Design, development and evaluation of a Telemonitoring System for Heart Failure patients

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Abstract. Objective: Heart Failure (HF) is a chronic and lifestyle-related disease that affects patient's quality of life. In the last years, telemonitoring systems (TSs) have been promoted as a strategy for HF management. However, the distinctive requirements that a TS should have, have not been clearly identified. To this aim, the most relevant requirements for telemonitoring of HF patients are derived from evidence-based Clinical Practice Guidelines (CPGs). The main objective of this work is to design, develop and evaluate a TS for HF patients, named SiTe iC, using widely accepted CPGs.

Methods: CPGs were thoroughly reviewed to pinpoint key functional requirements of TSs. Interviews with HF patients and specialist physicians in HF were performed to design the system.

Results: The functional requirements of TSs for HF patients were established. A TS (SiTe iC) was designed and programmed. The system was thoroughly assessed through a clinical trial that demonstrates that telemonitoring using SiTe iC actually improves patient's self-care when compared to usual care and it has the potential to avoid HF re-hospitalizations.

Conclusions: This study demonstrated that the identified functional requirements for TSs are relevant. In addition, thanks to SiTe iC, HF patients took an active role in their disease management.

Keywords: Telemedicine, mHealth, Telemonitoring, Health Informatics, Clinical Practice Guidelines.

1 Introduction

Heart failure (HF) is the leading cause of death in the Western World [1]. It is the most common reason for hospitalizations in adults over 65 years old and, due to the high cost of readmissions, it is a costly burden to any health system [2]. In Argentina, 30% of deaths are a consequence of cardiovascular diseases and HF is the principal cause of death (e.g. 22,101 deaths in 2017) [3].

Common reasons for HF re-hospitalizations include delays in symptom recognition, medication and dietary noncompliance, and lack of knowledge and skills for

competent self-management [4-6]. Multidisciplinary post-discharge treatment programs, such as telemonitoring or structured telephone support, have been promoted as a strategy to avoid a large portion of HF readmissions, with benefits related to reducing the risk of all-cause mortality, length of hospital stays and improving patients' quality of life [7]. Besides, for many patients, frequent clinic visits may be impeded by different barriers such as transport, cost, or other diseases. In these situations, telemonitoring is an attractive option for the recognition of early signs of HF decompensation.

Telemonitoring is defined as the use of information and communication technology to monitor healthy individuals or chronically ill patients by distance. The literature suggests that the most promising applications for home telemonitoring are for chronic illnesses such as HF [8]. Therefore, this article presents a telemonitoring system for HF patients, named Site iC, which overcomes the difficulties of existing systems.

The article is organized as follows. Section 2 describes the key issues related to the need for a new HF telemonitoring system. Section 3 describes the tools and methods used in the development of the proposed system. The results are presented in Section 4 and discussed in Section 5. Finally, the conclusions are drawn in Section 6.

2 Motivation and Objective

There are different types of telemonitoring systems for HF patients. In general, their monitor various clinical parameters, such as weight, blood pressure, etc. [9-11]. In some systems, patients enter the measurements of these parameters by typing, and in other cases (the minority) the parameter measurements are obtained wirelessly (by Bluetooth). Few systems analyze the collected measurements and activate automatic alerts, so in most systems, a nurse or a physician had to periodically review the data collected from each patient to assess their health status. In addition, few systems provide health education to patients. Therefore, most systems only collect information about patients' health and transmit it to the server so physicians can see it.

Some telemonitoring systems use TV sets as the main device for patients [12] others use video game consoles [4, 13, 14] and others use Smartphones. In the latter case, telemonitoring is better referred to as Mobile Health Technology (mHealth) [15].

As Schnall et al [16] have remarked, mHealth is a promising tool for actively involving patients in their own health care because most people own and regularly use a mobile phone. For these reasons, to develop a telemonitoring system to follow-up HF patients, an mHealth application using Smartphones as the main device for patients seems to be the alternative of choice for the management of this disease and to reach as many patients as possible.

On the other hand, in different reviews of telemonitoring systems for cardiovascular patients, the authors had concluded that it is still not clear as to whether or not existing telemonitoring systems actually improve patient condition and well-being [17]. Also, in previous works, it was recognized that further research efforts are needed to understand the reasons underlying the success or not of telemonitoring as a key driver to improve health conditions of chronically ill patients [18]. More specifically,

telemonitoring systems have been developed based on different functionalities and monitor different parameters, since the minimal set of functional requirements that an HF monitoring system should deploy have not been identified yet. However, there are many evidence-based Clinical Practice Guidelines (CPGs) of the most relevant cardiology associations about HF management. CPGs are statements that include recommendations intended to optimize patient care that are based on a systematic review of evidence and an assessment of the benefits and harms of alternative care options [19]. Besides, as Kang and Park [20] have highlighted, these CPGs need to be converted into a computer-interpretable guideline for the development of an mHealth app that provides tailored information and recommendations on lifestyle management based on accurate evidence.

