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Review

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E-Care Project: A Promising E-Platform for Optimizing Management of Chronic Heart Failure and Other Chronic Diseases

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ABSTRACT

Monitoring patients with heart failure by using telemedicine systems is a potential means for optimizing the management of these patients. The E-care project is developing an "intelligent" communicative platform enabling the home monitoring of patients with New York Heart Association (NYHA) Stage III heart failure using non-invasive sensors. As a result, this platform will assist health care professionals by providing an automated processing of these sensors' transmitted data in order to detect and report signs of cardiac decompensation early.

KEYWORDS: Heart failure; Telemedicine; Home support; Detecting signs of cardiac decompensation.

INTRODUCTION

Heart Failure (HF) is a serious chronic disease that, in addition to its significant morbidity and 50% mortality rate at 5 years for New York Heart Association (NYHA) Stages III – IV, involves frequent re-hospitalizations that impede patient quality of life, some of which could be prevented through early action.[1]

In France, nearly 1 million people suffer from HF, and over 120,000 new cases are diagnosed every year, thus presenting a major public health issue. Managing HF is a complex, lengthy, often difficult task, with great cost to our society, both in terms of healthcare and treatment time as well as from a financial standpoint.

Yet while HF treatment is currently well-standardized, according to evidence-based medicine, and has enabled undeniable progress, particularly with regard to mortality rates, there are still potential advances to be made in terms of life expectancy and the quality of life of these patients, notably by centering long-term management in the home.[1] Monitoring HF patients by using telemedicine systems is a potential means for optimizing the patient management process.

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In this paper, we discuss the role to be played by telemedicine in HF management and present a new e-platform that promises to optimize the management and monitoring of this chronic disorder.

The Role of Telemedicine in the Management of Chronic Diseases like Heart Failure

The monitoring of chronic disease patients using telemedicine systems is theoretically a promising means for optimizing patient management in these cases, as already demonstrated in certain diseases, such as diabetes or chronic HF.[2-6] Advances in telecommunication technologies have created new opportunities to provide telemedical care as complementary treatment to the medical management of HF patients. Meta-analyses have suggested that telemedicine can reduce morbidity and mortality in patients with these types of disorder.

Nevertheless, the results of telemonitoring studies and meta-analyses have been controversial. In reviews assessing these methods, telemedicine approaches range from computer-based support systems to ones founded on structured telephone support, or even to programs led by nurses and physicians.[2,6] It is thus difficult to have a definitive opinion based on what we know now on whether or not telemedicine has a significant role to play in HF management.

In the thorough 2011 meta-analysis from Anker et al., published in The Lancet, the results with respect to mortality and HF-related hospitalization decreases, in addition to improved quality of life, were well-documented.[4] In this meta-analysis, 11 studies were analyzed in the setting of a comparison between the effects of telemonitoring versus usual care (noninvasive telemedicine). Telemonitoring was found to reduce the following rates: all-cause mortality, achieving 147 events/1,410 patients (10.4%) vs. 200/1,300 (15.4%) ($p < 0.0001$); all-cause hospital admission, with 582 events/1,232 patients (47.2%) *vs.* 579/1,111 (52.1%) ($p=0.02$); hospital admission related to chronic HF, with 189 events/844 patients (22.4%) *vs.* 207/726 (28.5%) ($p=0.008$).

Similar results were reported in a more dated meta-analysis from the Cochrane group.[5] Of the 25 full peer-reviewed studies meta-analyzed, 16 evaluated structured telephone support (n=5,613 participants), 11 telemonitoring (n=2,710 participants), and two both interventions (included in counts). Telemonitoring was demonstrated able to reduce all-cause mortality (Hazard Ratio [HR]: 0.66; 95% CI: 0.54-0.81, $p < 0.0001$), with structured telephone support demonstrating a non-significant positive effect (HR: 0.88; 95% CI: 0.76-1.01, $p=0.08$). Both structured telephone support (HR: 0.77; 95% CI: 0.68-0.87, $p < 0.0001$) and telemonitoring (HR: 0.79; 95% CI: 0.67-0.94, $p=0.008$) reduced chronic HF-related hospitalizations. For both interventions, several studies reported improved quality of life, reduced healthcare costs, and high patient acceptance.

