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Results of the Experimentation of a Platform for Automated Detection of Situations at Risk of Cardiac Decompensation (E-Care Platform) in Elderly Patients with Multiple Comorbidities

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Abstract

Introduction: *Monitoring patients with heart failure by telemedicine systems is a potential means susceptible to optimize the management of these patients and avoid life-threatening emergencies. In this context, we experimented in patients with chronic disorders, especially heat failure, an e-platform E-care dedicated to automated, intelligent detection of situations at risk of heart failure.*

Methods: *The E-care platform based on medical sensors, communicating, to go up, in real time, to an intelligent physiological information and an analysis of the ontology medical, leading ultimately to the generation of alerts. These are related to a deterioration of the health status of patients in relation to a decompensation of chronic pathologies (criterion dHS), in particular of heart failure (criterion dCHF), leading to a potential hospitalization. To validate these alerts, an experiment was conducted between February 2014 and April 2015. The E-care platform was deployed to patients followed in internal medicine. During this phase, alerts were collected and analyzed retrospectively in terms of sensitivity (se), specificity (spe), positive predictive values (ppv) and negative (npv) in relation to clinical data.*

Results: *One hundred and eighty patients were included and 1,500 measurements were obtained. The patient profile included in this experiment was an elderly patient, with comorbidity in 90% of cases –mean Charlson score of 4.1), with chronic heart failure in more than 60% of cases. The analysis of the alerts shows: 1) for criterion dHS: se, spe, ppv and npv values of respectively 100%, 30%, 89% and 100%; and 2) for criterion dCHF: se, spe, ppv and npv values of 100%, 72%, 90% and 100%, respectively.*

Conclusion: *These results show that the remote monitoring platform E-care can detect 100% of cardiac decompensation and that in ¾ cases, the alerts are related to the latter. Only 10% of alerts are not directly related to HF. In this experiment, the results highlight that in the absence of alert, the patient has no problem, at the cost of many false alarms. In practice, the telemedicine system E-care therefore allows automatically, non-intrusive, generate alerts related to the deterioration of the patient's health and especially cardiac decompensation.*

Keywords: *Telemedecine, Heart failure, Detection of signs of cardiac decompensation, Chronic pathology*

Introduction

In France, more than one million people are followed for chronic heart failure (CHF) and 120,000 to 150,000 new cases are diagnosed each year [**1**]. In this setting, the management of patients with CHF presents a challenge for health professionals. Indeed, CHF remains a serious chronic disease, despite the therapeutic progress made in recent years, with significant mortality (30 to 50% at 5 years for NYHA Stage III-IV) and morbidity [**2**]. Thereby, patients with CHF have significant needs for medical resources. They are often hospitalized urgently, and required frequent and multiple re-hospitalizations, that compromise the quality of life of the patients [**1,2**]. In this setting, CHF is responsible, in our country, for more than 100,000 hospitalizations per year. It accounts for 5% of total hospitalizations and is the leading cause of hospitalization of the elderly. Some of these hospitalizations could be avoided by better monitoring of these patients. Telemedicine is likely to help or even optimize the management of these patients with CHF [**3**]. In fact, telemedicine makes it possible to avoid certain emergencies and iterative hospitalizations. In this context, we have developed a telemedicine project called *E-care*, dedicated to the early detection of situations at risk of chronic disease decompensation, especially cardiac decompensation [**4**].

In the present paper, we describe the results from the experimentation of this telemonitoring system in elderly patients with several comorbidities.

Material, Patients and Method

Patients, Method and Objective

The *E-care* telemedicine project was developed to optimize the follow-up of patients with CHF at home by detecting situations at risk of cardiac decompensation and re-hospitalization [**5**]. The *E-care* project had been the laureate of the first call for « *Projet Investissements d'Avenir* » (PIA, 2014) sur la *Santé et autonomie sur le lieu de vie grâce au numérique* » ("Future Investments Project (PIA, 2014) on Health and autonomy in the living area through digital technology").