Therefore, the main objective of this work is to design, develop and evaluate a telemonitoring system for HF patients, named SiTe iC, using widely accepted CPGs.

3 Methods

3.1 Requirements Elicitation

An update of a previous review of CPGs about HF was carried out by the authors [21]. Only papers that are related to telemonitoring or about remote follow-up of HF patients were included in the review. 34 CPGs [22-30] were selected and analyzed in order to assess the recommendations from the specialists on HF telemonitoring systems, such as functionalities to deploy and parameters to monitor.

As shown in Table 1, most of the cardiology associations recommend monitoring the following parameters daily: weight, blood pressure (BP), heart rate (HR) and symptoms (checklist of questions about swelling in ankles; short of breath; etc.). On the other hand, monitoring functional capacity and electrocardiogram (ECG) were recommended by 3 of the 11 associations that were studied and only in certain situations. For example, [25] recommends ECG monitoring only if the patient is suffering from an arrhythmia. Therefore, patient´s functional capacity and ECG were excluded from the parameters to be monitored.

Table 2 depicts the normal ranges of the selected parameters as defined by the CPGs.

According to the guidelines scrutinized, the following functional requirements were identified:

- to monitor measurements of weight, BP and HR daily,
- ask questions about HF symptoms daily,
- evaluate the measurements and the answer to the questions gathered to detect possible risky situations; then immediately alert physicians about them,
- provide health education to patients about the habits and care that they should have,
- access to patient data collected by the system from anywhere allowing close monitoring of HF patients by physicians and specialists.

Table 1. Parameters to monitor, following recommendations from cardiology associations.

Cardiology Associations	Recommended parameters to monitor					
	Weight	Blood Pressure	Heart Rate	Symptoms	Functional Capacity[a]	ECG
HFSA/ACC/ AHA	X	X	X	X	X	-
ESC	X	X	X	X	X	-
CCS	X	X	X	X	-	X
NHFA/ CSANZ	X	X	X	X	-	-
CSCCS	X	X	X	X	-	X
ASC	X	X	X	X	X	X
USC	X	X	X	X	X	-
MACAC	X	X	X	X	-	-

HFSA: Heart Failure Society of America [23], ACC: American College Cardiology, AHA: American Heart Association [22], ESC: European Society of Cardiology [24], CCS: Canadian Cardiovascular Society [25], NHFA: National Heart Foundation of Australia, CSANZ: Cardiac Society of Australia and New Zealand [26], CSCCS: Colombian Society of Cardiology and Cardiovascular Surgery [28], ASC: Argentine Society of Cardiology [27], USC: Uruguayan Society of Cardiology [29], MACAC: Medical Associations of Central America and the Caribbean [30].

[a]Functional Capacity describes a person's ability to perform daily activities that require physical effort. Patients diagnosed with HF demonstrate a compromised functional capacity.

Table 2. Normal ranges of parameters [21].

Parameter	Normal ranges
Blood Pressure	90mmHg < Systolic pressure < 140mmHg Diastolic pressure > 60mmHg
Heart Rate	50bpm < Heart Rate < 84 bpm
Weight	Weight gain of less than 2 kg in 3 days
Symptoms	Score to the Symptom question <= 3

These functional requirements were put into consideration of cardiologists and nurses with extensive experience in monitoring HF patients. Physicians agreed with these functional requirements noting that they do measure those parameters in most medical consultations, and they take into account the normal ranges in Table 2 during the evaluation of their patients. Moreover, physicians often provide health education to their patients during medical consultations, but they do believe that such information should be given more frequently.

HF patients also were interviewed using guidelines based on the functional requirements extracted from CPGs and they highlighted that they would like to know more about their disease and would like to have a closer follow-up by their physicians [31].

During the previous interviews with physicians and patients, other functional requirements for the system have arisen such as:

- changing the normal range of the parameters of each patient based on her/his health status and consequently, set custom alerts for each patient,
- modify the medication of each patient through the system (dose and drugs),
- a chat room to establish a communication channel directly with physicians,
- a calendar with the schedule for taking the pills,
- make an appointment for a face-to-face medical consultation,
- an easily accessible emergency (panic) button to request help in case of an emergency, among others.

Once all the functional requirements derived from the CPGs study have been identified, as a proof-of-concept, it was proposed to develop a first prototype of the SiTe iC system which is composed of the following three main parts (see Fig. 1):

1. A Patient Platform (iC mHealth app) through which patients will send their parameter measurements and receive health education,
2. A Professional Platform (iC monitor) through which physicians can visualize the measurements of their patients and based on these data receive relevant alerts of each patient condition, which allows a closer follow-up of her/his evolution,
3. The iC health server which has an Application Programming Interface (API) that allows communication between the previous platforms and stores data generated by each patient platform.

