FI-STAR Online Personalised Cardiac Rehabilitation Solution

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***Abstract*—*Background:* Advanced disease prevention solutions using telemedicine are vital for the future in order to decrease the burden produced by the cardio-vascular diseases. This solutions need to ensure more accessibility, high performance and good data privacy.** *Material and Method:* **Study groups consist of 48 acute myocardial infarction patients: 24 home monitored using telemedicine and 24 control group performing unmonitored rehabilitation. The process will have two phases: the inpatient period will be common (5-7 days) and the outpatient period (7 weeks). The monitored group will receive a set of Bluetooth capable monitoring devices at discharge, a blood pressure device, a cardio watch, a pulsoxymeter, an ECG chest strap and a Smartphone with the application installed. The application that will be built from scratch will contain the nutritional, medical and physical activity plan and also has monitoring and treatment adjustment functions by the medical personnel.** *Results:* **Before hospital discharge and at the end of the program all patients will perform an ECG treadmill test, which summed with other medical investigations, will quantify the cardiac fitness level and their improvement. Also using a MAST personalized model there will be assessed a set of performance indicators.** *Conclusions:* **The Online Cardiac rehabilitation solution will be a light and secure software, built using Specific Enablers, technology created as generic enablers in the FI-WARE project. This is hoped to offer more patient independence, improve their cardiac fitness and quality of life and reduces the high cost that cardiovascular disease brings to the medical system.**

***Index Terms*—cardiac rehabilitation, generic enablers, specific enablers, telemedicine**

I. INTRODUCTION

Health domain has evolved during the last 60 years thanks to the medical treatment advances.

FI-STAR is a FP7 FI-PPP 2nd Phase use case trial project in the domain of e-Health. The project started in April 2013 and will run for 30 months.

FI-STAR is establishing early trials in the health care domain building on Future Internet technology, creating a robust framework based on a "software to data" paradigm and validating the FI-PPP core platform concept by using generic enablers to build its framework. Its concept is to bring the software to the data, rather than bringing the data to the software.

A sustainable value chain following the life cycle of the Generic Enablers (GEs) will enable FI-STAR to grow beyond the lifetime of the project. FI-STAR will build a vertical community in order to create a sustainable ecosystem for all user groups in the global health care and adjacent markets based on protection of sensitive and personal data travelling in public clouds.

The selected test applications in the health domain aim at a diverse set of use case scenarios whose integration with advanced Internet-based network and service capabilities.

FI-STAR will deploy and execute seven early trials across Europe, serving more than 6 million people. Through the trials FI-STAR will validate the FI-PPP core platform concept by using GEs to build its framework and will introduce ultra-light interactive applications for user functionality. [1]

The University of Medicine and Pharmacy "Carol Davila" from Bucharest, is partner in the FI-STAR research program and owner of one of the 7 experimentation sites, the Online Cardiac Rehabilitation Scenario of the patients that suffered an acute coronary event.

Health domain has evolved during the last 60 years thanks to the medical treatment and IT solution advances. The average life expectancy from Europe increased from 65 years in 1950s to 80 years in 2010. The bad news is that the incidences of cardiovascular diseases, which are the main contributors to the European mortality rates are still growing. [7]

This is happening due to the improper management of the cardiac patients after an acute coronary event.

Cardiac rehabilitation represents a professional programmed, medical supervised, individualized according to the disease and to the needs of every patient. It has a decisive role in helping patients recover after an unwanted cardiologic event and mainly to help them in getting healthier and to pass easier throw the early outpatient period. [4]

Compared with usual care, cardiac rehabilitation has been associated with reduced all-cause mortality, and cardiac mortality greater reductions in total cholesterol level, triglyceride level and systolic blood pressure. [6]

Cardiac rehabilitation is basically structured in III phases:

Phase I - the inpatient period, always takes place in the hospital (from day 0 until hospital discharge)

Phase II - the early outpatient phase, can last from 6 up to 12 weeks, depending on the type of rehabilitation method, the patient's medical condition and his compliance to the program.

Phase III –long life outpatient phase, period where the patient will have to apply everything that he has learned during the first two phases.

In Romania, secondary and primary prevention programs in cardiac disease are at the beginnings. There are few centers specialized in Cardiac Rehabilitation services.

As types of Phase II Cardiac Rehabilitation programs can be mentioned:

- Cardiac Rehabilitation in specialized facilities. Requires hospitalization and usually involves high costs, limits the freedom of the patient's daily program. Beside these, studies have shown that on the long run, during phase III, the patient won't keep his healthy habits.
- Cardiac rehabilitation in small laboratories. This consists strictly in the patient monitoring during the physical activity session. This also produces low outcomes.
- Unmonitored rehabilitation known also as usual care, the most frequent type of Rehabilitation encountered in Romania, represents the individual rehabilitation without medical monitoring.
- Online Cardiac rehabilitation represents the newest type of cardiac rehabilitation.