After a development phase on healthy volunteers (members of the team), the *E-care* system was deployed as part of an experiment at the *Hôpitaux Universitaires de Strasbourg* (HUS; Strasbourg University Hospitals; in Strasbourg, France). The latter includes elderly patients (≥75 years) with several chronic diseases, especially CHF.

The aim of the present experiment was to validate the relevance of the "*alerts*" coming from the *E-care* telemonitoring platform [**5**], in regard to the deterioration of health status, deterioration that conducts to a hospitalization. Particularly, we focus our experimentation on the relevance of the "alerts" with regard on early detection of situations at risk of cardiac decompensation. It should be noted that during the experiment, these "alerts" were not accessible to the patient or to the health professionals, especially to respect the nature of the protocol of experimentation: « *soins courant* » ("current cares"). Thus, the patients benefited in addition to their usual care of a remote monitoring solution (*E-care*) without clinical decision of the later.

Thus since February 2014, all consecutive elderly patients (≥75 years) with one or more chronic diseases, especially CHF, admitted to the Department of Internal Medicine, Diabetes and Metabolic Diseases of the HUS, were considered potentially to be included in the experimentation of the *E-care* platform. Minors, pregnant women, patients with cognitive impairment or unable to sign the inclusion form, and initially infected patients (Clostridium difficile, BK, nosocomial infections, etc.) were excluded.

Material

As illustrated in Fig. 1, the communicating and "intelligent" platform resulting from the *E-care* project is based on:

- Non-intrusive medical sensors (blood pressure [BP], heart rate [HR], O2 saturation, weight), communicating via *Bluetooth*, allowing physiological information on the patient's health status to be traced back in real time;
- A touch pad, communicating via *Wi-Fi* with a box or by *3G / 4G*, on the other hand allowing interaction with the patient and hygiene-dietary and therapeutic education (not available at the time of the experiment);
- A hosting *Internet* server (ASIP accredited medical provider): patient data, an "intelligent" system in the form of an inference engine and a medical ontology, allowing the personalized analysis of data, specific to each patient , in real time or delayed, with ultimately the generation of "alerts";
- A secure *Internet* portal (*website*), allowing the patient and the various health professionals (referring Doctor, Cardiologist, nurse, etc.) to log in according to their right of access [**6**].

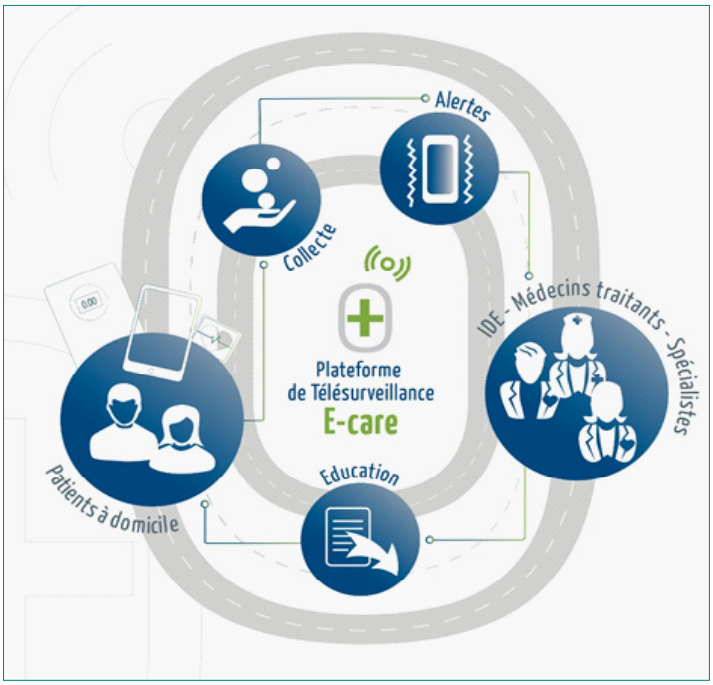

Figure 1. *Version 1 of the generic telemedicine platform developed in the E-care project for remote monitoring of patients with heart failure. This platform is based on: non-intrusive medical sensors (TA, FC, O2, weight), communicating via Bluetooth, allowing to trace, in real time, physiological information on the state of health of the patient; a touch pad, communicating via Wi-Fi or 3G / 4G; and an Internet server hosting an inference engine generating alerts. These last ones sign a deterioration of the chronic pathologies of the patient. They are accessible to health professionals via a secure Internet portal.*

