Gianfranco Borrelli<sup>1</sup>, Massimo Pistoia<sup>2</sup>, Paolo Casacci<sup>3</sup>, Alessandro Leone<sup>4</sup>, Pietro Siciliano<sup>5</sup>, Marina de Tommaso<sup>6</sup>, Eleonora Vecchio<sup>7</sup>, Marianna Delussi<sup>8</sup>, Antonio Greco<sup>9</sup>, Daniele Sancarlo<sup>10</sup>, Francesco Giuliani<sup>11</sup>, Cataldo De Benedictis<sup>12</sup>, Nicola Savino<sup>13</sup>, Paola Rametta<sup>14</sup>, Vincenzo Molendini<sup>15</sup>, Leonardo D'Alessandro<sup>16</sup>, Gianfranco Spalluto<sup>17</sup>.

<sup>&</sup>lt;sup>1</sup> Gianfranco Borrelli, Project Mgmt Unit Supervisor eResult s.r.l., gianfranco.borrelli@eresult.it

<sup>&</sup>lt;sup>2</sup> Massimo Pistoia, Project Office manager eResult s.r.l., massimo.pistoia@eresult.it

<sup>&</sup>lt;sup>3</sup> Paolo Casacci, Project manager eResult s.r.l., paolo.casacci@eresult.it

<sup>&</sup>lt;sup>4</sup> Alessandro Leone, Researcher IMM-CNR, Lecce, alessandro.leone@le.imm.cnr.it

<sup>&</sup>lt;sup>5</sup> Dr. Pietro Siciliano, Director of Research IMM-CNR, Lecce, pietro.siciliano@le.imm.cnr.it

 $<sup>^6</sup>$  Dr. Marina de Tommaso, Head of the Neurophysiopathology of Pain unit Bari University, marina.detommaso@uniba.it

<sup>&</sup>lt;sup>7</sup> Eleonora Vecchio, Researcher Bari University, eleonora.vecchio@ uniba.it

<sup>&</sup>lt;sup>8</sup> Marianna Delussi, Researcher Bari University, marianna.delussi@uniba.it

<sup>&</sup>lt;sup>9</sup> Antonio Greco, Head of the Geriatric Unit IRCCS "Casa Sollievo della Sofferenza", a.greco@operapadrepio.it

<sup>&</sup>lt;sup>10</sup> Daniele Sancarlo, Researcher IRCCS "Casa Sollievo della Sofferenza" d.sancarlo@operapadrepio.it

<sup>&</sup>lt;sup>11</sup> Francesco Giuliani, Researcher IRCCS "Casa Sollievo della Sofferenza" f.giuliani@operapadrepio.it

<sup>&</sup>lt;sup>12</sup> Cataldo De Benedictis, R&D Manager SABACOM, cataldo.debenedictis@sabacom.it

<sup>13</sup> Nicola Savino, Area Manager CETMA, nicola.savino@cetma.it

<sup>&</sup>lt;sup>14</sup> Paola Rametta, Area Manager CETMA, paola.rametta@cetma.it

<sup>&</sup>lt;sup>15</sup> Vincenzo Molendini, Area Manager CETMA, vincenzo.molendini@cetma.it

<sup>&</sup>lt;sup>16</sup> Leonardo D'Alessandro, Chief Executive Matrix s.p.a., dalessandro@matrixelettronica.it

<sup>&</sup>lt;sup>17</sup> Gianfranco Spalluto, Project Manager Matrix s.p.a., spalluto@matrixelettronica.it

2 Borrelli, Pistoia, Casacci, Leone, Siciliano, De Tommaso, Vecchio, Delussi, Greco, Sancarlo, Giuliani, De Benedictis, Savino, Rametta, Molendini, D'Alessandro, Spalluto.

**Abstract** The Care@Home project, funded by the Apulia Region, aims at developing an integrated system able to monitor and collect continuously vital parameters of the elderly or frail users in order to allow patients who require specific therapies or rehabilitation activities to perform them at home. By the means of ICT technologies and mobile devices simple to be used, such as smart phones or Tablet PCs able to carry out the monitoring activity noninvasively and assess the patient's health status at the same time, it will be therefore possible to allow frail users to live as long as possible in their own home environment and to receive assistance in remote as well. Miscellaneous testing and experimentation activities and stages are going to be undertaken over the months to come in order to develop a first prototype consisting of a solution to monitor frail person and an electronic medical record accessible via the Internet from any remote location.

Project objectives and initial results concerning the experimentation stage are here introduced.

