Follow-up by telephone was used frequently for the adjustment of treatment and evaluating interventions, as well as for the up-titration of medication at a distance, without seeing the patient at the outpatient clinic. The mean visit rate of patients in the MZH DMP (face-to-face visits) was 5 visits in a period of 18 months, excluding telephone calls (Table 1).

COACH

The COACH study was a multicenter, randomized controlled trial, designed to evaluate the effects of education and counseling by a HF nurse on clinical outcome. For our study, we pooled and used the data from the basic and intensive support groups. Because the COACH study did not differentiate between HF patients with reduced or preserved ejection fraction, for this analysis, we excluded the patients with a left ventricular ejection fraction above 45%. Patients in NYHA functional class II-IV were referred within 2 weeks after an admission for HF to the HF DMP, in addition to usual routine management by their cardiologist. This routine management included an outpatient visit after hospital discharge and then every 6 months afterwards. Patients were scheduled for additional visits to the HF nurse at the outpatient clinic and had monthly contact with the nurse (intensive treatment). Patients were educated using a protocol, and behavioral strategies were used to improve patient compliance. In addition, patients were instructed to contact the HF nurse if there was any change in their condition. In the first month after hospital discharge, weekly telephone contact was made and patients were visited at home by the HF nurse. Furthermore, telephone calls, 2 home visits, and multidisciplinary advice given by a physiotherapist, dietician and social worker were part of the intensive support intervention. The main focus of the COACH DMP was education, counseling and motivation. The designers of this study classified the treatment as "counseling intensive". Although starting and uptitration of HF medication by HF nurses within the time window of the protocol was allowed, the majority of the patients were pharmacologically treated by their cardiologists. Patients received at least 13 or 26 visits in an 18-month follow-up period (depending on the study protocol), including telephone calls (Table 1).

DEAL

The DEAL-HF study was a parallel group, randomized controlled trial designed to compare standard (usual) HF care to an intensive intervention by a combination of visits from an HF physician and a HF nurse. For this study, we used the data from the intensive treatment and control group. Patients in NYHA class III or IV after an admission or visit to the outpatient HF clinic were referred to the HF DMP. The patients received an intensive follow-up with 10 visits, performed at increasing intervals by both an experienced HF nurse and an HF physician. Comprehensive education and counseling was given to increase knowledge, skills and motivation. In the DEAL intervention, there was a strong focus on optimization of HF medication, facilitated by the presence of a physician, including the assessment of electrocardiography and laboratory results. The physician interpreted signs and symptoms, collected possible side effects of the prescribed medication and performed physical examination used clinical judgment and optimized pharmacological therapy. In addition there was emphasis on recognizing and how to anticipate adequately signs of deterioration. Increased access to healthcare, including extra visits or intervention by a cardiologist whenever needed, was optional. The total

follow-up period was 12 months with a total number of nine face-to-face instances of contact with the HF nurse and HF physician, excluding telephone contacts and extra visits when needed (Table 1).

Statistical analyses

Descriptive statistics were used to characterize the sample; data are presented as mean ± standard deviation when normally distributed, as median and interquartile range when non-normally distributed, and as frequencies and percentages for categorical variables. Differences between baseline variables were evaluated by Student's t test, Kruskal-Wallis test, Mann-Whitney U, Wilcoxon, chi-square or Fisher exact tests, as appropriate.

Data on medication at entry to the MZH HF DMP were not available. Therefore the differences in total percentage of medication at entry can be assessed only between the COACH and the DEAL group. To assess associations between the maximum dose of HF medication and the severity of HF, we performed multivariate logistic regression analyses with both variables associated with the severity of HF7 and with variables that were univariate associated (P=< 0.01) with maximum dose of HF medication, resulting in: age, sex, LVEF, previous hospitalization, days of hospitalization, hospitalizations during treatment, ischemic etiology, NYHA functional class, laboratory values (eGFR, sodium, hemoglobin), heart-rate, and blood pressure. As pointed out in the methods section we performed analysis with patients who were on (sub)-maximum recommended dose (100% and 75% of the target dose) of ACE-inhibitor, ARB, the combined ACE and ARB, beta blocker and Aldosterone antagonist. We performed these analyses on the composite of all HF medication as well on the separate medication To assess whether a DMP had an independent effect on the maximum and sub-maximum dose of prescribed medication, we introduced each DMP into our multivariate model. In order to gain insight into the observed survival, associated with the different DMPs we combined the care as usual groups of COACH and DEAL and tested them against the groups of patients allocated to the different DMP models. Because patients were not randomly assigned to the DMP models, we matched patients based on their probability or propensity to receive the model at study entry.[30,31] The Propensity Score is the conditional probability of receiving an exposure (e.g. a DMP model) given a vector of measured covariates, and can be used to adjust for selection bias when assessing causal effects in observational studies. The estimated propensity score was obtained from the fit of a multinominal logistic regression model for which we considered the following variables: age, gender, etiology, LVEF and NYHA class, co-morbidities, prior admission for HF, laboratory (hemoglobin, eGFR, sodium, creatinine), blood pressure and heart rate. We used caliper matching, restricting propensity score matches to be within 0.05. P-value was set at 0.05. Analysis were performed using PASW version 18.0, R version 2.15.1. and STATA 11.0.

Table 1: Characteristics of the three different heart failure disease management models

	MZH	**COACH**	**DEAL**
Intensive treatment	yes	yes	yes
Follow-up	18 months (regular care)	18 months (protocol)	12 months (protocol)
Visit rate	5 (mean) excluding telephone contacts	13-26, depending on the protocol, including telephone contacts	9, excluding telephone contacts
Inclusion in DSM	After readmission or outpatient clinic	After readmission	After readmission or outpatient clinic
HF nurse	yes	yes	yes
Physician	no	yes	yes
Assessment of physical condition, ECG and lab results	yes	yes	yes
Home visits	no	yes	no
Treatment plan	yes	yes	yes
Education/Counseling	yes	yes	yes
Compliance	yes	yes	yes
Monitoring signs and symptoms of deterioration	yes	yes	yes
Telemonitoring	yes (telephone)	yes (telephone)	yes (telephone)
Telephone access for patients	yes	yes	yes
Easy access to care	yes	yes	yes
Fulltime accessible (24/7)	yes	yes	no (working hours)
Focus optimalisation of medication	yes	no	yes
Multidisciplinary advice	yes	yes	yes
Multidisciplinary team	no	yes	no
ICT-guided DSM/CDSS	yes	no	no
Treatment according the ESC guidelines	yes	yes	yes

Table 2: Baseline characteristics of patients in the three different HF DSM models

characteristics	MZH N=426	COACH N=560	DEAL N=118	Control DEAL N=122	Control COACH N=338	P-value MZH vs. COACH	P-value MZH vs. DEAL	P-value COACH vs. DEAL
Mean age (SD), y	71 ±13	70 ±11	70±10	70	71			
Female	38%	34%	34%	21%	40%			
Etiology CHF: Ischemia	60%	42%	63%	65%	42%	<0.001		<0.001
Prior hospital admission for CHF	66%	31%	48%	51%	35%	<0.001	<0.001	<0.001
Days of hospitalization before inclusion, mean	5	10	23	17	13	<0.001	<0.001	<0.001
LVEF, mean	34%	28%	31%	31%	34%	<0.001	<0.001	0.008
NYHA functional class						<0.001	<0.001	<0.001
II	70%	48%	1%	1%	54%	<0.001	<0.001	<0.001
III	23%	48%	96%	94%	42%	<0.001	<0.001	<0.001
IV	2%	3%	2%	5%	4%			
History of MI	58%	45%	53%	43%	56%	<0.001		
Hypertension	52%	39%	39%	12%	46%	<0.001	0.018	
Atrial fibrillation	44%	41%	25%	28%	48%		<0.001	<0.001
Diabetes	27%	27%	32%	28%	30%			
Stroke	12%	10%	11%	9%	11%			
COPD	25%	26%	29%	28%	25%			
History of PCI	19%	12%	14%	16%	9%	0.044		
History of coronary bypass	18%	16%	19%	27%	17%			
Sodium, mean (SD)	140 ±3	139 ±4	138 ±3	138	139	<0.001	<0.001	<0.001
Creatinine (SD)	114 ±47	121 ±47	123 ±37	130	131	0.012	0.029	
eGFR, mean (SD)	60 ±21	57 ±21	53 ±15	51	52	0.029	<0.001	0.024
Hemoglobin (mmol/l) (SD)	8.4 ±1	8.3 ±1	8.4 ±1	8.4	8.0			
Mean systolic blood pressure (mmHg)	133	118	123	125	120	<0.001	<0.001	0.025
Mean diastolic blood pressure (mmHg)	76	68	73	76	68	<0.001	0.014	<0.001
Mean heart rate (bpm)	74	74	79	76	75		0.003	0.006
Diuretics	--	74%	94%	77%	96%	--	--	<0.001
ACE inhibitor	--	83%	84%	88%	69%	--	--	ns
ARB	--	11%	14%	7%	15%	--	--	ns
B-blocker	--	66%	60%	69%	65%	--	--	ns
Aldosteron antagonist	--	55%	36%	29%	54%	--	--	<0.001

Results

Baseline characteristics

In total, 1564 patients were included in our analyses: 426 from the MZH group, 898 from the COACH group (560 intervention, 338 control) and 240 from the DEAL group (118 intervention, 122 control). No differences in age and gender (mean age 70 years, female 35%) between the three DMPs were found. The mean LVEF was lower in the COACH group (28%), compared to the MZH (34%, p=<0.001) and DEAL groups (31%, p=0.008). The COACH group had a significantly lower percentage of patients with ischemic HF (42% versus 60-63%, p=<0.001) and the COACH and DEAL group had a lower percentage of prior hospitalizations before inclusion, compared to the MZH group (31%-48% versus 66%, p=<0.001). The majority of patients (70%) in the MZH group were in NYHA functional class II, whereas patients in the DEAL group were primarily in NYHA class III (96%, p=<0.001), a direct result of the different inclusion criteria. In the COACH group the distribution between NYHA class II and III was equal (48% vs. 48%) and also significantly lower than the DEAL group (p=<0.001). eGFR and mean systolic blood pressure were significant higher in the MZH group compared to the COACH and DEAL. Other baseline characteristics are presented in Table 2.

Total percentage of HF medication at entry and after follow-up period

At the point of patients' enrollment in the DMPs, the total percentages of ACE-inhibitors and beta blockers between the COACH and the DEAL groups were numerically not similar but did not differ significantly (ACE: 75% versus 83%, ACE/ARB: 84% versus 97%, beta blocker: 67% versus 60%) with the exception of a lower amount of prescribed Aldosterone antagonist for the DEAL population (36% versus 55%, p=<0.001) and a higher amount of prescribed diuretics (74% versus 93%, p=<0.001) for the DEAL group.

