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Design of a Service for the Management of Heart Failure Patients Using Telemedicine

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Abstract. The tremendous prevalence and mortality of heart failure (HF), along with the social and economic impact of its consequences, make an appropriate disease management utmost important. In this context, telemedicine offers promising possibilities. Current clinical guidelines and technological solutions do not address the problem of monitoring at-risk patients and patients affected by mild HF for prevention purposes. The goal of this work is to design a service based on a telemedicine framework for the management of heart failure patients. The proposed service grounds the monitoring of the patient on a custom multi-sensor array that we designed and developed for the purpose. The description of the processes involved in the service was carried out by means of Process Modelling tools, and in particular through Swim Lane Activity Diagrams. The results look promising for the implementation of the service in a real-life scenario. The main strength of the service resides in a) the use of noninvasive monitoring technologies to include patients with a mild HF or at-risk patients; and b) the integration of hospital and territory services to grant continuity and coherence in the treatment.

Keywords. Telemedicine service, medical devices, heart failure

1. Introduction

Heart failure (HF) is a complex clinical syndrome resulting from any structural or functional impairment of ventricle's ability to fill with or eject blood [1]. It typically evolves into a chronic condition and represents the last stage of most cardiovascular diseases. From a clinical point of view, both prevalence and mortality of HF are dramatically high. Currently, prevalence is estimated to be as high as 64 million cases worldwide [2], and it is expected to grow even more in the future due to population aging. Moreover, the prognosis is still very low and a 5-year mortality up to 50% was found [3].

In this context, telemedicine has started to play a leading role in the recent years [4,5]. Two aspects mainly benefit from the introduction of telemedicine tools in HF disease management, i.e. the education and the monitoring of HF patients [4]. Invasive and noninvasive telemonitoring was widely explored as a tool for early diagnosis and prompt prevention of acute episodes of HF [6], and thus hospital readmissions. The

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unavailability of a noninvasive devices limits the telemonitoring of at-risk patients or patients affected by a mild form of HF. Moreover, to maximize the benefit of such kind of services, there is a need for an integrated action of hospital and territory. In fact, it was proved that personalized post-discharge support is key to reduce the unplanned hospital readmissions [7]. For this reason, adding telemedicine technology in the clinical pathways requires the analysis of the processes, the choice of suitable tools, and the definition of the integration plan [8].

The goal of this work is to design a service based on telemedicine tools for the disease management of HF, through the integration of hospital and territory care services, to improve the quality of care offered to HF patients in the territory. The proposed service tackles the problem of the monitoring patients with mild HF using noninvasive technologies.

2. Noninvasive Telemonitoring of Heart Failure

The work was conducted in collaboration with the Cardiology Department of the Hospital of Ciriè (Turin, Italy) and with the Local Health Department. The Cardiology Department of the Hospital of Ciriè already offers a telemonitoring service to HF patients implanted with an ICD CRT or a CardioMems™ device. Patients whose HF status is not severe enough for an indication to an implantable device are not offered continuous monitoring. This is in line with current clinical guidelines [1,9].

At date, the noninvasive monitoring of HF patients is limited by the unavailability of appropriate sensor technology, capable of monitoring a biomarker whose changes are directly affected by the changes in the hemodynamics of the heart. Our approach relies on the monitoring of the Cardiac Time Intervals (CTIs) of the patient through combined recordings of an electrocardiogram (ECG) and the heart sounds. In fact, changes in the CTIs were proved to be associated with a worsening in the status of HF patients [10–12]. The noninvasive monitoring is performed by means of a flexible multi-sensor array that we developed. The array embeds 3 electrodes for the recording of an ECG, 48 microphones for the recording of the heart sounds from multiple positions of the patient's chest and a Magneto-Inertial Unit to detect the patient's posture and motion.