The *E-care* platform uses an ontology that is used to define a controlled vocabulary (pathologies, drugs, symptoms, etc.) and to model the concepts relating to the monitoring of chronic pathologies, in particular CHF [**7**]. The effective use of an ontology for reasoning purposes requires the addition of semantic operational semantics that specify how the knowledge modeled in the ontology will be used to reason and produce new knowledge automatically. The reasoning part is based on an inference engine whose rules are either introduced by the medical experts (here, Cardiologists, Internists, Geriatricians) or generated by a data mining and then validated by the medical experts [**6,7**]. These are not exposed here because covered by a patent.

During the experiment, the *E-care* telemonitoring platform was used daily by patients and healthcare professionals according to a defined protocol of use, specific to each patient, especially for the collection of measurements via connected sensors (in the morning or after a rest period of at least 15 min).

Studied parameters

The *E-care* platform generates indicators of deterioration of the patient's state of health called "alerts", related to a decompensation of chronic pathologies, in particular of the HF, at the origin, if not treated, of a potential hospitalization. These "alerts" are related to: a fact or a medical interfering, proven and documented event (e.g. high BP, tachyarrhythmia, weight gain, pulmonary infection, therapeutic observance, etc.). These indicators exclude in principle "vital alerts", such as chest pain, the occurrence of paralysis of a limb, etc., which are not concerned by the *E-care* platform. In this context, the patient, the right holders and the health professionals in charge of the patient are informed that the usual procedures in a vital emergency are to follow (EMS, firefighters, etc.).

During the present experiment, these "alerts" were collected along the experimentation. They were analyzed in relation to the clinical context at the time of the alert, relying for that on the letter and

the computer files (medical and nurse) of the patient concerned. This analysis was done retrospectively, by 2 independent persons of the caregivers, in charge of the daily life of the individual concerned, but involved in the present experiment. Each "alert" was thus classified as "relevant" or not, in relation or not to an event or clinical fact interfering that may result in or signing:

- Criterion dCHF: the "onset or aggravation of cardiac decompensation" which requires medical intervention (therapeutic adaptation) or which will quickly (in a few days) lead to hospitalization.
- Criterion dHS: a "deterioration of the patient's state of health", defined by a decompensation or an aggravation of the chronic pathologies (CHF, diabetes mellitus, COPD, etc.) which requires medical intervention (therapeutic adaptation) or which will quickly (in a few days) lead to hospitalization;

To determine the clinical "relevance" of these "alerts", we calculated the sensitivities (se), specificities (spe) and the positive (ppv) and negative (npv) predictive values.

Legal documents

A clinical research protocol was filed beforehand, with a passage in front of the « *Comité de Protection des Personnes* » (Committee for the Protection of Persons) of the *CHRU d'Angers* (University Hospital of Angers; in Angers, France) in May 2013, the project being initially bi-centric (reference: « *2013/14 - Projet E-care - santé et autonomie sur le lieu de vie grâce au numérique* » ["Health and autonomy in the living place thanks to digital"]). An authorization has also been sent to the « *Commission Nationale Informatique et Liberté* » (CNIL, National Commission for Data Protection and Freedom).

The experiment was recorded on the clinical trial site *clinicaltrials.gov*, under the reference: « *Anticipation and detection of heart failure with automatic treatment of information derived from non-intrusive sensors and devices* » ("Anticipation and detection of heart failure with automatic treatment of information derived from non-intrusive sensors and devices") (NCT02411279).

