Validation of a Flexible and Innovative Platform for the Home Monitoring of Heart Failure Patients: Preliminary Results

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Abstract

During the clinical validation of HEARTFAID, a platform of services for the medical-clinical management of heart failure (HF) in elderly subjects, performed in several European sites, special attention was paid to test Nurse@Home (N@H), a flexible and innovative application for the home monitoring of HF patients. This paper is focused on the validation performed in the sites of Catanzaro and Milan, Italy.

In both validation sites selected patients, complying with the inclusion criteria, after giving written informed consent, were enrolled into the HEARTFAID platform and assigned to a home monitoring phase. The flexibility of N@H allowed the implementation of different telemonitoring procedures in each validation site.

The flexible home monitoring, irrespective of the sensors used and of the transmission modality to the HEARTFAID platform, was generally well accepted and only minor difficulties were encountered. In Catanzaro, the evaluation of data coming from N@H was also useful to check two possible cases of decompensation The first results obtained put in evidence how the readiness of medical interventions on changes of the monitored parameters could be very important in order to prevent hospital readmission and to reduce health care costs.

1. Introduction

Heart failure (HF) is a pathophysiological state in which an abnormality of cardiac function is responsible for the failure of the heart to pump blood at a rate commensurate with the requirements of the metabolizing tissues [1]. HF is now recognized as a major and escalating public health problem in industrialized countries with ageing populations, affecting about 7 million Europeans and 5 million North Americans every year [2]. The major component of healthcare costs for congestive HF is hospital treatment, which accounts for more than two thirds of such expenditure and about 2% of total healthcare expenditure [3]. Although patients with chronic HF (CHF) often die from a sudden cardiac event, the progressive and unstable nature of the syndrome indicates that many patients require multiple admissions to the hospital in the last 12 months of life [2]. Despite new and more effective pharmacological and non-pharmacological therapeutic strategies, the prognosis of patients with CHF remains very poor [4]. However, there is growing evidence that improved organization of HF care can have a major impact on reducing hospitalizations and/or deaths but, within most populations, access to these programs is limited by barriers related to funding or geography and by the lack of healthcare staff able to provide expert management for HF. Novel methods for the delivery of high quality healthcare could increase the effectiveness of management while containing costs and using scarce human resources to maximum effect [5]. Consequently interest is increasing in remote monitoring models for delivering care. Such an interest has also been stimulated by the rising costs of hospital treatment, rapid advances in technology, and the wider availability of low-cost, patient-friendly equipment.

The HEARTFAID platform has been designed and implemented in the context of the HEARTFAID European funded project [6] and aims to provide the HF care providers with a powerful aid, supporting a new CHF management model. In 2009 this platform was

tested in several European clinical sites. A key part of it is the Nurse@Home (N@H), a flexible and innovative application for the home monitoring of HF patients, built with the main goal of easing the early detection of decompensation episodes.

This paper is focused on the first results of the validation performed in the clinical sites of Catanzaro and Milan, Italy, related to the use of N@H.

2. Methods

The N@H application is an innovative and flexible home monitoring tool for HF patients, developed using pure Java technology and other Java-based cross-platform solutions, able to operate in any modern operating system. It complies with the specifications of the doctors for the set of the vital sign measurements necessary in the home monitoring mainly focused on the early detection of decompensation episodes.

The graphical interface of the program is very simple and guides the user, step by step, to complete the necessary measurements, facilitating the workflow. Measurements can be acquired either manually or through the use of appropriate wireless devices, which measure the vital signs and transmit them to the application, thus minimizing the user interaction.

The application is very flexible allowing the manual or automatic acquisition of a selectable set of measurements and the operation by the patient herself, by a nurse in case of assisted home care or by an operator in case of remotely managed care.

2.1. Medical devices used by N@H

As stated before, the N@H application can collaborate with several wireless devices in order to receive the vital sign measurements performed by using the device and automatically transmitted by the device itself. The wireless devices currently integrated in N@H are shown in Figure 1 (more wireless devices could easily be added in future versions of the application).

The MagIC system is composed of a vest including textile sensors and a portable electronic board. At the thorax level, an ECG lead is obtained through two woven electrodes, made by conductive fibers, whose contact with the thorax is guaranteed by the elastic properties of the garment, without requiring application of gel or of any other medium. The vest also includes a textile-based transducer that provides a chest movement signal that can be used for the assessment of the respiratory frequency [7]. Through connections still obtained by using the same conductive fibers, ECG and chest movement signals feed a portable electronic module which is placed on the vest through a velcro strip. ECG and chest movement data are transmitted via Wi-Fi in XML format to the home gateway where the N@H has been installed.