II. OBJECTIVES

Our aim within the European FP7 research Project FI-STAR, as one of the seven Experimentation Sites, is to test an Online Personalized Cardiac Rehabilitation service using the research outcomes of FI PPP Phase 1 Project, validate and disseminate the Core Platform, the Generic Enablers and other relevant technologies and proactively prepare FI-PPP Phase 3 by demonstrating the benefits brought by the solution in reducing the number of deaths related to cardiovascular diseases and the rates of hospitalizations. With these reductions the outcome will be in reducing the health systems expenditures, faster patient recovery, lower levels of disease anxiety and to optimize medical personnel activity time. [3]

III. MATERIALS AND METHODS

The FI-STAR Online Personalized Cardiac Rehabilitation Scenario will consist of an Android Software that is being built from scratch for the Romanian Use Case. This will be installed on an Android Smartphone. Also computer Windows compatible software is created and will be installed on the patient monitoring unit.

The Online Personalized Cardiac Rehabilitation will be based on a personalized rehabilitation protocol that will involve 3-5 sessions per week of regular physical activity, a nutritional plan, a medical plan and secondary prevention measures(educational video-audio material) inserted in the smart phones application. Together with them the patient receives a set of medical devices that remotely transmit different medical parameters in the Smartphone at several moments during the day. Doing so the patient has more freedom in performing his activities, incorporating physical activity in the program whenever he has free time during the day, reduces his anxiety levels thanks to the feeling of being monitored by a medical professional and helps him in the process of reintegration in the economical circuit.

The research study will consist in comparing the Cardiac Rehabilitation outcomes of patients that suffered an Acute Coronary event by dividing them in two groups: online monitored patients group and the group of the patients that perform their rehabilitation unmonitored.

We want to quantify: the usability of the FI-STAR solution, the speed of reintegration in the community and into the economical circuit, the improvement of cardiac fitness, the evolution of rehospitalisation rates and the time saved by the caregivers, the cost-effectiveness efficiency and also the adherence to an Online, at home Personalized Telemedicine Rehabilitation Program.

The clinical trial will have two phases during ten months period: 5 months for testing the Alpha version of the application and 5 months for testing the Beta version of the application.

A. Patient Selection

Patients will be selected based on the following inclusion and exclusion criteria:

Inclusion criteria:

- Patients with a diagnostic of Acute Myocardial Infarction
- Age under 65 years
- Hospitalization in the Cardiology Department of the University of Medicine and Pharmacy "Carol Davila" located at Bagdasar Arseni Emergency Hospital

Exclusion criteria:

- Unstable angina
- Systolic resting blood pressure > 200mmHg, Diastolic>110mmHg,
- Blood pressure decrease with more than 20mmHg at standing position
- Severe Aortic stenosis
- Sepsis
- Uncontrolled arrhythmias
- Uncontrolled Atrial Tachycardia HR > 120bpm
- Decompensated Heart Failure
- Atrio-ventricular Grade 3 Transmission Block
- Recent Pulmonary Thrombembolism, Phlebites
- Persistent ST segment elevation of more than 2 mm
- Uncontrolled Diabetes
- Locomotor disabilities
- Thyroidities, Hypokalemia, Hyperkalemia, Hypervolemia

After that, in order to participate to the study they will have to sign an informed consent which has been already approved by the University of Medicine and Pharmacy "Carol Davila" Ethical Committee.

B. Clinical trial design

We will enroll groups of 6 monitored patients and 6 unmonitored patients, in 2 cycles of 8 weeks for the Alpha Version and another 6 monitored patients and 6 unmonitored patients, in 2 cycles of 8 weeks, for the Beta testing.

One cycle will consist of two phases:

Phase I the inpatient period (5-7 days) and Phase II the outpatient period that will take 7 weeks.

Phase I will be common for both groups. They will start early monitored physical activity. Complementary, in the morning and evening patients will receive video tablets containing audiovisual materials regarding the cardiac

event, psychological reactions to the event and cardiac pain/symptom management:

- Cardiac anatomy and physiology related to the event
- Cardiac pain and symptom management
- Risk factor management
- Benefits of physical activity
- Energy conservation/graded return to Activities of Daily Living
- Cardio protective healthy eating
- Medication
- Resumption of sexual activity
- Benefits and entitlements post-event

At the end of the inpatient period the monitored group will receive a pack of Bluetooth transmitting capable devices, consisting of a blood pressure device, cardio watch, pulsoximeter, chest strap and a Smartphone and they will be trained on how to use them. These devices will permit the online home monitoring of the vital parameters (detailed in Table II.)

At discharge, all patients will perform an ECG treadmill exercise stress test which will quantify the base cardiac fitness level. After that the patients will enter the second phase of the rehab process that will last for 7 weeks.

The unmonitored group of patients will perform the rehab process in conformity with what they learned during the inpatient period and following the instructions given in the discharge report and will come back for a revaluation after 7 weeks.

Home monitored patients will have to follow a personalized Rehabilitation Protocol containing a medical treatment plan, a nutritional one and 3-5 personalized session of physical activity. The rehabilitation protocol will be a function of the Mobile Application installed on the Android Smartphone received at home. This will have offer the possibility to be modified in real time by the caregiver depending on the patient's evolution. This Mobile Application is especially created for the Cardiac Rehabilitation program and will assure data privacy regulations using a private Cloud with a specific enabler with security characteristics, data anonymisation, encrypted data transfer, security access keys. The Private Cloud approach will allow the utilization of existing security facilities such as firewalls and access protection, which have been approved by local authorities and are compliant with legal requirements.