After the DMP follow-up period, the total percentage for ACE-inhibitor in the MZH group was 75%, COACH was 71% and DEAL was 83%, (no significant differences between the three groups). ARB in the MZH group was 22%, COACH 18% and DEAL 21% (no significant differences between the three groups). The combination of ACE and/or ARB in the MZH group was 96%, COACH 86% and DEAL 96%. (MZH versus COACH p=ns, MZH vs. DEAL p=ns, COACH vs. DEAL p=0.01). For B-blocker this is MZH: 82%, COACH 75% and DEAL 81%. (MZH versus COACH p=0.02). For Aldosterone antagonist MZH was 49%, COACH 51% and DEAL 60% (MZH versus DEAL p=0.05). Finally for diuretics the percentages were: MZH 75%, COACH 64% and DEAL 97% (DEAL versus MZH and COACH p=<0.001); see Table 3.

(Sub)-maximum doses of medication (100% and 75% of the prescribed target dose)

For the maximum doses of the separate HF medications (=100%) we observed that for all the DMP groups less than 50% of all patients had the maximum dose of HF medication (Table 3), with the exception of Aldosterone antagonist (25 mg), where we observed the highest percentage in the DEAL group (73%): MZH 56% and COACH 58%. (DEAL

Table 3: Medication at entry and end of disease management program in total percentages and quartiles of maximum dose.

	MZH N=426	COACH N=560	DEAL N=118	Control DEAL N=122	Control COACH N=338	P-value MZH vs. COACH	P-value MZH vs. DEAL	P-value COACH vs. DEAL
Medication at entry DMP-program								
ACE	Unknown	75%	83%	88%	69%	ns	ns	ns
ARB	Unknown	10%	14%	7%	15%	ns	ns	ns
ACE /ARB	Unknown	84%	97%	95%	84%	ns	ns	ns
B-blocker	Unknown	67%	60%	69%	65%	ns	ns	ns
Aldosterone	Unknown	55%	36%	29%	54%	ns	ns	<0.001
Diuretics		74%	95%	77%	96%	ns	ns	<0.001
Medication at end of DMP-program								
ACE	75%	71%	83%	91%	48%	ns	ns	ns
ARB	22%	18%	25%	12%	12%	ns	ns	ns
ACE /ARB	96%	86%	108%	102%	60%	ns	ns	0.01
B-blocker	82%	75%	81%	79%	54%	0.02	ns	ns
Aldosterone	49%	51%	60%	41%	59%	ns	0.05	ns
Diuretics	75%	64%	97%	99%	93%	ns	<0.001	<0.001
Percentage of prescribed dose at end of DM program								
ACE- inhibitor								
≥ 25%	75%	50%	77%	77%	42%			
≥ 50%	60%	33%	63%	64%	30%			
≥ 75%	32%	15%	36%	37%	12%	<0.001	0.46	<0.001
100%	31%	14%	35%	30%	11%			
ARB								
≥ 25%	23%	11%	20%	13%	12%			
≥ 50%	14%	8%	16%	12%	10%			
≥ 75%	3%	2%	6%	8%	4%	0.78	0.18	0.07
100%	3%	2%	6%	2%	3%			
ACE/ARB								
≥ 75%	34%	17%	41%			<0.001	0.24	<0.001
B-blocker								
≥ 25%	84%	48%	74%	53%	45%			
≥ 50%	60%	29%	59%	25%	30%			
≥ 75%	33%	13%	40%	1%	11%	<0.001	0.18	<0.001
100%	30%	11%	34%	1%	11%			
Aldosterone antagonist								
12,5 mg.	41%	17%	20%	16%	12%			
25 mg.	56%	58%	73%	68%	61%	ns	0.02	0.03
50 mg.	3%	24%	7%	16%	27%			

Table 4: Multivariate logistic regression analyses on the combination of (sub)-maximum dosage of HF medication (≥ 75% of the target dose), all groups; MZH, COACH, DEAL) adjusted for; age, sex, LVEF, previous hospitalization[1], days of hospitalization[2], hospitalizations during treatment[3], etiology (ischemic/non ischemic), co-morbidities, NYHA class II-III, laboratory, heart rate and blood pressure.

	OR	95% CI	P value
ACE-inhibitor (ACE)			
Age (years)	0.98	0.97-0.99	<0.001
Hospitalization[3]	0.68	0.51-0.92	0.012
NYHA III	1.01	1.00-1.02	0.002
Diast BP (mmHg)	1.02	1.01-1.04	0.005
Syst BP (mmHg)	1.01	1.00-1.02	0.008
Creatinine	0.99	0.99-1.00	0.027
eGFR	1.01	1.01-1.02	<0.001
Angiotensin- receptor blocker (ARB)			
Syst BP (mmHg)	1.02	1.00-1.03	0.079
Combination of ACE and ARB			
Hospitalization[3]	0.71	0.53-0.94	0.017
Diast BP (mmHg)	1.02	1.00-1.03	0.016
Syst BP (mmHg)	1.01	1.01-1.02	<0.001
Creatinine	0.99	0.99-1.00	0.03
eGFR	1.01	1.00-1.02	0.001
Beta-blocker			
Age	0.98	0.97-0.99	0.003
Syst BP (mmHg)	1.01	1.00-1.02	0.026
History of MI	1.33	1.06-1.67	0.015
History of hypertension	1.5	1.22-1.84	<0.001
History of AF	1.54	1.25-1.92	<0.001
History of DM	1.37	1.1-1.71	0.005
History of stroke	1.4	1.09-1.81	0.009
History of PCI	1.49	1.17-1.89	0.001
History of CABG	1.47	1.15-1.88	0.002
Aldosteron antagonist			
Syst BP (mmHg)	0.99	0.98-1.00	<0.001
Sodium	0.95	0.92-0.98	<0.001
Creatinine	0.99	0.99-1.00	0.012

Table 5: Multivariate logistic regression analyses on the combination of (sub)-maximum dosage of HF medication (≥ 75%of the target dose), adjusted for; age, sex, LVEF, previous hospitalization, hospitalizations during treatment, days of hospitalization, etiology (ischemic/non ischemic), NYHA class II-III, sodium, eGFR, heart rate, blood pressure and HF disease management model MZH, COACH, DEAL.

	OR	95% CI	P value
ACE-inhibitor (ACE)			
COACH-v-MZH	0.57	0.38-0.85	0.006
DEAL-v-MZH	1.93	1.0-3.78	0.05
DEAL-v-COACH	3.15	1.72-5.82	<0.001
Angiotensin- receptor blocker (ARB)			
COACH-v-MZH	1.31	0.48-3.68	0.60
DEAL-v-MZH	1.94	0.46-9.66	0.38
DEAL-v-COACH	2.22	0.63-7.76	0.20
Combination of ACE and ARB			
COACH-v-MZH	0.6	0.41-0.88	0.009
DEAL-v-MZH	1.94	1.03-3.69	0.04
DEAL-v-COACH	3.07	1.73-5.49	<0.001
Beta-blocker			
COACH-v-MZH	0.36	0.24-0.54	<0.001
DEAL-v-MZH	1.75	0.94-3.27	0.078
DEAL-v-COACH	4.63	2.55-8.56	<0.001
Aldosteron antagonist			
COACH-v-MZH	1.43	1.03-1.99	0.03
DEAL-v-MZH	0.86	0.47-1.56	0.62
DEAL-v-COACH	0.98	0.6-1.61	0.94

versus MZH p=0.02, DEAL versus COACH p=0.03) The percentage of (sub)-maximum dose of prescribed ACE-inhibitors, the combination of ACE/ARB and beta blockers at the end of the DMP were significantly higher in the DEAL and MZH group compared to the COACH (p=<0.001) (Table 3). A higher percentages of ARB tended to be prescribed in the DEAL group (p=0.07). The (sub)-maximum dose of Aldosteron antagonists was significant higher in the COACH and DEAL group compared to the MZH.

Relationship between severity of HF and (sub)-maximum dose of medication

Analyzing the relationship between the (sub)-maximum dose of separate HF medication and demographic and clinical variables, a significant relationship was found for ACE-inhibitors on age, hospitalizations for HF during treatment, NYHA class III, clinical variables co-morbidities and laboratory values. For ARB we found no significant

relationship between the sub-maximum dose demographic and clinical variables. For the combination of ACE and ARB we found a significant relationship with hospitalization for HF during treatment, blood pressure and laboratory values . For beta blockers we found a significant relationship with age, systolic blood pressure and co morbidities and for Aldosteron antagonist we found a significant relationship with the systolic blood pressure and laboratory values. (Table 4).

Effect of the DMPs on the maximum and (sub)-maximum dose of HF medication

Looking at the effect of the three different DMPs on (sub)-maximum dose of medication, adjusted for demographic (age, sex) and clinical variables indicating severity of HF LVEF, previous hospitalization, hospitalizations during treatment, days of hospitalization, etiology (ischemic/non ischemic), NYHA class II-III, sodium, eGFR, heart-rate, blood pressure) there was a significant difference between the MZH and DEAL versus the COACH on ACE, the combination of ACE/ARB, and beta blocker. The maximum dosage of ACE and the combination of ACE/ARB in the DEAL group was higher than in the MZH group (ACE: p=0.05, OR:1.93 CI[95%] 1.0-3.78, ACE/ARB: p=0.04, OR:1.94 CI [95%] 1.03-3.69). For Aldosterone antagonist we found a significant higher percentage of prescribed dosage in favor for the COACH versus the MZH group (p=0.03 OR:1.43 CI[95%] 1.03-1.99) Table 5.

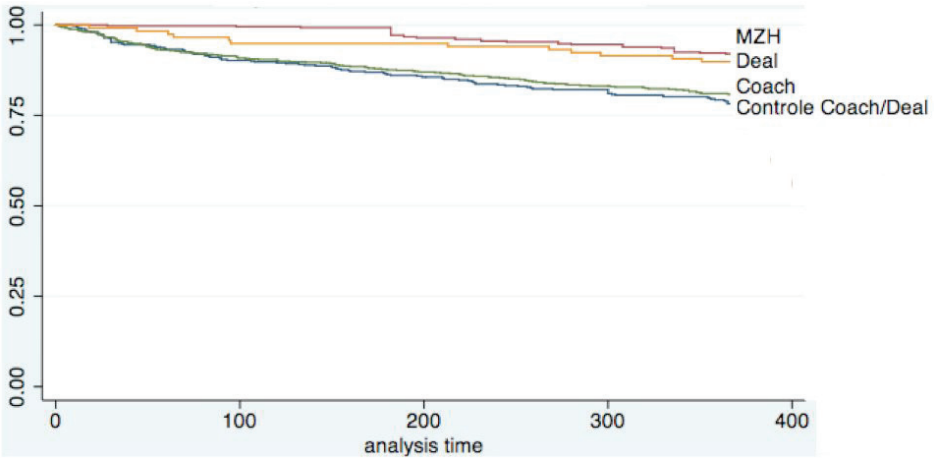

Figure 1: Kaplan Meier: survival curve of the three different HF DSM models at 365 days. (MZH vs. control . p=0.03, OR: 0.46, CI [95%] 0.22-0.92; COACH vs. control p=0.48, OR: 0.85, CI [95%} 0.55-1.29; DEAL vs. control p=0.15, OR: 0.55, CI [95%] 0.24-1.20).