The other devices are: a) the A&D UA-767PBT blood pressure monitor, which measures the blood pressure and the heart rate; b) the A&D UC-321PBT personal health scale, which measures the patient weight; c) the Nonin pulse oximeter, which measures the arterial oxygen saturation of the patient. All these devices transmit the acquired measurements via Bluetooth to the N@H.

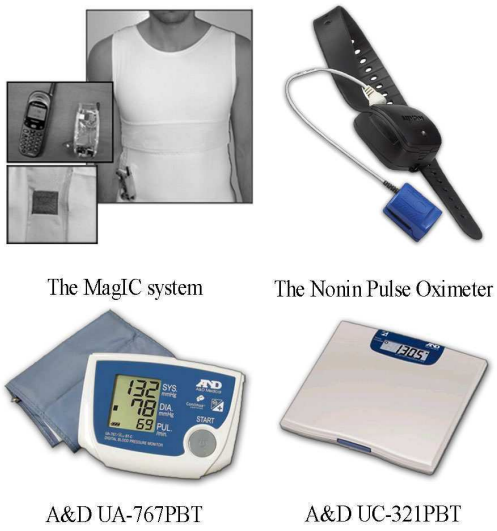

Figure 1. [Top] The MagIC system. [Middle] The A&D Bluetooth devices. [Bottom] The Nonin pulse oximeter.

2.2. N@H interface

The N@H application helps the patient to answer the questions of the Minnesota questionnaire, and then it guides the patient in each step to measure the systolic and diastolic blood pressure, the heart rate, the arterial oxygen saturation, the body weight, the respiratory rate, the body temperature, the urine output and the body water. The N@H can be configured to measure any combination of the previous vital signs (see Figure 2), while it also provides the user with the option to skip any of these measurements, which can be performed again at the end of the procedure.

The 21 questions of the Minnesota questionnaire measure the effects of HF and treatment for HF on the patient's quality of life during the last 4 weeks. When the patient has completely filled in the questionnaire, the program proceeds with the next measurements.

The window of measurements guides the patient through a step by step procedure to perform the medical tests (see Figure 3). The systolic blood pressure, the diastolic blood pressure and the heart rate are measured twice in order to extract the average values and to minimize the case of errors in a single measurement. The

three previous measurements can be acquired either manually (using a conventional mechanical sphygmomanometer) or automatically (using the A&D blood pressure device). The arterial oxygen saturation can be inserted either manually (after measuring it with a commercial pulse oximeter equipped with a display) or automatically using the Nonin device. The body weight can be inserted either manually or automatically (using the A&D scale). The respiratory rate can be extracted automatically by the MagIC system [8] or measured manually. The temperature and the remaining measurements can only be measured and inserted manually. The heart rate could also be extracted from the MagIC system [9] or from the pulse oximeter device, but the priority has been assigned to the measurement coming from the blood pressure device.

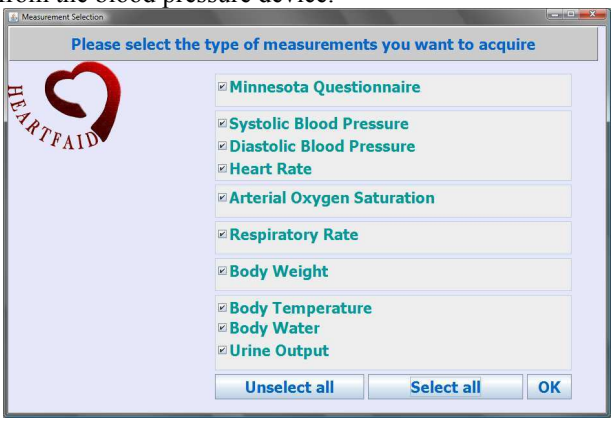

Figure 2. The patient can select any set of measurements.

3. Results

The validation of the N@H application has been performed in several EU clinical sites among which Catanzaro and Milan, Italy. In Catanzaro the clinical site has been set up in the cardiovascular Disease Unit at the University of Magna Graecia (UNICZ), while the clinical site in Milan has been set up in the Department of Cardiology, San Luca Hospital, Italian Institute for Auxology (AUXOL). In both validation sites the applied clinical protocols had been approved by the institution ethics committees. The selected patients, if meeting the inclusion criteria, after giving written informed consent, were enrolled into the HEARTFAID platform and assigned to a home monitoring phase.