As described below, meta-analyses have indicated that telemedicine could reduce morbidity and mortality in these patients. Still, two prospective clinical trials have produced results that do not support these findings.[7,8] The Tele-HF trial randomly assigned patients hospitalized for HF to either telemonitoring (n=826) or standard care (n=827).[7] The noninvasive telemonitoring system was an asynchronous, telephone-based interactive voice-response system that obtained daily information on the patient's symptoms and bodyweight. In this trial, no significant difference was noted between the telemonitoring and control groups in terms of rate of any readmission or death from any cause within 180 days of inclusion, which concerned 432 patients (52%) in the telemonitoring group and 426 (51%) in the usual-care group (HR: 1.04; 95% CI: 0.91-1.19).

The TIM-HF trial in Germany randomly assigned stable chronic HF patients to either telemonitoring (n=354) or usual care (n=356).[8] The noninvasive, synchronous telemonitoring system was based on a wireless Bluetooth device together with a personal digital assistant as the main structural element, all data being transferred to the telemedical center by cell phone. The integrated sensor network consisted of a 3-lead Electrocardiogram (EKG), blood pressure device, and weighing scales. The patient conducted his or her own daily self-assessment using these devices, with the data transferred to the telemedical center, which provided continuous physician-led medical support for the total study period. The telemedical center physician contacted the patients in accordance with the standard operating procedures or on patient request. The center contacted the patient's local physician at least every 3 months. In this trial, the total mortality rate for the primary outcome of death for any cause was 8.4 per 100 patient-years of follow-up in the telemedical group, compared to 8.7 per 100 patient-years of follow-up in the usual-care group (HR: 0.97; 95% CI: 0.67-1.41; $p=0.87$).[8]

The Role of Telemedicine in the Management of Heart Failure in France

In recent years, there has appeared to be renewed interest in France in the field of telemedicine and its applications for HF, with the development of several projects, such as SCAD (Suivi Cardiologique A Distance, remote cardiological monitoring); PIMP's (Plateforme Interactive Médecins Patients santé, doctor-patient interactive healthcare platform); OSICAT (Optimisation de la Surveillance Ambulatoire des Insuffisants CArdiaques par Télécardiologie, optimization of ambulatory heart failure monitoring with telecardiology), and MEDICA (Monitorage Electronique à Domicile de l'Insuffisance CArdiaque chronique, home electronic monitoring of chronic heart failure).[9-12] At the time of writing, no published results were available from these projects.

All these projects are non-invasive and designed to enable patient management at home or in nursing homes. They are mostly based on standard tools for monitoring HF, namely blood

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pressure monitors, weighing scales, and so on, at times integrating tools enabling the feedback and transmission of collected information (Bluetooth, 3G, 4G, etc.) as well as patient-healthcare professional interaction (call center, digital tablet, website, etc.).[13] Certain projects have also integrated motivational and educational tools. The PIMP's project also includes biological telemonitoring, with Brain Natriuretic Peptide (BNP) telemonitoring.[10]

These are based on prospective or cohort studies of HF patients, with widely varying sample sizes of 100 to 1000 patients, and different follow-up periods ranging from 3 months to 2 years, for the most part stemming from evidence-based medicine.[4]

It is important to emphasize that the objectives or indicators of these various projects vary from modest to the more ambitious, defined as anything from improved morbidity and mortality to reduced readmissions, enhanced quality of life, and improved health economic costs.