All cause mortality

For survival in the three groups, according to the propensity score analysis, we observed a better survival for the MZH and DEAL group compared to the control groups than for the COACH group versus the control groups. i.e., MZH: OR:0.46, CI [95%] 0.22-0.92, p=0.03,. COACH group versus control OR:0.85, CI [95%] 0.55-1.29, p=0.48, and DEAL group versus controlOR:0.55, CI [95%] 0.24-1.20, p=0.15,. (Figure 1).

Discussion

The main finding of this study is that the total percentage of medication of the DMPs at the end of follow-up were all considered quite acceptable. In examining the total percentages of prescriber adherence in the three different HF DMPs we found the DEAL to have the highest total percentages when compared to the other two models for ACE-inhibitors, Aldosterone antagonists and diuretics, although it had included, when looked at NYHA and eGFR, more compromised HF patients. For beta blockers we found a (slightly) higher prescription in the MZH model. It is therefore interesting to observe that the DEAL model had the highest prescriber adherence in terms of total percentages for almost all HF medications. However, total percentage of prescribed HF medication is different than the (sub)-maximum dose of prescribed HF medication. Because HF guidelines advise uptitrating to maximum dosage, it seems therefore better to focus on (sub)-maximum dosage of medication rather than total percentages alone. We found that less than 50% of all patients received the 100% of the target dose medication as advised by guidelines, with the exception of Aldosterone antagonists, even in DMPs that have medication uptitration as a specific component of DMP.

Many studies have pointed out that HF DMPs improve outcome in terms of mortality, readmissions and quality of life. Although the most effective DMP has not yet to be discovered,[32,33] patients are increasingly treated with evidence-based medication.[34,35] The MAHLER study showed a clear relationship between adherence to pharmacological guidelines (the actual use of the maximum dose of medication) and a lower rate of cardiovascular hospitalizations in HF patients.[11] Nevertheless, healthcare providers still experience difficulties when implementing those guidelines in daily practice.[36-39] On the other hand, it is important to realize that in most studies upon which the guidelines are based, patients did not achieve more than 75% of the target dose as advised.[27,28,42,43]

In the multivariate regression analyses, we observed that variables that significantly influenced the maximum dose of HF medication were pre dominantly present (age, re-hospitalization for HF, NYHA class, blood pressure and renal function). These variables are known for their negative influence on the dose of prescribed HF medication.[40] For example, age, frequent readmissions, and a lower NYHA class are challenging factors in targeting to maximum dosage of medication. Therefore, despite lacking data on reasons why patients in the DMP groups were not targeted to maximum dosage of medication, it seems plausible that the severity of HF in patients in terms of re-hospitalization for

HF, NYHA class, blood pressure and renal function in all the DMPs might explain why "only" 50% were titrated to a maximum dosage.[9,41] The exception was the prescribed dose of Aldosterone antagonist. Current HF guidelines do not give advice on how to deal (pharmacologically) with patients regarding co-morbidities, aging and frequent readmissions.

An important issue to address is that the COACH intervention was primarily designed to determine a possible effect of patient education and self-management provided by an HF nurse and optimizing medication was not part of the treatment protocol. The MZH and DEAL interventions were primarily aimed to optimize medication, although the way this was performed was essentially different. In the DEAL intervention this was performed by the intensive cooperation of an HF dedicated physician and HF nurse. In the MZH intervention, this was done by an HF nurse, supported by a CDSS system, which had the potential to help in start and uptitration of medication.[14-17] One of the advantages of working with a CDSS is the absolute certainty of data registration (e.g., side effects, maximum dosage in combination with clinical data) due to the simple fact that a CDSS does not work without constant data import. It follows exactly the predefined rules, often an exact copy of the guidelines. A CDSS can lead to faster therapeutic control because human-related factors (e.g., not up titrating medication because the patient is "feeling well and have no complaints", or not uptitrating immediately after a readmission) are much less influential when working with a CDSS.[44] This is mainly due to the alerts and reminders of the CDSS in the case of suboptimal HF medication. If there are updated therapeutic guidelines, changes can easily be incorporated into the CDSS and will immediately help the healthcare provider with advice based on most recent guidelines. A randomized controlled study was published recently with a similar DMP as the MZH, for patients with atrial fibrillation, with a positive outcome.[16] In terms of the costs of the different models, it is in our study not possible to identify the most cost-effective HF DMP because this requires data specifically collected for cost effectiveness analyses.

Although we are very aware of the limitations of this study, mainly caused by the different study designs (observational versus randomized controlled trials), baseline character differences at baseline, different treatment protocols and focus of the HF DM models, we still believe that it is valuable to compare HF DMPs on their degree of prescriber adherence because, the guidelines recommend that optimizing medication is an important component for an HF DMP. Therefore, based on our findings we conclude that HF DMP models with a focus on optimizing medication, regardless of whether this is via a CDSS or a dedicated physician, are an important contributor to the degree of prescriber adherence. It is well known that higher prescriber adherence is related to better survival and although using a propensity score analysis for this purpose has limitations, we assume that the observed higher prescriber adherence is reflected in the survival analysis. The fact that the DEAL survival, compared to the control groups in the propensity score analysis is not significant is probably caused by a small sample size. In the original DEAL study, the intervention group of the DEAL did show significant differences with respect to hospitalizations and all cause mortality compared to the

control group of the DEAL. This study explored the extent of prescriber adherence in terms of (sub) maximum dosage HF medication in different HF DM models. To obtain a better insight in the way optimal prescriber adherence can be achieved, more research is needed.

Conclusion

Prescriber adherence of HF medication in the three HF DMPs is high in terms of total percentages, but the number of patients that received a maximum dosage, as advised by the guidelines, was no more than 50%, with the exception of Aldosterone antagonists in the DEAL and COACH population. There is a significant association between the severity of HF and the maximum dosage medication, possibly indicating that a substantial number of the other 50% of the patients in the DMP models received medication up titrated to their optimum dosage. The HF DMP models in this analysis, that have a focus on optimization of medication, are more successful in accomplishing prescriber adherence, in terms of (sub)-maximum dosage medication, than the examined HF DM model with a focus on counseling alone.

Limitations

This study has some potential limitations that need to be addressed. First, the MZH data are not study data in terms of data collected through a study protocol. We collected these data from standard care by extracting them from electronic patient records with permission from the hospital and patients. Unfortunaly, the data on total percentage of medication at baseline of the MZH group were not available because of the transition of (paper) patients files to an electronic patient record. It might therefore be questionable whether the results obtained at the end of the follow-up period were solely achieved by the effort of the HF DMP alone. However, we believe that patients in the MZH, referred by the cardiologists to the HF DMP from 2003-2005, were not initially treated differently with respect to medication compared to the patients included in the two other models. Secondly, there were substantial differences in baseline characteristics of the three treatment groups. The most important one is that in the DEAL group more sicker patients were included and maximal adherence is more difficult to achieve in patients in NYHA-class III. To account for this we used multivariate and propensity score analysis. Thirdly, the outcome of this study could be influenced if data were available about why caregivers did not uptitrate to maximum dosage. It is conceivable that patients did not receive the maximum dosage of medication because their individual optimum dosage had been reached. Fourthly, the data of the three HF DMPs were assembled over a time period from 2000-2005. In this 5-year timeframe it became clear that a higher dosage of HF medication was associated with a better outcome and a shift toward a higher prescription in time could be expected. Finally, even though propensity score matching can balance observed baseline differences between exposure groups, they do nothing to balance unmeasured characteristics and confounders and remaining unmeasured confounding may still be present.

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Chapter 9

Summary, general discussion and future perspective

Arjen E. de Vries

The prevalence of heart failure (HF) is progressively increasing due to ageing and can result from unhealthy lifestyle of individuals. Although there is some discrepancy betweeen national and international studies regarding the prevalence, incidence and costs of HF, the overall conclusion is that the disease is associated with a high hospitalization and mortality rate. This imposes a significant economic burden on our healthcare system. To maintain accessible and affordable healthcare for HF patients and a consistent standard of quality, it is important to search for new and innovative ways to challenge this major health problem. This thesis concerns patient-related health outcomes and user-related expectations, experiences, barriers and guideline adherence of using telemonitoring in combination with computer decision support systems (CDSS) in HF care. The application of health information technology such as telemonitoring (TM) and CDSS, as part of disease management, can make a positive contribution to this challenge.

Aims of this thesis

To describe the benefit, practical use, and consequences, of using telemonitoring and computer decision support systems in heart failure care, the following aims have been formulated:

1. Explore the effects of telemonitoring combined with a CDSS on clinical outcome, adherence to guidelines, cost effectiveness and quality of life.
2. To explore the expectations, experiences, barriers and usability of telemonitoring and CDSS, used by HF nurses and cardiologists in the treatment of HF patients.
3. To gain insight into different heart failure disease management models (one of which is CDSS-driven) and explore differences in and effects of prescriber adherence to medication.

Main findings

Aim 1

To describe the effects of telemonitoring combined with a CDSS on clinical outcomes, adherence to guidelines, cost effectiveness and quality of life.

What is already known?

1. In the last decade, nine systematic reviews have been published concerning the use of telemonitoring in heart failure.[1] Eight of these reviews reported positively on outcome as mortality and/or readmission for telemonitoring. There are two recent randomized controlled trials that gave opposite (negative) results.[2,3]
2. CDSS in healthcare can improve guideline adherence,[4,5] however the current use of CDSS is limited.[6,7]

3. There is conflicting evidence about the cost effectiveness of telemonitoring.[8]

What this thesis adds:

First experience:

In the case study (Chapter 2), it was found that TM in combination with CDSS could be helpful in preventing HF readmissions and could have had a possible positive effect on the adherence of patients' experienced quality of life and the use of medication. An important finding was that, with the help of the CDSS in combination with TM, it was possible to up-titrate HF medication under safe conditions without contacting the patient at the outpatient clinic. Frequent contact between caregivers and the patient at a distance was possible without any problem and the technology at home facilitated the patient' education and caused a better understanding in terms of recognition of deterioration of the disease. With the help of TM and a CDSS, it was assumed that at least two HF readmissions were prevented for in a period of ten months.