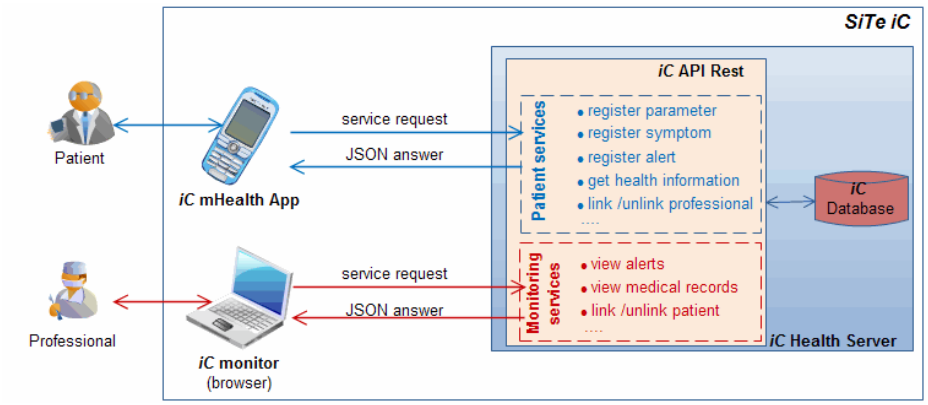


Fig. 1. SiTe iC architecture

For the measurement of patient parameters, the devices to be used must comply with the following technical specifications:

- Weight scale: accuracy up to +/- 0.5 kg;
- Blood pressure monitor: accuracy: ± 10 mmHg (pressure) / ± 5% (pulse) and measurement range: 20–280 mmHg (pressure) / 40–200 beats per minute (pulse).

3.2 Conceptual Modeling

No conceptual model representing the domain knowledge of SiTe iC was found in the existing literature, so it was defined by the authors. Figure 2 introduces a UML class diagram that depicting the main concepts of the proposed model and their relationships.

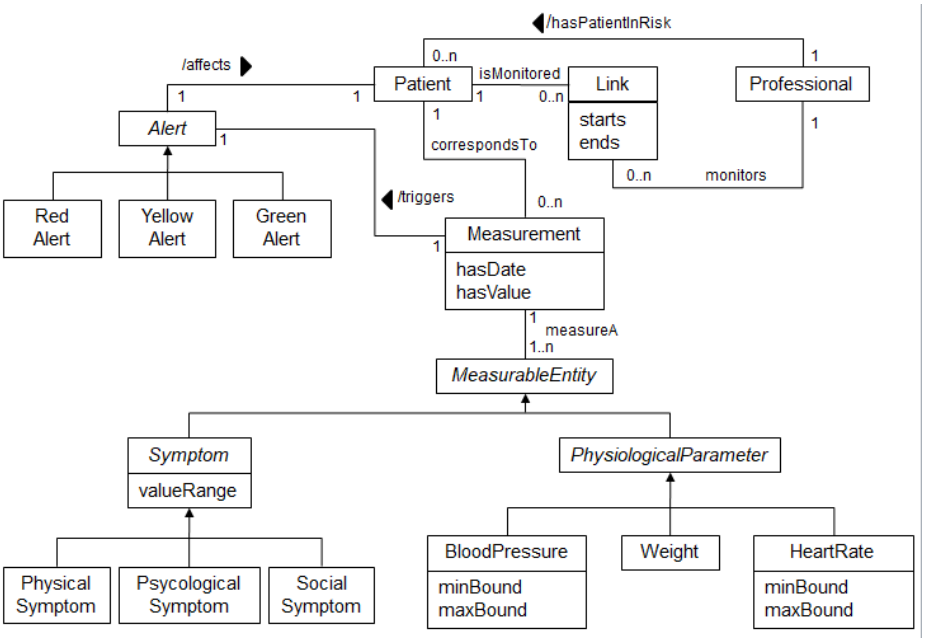


Fig. 2. Proposed Conceptual Model

The main concept is Patient which represents each person whose health data is going to be monitored by a Professional. The model includes a class association (link) to represent the link between a patient and the professional that monitors her/his health. The model lets capture the specific dates for beginning and ending a relationship between each patient and a physician (starts and ends attributes of link class).

According to the requirements identified in section 2.1, in this first prototype of the system, patients must enter measurements of their health parameters on a daily basis (instead of collecting the measurements through wireless devices, which are currently expensive). This is because, in this stage, the system prototype was designed to be used by any patient in the Argentine population. Therefore, devices to measure the health parameters of patients must be cheap and accessible to people of any economic

class. However, in the next prototype, the system will acquire these measurements wirelessly by Bluetooth devices.

In order to represent such patient data, the model includes the Measurement class. For each measurement, it is possible to record the measurement date (hasDate attribute) and the corresponding value (hasValue attribute).

