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# Closed-Loop Healthcare Monitoring in a Collaborative Heart Failure Network

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**Abstract.** Heart failure (HF) is a growing public health problem. The management of HF is usually multi-disciplinary and should comprise the cooperation of all groups of individuals involved in the care like clinicians, cardiologists, general practitioners, internists, nurses, relatives and patients. There is an ongoing debate with regard to monitoring and the optimal level and intensity of care for which kind of patients. Based on our experience with the recently established HF network HerzMobil Tirol, we developed a concept how to combine mHealth-based telemonitoring and disease management programs. The collaborative HF management concept timely and efficiently closes the feedback loop between patients and care providers and allows for continuity of care. The aim is to gradually adjust intensity of care according to the patients' level of disease severity and risk of readmission after hospital discharge along the overall trajectory of illness. Next steps will be to investigate how to define shared decision making, rights, duties, responsibilities and liabilities of the individual stakeholders as well as to analyze business models for reimbursement.

**Keywords.** Telemedicine, mobile health, heart failure, patient care management

## 1. Introduction

Heart failure (HF) is one of the most common chronic diseases in the aged human population and thus a growing public health problem. As a result of improved therapies and increasing life expectancy, incidence and prevalence of HF has significantly increased and it is expected that it will further increase. For example, it is estimated that over the next 20 years the prevalence of HF in the USA will increase by 25% [1]. Prognosis of HF is similar to that of common cancers. The average one-year mortality is 30% and the 5-year mortality is higher than 60% resulting in more than 15.000 HF-related deaths in Austria. Despite improvements in outcomes with medical therapy, readmission rates after hospitalization are still high. Between 30% and 50% of HF patients are re-hospitalized within six months resulting in more than 24.000 hospital admissions per year in Austria [2]. Prevention of decompensation and HF-related hospitalization is important not only for the patient, but also for economic reasons. Like other industrialized countries, Austria spends about two to four percent of the total health budget for HF, which is more than 350 million euros per year. Close to 70% of these costs are exclusively dedicated for financing inpatient care. These numbers

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implicate relevant saving potentials by optimizing HF therapy management.

The Heart Failure Association of the European Society of Cardiology recommends self-measurement of simple vital parameters for symptom monitoring and self-care incorporated into disease management programs [3]. The management of HF is usually multidisciplinary and should support the cooperation of all groups of individuals involved in the care of HF patients: clinicians, cardiologists, general practitioners, internists, nurses, relatives and patients. So far, different disease management programs have been investigated. These programs range from nurse-based disease management, to structured telephone support, to remote telemonitoring with or without the use of an implantable device and heart failure outpatient clinics. All the programs aim to decrease readmission rates, mortality and overall healthcare costs with varying degrees of success [4]. Some studies showed that transmission of body weight, blood pressure and heart rate (all measured by HF patients) leads to a reduction of morbidity and mortality [5-8], while others did not show a benefit [9-12]. A closer look into study designs reveals that those showing a benefit of telemedicine included very sick patients and/or started early after hospitalization for HF. Those showing no benefit abstained from this approach and included primarily stable patients with chronic heart failure.

In Austria, different programs are currently under investigation. “Kardiomobil” is a nurse-based program in the Province of Salzburg, Austria, where specialized nurses visit patients at home to control health status and treatment success and provide disease specific patient education [13]. A telephone-based nursing project was implemented in the region of Krems, Austria [14]. This disease management program comprises computer-based education of patients and their relatives and regular telephone calls that alternate with out-patient appointments. Based on the results of the randomized, multicenter MOBITEL trial [7] several mHealth-based telemonitoring projects were started in the past few years. In 2009 a mHealth-based telemonitoring program for HF patients and patients with pulmonary arterial hypertension was implemented at the Krankenhaus der Elisabethinen Linz, Austria [15]. A prospective, randomized, multicenter-study (INTENSE-HF) to evaluate multimodal support of patients following an episode of acute HF was started in Styria in December 2012 [16]. The primary objective of INTENSE-HF is to determine the effectiveness of the combined intervention of mHealth-based telemonitoring with frequent measurement of NT-pro-BNP compared to a control group without telemonitoring. Additionally, INTENSE-HF investigates the clinical evaluation of specific decision support software for guideline-based therapy optimization. In April 2012, the healthcare provider Tiroler Landeskrankenanstalten GmbH (TILAK) started a collaborative HF network called HerzMobil Tirol that combines mHealth-based telemedicine and nurse-led patient education and home visits embedded in a network of dedicated physicians in private practice [17]. The aim of HerzMobil Tirol is to investigate which HF management strategies are necessary to achieve a relevant and stable impact on readmission rates, mortality and overall healthcare costs.