The experiences with this model, described in the case study[9] were the rationale for the IN TOUCH study (the value of INnovative ICT-guided Disease Management combined with Telemonitoring in OUt patient clinics for Chronic Heart failure patients). IN TOUCH is a multicentre randomized intervention trial in 10 hospitals in the Netherlands, investigating the effects of ICT-guided disease management, versus ICT-guided disease management combined with TM in HF patients, including 179 patients for a 9-month follow-up period.[10] CDSS was a substantial part of the ICT-guided disease management system.

Outcome of the IN TOUCH study

Regarding the outcome of the IN TOUCH (Chapter 4) it was found that ICT-guided disease management in combination with TM, used in the management of HF patients did not affect the primary (composite) endpoint of mortality, HF readmission and quality of life, nor the separated parts of this composite endpoint. However, a significant reduction of HF-related visits to the outpatient HF clinic in the TM group was found. Because there was no difference between the two group on mortality and readmission this indicates that TM is safe to use and can reduce visits to the outpatient clinic, keeping HF care accessible. The adherence of using devices as a weighing scale and blood pressure measurement for patients in the TM group was extremely high (95%), which indicates that the devices used for this study, in combination with daily measurements, were well accepted and therefore applicable in regular care. Healthcare providers had a positive perception and experience with the 'ease of use' of TM. However using an ICT-guided disease management system (DMS) was rather difficult, specifically regarding the use of CDSS functionality for starting and titrating HF medication. This CDSS functionality was barely used, resulting in only a slightly higher percentage of medication use at the end of the study, compared to baseline.

Cost effectiveness

Because there was no effect on the primary (composite) endpoint of mortality, HF readmission and quality of life, nor on the separated individual outcomes of this composite endpoint, no cost effectiveness analysis was performed. Instead a Cost Minimization Analyses (CMA), was performed which gave insight into the actual costs of the interventions. Incremental costs for TM were calculated for a period of 9 months of 1360 Euro. Initially one might conclude that these higher costs for an intervention, without any profit in terms of effect are a waste of money. However, the cost of 1360 Euro might be of value for decision makers in the case of situations where patients do not have direct access to an HF outpatient clinic (e.g., primary care, long distance to travel, the inability to visit an HF outpatient clinic) or in the case of minimizing regular visits to the outpatient clinic that are only for uptitration of medication or assessment of physical condition. The cost of the intervention could be important in cases of reorganizing the care of HF patients to be efficient by reducing visits to the HF outpatient clinic and therefore keeping treatment for patients accessible.

In the descriptive study on usability and acceptability of heart failure related computer decision support (Chapter 5) it was found that the CDSS and the usability and acceptability were considered poor, mainly due to personal, organizational and system-related barriers. These findings were partly attributed to the fact that the CDSS was not integrated into the existing electronic patient record and therefore caused additional work. Besides this, the offered CDSS functionality was perceived as 'immature' and in need for further development. Another reason was that in some participating hospitals HF nurses were not allowed to titrate medication themselves because of cardiologists' doubts about the validity of the CDSS.

In conclusion

The outcome of the IN TOUCH study did not show an additional effect in HF patients who received TM and CDSS; however, there are some positive findings in this study. The two most important ones are that TM and CDSS are safe to use for HF patients and that the number of HF-related visits to the outpatient HF clinic was significant lower (partly protocol-driven) compared to the group that did not use TM. Therefore, the IN TOUCH contributed dually to the existing evidence. First, it remains questionable if TM in combination with CDSS can reduce mortality and readmissions in HF patients. Second, TM in combination with CDSS can be used to reduce visits to the HF outpatient clinic and therefore keep care accessible for patients who need treatment in outpatient clinics. TM in combination with CDSS can certainly contribute positively to HF care in terms of improvement of accessibility of care and the desire of patients to communicate with their care providers at a distance, a natural consequence of information technology in our society. The major challenge for the up-coming years is to find the right patients who will benefit most from this new technology and to get and keep it accessible and affordable.

What this study adds to the existing evidence:

1. ICT-guided DMS with telemonitoring in HF is safe to use and significantly reduces visits to the outpatient HF clinic.
2. The costs of using ICT-guided DMS with telemonitoring in the IN TOUCH study are relatively low and can be of value for decision makers in the case of situations where patients do not have direct access to an HF outpatient clinic or for re-organizing HF care.
3. Patients' adherence with telemonitoring is high, which indicates that the used protocol and devices are acceptable in regular HF care.
4. Using a CDSS for a better pharmacological guideline adherence remains difficult, mainly because of personal, organizational and system-related barriers.
5. Patients and healthcare providers are satisfied about the ease-of-use of telemonitoring but healthcare providers are less satisfied in working with a CDSS

Aim 2

Explore the expectations, experiences, barriers and usability of telemonitoring and CDSS, used by HF nurses and cardiologists in the treatment of HF patients.

What is already known?

1. In contrast to research about patients' experiences and expectations of telemonitoring, there is very limited research and knowledge about the expectations and experiences of telemonitoring by HF healthcare providers. It is unknown how many HF clinics actually uses telemonitoring and if the use of telemonitoring is based on protocols and/or patient profiles.
2. CDSS can significantly improve pharmacological guideline adherence.[5,11] Barriers by general practitioners in using CDSS are related to personal and demographic characteristics including a 'feeling of lost autonomy', a higher age and lower computer literacy, which result in a lower implementation rate.[12-14]

What this thesis adds:

Telemonitoring

TM has been seen as a promising new technology by workers in the field of HF care and the expectations of its effects are high. This high expectations has already led to its use in about 35% of all HF clinics in the Netherlands, without clear, predefined criteria of user requirements.[15]

The recent HF guidelines (2012) did not find sufficient evidence to recommend TM in HF care[16] and it is therefore questionable that, without solid evidence on patient outcome, TM is used on such a large scale. HF clinics may have other motives for

using TM in patient care than reduction of mortality and readmission. In the study on expectations and experiences of TM (Chapter 6) specific reasons and motives to use TM were: monitoring physical condition, signs of deterioration and treatment, adjusting medication and educating patients in self-management. All these motives seem realistic, even without evidence of preventing readmissions and the reduction of mortality. Another reason to start TM was to 'go with current developments and innovation's, showing that reasons other than 'evidence based medicine' alone are important to start TM. This is comparable to the introduction of other health information technology, partly driven by "high-tech" possibilities, marketing of the commercial industry and the desire of using state of the art technologies, being excellent and distinguished.[17] This is a serious threat to a solid use and implementation. Despite high expectations on working with TM, users did not experience reduction in re-admissions, reduction in workload, treating more patients or improving quality of care, possibly leading to disappointment in users. This disappointment is reflected in the fact that some users were already considering purchasing another TM system. Hence, it is questionable if the overall feeling of disappointment indeed is the result of a failing TM system or is due to a lack of efficient organization around the implementation of TM systems. It is expected that with the initial introduction of TM, workload will increase and this might be disappointing. To prevent TM being a potentially interesting health technology that becomes "another failed health technology", implementation should be addressed carefully, learning from the experiences (positive and negative) of other clinics, including monitoring of patients, providing education and improvement of self-management in other chronic diseases, and so work toward best practices and structural applications.

The implementation phase should start by defining and stating expectations, making clear agreements about who is responsible for the incoming data, the time for the care provider to respond on deviating data, the type of intervention, patient profiling to find out which are most suitable/beneficial for TM, the duration of TM and finally the determination of (predefined) markers in order to evaluate if treading a specific group of patients with TM is successful. Because these aspects of patient care lies within the working field of HF nurses, it seems reasonable that HF nurses should claim a central, coordinating role in working with TM.[18,19]

Barriers in using CDSS

In Chapter 7, we described the perceived barriers of HF nurses and cardiologists in using CDSSs. Other studies, focused on the barriers of using CDSS by general practitioners showed that earlier experiences with dysfunctional computer systems, potential harm the doctor-patient relationship, lead to unclear responsibilities and threats to clinicians' autonomy, resulting in major barriers in working with CDSSs. Aging of healthcare providers and a lack of computer experience were also pointed out as barriers. In our study, a strong similarity to some of these earlier findings in HF nurses and cardiologists was found. These barriers were categorized as: 'barriers and threats', 'responsibility and

trust' and 'knowledge management'. Both HF nurses and cardiologists perceived barriers in working with CDSSs in all the examined areas, which would be counterproductive for implementation.

However, a positive finding was that knowledge management has a strong correlation with the perceived barriers, indicating that increasing knowledge by specific training and education for users can decrease barriers. It is important to offer future users insight into the possibilities, but perhaps even more important, the impossibilities of a CDSS.

The fact that a CDSS is not a magic black box, but something that generates advice only by means of predefined formulas and data provided by the HF professionals themselves, will give more attention to and information about the system's capabilities. Future policymakers and managers that are involved in the introduction of CDSS should be aware of the risk of perceived barriers towards CDSS and should introduce education, additional and extended training, and the use of "super-users" as a constant element in their implementation strategy. In contrast to other studies, we did not find that a higher age and a lack of computer experience is a barrier towards working with a CDSS. In Chapter 5 we showed how important the findings of the described barriers are in case of using CDSSs in daily practice. In the study on usability and acceptability of CDSS, we have made the transition from theoretically expected barriers into real experienced barriers. All the users of a CDSS in the IN TOUCH study experienced a very low acceptability and usability of the offered CDSS. This resulted in a prescriber adherence to HF medication, which was lower than the observed percentage in the Euro Heart Survey II of 200520 Because better prescriber adherence directly results in a better outcome21, this stresses the importance of a successful implementation of CDSS.

Conclusion

Barriers towards working with a CDSS are a real threat in the actual use of CDSSs. In the analyses of the low acceptability and usability, we found again that barriers towards using a CDSS in HF care are relevant in a successful use. CDSS should be user friendly, not too time-consuming to work with, and sophisticated enough to give the required advice. Only if these primary characteristics are fulfilled in advance, can the implementation phase start and it must be monitored intensively, with respect to all the known barriers.

To gain insight into possible barriers, a pre-inventory of barriers is recommended. The questionnaire, developed for the study in Chapter 7 can be valuable for this purpose. Along with constant education and regular evaluation, successful use of a CDSS in terms of better guideline adherence can be expected.

What this study adds to the existing evidence:

1. HF nurses and cardiologists have high expectations about the effect and use of telemonitoring in heart failure care, but these high expectations are not reflected in their actual experiences.