Results

From February 2014 to April 2015, more than 800 patients were hospitalized in the medical unit "3722", from the Department of Internal Medicine of the HUS (in Strasbourg, France). This unit was a 20-bed unit, open on emergencies and specialized in the care of chronic diseases, especially CHF. During the experimentation period (14 months), 180 of these patients were included in the present experiment of the E-care platform and more than 1,500 measurements were collected. Of these 180 patients included, 5 patients never used the system; there was no alert generated. One hundred seventy-five patients have at least one measurement and are the subject of the present analysis

Characteristics of the patients

The mean age of the 175 patients was 72 years, with a sex ratio H / F of 0.7. The patient profile was consistent with poly-pathology, with an average *Charlson* score of 4.1. The main evolutionary pathologies included: CHF in more than 60% of individuals; anemia in more than 40%; atrial fibrillation (AF) in 30%; type 2 diabetes mellitus (T2D) in 30%; chronic obstructive pulmonary disease (COPD) in 30%; cancer in 20%; chronic renal failure in more than 15% of cases; memory disorders in 15% of subjects and history and sequelae of cerebrovascular accident (CVA) in 10% of patients. An almost complete loss of autonomy was reported in 25% of cases. These patients took an average of more than 17 medications a day, mainly cardiovascular drugs (diuretics, ACE inhibitors, antiplatelet agents, etc.).

Results on the Studied Criteria

During the experiment, 1,500 measurements were performed on these 175 patients, resulting in the generation by the *E-care* system of 700 "alerts" in 68 patients. One hundred and seven individuals (61.1%) had no "warning" during their follow-up. The study of the follow-up of these 107 patients shows that they did not present any significant clinical event, which could eventually lead to hospitalization. The meaning of these "alerts" is shown in Table. 1 and 2, respectively in terms of: "onset or aggravation of cardiac decompensation" (Criterion dCHF) and "deterioration of the state of health" (Criterion dHS).

Table 1. *Presence or absence of alarms (warning) with or without cardiac decompensation (n = 37)*

	Warning (+)	No warning (-)	n
Onset or aggravation of cardiac decompensation (+)	30	0	30
No onset or aggravation of cardiac decompensation (-)	3	8	11
	33	8	41

Table 2. *Presence or absence of alarms (warning) in the presence or absence of a deterioration of the state of health of the patients (n = 68)*

	Warning (+)	No warning (-)	n
Deterioration of the state of health (+)	147	0	147
No deterioration of the state of health (-)	18	8	26
	165	8	173

Table 3 reports the relevance of its alarms in terms of se, spe ppv and pnv for the 2 studied criteria.

Table 3. *Sensitivity, specificity, positive and negative predictive values of alerts (warning) from the E-care remote monitoring platform.*

	Onset or aggravation of cardiac decompensation	Deterioration of the state of health
Sensitivity	100%	100%
Specificity	72%	30%
Positive predictive value	90%	89%
Negative predictive values	100%	100%

Discussion

These results show that the *E-care* telemedicine system allows automatically, non-intrusive, generate "alerts" (warning) related to the deterioration of the patient's health, especially cardiac decompensation (dCHF). It is in this last situation that the system offers the best values of se, spe, ppv and pnv, respectively of 100%, 72%, 90% and 100% (Table 3). For the practitioner, this experiment underlines that the *E-care* telemonitoring platform makes it possible to early detect 100% of the cardiac decompensations and that in ¾ of the cases, the "alerts" are related to decompensation of the CHF. Therefore, the *E-care* system offers the clinician the opportunity to correct the therapeutic and avoid hospitalization. Only 10% of alerts are not directly related to CHF.

In this experiment, the *E-care* system was also able to detect the deterioration of the state of health (dHS) with regard to the poly-pathology of the studied patients, with values of se, spe, ppv and npv, respectively of 100%, 30%, 89% and 100% (Table 3). For the practitioner, this means that in the absence of an "alert", the patient has "no" problem (npv of 100%). However in this setting, there are many false alarms with a specificity of 30%, mainly by non-compliance with the protocol but also probably by too much sensitivity of the system.

The present experiment shows through its realization the relevance of the technological choices, the tools and the solutions developed and adopted in *E-care* system for the follow-up of the patients with CHF, although they are older (average age of 72 years for patients) and poly-pathological (*Charlson* average score of 4.1). All patients and health professionals used the *E-care* system without problems until the end of the experiment. It should be noted that several recent works go in the same direction [**8,9**]. In this work with older subjects, including octogenarians, age does not appear to be a limiting factor in the appropriation and use of new technologies.

