Quality Home Telemedicine Services for Chronic Cardiac Disease Patients through the INTERLIFE Platform

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Abstract

INTERLIFE is an EU IST e-TEN project aiming in enhancing healthcare services by introducing new means for quality health care management via telemedicine services, and by improving the patients' and citizens' quality of life. INTERLIFE, based largely on the results of the Citizen Health System (CHS) EU IST, is a technological and medical knowledge management and processing infrastructure able to support among others patients suffering from chronic cardiac diseases such as Congestive Heart Failure (CHF). The preliminary results of INTERLIFE CHF pilot presented here show the possibilities of this service in the treatment of chronic diseases, such as CHF, both in terms of hospitalization reduction and towards improvement of vital signs.

1. Introduction

Heart failure is a clinical syndrome that has become more prevalent in recent years. There are at least 10 million patients with CHF in European countries (total population of over 900 million). In 1996, almost 4.8 million Americans were afflicted with CHF, and each year approximately 400000 new cases of CHF were diagnosed (American Heart Association, 1998). With an incidence now approaching 10 per 1,000 population after age 65, increasing numbers of individuals have to live with the medical-functional consequences of heart failure and face a 5-year mortality rate of about 50%. Heart failure is the only major cardiovascular disorder that is increasing in incidence and prevalence. The disorder is responsible for more than 11 million physician office visits and causes or contributes to over 3.5 million hospitalizations annually, thus making it the leading cause of hospitalization in people over 65 years old. It must be also considered that, in addition to the cost of human life, heart failure poses a tremendous financial burden on the health care systems of many industrialized countries worldwide.

Research has shown the potential of telemonitoring applications in CHF management, in the sense of better regulation of the chronic disease and decrease of hospital re-admissions [1]. Within this context, the e-TEN project INTERLIFE, a continuation and enhancement of CHS project [2], offering telemonitoring services to CHF patients, aims to involve citizens in health care delivery through the use of microdevices and telematics, including a medical education based prompting system, and provide the clinical staff with better diagnosis opportunities. It also assesses the mechanism of home care delivery via randomized control trials and the development of a network for home care delivery in order to exchange data and experiences.

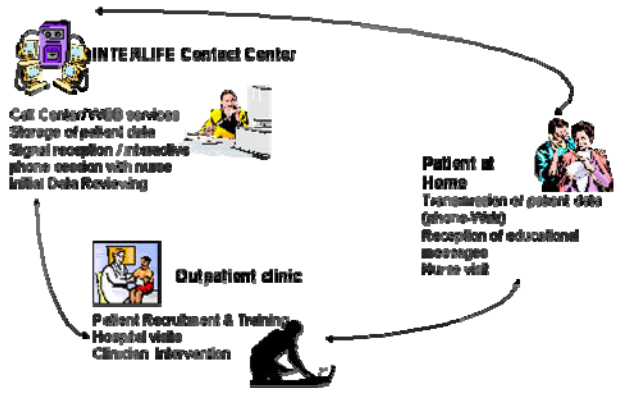
Through the INTERLIFE system the aim is to help CHF patients to prevent acute episodes and expensive hospitalization, to educate them to a healthy life and to monitor them during a follow-up. To meet this goal the system attempts to track patients much more regularly than through typical procedures and advice them about needed routines. A pilot study takes place (12 CHF, 12 control), with a Follow-up of 12 months. The plan includes monitoring 3 times per week of patients' health status, i.e. BP, HR, temperature, weight and questionnaire. The aim of this study is to test whether an intensified treatment, monitoring and guidance for CHF patients leads to a reduction in CHF-related hospitalisation & improvement in vital parameters. Initial results are very promising and seem to prove this concept.

2. Methods

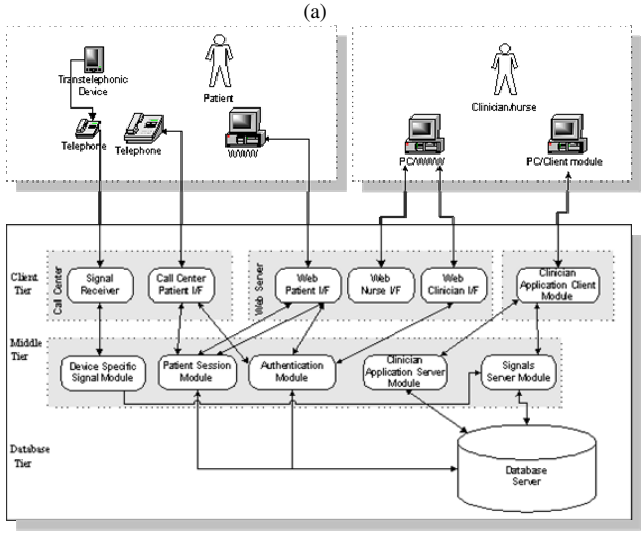
2.1. INTERLIFE services

In the INTERLIFE project, a home care system was developed; the central point in such a system is the Medical Contact Center (MCC), offering functionality both to the medical staff and the citizens seeking advice and/or therapy (Figure 1a). The services available for patients include monitoring of patient's condition based

on vital signs, education concerning the disease, and communication with the medical personnel. On the other side, the medical personnel need to administer patients, browse through or process all the medical information collected, and accordingly conclude to medical decisions and interventions for the patients.