2. Despite conflicting evidence, almost 35% of all Dutch HF clinics already use telemonitoring for regular care in the absence of pre-defined protocols and/or guidelines.
3. Both HF nurses and cardiologists have perceived practical barriers towards working with CDSS, and these barriers are an actual threat to successfully using CDSS. Knowledge management is significantly related to barriers, implying that increasing knowledge might be a tool to decrease barriers.

Aim 3

To gain insight into 3 different heart failure disease management models (one of which is CDSS-driven) regarding their rate of prescriber adherence of medication.

What is already known:

1. According to the recent HF guidelines, patients with a reduced left ventricular ejection fraction should receive optimal medication, titrated to target dosage, in order to reduce mortality and readmissions.[22] However it is known that the number of patients that receive this target medication is suboptimal.[20,21]
2. Optimizing medication is an important component of HF disease management[23] and should be an essential part of the tasks and responsibilities of HF clinics[22]
3. Differences are known in prescriber adherence of heart failure medication between HF clinics related to the applied disease management model.[20,24-26]

What this thesis adds:

Prescriber adherence

Optimal HF medication is related to the improvement of outcome in terms of mortality, readmissions and quality of life.[21] In search for the most optimal HF disease management model, prescriber adherence, according to the HF guidelines, is an important component and often used as an indicator for the successfulness of a HF disease management model. HF nurses and cardiologists still experience difficulties when implementing these guidelines into daily practice.[24,27] As described in chapter 8, the prescriber adherence to medication of the three examined models, in terms of maximum dosage of medication is suboptimal.

In chapter 8 it is reported that less than 50% of all patients in the 3 included models received the maximum dosage of HF medication, with an exception for the combination of ACE-inhibitors and Angiotensin receptor blockers. As expected, and confirmed in earlier studies,[24,28,29] characteristics of patients that indicate the 'severity of the disease' HF, is significantly related to the maximum dose of prescribed HF medication. These characteristics are present in our study as in other studies[20,21,27] and are thus a plausible explanation for the results. The two HF disease management models that focus on optimalization of medication more often prescribe maximum dosage of medication.

One of these models uses a CDSS, operated by a HF nurse and is a even effective in prescriber adherence than the model with a dedicated HF physician. Using a propensity score for analyzing groups of patients, with differences at baseline characteristics and different study protocols, has several and potential limitations as addressed in Chapter 8. Taking into consideration this limitations, the patients treated in the disease management models that focus on optimal medication have a better outcome in terms of survival, which is in line with the existing evidence[30-35] as described in the HF guidelines[22] However, there are still some unanswered questions from the study described in chapter 8. Besides the influence of characteristics such as co-morbidities and clinical variables, it remains unclear why HF patients overall do not receive more than 50% of the maximum doses. It could be possible that 50% of the target dosage is the individual optimum, or perhaps healthcare providers just stop targeting to a higher dose. If this latter is the case, it is important to understand why. It might be caused by an acceptable 'steady state' of a patient who claimed no complaints at the time of the consultation, or the prescriber might experience a feeling of lost autonomy, caused by the advice of a CDSS. It is also possible that patients' experience undesirable side-effects of higher doses, or they are not willing to take higher doses. These are some important issues that need to be addressed to obtain more insight in the concept of prescriber adherence. This information is often not available in the patient record. A CDSS can help in answering these questions due to its repeatable alarms and reminders[36] when patients do not receive maximum dosages and the obligation for the precriber to describe why a patient did not received 100% of the target dose. With the gathering of this precriber data of a CDSS, together with other important clinical information such as laboratory and physical parameters, it is possible to gain more insight into factors that influence the prescribed dose of medication in HF patients.

Conclusion

Even in HF disease management models that focus on optimizing medication, the actual dose of medication for patients is overall not higher than 50% of the target dose. Patient characteristics like age and co-morbidities and the severity of the disease (leading to frequent readmissions) are important 'negative' contributors. Working with a CDSS that is specially built for starting and uptitrating medication can be an important and effective contributor to prescriber adherence.[11] It is safe to use and it will fit perfectly in the scope of HF nurses, in terms of responsibility for optimal pharmacological therapy as part of a disease management program.

What this study adds to the existing evidence:

1. Prescribed medication is high in all of the examined HF DMS models. However, less than 50% of all patients were prescribed the maximum medication, despite the fact that two HF clinic models had a focus on optimizing medication.

2. Age, co-morbidities and clinical variables as blood pressure and eGFR influence the prescription of the maximum dosage of medication. Readmissions and the physical condition of the patient, reflected in the NYHA class, are negatively influencing the maximum dose of medication.
3. A disease management model with a CDSS is as effective in terms of prescription of HF medication as a model with a dedicated physician, with differences observed in ACE-inhibitors and beta-blockers. This CDSS-driven outcome on prescriber adherence of maximum HF medication is reflected in better survival according to a propensity score analysis.

Telemonitoring and CDSS: the holy grail for (future) clinical practice?

Currently there is conflicting evidence on the effectiveness of TM and CDSS on clinical outcomes like mortality and readmissions for HF patients.[37] In the past 5 years, many studies, in which TM was the main intervention, were published.[1,38-41] These studies provided as many positive as negative outcomes[2,3] The most important reason for this conflicting evidence seems the absolute absence of comparable study designs: different technology used, different follow-up time (mostly short for a chronic disease), different interventions and different patient-profiles. This is a major concern in the recent published meta-analysis in which all these studies with different designs were combined. Richard Wootton, editor in chief of the Journal of Telemedicine and Telecare concluded in his review "Twenty years of telemedicine in chronic disease management", that the evidence base for the value of telemedicine in managing chronic diseases on the whole is weak and contradictory[37] So how is it possible that the majority of healthcare providers are still positive about telemedicine? And why should we use it?

Although not confirmed in the IN TOUCH study, the overall common positive finding in most studies is an increased quality of life for patients as a result of TM. Patients performed better self-management and had a feeling for a sense of control. The fact that patients are able to directly contact their healthcare providers in case of emergency probably plays an important role in this feeling. We did not find any publication that described negative effects in terms of worsening of outcome. With the help of TM, it is possible to keep care (especially for outpatient clinics) accessible. One might wonder why we should we ask patients to visit the outpatient clinic for a visit of 10 minutes in the company of their relatives, which may cost them half a day of time, for only a blood pressure measurement and adjustment of medication, instead of aggregating that information at home with TM. Important physical variables like weight, blood pressure, heart rate, glucose, peak flow, temperature, EKG and even the actual health status, delivered by digital questions are already available through TM and more applications will be available in future developments. Companies are actually developing technology to gain a fluid

status of a patient and laboratory values with the help of a camera (smart)phone. Because of the growing computerization level of our society, patients themselves already ask for using health information technology. Healthcare insurance companies are reacting to this demand with the inclusion of TM in their insurance policies and policymakers in the government/Ministry of Health believe strongly in the implementation of eHealth. In the end it seems unrealistic to wait for new evidence in terms of lower mortality and reduction of readmission. TM and CDSS have much more to offer from a point of view of the patient, healthcare provider and policymakers.

Recommendation for clinical practice:

1. Implementing telemonitoring and CDSS in clinical practice does not automatically decrease patient outcomes like mortality or readmissions. It can contribute to keeping HF care accessible in terms by decreasing visits to the outpatient HF clinic, and it can help in monitoring physical condition, monitoring signs of deterioration, monitoring treatment, adjusting medication and educating patients. The costs of using telemonitoring and CDSS are relative low and could be a factor re-organizing HF care.
2. Using telemonitoring and CDSS requires a careful look at users in terms of patient-profiling. It is obvious that telemonitoring is not a "one size fits all" solution. It is advisable to start and monitor a pre-defined group of patients, for example new diagnosed patients who had a recent (re)admission and who experienced difficulties in recognizing signs and symptoms of deterioration.
3. Using telemonitoring and CDSS will lead initially to an increased workload for healthcare providers. This requires intense monitoring by management of the implementation phase and the need for agreement/protocols about data management, responsibilities and accessibility of staff.
4. For successful implementation of telemonitoring and CDSS, it is important to focus on existing barriers and thresholds. Implementation should be monitored intensively, with respect to all known barriers and only with constant education and regular evaluation can successful use of telemonitoring and CDSS in terms of better guideline adherence be expected. We must be aware of high and/or unrealistic expectations of health care providers.
5. CDSS should be user friendly, not too time consuming to work with, and sophisticated enough for the required tasks. Only if these primary characteristics are fulfilled in advance, the implementation phase can start. Using a CDSS lacking these primary characteristics is a serious threat to its usability and acceptability.

Implications for further research

This thesis demonstrates that health oriented information technology, such as TM and CDSS, is a promising tool to help healthcare providers improve care and performance, but only if implementation and use are monitored under strict and predefined conditions. It is questionable whether further research will contribute to the existing evidence about readmissions and mortality. This will be successful only if future studies are comparable in terms of interventions and patients. We need a consensus of endpoints in new studies such as costs to society, the number of visits to the emergency room and outpatient clinic, the way we measure quality of life and the added value of focusing on 'only' readmission/mortality.

Because HF is a chronic disease it is questionable if studies with a short follow-up (< 1 year) will contribute to the known evidence. Currently it is unclear which patients will benefit most from these new interventions. Therefore, it is necessary to focus on patient profiling. Besides the fact that new studies might provide new evidence, it is important to learn from experiences to gain "best practices". The evidence for using a CDSS to improve prescriber adherence is growing. However, in the case of practical applications of CDSSs we often do not know why healthcare providers stopped targeting to a higher dose of medication. Because this could be behavioral, clinical or patient determined we need to gain more insight into reasons for this, which could be partly helped by using a CDSS. With the help of a CDSS we can possibly titrate more patients to optimal medication, leading to a better outcome. Future CDSS studies should focus on this specific reasons or motives why patients do not receive the target dose of HF medication as advised.

Limitations/critical reflection

An important limitation concerns the generalizability of this thesis. Most of the studies have been performed in Dutch HF clinics with only one type of TM and one type of CDSS. Despite of the fact that at this moment there are no other HF CDSSs on the Dutch market available, the overall comments of the users, described in Chapter 6, are explicit; they experienced the offered CDSS as immature and not sophisticated enough to use in their daily HF care at this moment. This is important information because it is known that a low experienced usability and acceptability of CDSSs results in barely using it and thus the absent of an in potential helping instrument to improve guideline adherence (Chapter 6). However, at this moment it is unclear if the user's attitude on CDSS, which is defined as a personal related barrier, influenced patient outcomes. This should be the focus of future research.