To our knowledge, this is the first time that such a communicating and "smart" system has been developed using the support of new technologies tools (Figure 1), deployed in "real life" [**1**]. Many telemedicine projects have been developed or are under development in CHF.

Their results in terms of clinical benefit (hospitalization, re-hospitalization, and morbidity-mortality)are more or less discordant according to the studies, even if they are not very convincing, especially with regard to the criterion of the statistical significance of the results [**4-22**]. As a result, expert opinions are divided. Nevertheless, all the work seems to go in the direction of a clinical benefit, and / or at least economic, with the use of solutions of telemedicine in the management of CHF [**3,8-22**]. It should be noted, however, that these projects, especially for the older ones, are more like telephone follow-up, with the displacement of home care staff, than telemedicine as it is nowadays conceived: remote follow-up, non-intrusive, automated, intelligent, relying on connected sensors and modern technologies or tools of communication [**4,19,22**]. In addition, the studies are carried out, with regard to factual medicine, with small numbers of patients (from 50 to 1,000 patients) and a very short follow-up (3 months to 1 year), making the demonstration of a clinical benefit to our illusory sense [**4,22**]. These limits are nevertheless also those of the present work.

In their review on telephone follow-up or remote monitoring of CHF patients, Inglis *et al*. [**19**] show that telemedicine has an effect on all-cause mortality with a significant reduction of 34% (p <0.0001). In this study, there is also a 20% reduction in HF re-hospitalization, improved quality of life for patients, cost of care and good system acceptability. In the meta-analysis of Anker *et al*. [**3**], 11 studies were analyzed as part of a comparison between the effects of telemonitoring compared to usual care (non-invasive telemedicine). In this work, telemonitoring showed the reduction of the following elements: all-cause mortality (10.4% *vs*. 15.4%, p <0.0001), all-cause admission to hospital (47.2% vs 52.1%, p = 0.02), hospitalization related to chronic CI (22.4% *vs*. 28.5%, p = 0.008). Two prospective clinical trials have shown results that contradict these conclusions [**20,21**]. The *Tele-HF* study randomized inpatients for HF to either telemonitoring (n = 826) or standard care (n = 827) [**20**]. In this study, no significant difference was observed between the telemonitoring and routine clinical control groups in terms of any readmission or all-cause mortality rates within 180 days of inclusion (OR: 1.04; 95% CI 0.91-1.19). The *TIM-HF* study in Germany randomly compared 2 groups of patients with stable CHF: those followed by telemonitoring (n = 354) or those receiving usual care (n = 356) [**21**]. In this study, the all-cause mortality rate was 8.4 per 100 patient-years of follow-up in the telemedicine group *vs*. 8.7 per 100 patient-years of follow-up in the usual care group (OR: 0, 97, 95% CI: 0.67-1.41, p = 0.87).

In recent years, a renewed interest seems to have emerged in France in the field of telemedicine in CHF with the development of several projects more or less advanced and advanced around this theme [**4**]. It is in this context that the *E-care* project fits. The latter allows automatic, non-intrusive, generate alerts related to the detection of situations at risk of cardiac decompensation (Figure 1). Unlike the others, it is a system that allows a certain way to anticipate a degradation of the CHF. The projects currently being developed in France are mainly represented by the projects:

- « *Suivi Cardiologique à Distance* » (SCAD; "Remote Diagnosis Monitoring"), carried out by the University Hospital of Caen (in Caen, France) [**23**];
- « *Plateforme Interactive Médecins patients Santé* » (PIMP's; "Interactive Platform Doctors Patients Health"), worn by the René-Dubos' Hospital in Pontoise (in Pontoise, France) and Pr Jourdain [**24**];
- « *Optimisation de la Surveillance ambulatoire des Insuffisants CArdiaques par Télécardiologie* » (OSICAT; "Optimization of the outpatient surveillance of patients with heart failure by telecardiology"), based on 12 local research centers, coordinated by the University Hospital of Toulouse (in Toulouse, France) and Prof. Galinier and Pathak [**25**];
- and « *Monitorage Electronique à Domicile de l'Insuffisance CArdiaque chronique* » (MEDICA; "Electronic Home Monitoring of Chronic Heart Failure"), carried by the *REUNICA* and *GMC-Health Solutions* groups [**26**].