(a)



(b)

Figure 1. a) The INTERLIFE services b) The component architecture of the INTERLIFE System

The INTERLIFE system provides a variety of care support functions, including: a) Reception of information from biosignal measurement devices, b) Step by step instruction for the patient to perform measurements, c) Decision support to identify and correct measurement problems, d) Storage of collected information in a patient data base, e) Forwarding and downloading data to and from the clinical centre unit, f) Additional tools to support medical procedures, i.e. to treat simple but important clinical problems that do not require direct consultation with clinicians (physicians or nurses), g) Prompting the patient with messages to address education, disease management and monitoring issues.

As shown in Figure 2b, a multi-tier architecture allows for system's flexibility and adaptability, i.e. new modules can be plugged in the system. While the applications for the medical personnel are WEB-based, patients may also access the system by standard phone via Computer Telephony and a Call Center at the MCC. Multilingual interfaces are supported. The data model allows for system's customization in various monitoring setups.

Regarding the decision support system, classical rule-based decision support systems are used in the patient monitoring and data entry sessions, especially for artifact rejection issues, while more sophisticated methodologies are used at the MCC site for more elaborate biosignals and bioparameters analysis, such as Data-Mining tools [3] for large medical databases with missing data, Clinician and Administrative Agent-based Alert Tools [4], CT Log-file Analyzer and ECG/HR Processing tools.

2.2. The CHF pilot and aims

In the context of the current project, the INTERLIFE services have been customised for the following target groups: Patients with obesity and or diabetes, Patients with Congestive Heart Failure (CHF), Women in High Risk Pregnancy, Post-trauma Patients and Patients with Chronic Obstructive Pulmonary Disease (COPD).

In the CHF pilot, the primary aim is to test the hypothesis that intensified treatment monitoring and guidance for patients with congestive heart failure through the use of easy to use telematic systems will lead to reduced CHF-related hospitalization, decreased complications and improvement in their vital parameters, with increased patient compliance rate. Specifically, criteria for this hypothesis are a) the number of hospitalizations and hospital days during the follow up period for the intervention group compared with the same parameters of the control group, b) the status of each patient's vital parameters after the monitoring period compared to the values at the beginning of the intervention as well as to the same parameters of the control population respectively, c) the Patient's quality of life, d) Global sense of Satisfaction including cognitive, emotional and behavioural aspects and e) System usage and patient compliance (number of contacts logged).

Secondary aims of the study include the quantification of new technology interventions by CHF patients in the domains of acceptance, patient satisfaction and quality of life, as well as technical evaluation of the INTERLIFE platform, aiming to prove that the INTERLIFE service provided to CHF patients is fully operative. System logfiles are used for the assessment of technical failures, performance and system usage. All interaction via the Call Centre is recorded in log files. Additionally, error reports are used for users comments and logging of technical problems directly by the users.

2.3. The CHF pilot protocol

Patients with heart failure for at least 5 months, with EF<40%, classified as NYHA II or IV, with therapy with b-blockers and/or ACE-I for at least three months and without any curable cause of heart failure are eligible for the pilot. CHF patients with other severe chronic diseases, severe dementia, serious psychiatric illness, inability or unwillingness to operate the technical equipment, planned discharge to a long-term care facility or anticipated survival of less than 12 months were excluded.

In addition to their usual care, patients at home receive the full service of INTERLIFE that includes extensive home monitoring and periodic learning from educational messages. Patients sign a consent form and receive the appropriate instruction brochures and material (the SF-36 Questionnaire, INTERLIFE instructions brochures and the Telemedicine Satisfaction Questionnaire). Following, the clinician explains to the patient the INTERLIFE home monitoring procedure. It is very important to have patients who are committed to a prescribed health care behaviour, in order to ensure that they will follow-through with recommended actions. For this reason, patients are provided with devices (such as blood pressure meters, digital weight scales) that they can keep even after the end of the study, as incentives to participate and follow the clinician's advice. All patients also receive a single lead ECG transtelephonic microdevice.

The patients call in to report their measurements three times per week (Table 1). The selected questions target two objective symptoms (paroxysmal nocturnal dyspnoea and peripheral oedema), two subjective symptoms (fatigue and dyspnoea) and a gentle reminder to take their medicine. Patients send single lead ECG signal via telephone once a week. The ECG gives us information about the cardiac rhythm and is very useful in case of heart arrhythmias such as atrial fibrillation. After dialling their parameters, patients also receive a CHF education tip. Then they have the opportunity to listen to one of 24 educational messages on various topics (Table 1), approximately 1-2 minutes long. Patients may call any time to receive such information.

Clinicians are responsible for monitoring their patients' condition by checking the transmitted measurements, using a client/server or WEB INTERLIFE application. Daily review of patient data is performed by a clinician at the MCC; the cardiologist, who also reviews patient data through the INTERLIFE clinician application, is contacted for advice in special cases during the week. When needed, he/she can communicate with the patients either via SMS or through the telephone.