There is an ongoing debate with regard to home monitoring in HF patients and improved patient outcomes [1, 18]. The optimal level and intensity of care for which kind of patients are still unclear [4, 18]. Close monitoring of signs and symptoms of congestion and gaps in transitions of care are critical in the post-discharge period. Poor medication adherence, poor recognition of early signs of cardiac decompensation and insufficient collaboration among care providers can be addressed by comprehensive multidisciplinary disease management and closed loop telemonitoring programs. Additionally, mobile phone applications can be designed to enhance patient

empowerment and patient self-efficacy. Mobile communication devices, such as mobile phones, and other wireless devices together with Internet and social media, present opportunities to prevent disease progression and improve disease management by extending health interventions beyond the reach of traditional care – an approach referred to as mHealth [19], where a clear focus on chronic conditions can be seen [20]. One of the open questions is how to combine mHealth telemonitoring and disease management programs to HF disease management that timely and efficiently closes the feedback loop between patients and their providers and supports continuity of care. What is the best approach to implement these concepts into clinical practice for a wide range of patients along the trajectory of illness – from low-risk to high-risk patients and from patients supervised by HF specialists to patients out of reach of specialized HF centers?

In the present paper we analyze various elements of a next-generation HF disease management program – mHealth-based closed-loop healthcare monitoring and HF management within a collaborative HF network (methods section), present a concept on shifting the level of intensity of care during the stages of the disease (chapter results) and discuss the concept and next steps (chapter discussion) with respect to the recently established HF network HerzMobil Tirol.

## 2. Methods

### *2.1. mHealth-based closed-loop healthcare monitoring*

Desai and Stevenson have previously proposed a concept illustrating how home monitoring can be embedded in a comprehensive HF management approach [21]. They defined a sequence of steps needed to successfully implement home monitoring: a) transmission of physiological data by the patients themselves, b) data retrieval and analysis, and to close the loop c) patient contact to implement the prescription and finally d) continued monitoring for response and revised intervention. Such a closed-loop-healthcare approach is shown in Figure 1 illustrating three parts within this loop that are essential preconditions to efficiently close the HF therapy cycle: monitoring at home (mHealth monitoring), signal processing and analysis of the monitoring data and clinical decision support e.g. using guideline-based recommendations for medication.

Mobile health monitoring offers new opportunities for therapy management of HF patients at home and to enhance patient compliance to medical treatment. Mobile phone applications are available that enhance patient empowerment and facilitate reliable and efficient data transfer of measured physiological data [15, 20]. Based on lessons learned from the Austrian MOBITEL trial [7], an innovative mHealth approach called Keep-In-Touch (KIT) was developed to facilitate efficient and reliable data transfer and to document drug intake and well-being based on Near Field Communication (NFC) enabled mobile phones and medical devices [22]. Inadequate medication adjustment has been identified as a serious problem. Mobile Health monitoring offers the opportunity for dynamic medication management of HF patients [23]. Physicians are empowered for both, timely react on patient noncompliance or clinical deterioration.

Signal processing and analyzing algorithms filter the relevant signals from the noise of physiological data and should timely detect upcoming adverse events.