In Chapter 8 it was described that using a CDSS was at least as effective in terms of prescriber adherence than a dedicated physician. However, this was examined in a retrospective study and performed in HF patients with different profiles and study protocols. This consequently affects the generizability of this study. It is important to

know if the observed outcomes of the study described in Chapter 8, are as present in comparable HF patients and with a specific focus on the reasons why prescribers do not prescribe to maximum dose and/or patients do not take the maximum dose of HF medication, this requires further research.

In general, there are two different ways of looking at the present TM evidence. One is that there still is a lack of solid evidence in terms of lowering mortality and readmissions, making the implementation of TM as a new intervention too premature and therefore not accountable. The other way of interpreting the present evidence is that TM as an intervention alone, might not bring a better patient outcome but maybe the intervention should be considered as a helping tool, together and integrated with other components of disease management, which in the end might lead to an improvement of patient outcomes. In designing a new TM study we should more focus on the value of TM as a substantial part of disease management and not as an intervention alone, in order to improve education, self management/empowerment of patients and health-related quality of life. To find a cohort of patients who will benefit most this might be done by selecting different patient profiles; immediately after a first readmission for HF in new diagnosed patients, after worsening of HF caused by not acting appropriately on signs and symptoms, or after several readmissions in a short period of time. Beside this different profiles it is important to explore the edit value of different time intervals in using TM (e.g., 3, 6, 12, or 24 months).

Conclusion

This thesis shows that TM as well as CDSS are capable of transferring patient data from a home environment to a healthcare provider and with this data, the healthcare provider is able to interpret data and to act. TM is not a "one size fits all" solution and in contrast to the of use 'new' TM, the development, use and evidence of CDSSs is different. We do not have a long tradition of CDSSs in healthcare, but with the introduction of evidence-based healthcare and guidelines, CDSS can help in making clinical decisions, preventing medical errors and improving prescriber adherence. This thesis shows that the difficulty in using CDSSs lies not in the absence of evidence of accomplishing higher dosage of medication as integrated part of disease management, but in the number of barriers and risk of low usability and acceptability. To turn this risk into a positive implementation, we must not only monitor patients, but also healthcare providers regarding the implementation-phase and use of TM and CDSS. Realizing the potential of TM and CDSS and the need for innovation in the healthcare system, especially for HF, leads us to an interesting challenge, which will force change in many different aspects of healthcare delivery.

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Nederlandse samenvatting

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Het ontstaan van hartfalen en de toename van het aantal mensen dat er aan lijdt, worden in hoge mate bepaald door leeftijd en een ongezonde leefstijl. Deze factoren zijn gerelateerd aan het optreden van hoge bloeddruk, overgewicht of een hartinfarct, en daarmee op de lange termijn met hartfalen. De diagnose hartfalen is voor patiënten een sterke last. Het veroorzaakt veelvuldige ziekenhuisopnames, een sterk verminderde kwaliteit van leven en een hoog sterftecijfer. Daarnaast wordt hartfalen ook geassocieerd met aanzienlijke kosten voor onze gezondheidszorg.

Om het gezondheidsprobleem van hartfalen in de nabije toekomst beheersbaar te houden, moet de zorg voor patiënten toegankelijk, kwalitatief hoogstaand en betaalbaar blijven. Daarom is het belangrijk naar nieuwe en innovatieve manieren van zorgverlening te zoeken.

Dit proefschrift gaat over twee voorbeelden van innovatieve ICT ontwikkelingen die ingezet worden bij de zorg voor patiënten met hartfalen: telemonitoring (TM) en computer beslissingsondersteunende systemen (CDSS). In wetenschappelijke literatuur is beschreven dat de toepassing van deze ICT technologiën, als onderdeel van disease management, een positieve bijdrage kan leveren aan het beheersbaar houden van de gezondheidsproblemen rond hartfalen. Disease management wordt omschreven als een gecoördineerde aanpak van zorg voor patiënten met een chronische ziekte die onder andere de doelmatigheid, de kwaliteit van zorg en de zelfzorg van patiënten moet verbeteren.

Er zijn vele vormen van TM. Het gebruik van de telefoon tussen hulpverlener en de patiënt of het per e-mail sturen van een digitale foto van een afwijking door een huisarts naar een specialist zijn de oudste en meest simpele vormen. In het afgelopen decennium zijn er vele ontwikkelingen geweest op het gebied van nieuwe vormen van TM. Voor dit proefschrift is de volgende definitie van TM gebruikt: 'Het meten, monitoren, verzamelen en versturen van gegevens over de gezondheidsstatus van de patiënt in zijn eigen omgeving, door gebruik van informatie- en communicatietechnologie'. Voor TM bij hartfalen gebruikt men tegenwoordig vaak gegevens als gewicht, bloeddruk, hartfrequentie en eventuele klachten van de patiënt. Deze gegevens geven een goed beeld van de situatie van de patiënt op afstand. Met behulp van TM kunnen patiënten nu op een veilige manier thuis geobserveerd worden, waardoor eerder kan worden ingegrepen bij verslechtering en (her)opnames kunnen worden voorkomen. Daarnaast kunnen patiënten door TM beter leren omgaan met hun ziekte, onder andere door verbetering van hun zelfmanagement. Nog een andere toepassing van TM is het op afstand instellen van medicatie, zonder dat patiënten daarvoor naar de polikliniek hoeven te komen.

CDSS systemen zijn computerprogramma's die met behulp van ingevoerde gegevens de gebruiker kunnen adviseren om bepaalde (behandel) beslissingen te nemen, gebaseerd op richtlijnen en protocollen. Deze systemen blijken vooral waardevol in complexe situaties waarbij een CDSS bijvoorbeeld prioriteiten kan aangeven in de behandeling. CDSS systemen kunnen onder andere het proces van veilig medicatie voorschrijven, bewaken en bevorderen. De behandelaar kan zo herinnerd worden aan het feit dat de medicatie nog niet in een optimale dosering is voorgeschreven aan de patiënt. In het geval van dit proefschrift is de behandelaar de hartfalen verpleegkundige en/of de cardioloog.

Daarnaast kan een CDSS ook de loop van de behandeling volgen en daar advies over geven. Een voorbeeld hiervan is wanneer met behulp van TM het gewicht van een patiënt wordt gemeten. Het CDSS kan vervolgens beoordelen of dit gewicht te hoog is als gevolg van het vasthouden van vocht, en kan de behandelaar adviseren om contact met de patiënt op te nemen en de dosering plastabletten te verhogen. Op deze manier is het voor de behandelaar mogelijk om op een relatief eenvoudige manier veel patiënten veilig op afstand te volgen.

Doelen

In hoofdstuk 1 worden de doelen van het proefschrift beschreven. Het algemene doel van dit proefschrift is:

1. Het beschrijven van de mogelijke voordelen, het praktisch gebruik en de gevolgen van telemonitoring (TM) en computer beslissingsondersteunende systemen (CDSS) bij hartfalen (HF).

Specifieke subdoelen zijn:

1. Het beschrijven van de effecten van het gebruik van TM in combinatie met CDSS bij de naleving van richtlijnen door behandelaars, bij kosteneffectiviteit en bij de kwaliteit van leven van patiënten.
2. Het beschrijven van de verwachtingen, ervaringen, belemmeringen en de bruikbaarheid van TM en CDSS door hartfalen verpleegkundigen en cardiologen bij de behandeling van patiënten.
3. Inzicht verkrijgen in het voorschrijfgedrag en de mate van opvolgen van richtlijnen binnen verschillende hartfalen disease management modellen (waarvan 1 model met behulp van CDSS)

In hoofdstuk 2 is in een case studie beschreven dat TM in combinatie met CDSS heropnames kan voorkomen. In deze case studie is beargumenteerd dat bij hartfalen een

dergelijk systeem een positief effect kan hebben op de ervaren kwaliteit van leven en het gebruik van geneesmiddelen. Een belangrijke bevinding was dat het met de combinatie van TM en CDSS mogelijk bleek om zonder contact op de polikliniek de HF-medicatie van de patiënt onder veilige omstandigheden te optimaliseren. De toegepaste technologie bij de patiënt thuis zorgde voor een beter inzicht van de patiënt op het gebied van het herkennen van tekenen van verslechtering van de ziekte. Met behulp van TM en CDSS zijn in de case studie bij de patiënt in een periode van tien maanden ten minste twee HF-heropnames voorkomen.

Deze positieve ervaring met de toegepaste technologie was aanleiding om de IN TOUCH studie te starten. IN TOUCH staat voor de waarde van ICT-gestuurd disease management in combinatie met telemonitoring op poliklinieken voor patiënten met chronisch hartfalen. Het ontwerp van deze IN TOUCH studie is beschreven in hoofdstuk 3.

Uitkomsten van de IN TOUCH studie: effecten van het gebruik van TM en CDSS

Effecten voor HF-patiënten

De uitkomst van de IN TOUCH studie (hoofdstuk 4) liet zien dat ICT-gestuurd disease management in combinatie met TM de mortaliteit en HF-opnames niet kon verminderen en dat de ervaren kwaliteit van leven niet verbeterde. Wel was er in de TM groep een significante vermindering van het bezoeken van patiënten aan de HF-polikliniek. Omdat er geen verschil bestond tussen de twee groepen (met en zonder TM) op mortaliteit en (her)opnames, gaf dit aan dat TM veilig in gebruik is en het de bezoeken aan de HF-polikliniek kan reduceren. Dit is in termen van beheersbaarheid en het anders inrichten van zorg voor HF-patiënten een belangrijke bevinding. Het onderzoek liet ook zien dat het niet voor iedere patiënt noodzakelijk is om voor controle naar de HF-polikliniek te komen.

Daarnaast bleek dat het gebruik van de apparatuur, zoals een weegschaal en een bloeddrukmeter, voor patiënten in de TM-groep hoog was (95%). Dit bevestigde dat – in combinatie met dagelijkse metingen - in de praktijk de apparaten die werden gebruikt voor dit onderzoek goed toepasbaar waren. Het gebruik van het CDSS werd door de hulpverleners daarentegen als lastig en omslachtig ervaren, met name voor gebruik bij het starten en optimaliseren van HF-medicatie. Deze functionaliteit van het CDSS is gedurende de IN TOUCH studie nauwelijks gebruikt. Dit resulteerde in slechts iets hogere percentages voorgeschreven medicijnen aan het eind van de studie vergeleken met de start van de studie.