Most of these projects are based on the usual CHF monitoring tools (sphygmomanometer, scales, etc.), sometimes incorporating tools for the feedback of collected information, as for *E-care* (*Bluetooth*, *3G*, *4G*, etc.) and interactivity between patient and healthcare professionals (call center, digital tablet, website,

etc.) [**4**]. For some, they combine motivational and educational tools (currently being developed for the *E-care* platform). They also sometimes include questionnaires about symptoms experienced by patients. The PIMP's project also integrates a biological monitoring of the natriuretic factor (BNP) [**24**]. They are based on prospective studies or cohorts of CHF patients, with more or less large numbers of patients, most of which are based on evidence-based medicine. The OSICAT study seems the most advanced [**25**]. It was launched in 2013 and relies on 990 patients divided into 2 groups: "home monitoring" and "control" with standard care. The results including a medical and economic evaluation are expected for 2018.

The *E-care* platform aims to detect situations at risk of cardiac decompensation. Deployed at the patient's place of residence (home, dependent senior care facility, etc.), this system could be able to prevent hospitalizations by detecting early the patient's deterioration and offering healthcare professionals in charge of the patient the possibility of being informed and intervene. This point, however, needs to be validated, especially in a prospective study and on a larger number of CHF patients. In fact, we finally had little cardiac decompensation during the present experiment (30 episodes) (Table 2). With this objective, an improved version of the *E-care* platform (developed in collaboration with the *PREDIMECH Technology* company) will be rolled out during the first quarter of 2018 to CHF patients' homes in the Strasbourg area (France), as part of the PRADO INCADO project (project funded by the *Agence Régionale de la Santé [ARS] d'Alsace* [Regional Health Agency of Alsace, France) (Figure 2) [**27**]. This project proposes to follow for a few months 100 CHF patients according to the organizational model « *PRADO Insuffisance cardiaque* » ("PRADO Heart Failure") carried by the *Caisse Primaire d'Assurance Maladie* (CPAM, Primary Health Insurance Fund) [**28**]. For the recruitment of CHF patients, the PRADO-INCADO