There are two types of data entities that each patient could provide: objective parameters (PhysiologicalParameter abstract class and its subclasses in Figure 2) such as weight, BP and HR, and subjective parameters (Symptom abstract class). It is worth mentioning that the minBound and maxBound attributes of the BP and HR parameters allow to store their normal ranges. The subjective parameter represents the answers to questions rated on a six-point Likert scale -from 0 to 5- about physical, social and psychological aspects, represented by PhysicalSymptom, SocialSymptom and PsychologicalSymptom classes, respectively. Figures 3 and 4 illustrate the instances proposed in the conceptual model for each of the concrete classes mentioned in this paragraph.

Some measurements outside the normal ranges or lack of data for a few days may trigger an alert, therefore, the Alert class and its three subclasses (red, yellow and green), that highlighted the severity of the alerts, are proposed as shown in Figure 5.

The Alert class is related to the following classes through three different associations (Figure 2):

- Measurements (/triggers), a measurement triggers an alert;
- Patient (/affects), an alert affects a patient´s health condition;
- Professional (/hasPatientInRisk), one patient monitored by a professional is related to a measurement that triggers an alert.

These three relationships are defined as UML derived associations, which means that their instances are not explicitly defined but computed using inference rules (see Table 3).

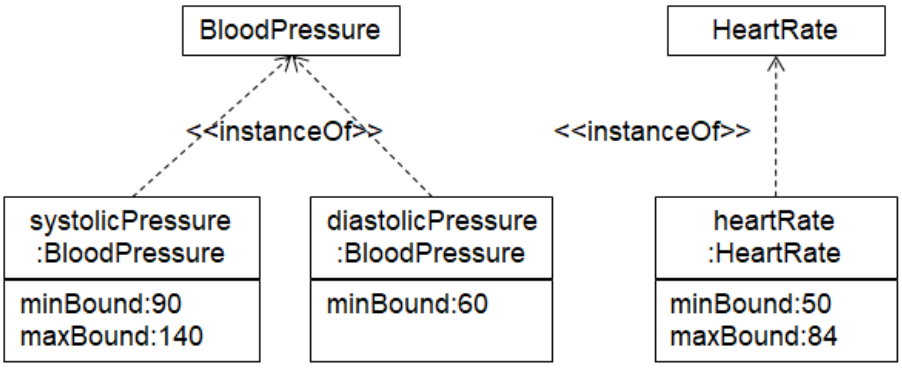


Fig. 3. Instantiation of the proposed BloodPressure and HeartRate classes

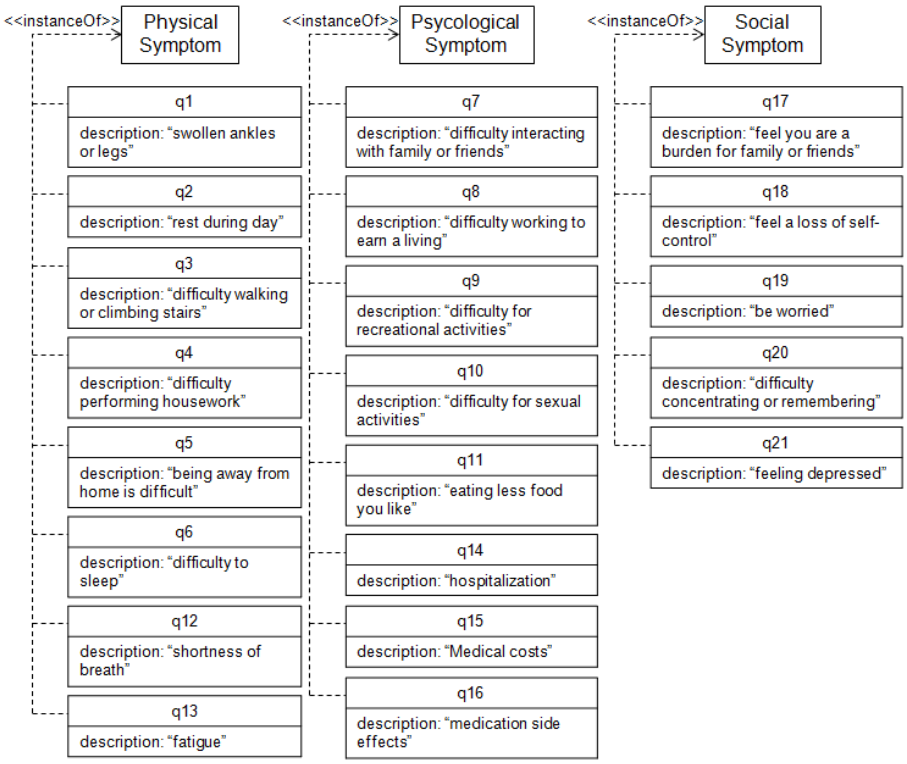


Fig. 4. Instantiation of Symptom subclasses proposed

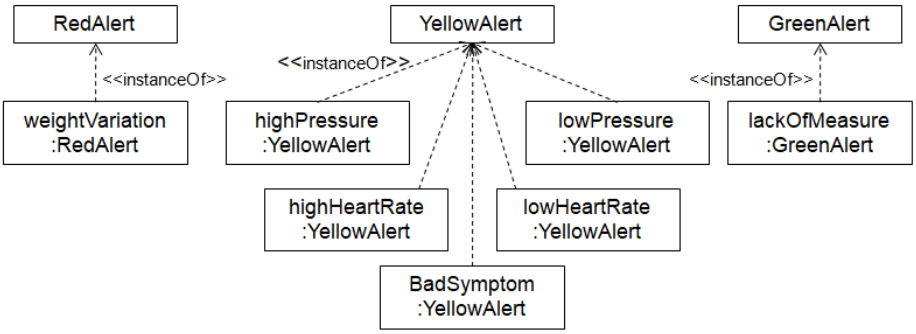


Fig. 5. Instantiation of Alert subclasses

Table 3. Proposed rules for inferring derive relationships

No. Rule	Rule
1	triggers(M2,weightVariation):- measurement(M1), measurement(M2), M1\=M2, measureA(M1,weight), measureA(M2,weight), correspondsTo(X,M1), correspondsTo(X,M2), hasDate(M1,F1), hasValue(M1,V1), hasDate(M2,F2), hasValue(M2,V2), dateDiff(F1,F2,3), WeightDif is V2 - V1, WeightDif > 2.
2	triggers(M1,lowPressure):- measurement(M1), measureA(M1,systolicPressure), minBound(systolicPressure,MinB), hasValue(M1,V), V < MinB. triggers(M1,lowPressure):- measurement(M1), measureA(M1,diastolicPressure), minBound(diastolicPressure,MinB), hasValue(M1,V), V < MinB.
3	triggers(M1,highPressure):- measurement(M1), measureA(M1,systolicPressure), max-Bound(systolicPressure,MaxB), hasValue(M1,V), V > MaxB.
4	triggers(M1,lowHeartRate):- measurement(M1),measureA(M1,heartRate), hasValue(M1,V), minBound(heartRate,MinB), V < MinB.
5	triggers(M1,highHeartRate):- measurement(M1), measureA(M1,heartRate), max-Bound(heartRate,MaxB), hasValue(M1,V), V > MaxB.
6	triggers(M1,badSymptom):- measurement(M1), measureA(M1,S), symptom(S), hasValue(M1,V), V > 3.