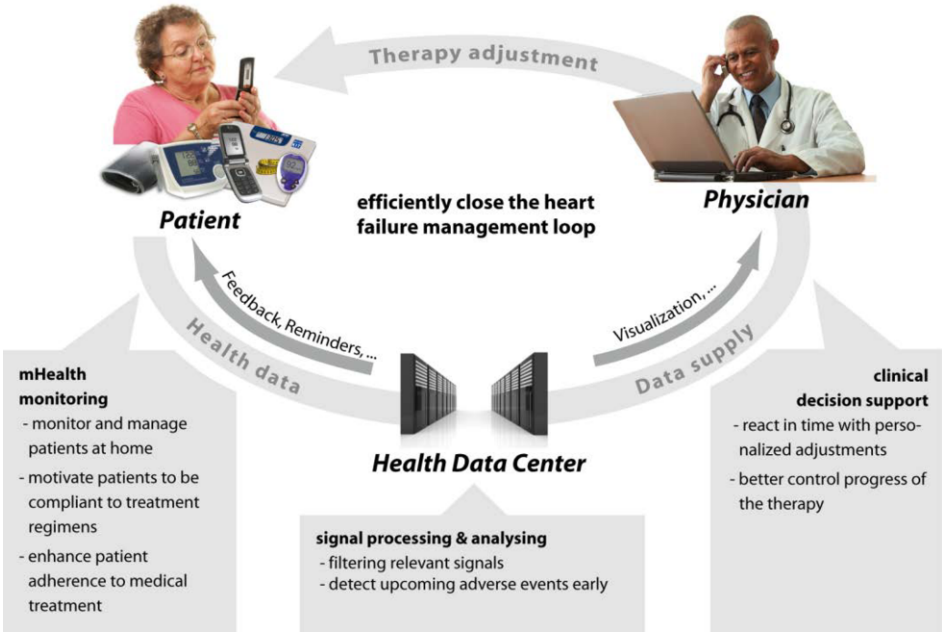


**Figure 1.** Closed-Loop-Healthcare Telemonitoring.

Automatic event detection in terms of missing values, off-limit measurements and weekly checks signals the need for therapeutic decisions and facilitate optimized distribution of attention to those patients who might need early intervention [15].

Clinical decision support assists physicians in taking action in case of deterioration or in adjusting medication according to guidelines. The latter is a cornerstone of the INTENSE-HF clinical trial where specific decision support software supports guideline-based medication management optimization [16].

### *2.2. Collaborative Heart Failure Network*

Even if clinical deterioration or impending decompensation can be detected efficiently through automated home monitoring, additional steps are necessary to effectively connect the circle of HF management and prevent hospitalization events [18, 21]. Comprehensive HF management requires multidisciplinary collaborative care in particular with respect to longitudinal care across venues. During the transition after hospitalization, information is often lost in the handoff from the discharging hospital to the next venue of care and vice versa. Gaps in transition of care in HF are found in the fields of medication errors, handoff communication and discharge planning [24]. Lack of communication for example could result in inadequate and incomplete discharge instructions to the home healthcare team.

The complex medical, social, and economic factors in combination with typical intermittent exacerbations [25] necessitate an integrated team-based approach. Patients, relatives, general practitioners, hospital physicians, cardiologists, other specialty care physicians (e.g., endocrinologists, pulmonologists, or psychologists), and nurses all provide valuable contributions. As a part of disease management programs HF outpatient clinics have been established which usually include a specialized HF

cardiologist, HF nurses, and other HF-related experts responsible for diagnostic services, establishment of an optimal evidence-based drug therapy, and patient education on the disease per se and on self-care behaviors [3]. Especially, HF-nurses will have an important role in mHealth telemonitoring-based collaborative HF networks being the direct link to the patient in almost all levels of care. Thus, they will need to be empowered and better trained in issues relating both to home-based nursing and medical HF to make care and sometimes also medical coordination decisions. Supported by the working group on HF as well as the Board of the Austrian Society of Cardiology, an in-service training for HF nurse care of graduated nursing staff was recently be designed to assist intramural and extramural patient care on a high level [26]. General practitioners are important partners in the medical attendance of HF patients and a close and ongoing cooperation between general practitioners and HF outpatient clinics is needed [27].

Based on the evidence from previous trials and our own experiences, we started to implement a collaborative HF network called HerzMobil Tirol at the healthcare provider TILAK in April 2012 [17] that integrates various physicians - internists as well as general practitioners - in private practice and HF outpatient clinics. This hybrid network model combines elements of different HF management programs like physician-controlled mHealth telemonitoring, nurse-led care including intense patient education within a multidisciplinary approach. Communication between the HF management stakeholders circles the patient and ensures optimal treatment without delay. All relevant information can be shared on the web-based TMScardio telemonitoring software and can instantly be reviewed by everyone who has access to the system. The TMScardio software was developed based on experiences of several mHealth-based telemonitoring projects [7, 15-17] and serves as the IT backbone of the HF management network HerzMobil Tirol. The software is operated at the IT infrastructure of the healthcare provider TILAK. Currently, no interfaces to other healthcare IT systems are used. The users can upload documents like hospital discharge letters and for each patient a telemonitoring report can be generated.

Patients with acute heart failure are included into the program by integrated hospitals and heart failure clinics. HF-specialists and clinicians also serve as last instance in case of serious problems. Patients are allocated to network physicians in primary care who are responsible for HF management and therapy adjustments according to prevailing guidelines. The allocated network physician reviews obtained patient data at least once a week. Out-of-limit data, however, that are detected automatically by the telemonitoring system are transferred and reviewed immediately. HF-nurses provide patient education and home visits if necessary. Finally, a coordinator has to orchestrate all stakeholders and has to manage that all partners can efficiently work together.