# **1** Introduction

One of the key-points of a mature and structured welfare system is the efficient and correct evaluation of the self-sufficiency degree and health status of its citizens, with particular regard to frail and elderly individuals. Although the majority of patients are usually affected by conditions of general frailty or functional decline, also related to chronic conditions caused by rare diseases, they are nevertheless endowed with a potential good level of self-sufficiency, if supported by proper remote assistance and monitoring systems able to assess continuously their health status. If the hospitalization may be central in the early stages of a disease, for what concerns the diagnostic and therapeutic aspects, hospitals, instead, are not able to provide in the aftermath appropriate responses to patients' needs which are then entrusted to caregivers, family networks and local health care facilities.

In this context, the Care@Home [3] project – funded by the Apulia Region in the framework of the Apulian Living Labs [1] – aims at developing an integrated information system for the management of the continuity of the treatment of frail patients through advanced ICT home care solutions [2].

The services which are meant to be proposed through this project aims thus at the development of a remote monitoring and assistance system able to assess the endusers' health status, by detecting critical events such as fall-risk or alteration of vital signs and fostering as well the communication with caregivers and family networks, in order to operate a coordination of the miscellaneous therapy or rehabilitation activities.

It will be used a mobile device in order to detect the user's vital parameters at the user's premises, whereas, the collected data will be stored – by using appropriate security protocols – in the central server of a database which can be accessed by all of the previously authorized stakeholders.

The system will allow then to represent the individual patients' summary data and the detail ones, highlighting significant changes and reporting through appropriate algorithms the need for intervention.

Besides, the system considers the development of an electronic medical record accessible by each operator on the basis of his competence, enabling so a multi-level communication frame work.

## 2 Development Methodology and main system features

The conceptual development methodology of the Care@Home system is based on the UCD - User Centered Design [4-7] approach. The core of this process - which considers the involvement of the end-user of the product throughout the whole conception, design and development cycle - can be described as "the practice of designing products so as to allow the user to carry out his duties with minimum stress and maximum efficiency". The purpose of this approach is to tailor then the system around the user's needs, expectations and limits, employing a co-design procedure, which implies that designers, technicians and providers have to necessarily work in direct and close contact with end-users in each of the design phases.

The user is therefore placed at the center of each step of the development process in order to maximize the usability and acceptance of the product, optimizing it around the needs of the users. The UCD methodology is characterized by a multi-level co-design and problem solving process which requires designers not only to analyze and foresee how the user will utilize the final product, but to test and validate at the same time their assumptions by strongly taking into consideration the end-user's behavior during the usability and accessibility tests into the real world. This methodology enables so the creation of the final product through an interactive process that provides the development of a first prototype and a following test and assessment stage on the basis of which to proceed with the development of the next prototype.

Therefore, each cycle leads to the creation of a product that is closest to the real and practical needs of the user. On the basis of the feedback collected after each stage of experimentation activities, indeed, it will be implemented a more precise prototype up to the one that most meets the needs of the end-user and the purposes of the project. In

4 Borrelli, Pistoia, Casacci, Leone, Siciliano, De Tommaso, Vecchio, Delussi, Greco, Sancarlo, Giuliani, De Benedictis, Savino, Rametta, Molendini, D'Alessandro, Spalluto.

compliance with the principles of the UCD methodology, each experimentation phase influences the development of the next prototype, thus leading to a product which is more and more refined and tailored on the end-user's needs and requirements. In particular, two are the planned cycles of experimentation activities for this project which have just started and will lead to the implementation of the next prototypes.

The system provides for the involvement of the following stakeholders:

- 1. Patients in need of care and rehabilitation activities;
- 2. Family networks and caregivers;
- 3. Medical operators;
- 4. ICT Companies (eResult, Sabacom, AserNet)
- 5. Scientific Partners (e.g. CNR-IMM, IRCCS Casa Sollievo dalla Sofferenza; Università di Bari, MATRIX S.p.A., CETMA)

On the basis of a match between the users' needs and expectations in terms of selfsufficiency in their own living environment and the information provided by the medical providers concerning healthcare treatments and rehabilitations activities the patient has to undergo, a technological platform of services and solutions has been developed.

### 2.1 The ICT platform

The system makes use of an ICT platform which integrates on the one hand the OMNIACARE platform [6] developed by eResult and on the other hand the management software developed by Sabacom SRL for what concerns the implementation of an electronic medical record.

OMNIACARE is a system specifically designed for the social welfare and healthcare sector and provides tools to both operators providing assistance and the patients. To promote the independence of frail users and to help them to carry out an independent life as long as possible in their own home environment, the platform makes use of advanced technologies that allow to perform a continuous remote monitoring of the health status of the patients.

The system is composed of a hi-tech kit which includes a mobile device such as a smart phone, a Central Server able to store data collected from smart sensors that detect vital and environmental parameters such as degree of humidity, temperature, ECG, RR interval, body heat, body posture, heart rate etc. An Integration Module (developed by the Research Lab CETMA) allows then data exchange through a wireless connection.