Kosteneffectiviteit

Omdat er geen effect is gevonden op het primaire, samengestelde eindpunt van mortaliteit, hartfalen heropnames en de kwaliteit van leven, leek een kosteneffectiviteit analyse niet zinvol. In plaats daarvan is een kosten minimalisatie analyse (CMA) uitgevoerd die inzicht gaf in de werkelijke kosten van de interventies. De kosten voor TM bedroegen 1360 Euro per patiënt en werden berekend voor een periode van negen maanden. In eerste instantie zou men kunnen concluderen dat deze hogere kosten voor een interventie, zonder enige winst in termen van effect als reductie van mortaliteit en heropnames een verspilling van geld is. Echter, deze extra investering kan van doorslaggevende betekenis zijn voor behandelaars in situaties waarbij patiënten geen directe toegang tot een HF-polikliniek hebben. Bijvoorbeeld in de eerstelijnszorg bij lange reisafstanden, of bij het onvermogen om een HF-polikliniek te bezoeken. Ook kan deze investering van belang zijn bij een wens om regelmatige bezoeken aan de HF-polikliniek te minimaliseren, bijvoorbeeld in het geval van het op afstand optimaliseren van medicatie.

Bruikbaarheid en acceptatie door behandelaars:

In de studie over de bruikbaarheid en acceptatie van CDSS bij hartfalen (hoofdstuk5) bleek dat vooral persoonsgebonden, organisatorische en systeemgerelateerde barrières een rol speelden bij het niet gebruiken van het CDSS. Een veel voorkomende persoonsgebonden barrière was dat gebruikers aangaven zelf voldoende kennis te hebben om de medicamenteuze behandeling te starten en uit te voeren en daarvoor geen CDSS nodig hadden. Daarnaast bestond er gebrek aan vertrouwen in de juistheid van het systeem. Een organisatorische barrière was het feit dat het CDSS niet geïntegreerd was in de bestaande elektronische patiëntendossiers en daarom extra werk veroorzaakte. Een systeemgerelateerde barrière was dat het te veel tijd kostte om goed met het systeem te werken en dat de gebruikers het systeem niet voldoende doorontwikkeld vonden.

Het gebruik van telemonitoring door Nederlandse hartfalen poliklinieken

Telemonitoring (TM) wordt gezien als een veelbelovende nieuwe technologie en de verwachtingen van de effecten ervan zijn hoog gespannen. Dit heeft er toe geleid dat in ongeveer 35% van alle HF-poliklinieken in Nederland TM al wordt ingezet, zonder dat er duidelijke, vooraf bepaalde criteria of protocollen zijn vastgelegd. Recente HF-richtlijnen (2012) geven aan dat er nu nog onvoldoende bewijs is van de toegevoegde waarde van TM. Het is dan ook opmerkelijk dat zonder duidelijk bewijs TM nu al op een dergelijk grote schaal wordt ingezet. Het aantal patiënten dat met TM behandeld wordt is overigens nog relatief laag. HF-klinieken lijken dus andere motieven te hebben voor het gebruik van TM in de directe patiëntenzorg dan alleen het verminderen van mortaliteit en heropnames.

In hoofdstuk 6 werden specifieke redenen en motieven van Nederlandse HF-poliklinieken

onderzocht om TM te gebruiken. Veel genoemde redenen waren het bewaken van de fysieke conditie van de patiënt, het monitoren van tekenen van verslechtering, het aanpassen van de medicatie en het begeleiden/instrueren van patiënten wat moet leiden tot een beter zelfmanagement. Ondanks de hoge verwachtingen over het effect van TM bij HF-patiënten ervoeren de gebruikers ervan geen vermindering van heropnames of vermindering van de werklast en ondervonden ze evenmin dat ze meer patiënten konden behandelen. Ook zagen ze (nog) geen verbetering van de kwaliteit van de zorg.

Deze tegenvallende ervaringen zouden kunnen leiden tot teleurstelling. Deze teleurstelling werd zichtbaar in het feit dat sommige gebruikers in de studie overwogen om bij een nieuwe keuze van een TM systeem een ander systeem te kiezen. Het is echter maar zeer de vraag of dit algemene gevoel van teleurstelling een direct gevolg was van het gebruik van het specifieke TM systeem of dat de teleurstelling veroorzaakt werd door een gebrek aan efficiënte organisatie rondom de uitvoering van TM.

Uit de studie bleek verder dat behandelaren diverse patiëntenprofielen hanteerden om TM in te zetten. Veel genoemde redenen om TM in te zetten waren: 'eerdere HF-opname', 'op basis van de mate van ziektelast', 'voor educatiedoeleinden' en 'op basis van klachten'. Uit dezelfde studie bleek ook dat behandelaren nog niet goed konden aangeven welk profiel nu het best geschikt was om TM in te zetten en vooral waarmee de meeste 'patiëntenwinst' te behalen was.

Aanbevelingen voor succesvolle implementatie van TM

Om TM succesvol te implementeren is het belangrijk dat de introductie, implementatie en uitvoering zorgvuldig worden aangepakt. Het leren van ervaringen - zowel positief als negatief - van andere HF-klinieken is een essentieel onderdeel in het leren werken met TM. Een ander onderdeel van zorgvuldige implementatie is het vooraf vaststellen van succescriteria waardoor men kan bepalen of een behandeling met TM succesvol is geweest. Een voorbeeld van een vooraf vastgesteld doel kan zijn: 'geen enkele verslechtering mag leiden tot een (her)opname' of 'met behulp van drie contacten op afstand moet het probleem bij de patiënt afgehandeld zijn'. Daarnaast is het van belang te weten waardoor de behandeling bij een patiënt succesvol is geweest. Het is daarom belangrijk om in de implementatiefase van het werken met TM regelmatig te evalueren en beleid en afspraken bij te stellen op basis van de opgedane ervaringen.

Voorafgaand aan de praktische uitvoering is het aan te bevelen dat het behandelteam de verwachtingen over het toepassen van TM, ook die van de patiënt, gaat inventariseren en vaststellen. Zo kan worden voorkomen dat er onrealistische verwachtingen ontstaan.

Daarnaast is het zinvol dat er heldere afspraken worden gemaakt over:

- wie verantwoordelijk is voor de binnenkomende gegevens;
- de maximale responstijd;

- hoe en wanneer te reageren op (afwijkende) data;
- het type interventie dat wordt toegepast bij de afwijkende data;
- de wijze waarop de effecten van de interventie gevolgd moet worden.

Het is ook van belang vast te stellen hoe lang een TM interventie zinvol is bij een patiënt en of er door de kliniek invulling gegeven moet worden aan een full continue bewaking (24/7) of alleen tijdens kantooruren. Tenslotte is het belangrijk dat er getest gaat worden met de inzet van TM bij verschillende patiëntprofielen om te achterhalen welke patiënten nu het meest baat hebben bij de inzet van TM. Omdat veel van bovengenoemde aspecten in het werken met TM binnen het werkveld van HF-verpleegkundigen ligt, lijkt het logisch dat zij dan ook een centrale, coördinerende rol kunnen gaan vervullen in de behandeling met TM.

Wat draagt dit proefschrift bij aan de al bestaande onderzoeken over TM:

1. ICT-gestuurd disease management met telemonitoring in hartfalen is veilig en creëert mogelijkheden om bezoeken aan de HF-polikliniek te verminderen.
2. De kosten van het gebruik van ICT-gestuurd disease management met telemonitoring in de IN TOUCH studie zijn relatief laag. Bovendien kan telemonitoring van waarde zijn voor behandelaars in situaties waarbij patiënten geen directe toegang hebben tot een HF-polikliniek of om de bestaande zorg voor HF-patiënten te herorganiseren.
3. De therapietrouw van patiënten in het gebruik van telemonitoring apparatuur is hoog, wat aangeeft dat het gebruikte protocol en de apparatuur acceptabel zijn.
4. Een betere naleving van de bestaande richtlijnen voor hartfalen met behulp van een CDSS blijft moeilijk, voornamelijk als gevolg van persoonsgebonden, organisatorische en systeemgerelateerde barrières.

Belemmeringen en barrières bij behandelaren in het gebruik van CDSS

In hoofdstuk 7 zijn de barrières van HF-verpleegkundigen en cardiologen bij het gebruik van een CDSS beschreven. Uit eerdere onderzoeken, gericht op de belemmeringen van het gebruik van een CDSS door huisartsen, bleek dat ervaringen met disfunctionerende computersystemen en het gevoel van verstoring van de arts-patiënt relatie door een computer resulteerde in barrières. Voor deze studie definieerden we een barrière als de mate van -subjectief of objectief - ervaren belemmeringen in het werken met een CDSS. Daarnaast speelden onduidelijke verantwoordelijkheden en bedreigingen in de autonomie van een behandelaar een negatieve rol in het werken met een CDSS. Een hogere leeftijd van zorgverleners, al dan niet in combinatie met een gebrek aan ervaring in het werken met computers, werden ook opgemerkt als belangrijke barrières.

In het onderzoek uit hoofdstuk 7 werd een sterke gelijkenis met een aantal van deze eerdere bevindingen bij HF-verpleegkundigen en cardiologen gevonden. Deze barrières werden gecategoriseerd als: 'barrières en bedreigingen', 'verantwoordelijkheid en vertrouwen' en 'kennismanagement'. Zowel HF-verpleegkundigen en cardiologen ervoeren barrières in het werken met een CDSS in alle onderzochte categorieën. Deze barrières kunnen contraproductief zijn voor het werkelijke gebruik van een CDSS.

In tegenstelling tot andere onderzoeken hebben we bij cardiologen niet kunnen vaststellen dat een hogere leeftijd of een gebrek aan ervaring in het werken met computers leidde tot een barrière bij het werken van een CDSS.

Aanbevelingen voor vermindering van ervaren barrières

Het vergroten van kennis door middel van specifieke opleidingen en onderwijs kan de ervaren barrières verminderen. Het is daarom belangrijk om de toekomstige gebruikers van een CDSS inzicht te geven in de mogelijkheden, maar misschien nog belangrijker, de onmogelijkheden van een CDSS. Het gegeven dat een CDSS geen magische zwarte doos is maar een systeem dat alleen maar advies kan genereren door middel van vooraf gedefinieerde richtlijnen en gegevens die door de HF professionals zelf zijn ingevoerd, zal meer begrip geven over hoe een advies van een CDSS tot stand komt. Toekomstige beleidsmakers en zorgmanagers die betrokken zijn bij de introductie van een CDSS moeten zich bewust zijn van het risico van aanwezige barrières bij gebruikers omdat deze een goede implementatie en daarmee dus goed gebruik in de weg staan. Onderwijs, aanvullende scholing en de introductie van zogenaamde 'super-users' zouden een vast onderdeel kunnen uitmaken van de implementatiestrategie. Met 'super-users' worden personen bedoeld die extra opleiding en scholing krijgen en andere gebruikers kunnen helpen in de praktische uitvoering.