E-care: An Innovative Platform for the Early Detection and Reporting of Risk Situations in Heart Failure Patients

The E-care project,[14] selected in 2011 as part of the call for projects in "Health and autonomy at home through digital technology", from Investissements d'Avenir, (a national group for funding innovative research projects in France), was designed with the principal objective of optimizing patient monitoring by detecting precursor signs of cardiac decompensation or acute HF *via* a telemedicine system, combined with motivational and educational tools. This project should theoretically enable i) the reduction of the number of readmissions; ii) the reduction of the total number of hospital days, a figure that progressively and systematically increases when the patient is hospitalized; and, ultimately iii) improvement of quality of life for these patients.

The E-care platform enables patients with NYHA Stage III HF to be monitored, notably at home, using non-invasive sensors.[14] It provides assistance to the medical staff by automating the processing of data sent from the sensors, automatically generating alerts in order to detect and report risk situations of HF early (Figure 1).[15,16] This platform also enables the sharing and management of heterogeneous data so as to integrate the necessary information required for monitoring any underlying pathology, such as diabetes mellitus, renal failure, respiratory insufficiency, and so on.

The early detection of cardiac decompensation involves processing data from multiple factors, namely the signal from the EKG, heart sounds (Phonocardiogram [PCG] signal), weight, Blood Pressure (BP), oxygen saturation, patient ergonomics, in

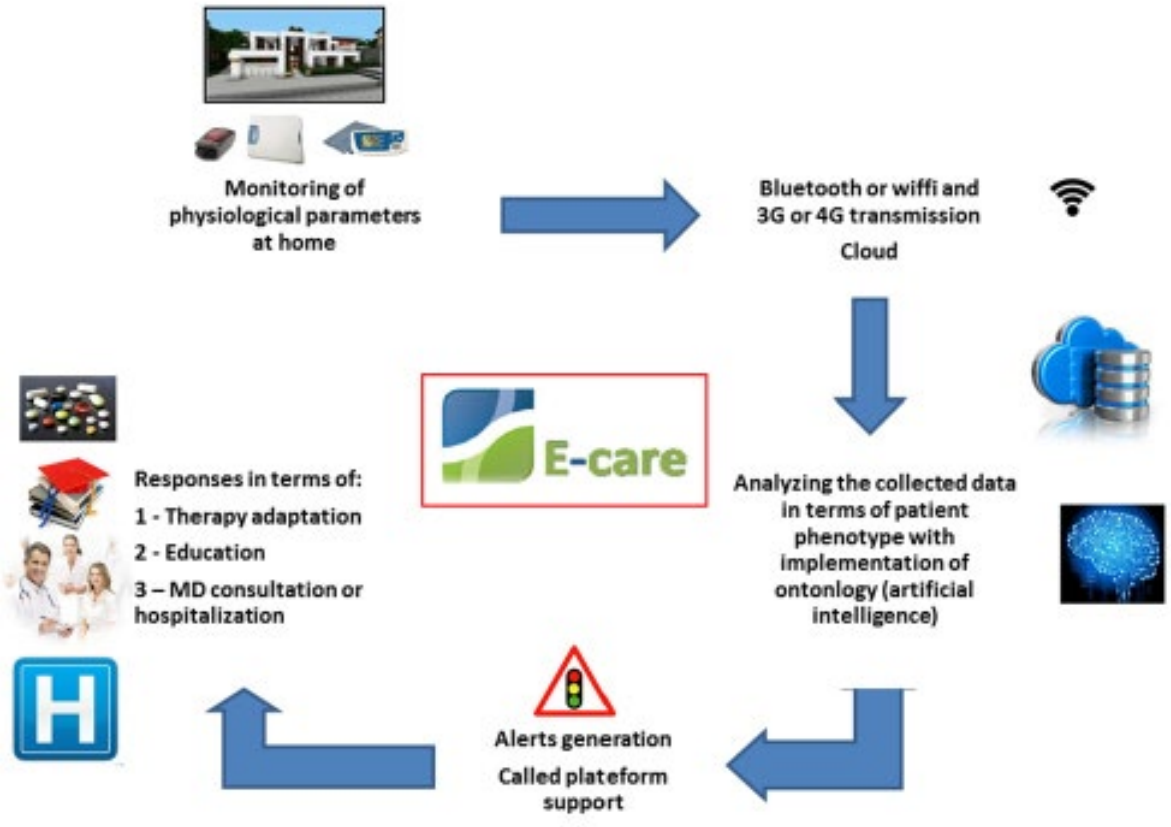

Figure 1: Overall architecture of the E-care platform for monitoring heart failure.