7	triggers(P,lackOfMeasure,Days):- patient(P), lastMeasure(P,M), hasDate(M,F), diffFromToday(F,Days), Days > 1.
8	affects(P,A):- patient(P), alert(A), measurement(M), correspondsTo(P,M), triggers(M,A). affects(P,A):- patient(P), alert(A), causes(P,A,C).
9	hasPatientInRisk(Prof,P):- professional(Prof), patient(P), link(L), isMonitored(P,L), controls(L,Prof), affects(P,A).

Rules labeled from 1 to 7 compute triggers association instances, while rules 8 and 9 let the instances of /affects and /alerts associations to know about changes in health conditions of a patient, respectively.

The alerts derived from rules 1 to 6 are triggered because the value of a measurement is outside of the defined normal range. However, the lackOfMeasure alert is triggered when no incoming data has been loaded for a specific patient for more than 24 hours or an entire day (rule 7). All these rules were used later for designing and programming the prototype.

In this prototype, the alert system may be considered rudimentary because it is based on fixed thresholds to generate alerts, but it is important to remember that few systems described in the different reviews incorporate an alert system [9-11]. In addition, our current goal is to improve the alert system incorporating artificial intelligence techniques, such as machine learning, to achieve a more personalized alert system that allows predicting risky situations.

3.3 Tool Selection

For the Patient Platform, an Android native app was developed since such type of apps are faster, safer, consume less memory and have better performance than hybrid applications [32], and because Android is the operating system used in most mobile devices in Argentina -88%-, country where the system was tested [33].

The iC mHealth app was implemented using Java programming language in Android studio. The iC monitor for the physicians was implemented with HTML, CSS and JavaScript while the API is a RESTful API that was implemented using PHP. In particular, the authentication of each user in both platforms via the API is made using OAuth 2.0 [34, 35].The data exchange between the iC mHealth app and the iC monitor with the API was done using JSON format. The mHealth app works on smartphones running the Android operating system versions 4.0.0 or later.

3.4 Evaluation

During the development process, the prototype has been tested using Android Studio emulator and Postman Inc. Once the first deployment has been released, a clinical trial involving real patients was carried out [36].

The randomized clinical trial compares an intervention group (IG) –HF patients using the SiTe iC system– versus a control group (CG) –HF patients receiving usual care- over a 90-day monitoring period. The outcomes observed were significant changes in patients' self-care (European Heart Failure Self-care Behaviour Scale –EHFScB-), treatment adherence (Morisky Modified Scale –MMS-) and re-hospitalizations over the follow-up period.