. Once stored in the Server, data are accessible via the Care@Home website. (In Figure 1 an example of the architecture of the system is detailed).

Besides, the system is configured with the user's profile which contains information about its needs, habits, limits, impairments, therapies etc. The mobile device will support the user during daily life activities allowing him/her to live in his home environment and to receive remote assistance by caregivers or medical providers. In case of detection of critical situations, indeed, the system is able to generate an automatic message or alarm to alert a caregiver.

Sabacon S.r.l., contributed with the development of a new software application to record medical and diagnostic data of patient with special focus on cardiopatic patient in strict collaboration with IRCCS. Toghether they have also developed a module for the Multidimensional Prognostic Index test (MPI test) which can help doctors to elaborate a patient anamnesis on his social and health status at the time of hospitalization and it is maintained together with the clinical record. Finally, they implemented a software module for the management of healthcare operator connected to the clinical record of a patient.

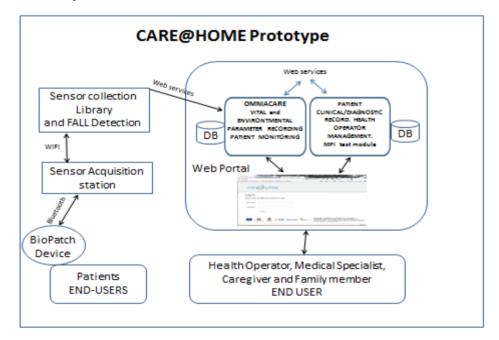


Figure 1. System Architecture Structure

6 Borrelli, Pistoia, Casacci, Leone, Siciliano, De Tommaso, Vecchio, Delussi, Greco, Sancarlo, Giuliani, De Benedictis, Savino, Rametta, Molendini, D'Alessandro, Spalluto.

Data exchange process is performed by Integration Module, that gets Smart Sensors'data through Multi-Protocol Gateway (developed by the Research Lab Matrix), as the Figure 2 shows.

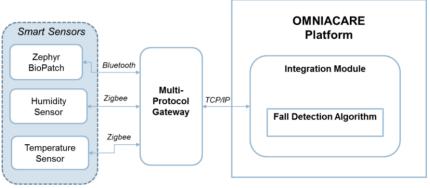


Figura 2: Data exchange process

Integration Module has the following tasks:

- managing vital parameters: the module gets data packets from Zephyr BioPatch device, through Multi-Protocol Gateway (Bluetooth-TCP/IP communication) and processes them;

- managing environmental parameters: the module gets humidity and temperature data, through Multi-Protocol Gateway (Zigbee-TCP/IP communication) and processes them;

- integrating Fall Detection algorithm (developed by the Research Lab CNR-IMM) in order to recognize the fall episode of patients wearing the Zephyr BioPatch device;
- sending relevant data to Omniacare Platform.

### 2.2 Scenarios

The prototype that will be developed in the framework of this project contemplates the existence of at least 4 possible usage scenarios related to the Care@Home system and to be provided by the means of ICT devices.

A first scenario concerns the remote assistance and monitoring of frail and/or elderly users through wearable and non-invasive smart sensors able to detect their vital parameters and to send data collected to a Central Server. The mobile device allows the users to interact with the family network or caregivers when they need to, enabling

then the elderly to carry out their life in their own living environment in independence conditions, as long as possible.

Secondly, other modules of the research project concern, instead: the possibility to measure subjective pain for patients with mild cognitive impairments; the development of a fall-risk detector in order to define an algorithm able to evaluate and detect events, signs and features leading to a fall episode and thus avoid it and finally the effectiveness of monitoring of cardiac patients through the Care@Home system.

#### 2.2.1 Android Application for Subjective Pain Measurement

A software android application for subjective pain measurement for patient with mild cognitive impairment has been developed. The application is able to define the analgesic therapy and the time intervals during which the patients will have to take the therapy.

The application is configured with specific reminders according to the time intervals of the therapy program. Each time a patient should take the painkiller medication the system reminds the user to take it and presents him/her with a scale of discomfort or well-being level represented by a set of images with a differentiated scale of colors which represents the individual mood, as showed in **Figure 2** and **Figure 3**.



Figure 2. Discomfort Level

8 Borrelli, Pistoia, Casacci, Leone, Siciliano, De Tommaso, Vecchio, Delussi, Greco, Sancarlo, Giuliani, De Benedictis, Savino, Rametta, Molendini, D'Alessandro, Spalluto.



Figure 3. Options for mood level to chose from.

All information is then collected in a database. Medical providers and caregivers can thus monitor each patient and decide if and when it is necessary to intervene to support the patient and the proper tools to be used. If the max level of pain is then recorded an alert message is also sent to one's own caregiver.