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addition to dietary monitoring, based on the phenotypic data of each patient (personalized medicine).[14-16] All of these consolidated elements, combined with each patient's individual profile, facilitate not only the detection of cardiac abnormalities, but also the prevention of cardiac decompensation risk factors.

The E-care platform uses an ontology designed to define a controlled vocabulary of diseases, medications, symptoms, and so on, as well as to model concepts related to HF monitoring. The effective use of ontology for the purposes of reasoning assumes the addition of operational semantics, which specifies the manner in which the model findings in the ontology will be used for reasoning and to produce new knowledge automatically.[15-17] The reasoning portion is based on an inference engine in which the rules are either introduced by medical experts or generated by a data search and subsequently validated by medical experts. The E-care system fully capitalizes on its ability to consolidate different data information concerning the patient. For each patient, E-care processes in real-time the personal data collected by the sensors, then analyzing it in conjunction with the domain ontologies describing their pathologies, medications, and symptoms. This first inference constitutes its first learning process by adding new information to the patient ontology. In the second stage, E-care consolidates all the information relative to all patients in order to enhance the system. New rules are then added by searching for similar patterns describing critical events. This second step is effective as soon as there is a lot of data to process.

Compared to other telemedicine projects, the E-Care project thus envisages an "intelligent" and communicative platform to carry out home monitoring, using non-invasive sensors, of patients with NYHA Stage III HF.[14] As such, this platform assists the medical team by automating the processing of information transmitted by these sensors in order to detect and report risk situations of cardiac decompensation early.

The platform is built around:

• A console installed in the patient's home, for collecting vital signs;
• Non-stationary signal description tools (emitted from the sensors) for the association and synchronization of measurements (EKG and PCG);
• A central application for the reasoning and processing of physiological and medical data based on semantic web technologies.

The console, installed in the patient's home, will enable the management, collection, collation, and integration of the data generated from the different non-invasive medical sensors .[14-17]

All of the above data sets will be input into a computer tablet in order to allow greater patient autonomy.

This console will be comprised of (Figure 2):

• Medical sensors: BP monitor, thermometer, weigh scale, and pulse oximeter;
• A tablet-type computer interface connected to all of these medical sensors enabling the data to be transferred and accessed.

E-care: A Prototype in Use at the Strasbourg University Hospital since October 2013

Our experimentation with the E-care system (Figure 3) began, in the first phase, at the University Hospital of Strasbourg (Strasbourg, France) in October 2013.[18] This enabled us to pro-