According to Marrugat et al [37], a minimum of 30 patients are required between the control group and the intervention group to assess whether there is a statistically significant difference between them. The sample size was calculated using Epidat version 4.1 and was based on the differences of the EHFScB scores between a CG and an IG reported in previous studies recently published [38, 39]. These studies reported standardized mean differences of 10 and 22 points, respectively. Then, we assume the average of these data, and we determine a mean difference of 16 points. More specifically, the data to calculate the sample size were means difference to detect (16), standard deviation of CG (14), standard deviation of IG (16), confidence level (95%) and power (80%). Accordingly, the estimated sample size was 15 patients for each group.

Intergroup and intragroup differences were analyzed using hypothesis tests; differences with a p value less than 0.05 were considered statistically significant.

Baseline characteristics of patients were assessed using either Fisher's exact test or a chi-square test for categorical variables, depending on whether they were dichotomous variables or not. For quantitative variables, the normal distribution assumption was tested using the Shapiro–Wilk test. Whenever variables did not follow a normal distribution, the non-parametric tests were used.

For more details about the clinical trial see Yanicelli et al, 2020 [36].

4 Results

A non-invasive telemonitoring system (SiTe iC) was designed and implemented as a prototype. It provides an mHealth application for the HF patients, a monitoring platform for the professionals and a Server to allow communication between both platforms and the data storage.

Patients and professionals alike have functionalities available to create a user account, sign up, log into the system, edit their personal data and handle the process of linking between different accounts with appropriate roles (link up or unlink). The mHealth app main screen and its menu are shown in Figure 6.

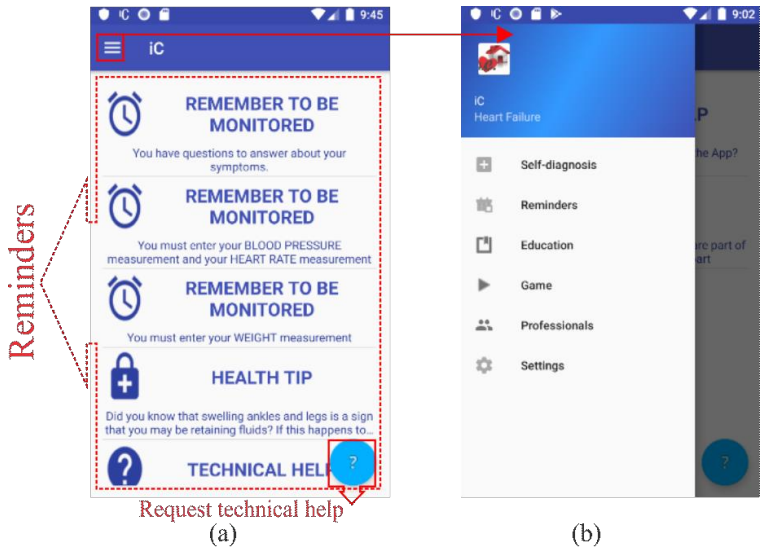


Fig. 6. (a) Main screen of the iC mHealth app. (b) Main menu.

Patients can set a schedule for reminders to measure their parameters using the settings section. At the scheduled time for each parameter, a reminder appears in their smartphones as a notification and it is stored in the data storage. Patients can access their reminders through the reminders section, which is the main screen of the system.

Patients enter their data related weight, BP, HR and answer questions about their symptoms through the screens shown in Figure 7. Patients can access these screens through the self-diagnosis option of the menu, or through the reminders that the app sends every day at the time set by the user (Figure 6).

The mHealth app analyzes data entered by a given patient and creates an alert if these values are outside of the normal ranges according to the rules in Table 3. Generated alerts are then sent to the server so that the professionals linked to the patient can visualize them (Figures 8 and 9). Furthermore, professionals can view the medical records of their linked patients as shown in Figure 10. It should be noted that Figures 8 to 10 were edited to hide the identity of the users of the system.

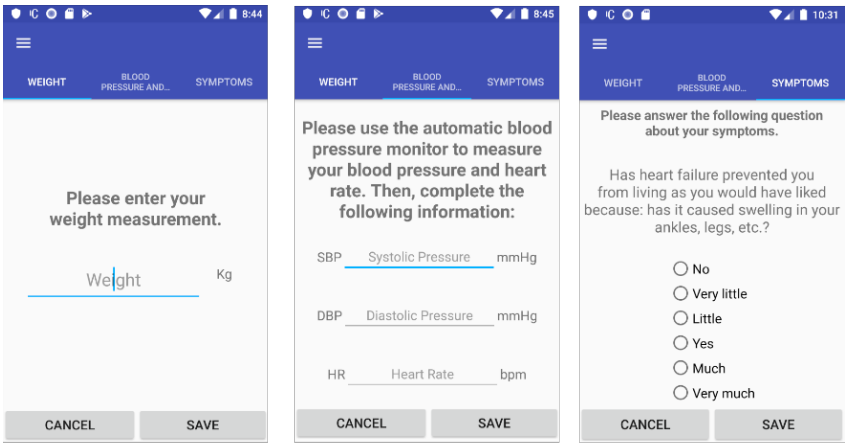


Fig. 7. Screens to enter measurements for weight (a), BP and HR (b), and answer questions about HF symptoms (c).