In the validation site of Catanzaro, 10 elderly CHF patients (9 males and 1 female) were selected with a CHF severity ranging from NYHA class II and NYHA class III. The N@H application had been installed on their personal computer. All patients, once a week, filled in the Minnesota questionnaire and, every morning, measured body temperature and respiratory rate. In particular, for 7 of the 10 patients, blood pressure, heart rate and body weight were manually acquired, while, for the remaining 3 patients, the measurements acquisition was automatic, by using the appropriate A&D Bluetooth devices.

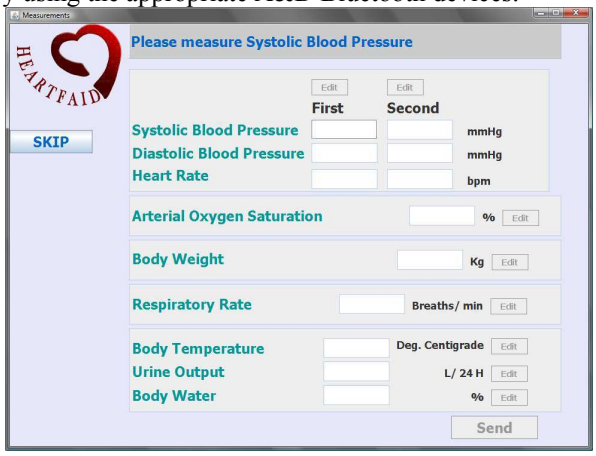

Figure 3. The window of measurements in the N@H.

During the phase of testing and validation, the data coming from N@H of two patients were used to check two possible cases of decompensation. In one case the employment of anti-inflammatory drugs for a patient caused a dangerous increase in systolic pressure. Thus, the doctor in charge was able to immediately contact the patient, to stop the anti-inflammatory drugs and to improve the antihypertensive therapy regimen. In the other case, the home monitoring service was useful to discover that a patient, who showed an increase in body weight, had discontinued the diuretic therapy. In this case the doctor involved in the project could readjust the diuretic therapy immediately. Thus, using this service, two possible hospitalizations were avoided. Using N@H for home care monitoring, it was observed an improvement in patient's care, due to an easier and better management of the disease, and a positive influence on the quality of life, evaluated by Minnesota questionnaire. Telemonitoring of clinical parameters at home was found highly useable by the patients, with good patient satisfaction. Only 4 patients needed the help of a relative in the use of N@H and there was only a single technical problem (Internet connection), which was immediately solved during the same day.

In the validation sites of Milan, 7 patients were enrolled in the HEARTFAID platform and performed a one month daily monitoring of selected biological parameters. A subgroup of 3 patients completed the home monitoring by means of an integration of the MagIC system in the N@H application. Details of this specific validation are reported in another paper presented at this conference [10]. The subgroup of the remaining 4 patients completed the data collection in the home setting

by means of either the manual acquisition procedures or the automatic acquisition procedure using the A&D Bluetooth devices.

All 7 patients monitored at home by N@H (with or without the MagIC vest) did not exhibit, according to both the clinical judgment and the HEARTFAID platform, a risk of incipient decompensation. Daily home data on blood pressure prompted fine titration of pertaining medications by the physicians in two patients. The achievement of stable clinical conditions in these patients during the home monitoring phase, despite being at high risk of decompensation, can either be due to the tight time frame (short duration of follow up phase) or to the fact that the patients improved their compliance to the pharmacological regimen, being involved in a research study. It has to be noticed that all the patients demonstrated a good acceptance and relatively quick familiarization with the system.

All the patients found the N@H application easy to use. The N@H application in every case worked seamlessly and only a couple of times the patient had to repeat the measurement due to Internet congestion. All the patients have felt "safely supervised" and many of them expressed interest in acquiring the package of the N@H application and the measurement devices.

4. Discussion and conclusions

The results obtained by the clinical partners suggest that the HEARTFAID platform exerts an impact on the timelines of medical interventions in response to changes of the monitored parameters. In particular, it allowed a prompt reaction by the medical personnel to changes in patients' clinical parameters, which may result in prevention of hospital readmission and in reduction of health care related costs. After evaluating the accuracy of the acquired data, the physician may modify pharmacological treatments according to daily clinical findings. This seems to represent a key factor in the effort to improve and stabilize the clinical conditions of HF patients, with the aim of increasing the time free from hospitalization and/or of reducing hospitalization days. In addition, the support offered by the platform also to hospital care of CHF patients can improve the management of this complex condition, favoring correct behaviors according to current guidelines. This approach may thus in the end allow reducing the social and economic costs of CHF management.

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