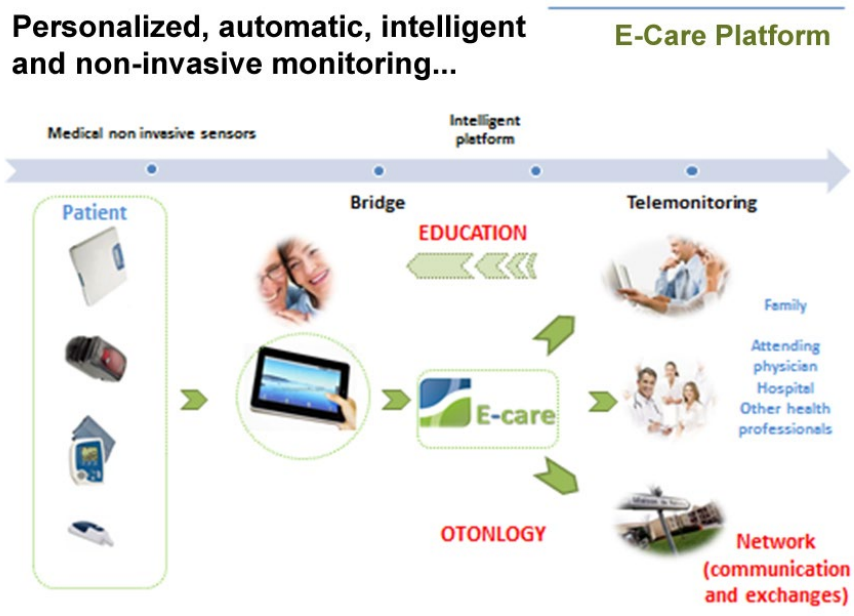

Figure 2: Version 1 of the E-care platform deployed in the Department of Internal Medicine, Diabetes and Metabolic Diseases of the University Hospital of Strasbourg.

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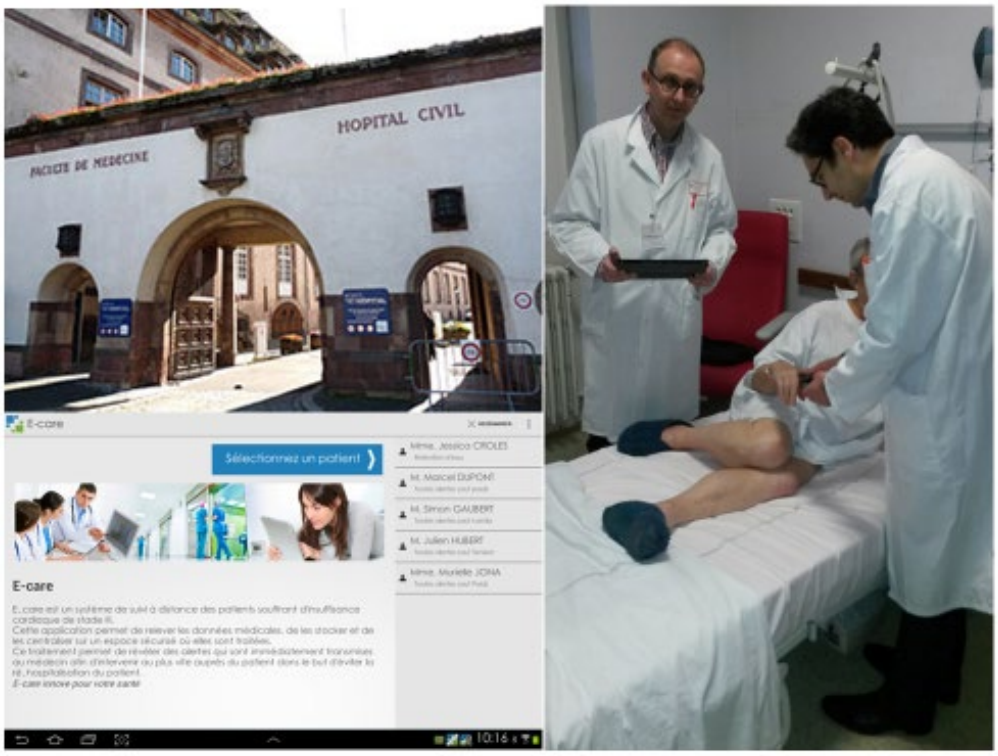

Figure 3: E-care system tested by Prof. E. Andrès and Dr. S. Talha at a patient's bedside at the Strasbourg University Hospital.

duce a preliminary report, test the various functions, improve the ergonomics, detect any vulnerabilities, and identify its strengths, with the primary objective of validating the technological and medical choices made.