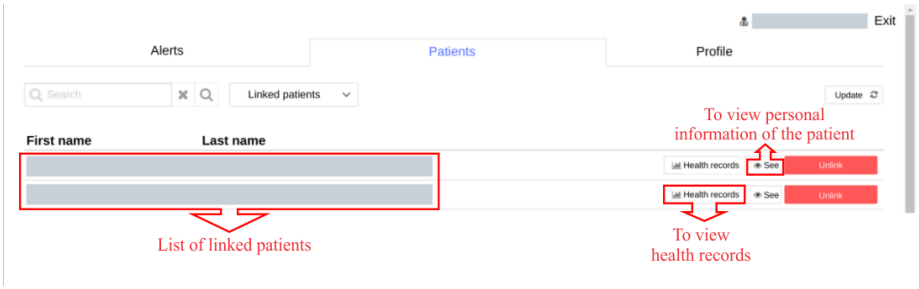


Fig. 8. Main screen of the Professional Platform.

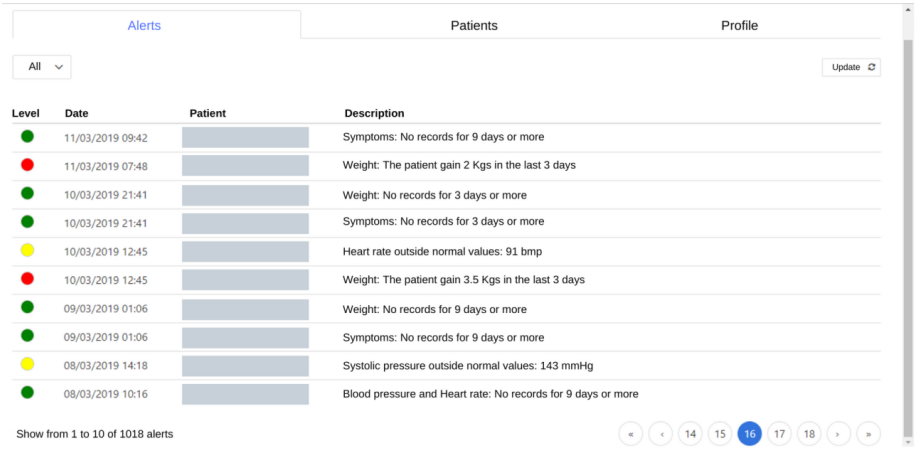


Fig. 9. Alerts screen: generated alerts are sorted by date, indicating a red, yellow or green level.

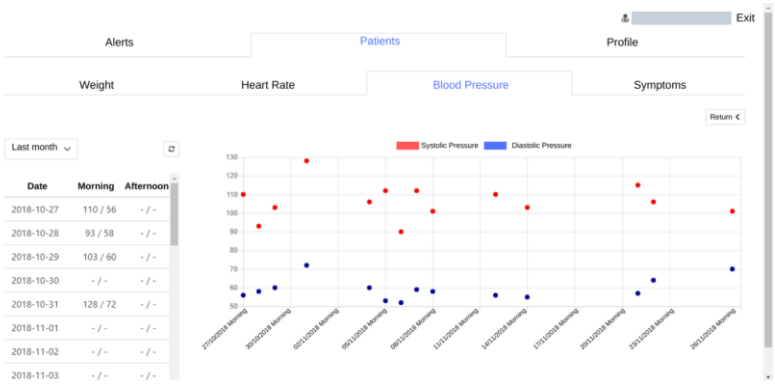
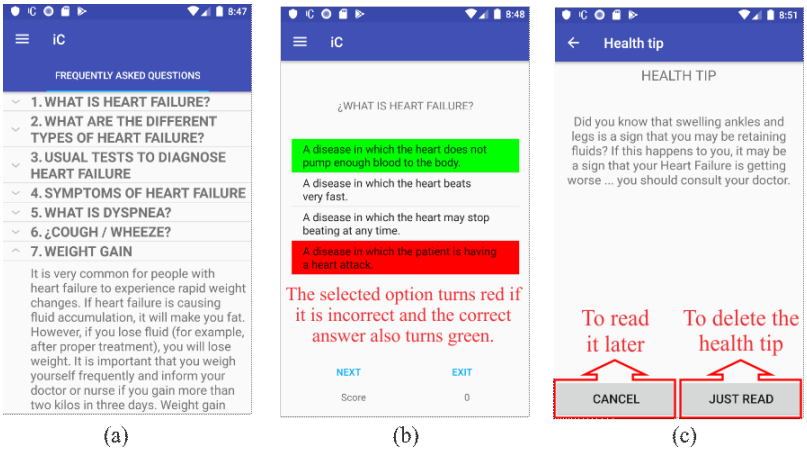


Fig. 10. Medical records of a patient's blood pressure through the professional.