Wat draagt dit proefschrift bij aan de al bestaande onderzoeken over het gebruik van TM en CDSS:

1. HF-verpleegkundigen en cardiologen hebben hoge verwachtingen van telemonitoring maar deze hoge verwachtingen worden niet gereflecteerd in hun feitelijke ervaringen.
2. Ondanks het gebrek aan solide bewijs van effectiviteit van TM gebruiken bijna 35% van alle Nederlandse HF-poliklinieken telemonitoring voor hun reguliere zorg, zonder vooraf gedefinieerde protocollen en /of richtlijnen.
3. Zowel HF-verpleegkundigen als cardiologen ervaren barrières in het werken met CDSS. Deze barrières zijn een actuele bedreiging voor een succesvol gebruik. Kennismanagement is significant gerelateerd aan deze barrières, hetgeen impliceert dat het vergroten van kennis een hulpmiddel kan zijn om deze barrières te verlagen.

Voorschrijfgedrag van behandelaars bij het gebruik van TM en CDSS

Het voorschrijfgedrag van de behandelaar (in het proefschrift: prescriber adherence) is de mate waarin een voorschrijver zijn gedrag afstemt op aanbevelingen zoals de standaarden voor zijn of haar vakgebied. Één van deze standaarden bij hartfalen is het zorgdragen bij patiënten voor optimale medicatie. Optimale (hartfalen) medicatie geeft een verbetering in uitkomst op het gebied van sterfte, heropnames en kwaliteit van leven. Het streven naar maximale doseringen medicatie is daarom opgenomen in de richtlijnen voor het behandelen van HF-patiënten en vormt een belangrijk onderdeel van disease management. De mate van voorschrijfgedrag van de behandelaar is al in de EuroHeart failure Survey 2003 beschreven als een voorspeller op het gebied van mortaliteit en heropnames en is een indicator voor het succes van een HF-disease management model.

HF-verpleegkundigen en cardiologen ondervinden bij het toepassen van deze richtlijn in de praktijk echter nog steeds moeilijkheden. In hoofdstuk 8 is de mate van voorschrijfgedrag van de behandelaar in drie verschillende HF-disease management modellen onderzocht. Namelijk in een model waarbij een HF-verpleegkundige een centrale rol speelt, in een model waarbij een CDSS is gebruikt voor de behandeling, en in een model met een combinatie van een arts en een HF-verpleegkundige. In alle drie de onderzochte modellen blijkt dat de individuele dosis medicatie niet meer dan 50% bedraagt van wat maximaal kan worden voorgeschreven en wordt geadviseerd door de richtlijn. Patiëntkenmerken zoals leeftijd, co-morbiditeit en de ernst van de ziekte leiden niet alleen tot frequente heropnames, maar zijn ook de factoren die ervoor zorgen dat de patiënt niet de maximale dosering medicatie krijgt. Het werken met een CDSS dat speciaal ontworpen is voor het starten en het optitreren van medicatie kan een bijdrage leveren aan het voorschrijven van maximale doseringen medicatie. Het is veilig te gebruiken en kan worden toegepast door HF-verpleegkundigen die een belangrijke verantwoordelijkheid hebben in het zorgen voor een optimale medicamenteuze behandeling, als onderdeel van een HF- disease management programma.

Wat draagt dit proefschrift bij aan de al bestaande onderzoeken over voorschrijfgedrag van de behandelaar (prescriber adherence):

1. De totale percentages voorgeschreven medicatie (ACE-remmers, bètablokkers, aldosteron antagonisten) zijn hoog in alle onderzochte hartfalen disease management modellen. Echter, minder dan 50% van alle patiënten gebruiken een maximale dosering ondanks het feit dat twee hartfalen-modellen gericht zijn op het optimaliseren van medicatie.
2. Er is een significante relatie tussen de ernst van de ziekte hartfalen (onder andere in heropnames en de fysieke conditie van de patiënt) en de voorgeschreven dosering medicatie in individuele patiënten. Dit betekent dat een substantieel deel van de onderzochte patiënten de voor hun optimale dosering gebruikt.

3. Een disease management model met een CDSS blijkt net zo effectief te zijn in termen van voorschrijfgedrag van de behandelaar, als een model met een arts, op enkele waargenomen verschillen in doseringen ACE-remmers en bètablokkers na.

Conclusie

Dit proefschrift toont aan dat innovatieve informatie- en communicatietechnologieën zoals telemonitoring (TM) en computer beslissingsondersteunende systemen (CDSS) veelbelovende instrumenten zijn die kunnen helpen om zorgverleners te ondersteunen in het verbeteren van zorg voor hartfalen patiënten. TM en CDSS kunnen patiëntgegevens overbrengen vanuit de thuissituatie van patiënten naar een zorgverlener. Met behulp van deze patiëntendata is de zorgverlener in staat gegevens te interpreteren en daarop te handelen.

In de praktische toepassing van evidence based richtlijnen kan een CDSS helpen bij het maken van de juiste klinische beslissingen. TM en CDSS zijn echter geen 'one size fits all' oplossingen. Dit proefschrift laat zien dat het inzetten van TM niet automatisch leidt tot vermindering van heropnames, sterfte en verbetering van kwaliteit van leven. Het ontbreken van specifieke profielen van patiënten die het meest baat hebben bij TM speelt hierbij een rol. De moeilijkheid in het gebruik van CDSS ligt voornamelijk in de praktische ervaren barrières, die weer leiden tot het risico van een laag gebruik en een slechte acceptatie. Om dit risico om te buigen naar een positieve en succesvolle implementatie moeten we niet alleen onze zorgvragers/patiënten monitoren en behandelen maar ook de zorgverleners. Hierbij essentieel zijn goede afspraken over het praktische gebruik van TM en CDSS, het vaststellen van patiëntenprofielen, behandeldoelen, interventies en continue evaluatie en zo nodig het bijstellen van de behandeldoelen.

Het besef van het potentieel van TM en CDSS en de noodzaak tot innovatie in de Nederlandse gezondheidszorg, in het bijzonder voor hartfalen, leidt tot een interessante uitdaging die ons zal dwingen tot verandering in vele verschillende aspecten van onze gezondheidszorg.

Dankwoord

Arjen E. de Vries

'Geen Promotie zonder hulp van en samenwerking met anderen'

Gedurende mijn aanstelling als promovendus in de periode van mei 2009 tot mei 2013 hebben vele personen substantieel bijgedragen aan het tot stand komen van dit proefschrift. Graag wil ik ze daarom hier persoonlijk bedanken.

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wat overbodig is; niet doen.

en ja, vanaf aanstaande maandag zal ik de vuilnis weer buiten zetten.

Deelnemende patiënten en Ziekenhuizen

Medisch wetenschappelijk onderzoek is niet mogelijk zonder patiënten die bereid zijn om hun tijd en energie te geven aan onderzoek. Dankzij deze patiënten hebben we een klein stukje van het vraagstuk telemonitoring kunnen verhelderen. Ik wil daarom in het bijzonder alle patiënten hartelijk danken die volstrekt belangeloos hebben meegewerkt aan de IN TOUCH studie. Daarnaast wil ik graag alle Nederlandse hartfalen klinieken bedanken welke hebben meegewerkt aan 1 of meerdere onderzoeken van dit proefschrift, in het bijzonder: het Antonius Ziekenhuis Sneek, Catharina Ziekenhuis Eindhoven, Canisius-Wilhelmina Ziekenhuis Nijmegen, het Deventer Ziekenhuis, Diakonessen Ziekenhuis Utrecht, HAGA Ziekenhuis Den Haag, Martini Ziekenhuis Groningen, Medisch Centrum Leeuwarden, Rijnland ziekenhuis Leiderdorp en het UMC Groningen.

Curriculum vitae

Arjen E. de Vries

Arjen de Vries is geboren op 7 augustus 1968 in Groningen, Nederland. In 1986 behaalde hij zijn middelbare school diploma, waarna hij zijn militaire dienstplicht vervulde op de polikliniek Geneeskundige Dienst van de luchtmachtbasis Leeuwarden.

In 1988 ging hij als verpleegkundige in opleiding werken op verschillende afdelingen van het Diaconessen Ziekenhuis Groningen (nu Martini Ziekenhuis). In zijn laatste studiejaar volgde hij tevens de Coronary Care (CCU) opleiding op de afdeling Cardiologie, waar hij tot 1996 bleef werken. Na een uitstapje naar onderwijs en de ondernemingsraad ging hij in 1998 naar de Polikliniek Cardiologie, waar hij verantwoordelijk was voor het opzetten en uitvoeren van een 'nieuwe stijl' Hartfalen en Preventie Polikliniek voor patiënten met hart en vaatziekten. Daar ontstond ook zijn interesse voor reorganisatie van zorgprocessen met ondersteuning van ICT in combinatie met taakherschikking. In 2001 volgde hij de Master Advanced Nursing Practice te Groningen.

In de periode 2006 tot 2009 werkte hij als consultant bij Pink Roccade, Getronics, Kader Software en Curit B.V., waarbij hij verschillende toepassingen van 'Health Information Technology' implementeerde in Nederlandse ziekenhuizen. In 2007 was hij direct betrokken bij de oprichting van Cavari Clinics, een centrum voor cardiovasculaire aandoeningen. In de jaren daarna bleef hij bij Cavari Clinics werkzaam, waarbij het zijn uitdaging was om - samen met dr. Rene van Dijk, cardioloog - vorm te geven aan het inzicht dat het verlenen van (cardiologische) zorg veel beter en efficiënter kan met behulp van ICT. Een belangrijke component van deze efficiëntere zorg was de inzet van computer decision support systemen en telemonitoring. Voor de ontwikkeling en toepassing van 'slimme' ICT in combinatie met taakherschikking ontvingen Arjen de Vries en Rene van Dijk meerdere onderscheidingen en Awards.

Van 2001 tot 2008 was Arjen de Vries tevens voorzitter van de Nederlandse Vereniging van Nurse Practitioners en hij liet zich in 2009, na invoering van de nieuwe BIG wetgeving voor Verpleegkundig Specialisten, als één van de eerste Nurse Practitioners registreren als Verpleegkundig Specialist preventieve zorg. In 2012 volgde een tweede registratie voor intensieve zorg.

In Mei 2009 startte hij zijn promotietraject aan de Faculteit der Medische Wetenschappen van de Rijksuniversiteit Groningen met dit proefschrift als resultaat. De promotie is uitgevoerd op de Afdeling cardiologie van het Thoraxcentrum van het Universitair Medisch Centrum Groningen, onder leiding van Professor dr. D.J. van Veldhuisen.

Momenteel is Arjen de Vries werkzaam als Verpleegkundig Specialist cardiologie in het Centrum voor Revalidatie 'Beatrixoord' in Haren en is hij vicevoorzitter van het Nederlands Netwerk voor Verpleegkundig Specialisten cardiologie.