The system has been deployed for 10 months, counting from the time of writing, in a 20-bed unit of the Department of Internal Medicine, Diabetes and Metabolic Diseases of the Medical Clinic B of the Strasbourg University Hospital (France). This unit is "open" to the emergency wards and constitutes part of the HF division implemented at the Strasbourg University Hospital. The patient profile included in this experiment is an elderly patient, as is the case in over 90% of cases (chronic HF >60%, anemia >40%, arrhythmia due to Atrial fibrillation (AAF) >30%, Type 2 diabetes >30%, Chronic Obstructive Pulmonary Disease (COPD) >30%, cancer 20%, renal failure >15%, higher function disorders 15%, and stroke 10%), taking more than 17 pills a day on average, with loss of autonomy observed in 25% of cases.[18]

In the first experimental phase, lasting 2 months, we validated the selected sensors deployed as part of the E-care platform using a protocol of comparative measurements from conventional hospital measuring devices (BP, heart rate, oxygen saturation, and weight) and those of the E-care system. Over 150 measurements were performed by 5th and 6th year medical students of the Faculty of Medicine of Strasbourg during their full-time immersion internship in the Department.

The retrospective analysis of these various measurements revealed a concordance between the different devices used on a daily basis in the hospital and those proposed by the E-care solution. The system operated perfectly and the experimental phase enabled us to validate the technological choices. A qualitative survey of the students helped to positively assess the system's ergonomics. A preliminary analysis of the relevance of alerts with our first inference engine design resulted in no malfunctions. In the second phase, we tested the system using (pre) determined indicators, verifying the relevance of triggered alerts, in order to assess improvements that could lead to improved patient management. The goal was to detect risk situations of cardiac decompensation early, before they degraded into acute HF. At the time of writing, the second test phase was underway in the Department, commenced in February 2014.[18] To date, over 130 patients have been enrolled and over 1,000 measurements performed. Nurses use the E-care measurement devices on a daily basis when carrying out their patient rounds. This phase relies notably on the establishment of a new human-machine interface and new inference engine. This phase includes a satisfaction and practical use survey of the system's ergonomics, filled out by caregivers and patients. The continuous gathering of data during this second phase enables us to obtain the critical mass of patients needed to conduct a more detailed analysis of the relevance of the alerts.

Once the system consolidates all the data, the third phase will consist in implementing E-care in patients' homes, first in the Strasbourg and Angers areas, as well as in mid-term hospital stays, post-care, long-term care, and in retirement homes (Figure

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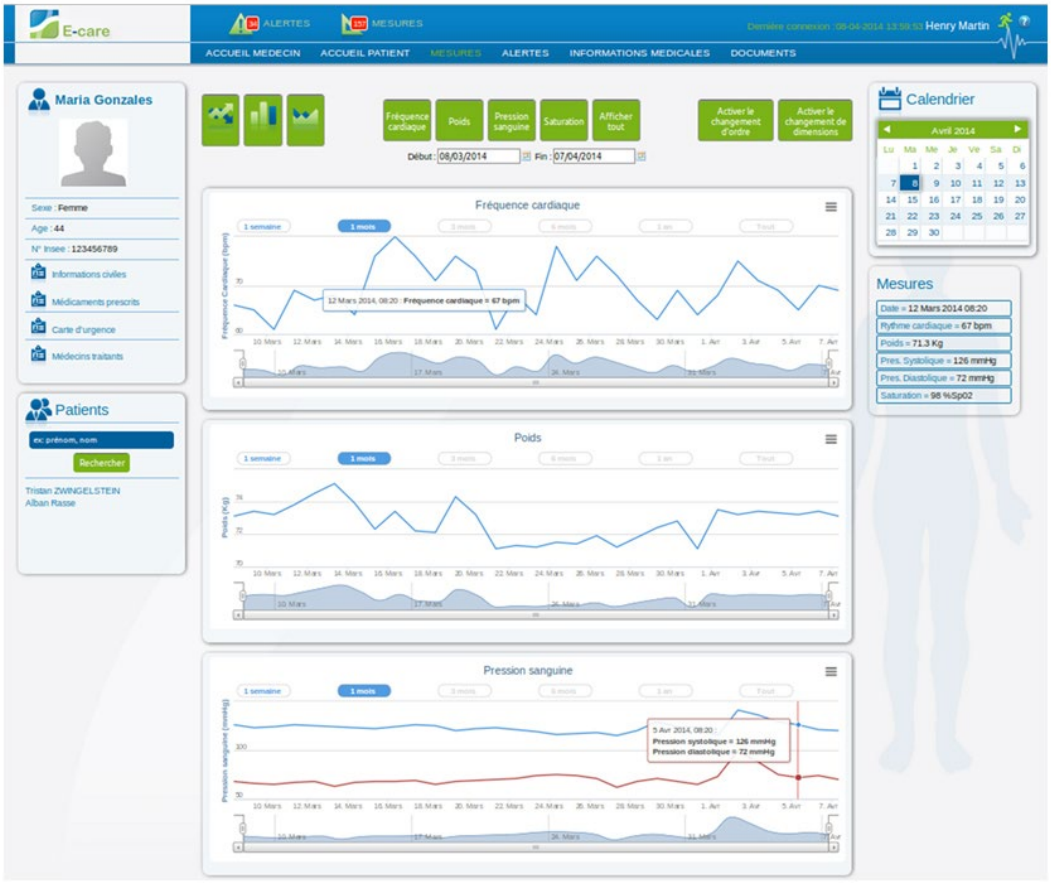