## 3. Results

Not all cases of decompensated HF require hospital admission and up to 50% of emergency department patients with HF might be safely discharged after a brief period of observation, in particular low-risk and intermediate risk patients being managed in a special observation unit [28]. The appropriate level of care depends on the degree of acute decompensation or HF risk profile. Patients' level of disease severity may be one of the determinants of where (home vs. observational unit vs. hospital) and for what

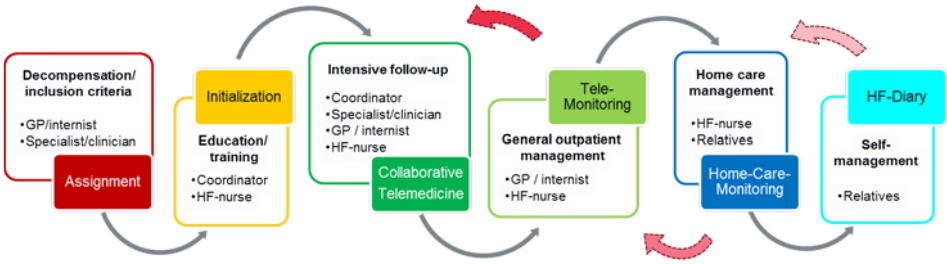


**Figure 2.** Levels of telemonitoring-based heart failure care along the trajectory of illness.

duration (6 month follow-up after discharge vs. lifetime care) they may be managed. The risks of readmission after hospital discharge as well as the number of avoidable readmission vary according to the location along the overall trajectory of illness [29, 30]. The risk is high in the early post-discharge interval (transition phase), falls off to a lower plateau after 2 to 3 months (plateau phase), and then reaccelerates as patients approach the end of life (phase of palliation and priorities). The number of avoidable hospitalizations is assumed to be high in the transition phase and falls off in the plateau phase [29] in which the stable phase of the disease might be disrupted by some unavoidable readmissions due to new medical conditions (e.g., atrial fibrillation). These conditions will require complex treatment decisions and inpatient stay will offer the best setting of care with respect to the rest of the journey [30]. In the last phase, the number of avoidable hospital admissions of patients at the end stage of their disease increases again and might be prevented if appropriate support for palliative care is available.

Thus, the level of care and monitoring of HF patients should be adapted according to the location along the overall trajectory of illness in order to obtain optimal tradeoff between costs (care effort and manpower) and benefit (reduced hospitalizations and increased quality of life). Figure 2 illustrates how the level of HF care can gradually be adjusted within a mHealth telemonitoring-based collaborative HF network. During an acute hospitalization patients are screened whether they can be assigned to the collaborative HF network followed by an initialization phase in which special trained HF-nurses provide patient education with respect to their disease and opportunities of self-management. After discharge patients are trained in using the mHealth-based telemonitoring equipment and afterwards enrolled to the collaborative telemedicine program with intensive follow-up for 6 months under supervision of all stakeholders of the collaborative HF network like the HerzMobil Tirol network. During this phase patients will learn how to adhere to treatment and will improve self-management abilities. In the late post-discharge interval HF management can be done by general outpatient management (“classical” telemonitoring).

As patient empowerment and stability of the health status increases the level of care can further be reduced switching from medical supervision for a limited time to lifetime home care with the support of HF-nurses or in some cases without any professional care support only assisted by a mHealth-based HF diary. For patients with reduced cognitive abilities, relatives are supporting those patients in self-management. As level of care can gradually be reduced until the end of the plateau phase (i.e., running from left to right in Figure 2), it might be again increased in case of worsening HF (indicated by red arrows in Figure 2) or in the phase of palliation and priorities but

with more focus on palliative care. In all levels patients should monitoring selected physiologic parameters and patient-reported health status measures (maybe with different sampling rate) so that they can simply and safely be enrolled to a more intensive care level in which the HF management loop can efficiently and timely be closed due to already available monitoring data.

## 4. Discussion

For patients with HF, shared decision making has become both more challenging and more crucial as duration of disease and treatment options have increased [31]. Since shared decision making is an iterative process, we expect new challenges with respect to rights and duties as well as responsibilities and liabilities of the individual stakeholders of the proposed HF network. Promoting the delivery of patient-centered health care will not only demand organizational changes but also changes in reimbursement structures. In the USA, public and private payers have increasingly targeted reduction in readmission rates as a primary focus of pay-for-performance initiatives because of estimates that nearly three-fourths of early readmissions may be preventable. In Austria, reimbursement structures are different and it is still an open question what kind of services will be provided by public payers and what have to be covered by private stakeholders. The concept illustrated in Figure 2 might allow private as well as public reimbursement. Services located more on the left side could be provided by public payers whereas the private sector could focus on services on the right side although such public/private handshake might complicate continuity of care.

Next steps will be to analyze existing data from the HF network for identifying typical individual risk profiles that defines the level of telemonitoring-based HF care and hence the allocation of resources.

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