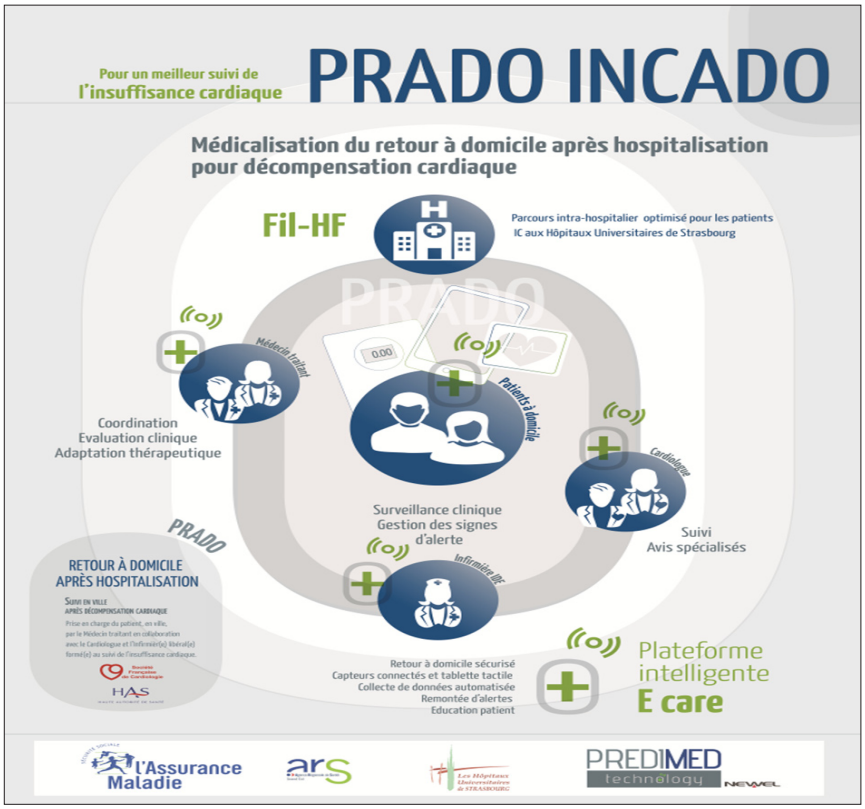

Figure 2. *PRADO INCADO Project. The aim of this project is to monitor the use of the E-care remote monitoring platform for heart failure patients at home, following the organization set up by CPAM as part of the national PRADO Cardiac Deficiency program. The latter aims to facilitate the return home of patients with heart failure and optimize their care. PRADO INCADO adds a telemedicine solution to structure the care path of patients, connect health professionals and add a remote monitoring solution*

project capitalizes on the CHF care management system that we developed at the HUS (Strasbourg, France), in consultation with cardiologists (Pr G. Roul, Dr. S. Talha), emergency physicians (Pr. P. Bilbault) and geriatricians (Pr T. Vogel) [29**].** This pathway was created to optimize the care and treatment of CHF in our hospital, from admission to the emergency department and to return to the patient's home.

Data from the PRADO INCADO project, consolidated with the patient's profile (patient history, medication, adherence to therapy and diet and dietary rules, observance of the use of the system itself) and data from his / her environment should be eventually make the remote monitoring system even more efficient [**30**]. This phase should last from 6 to 12 months before a definitive solution is put on the market. This last phase will lead to an in-depth study in order to work, in particular, on the improvement of the medical diagnosis, by favoring the self-learning of the system, and, consequently, on the earlier detection of any anomaly [**31**]. This is in line with the work of Mortazavi *et al*. around the contribution of "artificial intelligence" (AI) in the follow-up of CHF patients, particularly the possibility using AI to predict re-hospitalization for acute HF [**32**].

In the coming months, a new version of the *E-care* platform should be adapted to the diabetic patient should be deployed to "complex" diabetic patients: diabetic patients at high cardiovascular risk or diabetic patients treated by multi-injection under the *DIABTe* project (Pre N. Jeandidier). The latter has just been labeled by the *Pôle de Compétitivité de l'Innovation Alsace Biovalley* ("Innovation Competitiveness Cluster Alsace Biovalley"; in Strasbourg, France).

This experiment is, to our knowledge, the first performed with "real" patients with a telemedicine solution to detect upstream situations able to degenerate into acute HF. We are at this level in the context of a predictive medicine, which as part of the *E-care* platform is more personalized. This is the highlight of this work. For the future, it should be noted that the remote monitoring solution *E-care* is being marked "*CE medical*", which is a guarantee of excellence, and not just "*CE*" as the number of tools currently on the market. In addition, it should be noted that the solution and the organization set up within the framework of the PRADO INCADO project, integrating an up-graded version of *E-care* meets the telemedicine requirements in France set by the « *article 36 de la Loi de Financement de la Sécurité Sociale* » ("article 36 of the Act. Social Security Financing"), which is an undeniable asset for the deployment of *E -care* in the rest of the country.

This experimentation certainly deserves to be consolidated by a study on a larger staff, including more IC patients, by deploying the telemedicine solution over a longer period (weak points of the present experiment). Subsequently, if the results obtained were in the same direction, it would be advisable to consider a comparative study between a "best current care" arm and second integrating in addition the platform of remote monitoring with the proposed organization, which could be done as part of a national clinical project.

Conclusions

The results of the present experiment, following the deployment of the *E-care* system with patients followed in internal medicine, show that the *E-care* telemedicine system allows an automatic, non-intrusive, generation of "alerts" related to the degradation of the state of health of the patient and above all cardiac decompensation. The *E-care* telemonitoring platform can detect 100% of cardiac decompensation. In this setting, the alerts are related to the latter. Only 10% of alerts are not directly related to HF. In this experiment, the *E-care* system was also able to detect the deterioration of the state of health with regard to the poly-pathology of the patients studied. Above all, this work highlights that the absence of alerts by *E-care* signifies the absence of medical problem.

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