Figure 4: Version 2 of the E-care system deployed in mid-term hospital stays, post care, long-term care, and in retirement homes, as well as in patient homes.

4). This phase is expected to last 6-12 months before the solution can be marketed. The *Agence Regionale de Santé* (ARS – the French regional healthy authority) *d'Alsace* (Alsace branch) (France) (INCADO project) will provide funding for this phase as part of a national project for telemedicine HF management. This last phase will enable us to conduct a comprehensive study, notably in order to work on improving medical diagnosis by promoting the self-learning capacity of the system, therefore improving the detection of any anomaly at an even earlier stage.

The expected future development of this platform in providing a coherent solution in the field of medical monitoring will involve taking into account various diseases and equipment limitations. E-Care is an open and scalable platform enabling the sharing and management of heterogeneous data relating to different diseases.

In the future, the E-care platform should progressively be enriched with other communicating sensors, such as EKG, the electronic stethoscope, and so on, which will integrate signal processing tools enabling us to refine the detection of risk factors. Other communicating sensors could also be envisaged, such as an electronic spirometer, in order to further improve the E-care platform and extend its application to other chronic diseases, such as COPD, chronic renal failure, and other.[19,20]

CONCLUSIONS

The benefit of telemonitoring in HF remains controversial. However, this approach's various design possibilities (type of trial, number of patients, follow up, type of endpoint, etc.), technologies (structured phone support, computer support), and devices, in addition to the varying presence or absence of human intervention, have been so heterogeneous that no definitive conclusion could be made. In our opinion, recent well-designed home telemonitoring programs that used more advanced technology in HF patients have proven successful in reducing unnecessary hospitalizations.

Our telemonitoring E-Care platform uses advanced technology in order to ensure the home telemonitoring of vital signs. E-Care assists the medical staff by automating the processing of information transmitted by the sensors, automatically generating alerts in order to detect and report risk situations of HF early. The E-care platform uses an ontology designed to define a controlled vocabulary (diseases, medications, symptoms,

etc.) and to model concepts related to the monitoring of HF.

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All the authors collaborated on this work. E. Andrès and S. Talha designed the study, wrote the protocol, and wrote the first draft of the manuscript. E. Andrès, S. Talha, and A. Hajjam conducted the literature searches and the analysis of the results of the study. All authors read and approved the final manuscript.

CONFLICTS OF INTEREST: None.

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