C. Data Flow

The patient will have to use the devices only at certain moments during the day. The monitoring and data collection process will be performed automatically from the devices to the Smartphone using Bluetooth technology as shown in Table II.

Data gathered from the sensors will be automatically sent to the Smartphone and then throw the Internet into the Monitoring Center, located at the UMFCD Cardiology Department from Bagdasar Arseni Emergency Clinical Hospital for analysis (Figure 1.). In case of abnormal values, an alarm will be automatically transmitted to the monitoring centre and to the medical doctor than the patient will be contacted by the caregiver. Also the phone application has the possibility to offer audio notifications (i.e. to notify the patient to reduce or increase the intensity

TABLE I.
EDUCATIONAL SESSIONS TIMING

Movies 1.heart pathology movie 2.secondary preventive measures movie/(s)	Tablet with educative movies	Two educational sessions per day of half an hour length 9.00-10:00 19.00-20:00

TABLE II.
VITAL PARAMETERS MEASURED BY EACH DEVICE

Parameter	Device	Timing, Frequency
Heart Rate, Calories Burned.	Basis watch	All the time.
I derivation ECG	Bioharness ECG strap band	During physical activity sessions
Blood Pressure	Automatic-Bluetooth-Pressure-Monitor-A&D	Morning, Evening, Pre and Post activity sessions
O2 Saturation	Nonin 9560 PulseOximeter	Morning, Evening, Pre and Post activity sessions

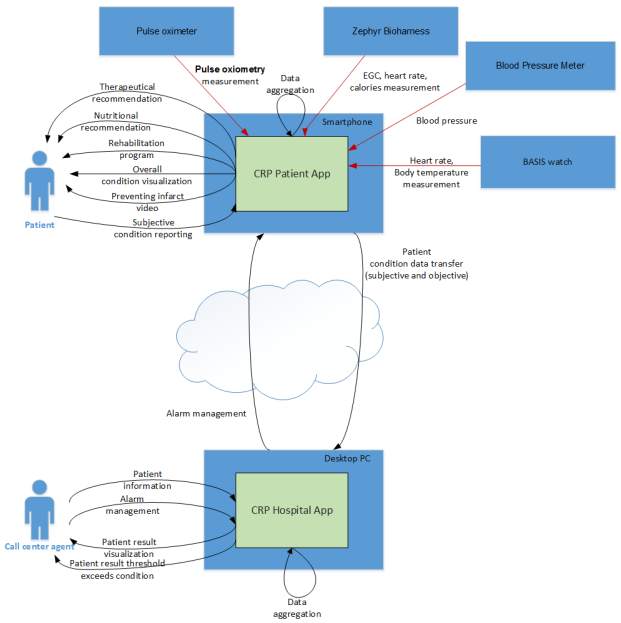

Figure 1. Overview of the patient-call centre agent relation

of the physical effort during his sessions to maintain his heart rate between the safety thresholds).

At the end of the 7 weeks a new ECG Treadmill exercise stress test will be performed in order to quantify the evolution of the cardiac fitness level and work capacity.

IV. EXPERIMENTAL RESULTS

It is well known that the validation and evaluation of e-Health solutions is still a challenge, regarding the insufficient supporting solid studies and frameworks. MAST (A Model for Assessment of Telemedicine Applications) is an assessment framework for telemedicine solutions, or any healthcare service delivery solution that is being delivered through the internet and telecommunication facilities.[2]

MAST is developed on the findings of MethoTelemed, a European Commission initiated project in 2009.[5]

MAST domains are :

1. Health problem and characteristics of the application
2. Safety
3. Clinical effectiveness
4. Patient perspectives
5. Economic aspects
6. Organizational aspects
7. Socio-cultural, ethical, and legal aspects

We started from the highly-accepted available MAST framework and customized it according to our Cardiac Rehabilitation scenario and the FI-STAR project vision. As a result we created a set of Key Performance Indicators that will be measured during the clinical trials.

This will cover seven main domains:

1. Patient Perspectives,
2. Clinical effectiveness,
3. Life improvement quality,
4. Economic aspects,
5. Organizational aspects,
6. Treatment aspects,
7. Legal Aspects and Technical aspects

This will be measured using the controlled study, questionnaires, interviews in retrospective and hospital statistics.

V. CONCLUSIONS AND FURTHER WORK

The entire FI-STAR project will take 30 months. In the present we are in month 16 in the project. The clinical testing of the application in real environment is expected to start at the end of 2014 when Alpha version is planned to be ready. The process of Cardiac Rehabilitation software development is going as planned. Complementary with the software development process there have been performed intensive activities performed for preparing the experimentation site, setting the clinical team and complying with ethical and legal requirements. The specific sensors and the infrastructure needed have been completed. Final results will be delivered in September 2015 at the end of the FI-STAR project.

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