It is emphasized that INTERLIFE is not an emergency system. It provides continuous monitoring to the patients, thus helping the healthcare provider to assess patient status and timely intervene when there is such need, however, if the patients have an emergency situation they will still have to contact the emergency department.

Table 1. Monitoring Protocol for the CHF Patient.

Time Interval	Activity
Three times per week	Measurement and electronic transmission of • body weight, body temperature, heart rate, systolic/diastolic blood pressure • yes/no answers on five simple questions: a) "Were you breathless during the night?" b) "Are your legs swollen?" c) "Do you feel more tired today?" d) "Do you have more dyspnoea today?" and e) "Have you taken all the medications?"
Once a week	Patient sends single lead ECG via telephone (phone call initiated by Contact Center)
According to patient needs	Visit to the outpatient clinic
Patient may call any time	Educational Messages on CHF, available via the Automated Call Center. Topics: Knowledge and Prevention, Therapeutic treatment, Exercise, Salt, Fat, Cholesterol and weight, Fluids and alcohol. Same information available on the WEB

3. Results

The trial takes place at the Department of Cardiology of AUTH at the AHEPA Hospital of Thessaloniki, Greece. Totally 24 patients are planned to participate, 12 intervention and 12 controls. So far 7 patients have been enrolled to the intervention group and one more has dropped out, while 3 patients have been assigned to the control group. The mean ages of the two groups are 57.14 and 70 years respectively.

Preliminary statistical analysis of the transmitted data from the patients during the first six months of monitoring revealed that the users showed a slight decrease in the Systolic Blood Pressure and weight values, although not generally followed by a similar improvement in their Pulse Rate and Diastolic Blood Pressure; however those differences were not statistically significant, according to the t-test criterion. Overall, the average and median relative differences in bioparameters between the first and last 2-month monitoring period for all patients was: -3.76% and -3.68% for the BPS, -0.61% and -0.54% for the weight, 1.31% and -0.29% for the BPD, 2.89% and -0.46% for the pulse (one patient showed significant increase). In the same manner, improvements were observed in the patients' responses concerning their dyspnoea, fatigue and swelling symptoms, as well as their compliance to medication, but the changes were not statistically significant.

On the other hand, there was a significant decrease in the number of hospitalizations related to CHF during this initial period, from an average of 1.71 to 0.14, $p<0.01$. Besides the improvement in the patients' quality of life, there are economic implications of such a decrease. An initial quantification of the economic impact of such a reduction in the number hospitalizations was performed, for the Greek healthcare system. In this case, for a 100 patients monitoring system, which succeeds to decrease the hospitalization rate from 2/yr to 1/yr, the hospitalization savings are more than four times higher than the telemonitoring system's expenses.

3.1. Example of intervention to a patient

A 60 years old male participating in the CHF study sent an ECG signal with signs of ischemia (Fig 1) and reported relevant symptoms as well. The doctor prompted the patient to take isosorbite mononitrate and visit his local cardiologist. After that, the patient was relieved from symptoms and his next ECG was within the normal range (Fig 3).

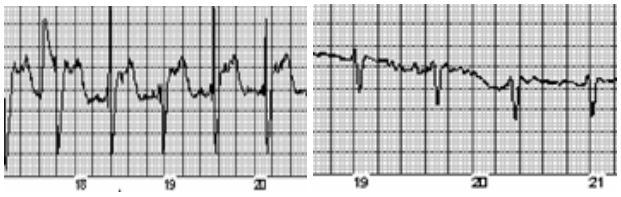


Figure 3. ECG before (left), and after (right) intervention.

In another example, a 51 years old female suffering from CHF and arterial hypertension presented a prolonged deterioration in her transmitted arterial pressure values during the first 4 months of monitoring (Mean Systolic BP reached 179.3 mmHg). She was prompted to visit her cardiologist, who altered her medication twice before achieving normalized BP values two months later (Mean Systolic BP was 139.6 mmHg).

These examples highlight the ability of INTERLIFE service to detect complications for each patient, enabling timely interventions by the medical personnel, which facilitate a smooth regulation.

4. Discussion and conclusions

As is true with other chronic diseases, CHF requires rigorous disease management to improve quality and longevity of life. When telehealth technology is utilized for CHF patients, it offers them independence and the ability to perform sophisticated clinical and diagnostic measurements, allowing practitioners to treat, evaluate, and educate patients right in the comfort and safety of their own homes. Scientific literature denotes CHF as one of the major disease states well suited for telehealth applications [5].

Accordingly, INTERLIFE is a service with potentials to become part of the future Telemedicine practices, integrated into the "real-world" working environment of healthcare professionals. Specifically, the initial use of the specific CHF telemonitoring system led to decreased patients hospitalizations and there is also an evident tendency towards a further improvement in their monitored vital parameters. However this tendency remains to be proven at the end of the full one year period of use of the system. Finally, the application has shown its value in certain cases of medical intervention whenever such a need was present. However, such interventions based on much denser data than the usual clinical practice is based upon, highlight the need for elaboration and enhancement of telemedicine-based medical algorithms, treatment procedures and guidelines, based on evidence.

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