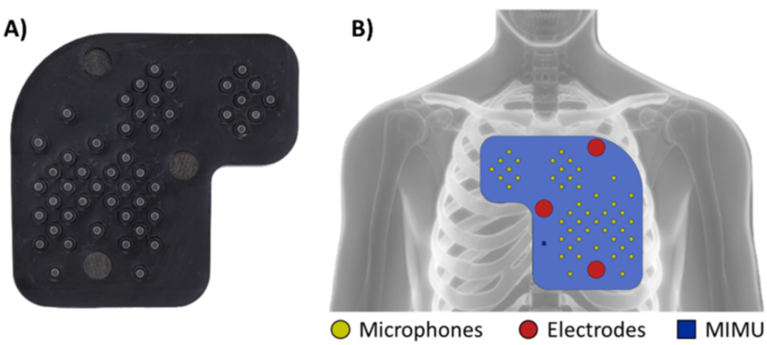

Figure 1. Picture of the device (panel A) and graphical representation of the distribution of the sensors over the subject's chest, which enables the use by inexperienced users (panel B)

The microphones are located with the scope of covering the traditional auscultation areas, as shown in Figure 1. By employing a high number of microphones at a high spatial resolution, the multi-sensor array enables the recording of the heart sounds by inexperienced users. In fact, contrarily to what happens with the traditional stethoscope, that must be placed in specific positions to auscultate the heart valves, the positioning of our multi-sensor array is not critical and can be performed even by users with no technical nor clinical knowledge. The usability of the proposed device by inexperienced users was previously demonstrated [13].

3. Design of the Telemedicine Service

To design the novel integrated service based on a telemedicine tools, we used Process Modeling (PM). PM comprises a set of graphical tools allowing to describe the workflows performed in an organization, to obtain a comprehensive understanding of activities, actors and resources. PM tools have been widely employed in the healthcare field [14–17] and their effectiveness in the telemedicine context has been also demonstrated [18]. In this study we used the Swim Lane Activity Diagram, that have a vertical structure where each column represents an actor involved in the process. This allows for clearly defining roles and responsibilities, which is particularly useful in the phase of designing a new service. Moreover, in the Swim Lane Activity Diagram the sequence of the activities of the process is described and the possibility of inserting selections and parallels among activities increases the flexibility of the tool in describing complex workflows [14].

Figure 2 presents the Swim Lane Activity Diagram of the process of the novel service that we propose in this work. The colors of the columns highlight the setting where the corresponding actor is located. In particular, the orange column refers to patient home, the blue column refers to hospital, the green columns refer to community health center. In the proposed service, the community health center doctor assesses the health status of the patient and the services to be offered to her/him. The patient is trained to use the device and record and transmit data directly from home. Data is processed by a web platform, which raises an alarm in case the CTIs are found outside the predefined range of normality. The cybersecurity and the privacy of the patient data are ensured through adherence to the MDCG 2019-16 and the GDPR legislation. The community health center doctor examines the alarms and, if needed, sends the patient to the Emergency Department. Among the offered services, the patient is periodically visited by a community health center nurse who at every visit fills a form.

4. Discussion and Conclusions

In this work we designed a service based on telemedicine for the monitoring and treatment of at-risk patients for HF or patients affected by a mild form of the pathology. The proposed service grounds on the remote monitoring of the patient through a noninvasive multi-sensor array devoted to the monitoring of CTIs. The novelty of the array resides in its usability by the patient himself, and therefore enables the domiciliary monitoring of at-risk patients or patients affected by mild HF. In this way, the multi-sensor array widens the target population of the telemonitoring service.