From a previous review of different telemonitoring systems [40], three ways of providing education through the mHealth app were proposed (see Fig. 11):

1. a Frequently Asked Questions section as a drop-down list, which allows patients to search for information on a specific topic,
2. a question and answer game about HF that allows learning about HF through playing,
3. health education messages are sent every day, such as notifications delivered to patients smartphones (health tip). Health education issues were extracted from CPGs.

Finally, the mHealth app allows patients to request technical help through the floating button located at the right-bottom of the main screen (see Fig. 6). This option was an improvement that was developed for patients enrolled in the clinical trial carried out to evaluate the system.



(a) (b) (c)

Fig. 11. iC mHealth app educational screens: (a) Frequently Asked Questions, (b) Game, (c) Health education advice (Health tip).

4.1 Evaluation

The system was tested involving real patients through a clinical trial. In total, 104 HF patients in the Zenón Santillán Health Center Hospital in the city of San Miguel de Tucumán, Tucumán, Argentina between August and December 2018 were screened; only 40 of them met the inclusion criteria. They were randomly assigned, in a 1:1 ratio, to the intervention group –IG- (telemonitoring) or the control group –CG- (usual care). During the follow-up period, 10 patients were excluded.

After the follow-up, intragroup analysis of the CG indicated a decrease in treatment adherence ($p=0.02$). The mean European Heart Failure Self-care Behavior Scale overall score indicated an improved self-care in the IG patients ($p=0.03$) and a worsened self-care in the CG ($p=0.04$) with a p value of 0.004 in the intergroup analysis.

Regarding re-hospitalizations, during the follow-up period two patients from the CG (13%) had decompensations and were hospitalized during 2 and 8 days, respectively. Ankle and leg swelling, progressive dyspnea and weight gain were the main signs that caused the readmissions. Physicians concluded that patients were not complying with hygienic and dietary indications. There were no re-hospitalizations in the IG (0%), but the SiTe iC system detected two risky conditions for patients in this group. Both situations consisted of a weight increase of more than 2 kg in a few days, which triggered an alert in the system, and the nurse contacted the patients to ask them to attend the hospital for a medical interview. After these consultations, physicians reminded the concerned patients of the importance of healthy habits and treatment adherence to avoid re-hospitalization. There was no significant difference in re-hospitalizations between CG and IG ($p=0.5$), but physicians believe that thanks to the home telemonitoring system alerts, two re-hospitalizations were avoided.

The evaluation of the SiTe iC system demonstrated that it improves patient self-care when compared to usual care and has the potential to avoid re-hospitalizations, even considering patients with low literacy levels.

5 Discussion

Few studies show the intervention characteristics of the systems used in the HF management, but in the review by Maric et al [9] only 20% of the selected systems provide health education and in most cases, education is provided by a nurse through telephone calls, i.e. most systems do not have a self-learning functionality. For these reasons, the physicians highlighted the importance of the educational functionality during the development process of the SiTe iC system.

Maybe as Yun et al [11] remarked the different type of telemonitoring interventions in the different trials avoid comparing the interventions among them to establish which is indeed the best. However, the results obtained in the evaluation of SiTe iC through a clinical trial (improves self-care of patients and has the potential to prevent re-hospitalizations) suggest that requirement elicitation from CPGs seem to be a promising avenue to start a telemonitoring system development. In addition, the quality of the proposed prototype system was supported by Paglialonga et al [41] who highlighted that two of the key components of quality in health applications is that

their contents are evidence-based and have a clinical validation. These components were covered during the SiTe iC design when obtaining the requirements of the CPGs and by validating the system through the clinical trial.

Finally, considering the rapid advances in science and technology that exists today, we can think that the best way to design a telemonitoring system is, on one hand, to take advantage of the previous medical experience of several years, which is reflected in CPGs. And, on the other hand, using the promising technologies as Artificial Intelligence and Internet of Things to add value to this type of systems, improving the alert system and customizing the algorithms for each patient, which is another of our current research goals.

6 Conclusions

This article presents a system for the follow-up of HF patients, the requirements that this type of systems must fulfill and the results of its evaluation in a clinical trial.

The functional requirements that fed the prototype design of the system (SiTe iC) were extracted from a systematic and thorough analysis of the known CPGs. The system was evaluated through a clinical trial with real patients that demonstrates that it engage patients to have an active role in their disease management.

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