In this context, we described the entire process by means of Process Modelling, and in particular, using Swim Lane Activity Diagram. From the presented diagrams it can be observed that three main settings are involved in the service, namely the patient home,

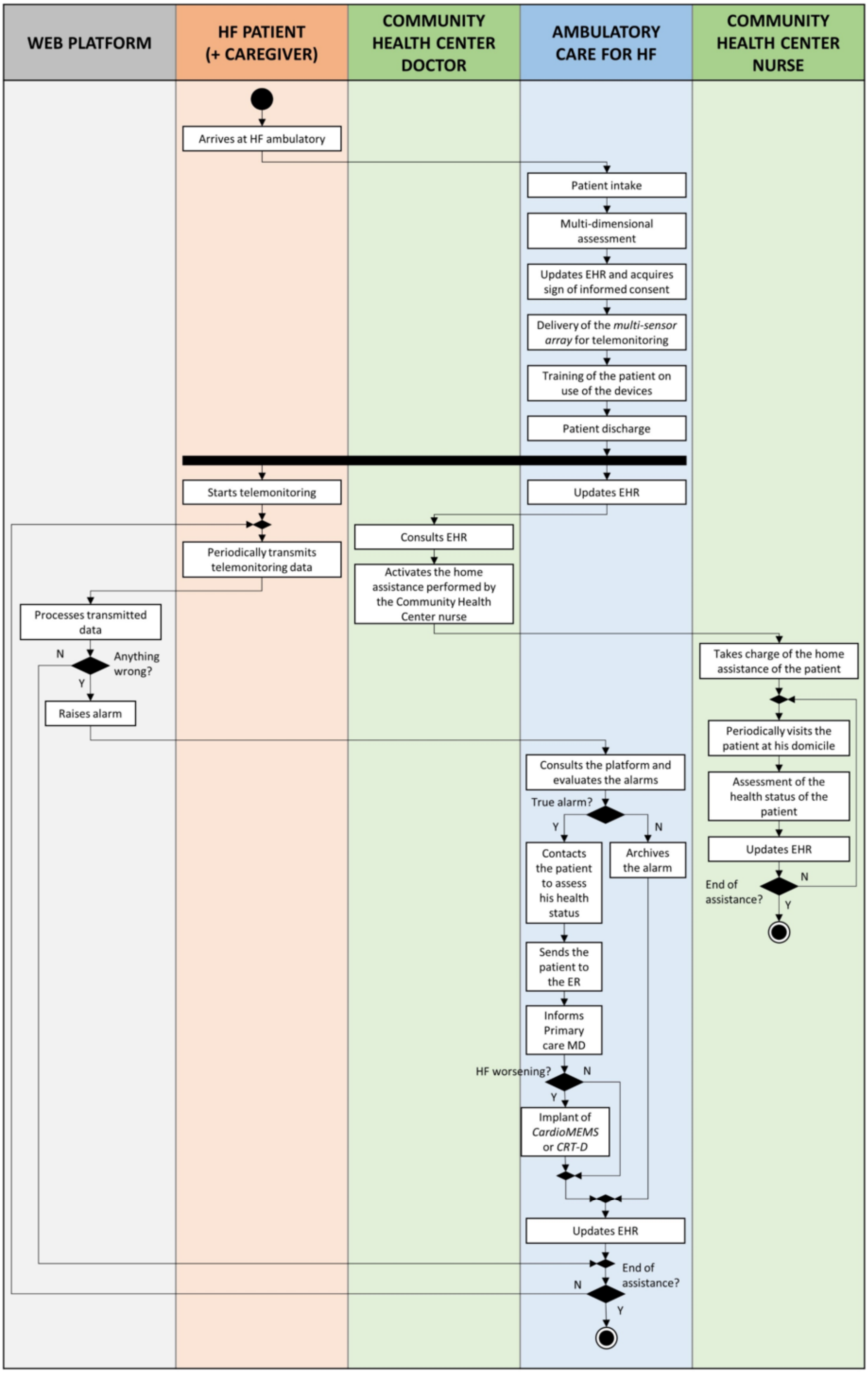

Figure 2. Swim Lane Activity Diagram of the proposed service for the telemonitoring of HF patients.

the community health center, and the HF ambulatory of the hospital. The designed service provides care to patients who are affected by a mild form of HF. As a consequence, a more reliable prevention of acute episodes can be carried out, with a potential positive effect on the clinical outcomes and a reduction of hospitalization events, which will be investigated in the future.

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