#### 2.2.1 Monitoring of elderly cardiac patients

Heart failure is often one of the leading cause of hospitalization in the elderly. About 20% of discharged patients tends to be re-hospitalized with a poor prognosis. A recent meta-analysis has shown that the use of tele-monitoring systems can reduce the rate of mortality of 17% and even the re-hospitalization rate of almost 7% in reference to the only cardiac failure.

In this perspective, the multidimensional assessment resulting from a combination of biological, functional, psychological and environmental factors, may be of concrete help in the identification of frail patients that could benefit from the use of these technologies.

Another significant goal of the project is to assess the effectiveness of the Care@Home monitoring services, specifically, by applying them to cardiac patients. This part of the project is still in the experimental stage. In particular, two cohorts of patients are examined for the purposes of the research:

- 1. patients treated according to the current standard treatment protocols;
- 2. patients treated by the means of the Care@Home integrated system of telemonitoring.

The study is carried out according to the rules of good clinical practice and in accordance with the privacy policy and current legislation. Each patient included in the trial will be followed at his/her premises for two weeks by using a small seized monitoring system able to detect the following vital signs: ECG, respiratory rate and heart rate.

Primary outcomes will be on the one hand of technological nature (acceptability, functionality, ease of use of the device, etc) and on the other hand of clinical nature (mortality rate at one month, re-hospitalization with its cause and duration, institution-alization, weekly number of medical checks, quality of life, mood level).

## **3** Experimentation process

The experimentations phases have just started and are going to be carried out throughout the months to come. Two are the principle bodies involved in this stage: on the one hand the IRCCS – "Casa Sollievo della Sofferenza" and on the other hand the Neurophysiopathology of Pain Unit of the University Aldo Moro, Bari.

Both of them will be engaged in recruiting potential patients for the purposes of the project and in particular over-65 frail and/or elderly users or individuals affected by heart problems or mild cognitive impairments such as Alzheimer at its first stages or Huntington's Disease. Medical providers and researchers involved in the project will present its goals to them and propose the opportunity to take part in the experimentation stages providing them with all of the necessary information. Those who wish will be provided with the prototype of the technological kit and its mobile devices in order to carry out the testing and validation phases related to the tools and solutions already developed.

In particular, the University of Bari will be responsible for the experimentation stage concerning the android application for subjective pain measurement for patient with mild cognitive impairment. It will recruit potential patients – approximately 40 users – who are undergoing analgesic treatment and ask for their willingness to try out the application developed.

It will be tested the acceptability degree of the proposed technologies, their effectiveness in comparison with the traditional current standard treatment protocols and their ability to meet the users' needs and requirements.

Moreover, at the "IRCCS – Casa Sollievo della Sofferenza", it will be implemented a counseling center in order to take charge of the patient, once dismissed, collecting all the information suitable to create the user's profile through the system and to manage the monitoring activities during the rehabilitation phase. 10 Borrelli, Pistoia, Casacci, Leone, Siciliano, De Tommaso, Vecchio, Delussi, Greco, Sancarlo, Giuliani, De Benedictis, Savino, Rametta, Molendini, D'Alessandro, Spalluto.

### 4 Conclusion

Most of the development process of the whole system, both in terms of hardware and software components, has been almost completed and experimentation phases are planned. The *Health Check Application* for subjective pain measurement for patient with mild cognitive impairment has been already entirely developed and testing and validation phases are already in progress as planned.

Concerning the implementation of the abovementioned fall-risk detection device, instead, the CNR-IMM has already developed a proper algorithm [5] able to detect the information, parameters and signs related to the recognition tasks of the fall episode. Testing stages are going to be undertaken in the next weeks.

Also the electronic medical record accessible via the Internet from remote has been developed by Sabacom SRL with particular regard to cardiac records, but with possible future integrations concerning the recording of parameters related to other diseases.

Finally, researchers and personnel involved in the project have already accomplished the integration stage of the whole system, putting together each tool and device developed up to now, integrating all the different libraries, components and applications and shaping thus a first prototype of the integrated ICT system to be further improved with the next two cycles of the experimentation activities.

#### References

- 1. Apulian Living Labs official website: <u>http://livinglabs.regione.puglia.it/</u>.
- Bagüés M.I., J. Bermúdez, A. Illarramendi, A. Tablado and A. Goñi. Using Ontologies in the Development of an Innovating System for Elderly People Tele-assistance. In Proc. of the 2003 Int.l Conf. on Ontologies, Databases and Applications of Semantics (ODBASE'03), Catania, Italy, November 3–7, 2003
- 3. Care@Home project website: <u>http://careathome.eresult.it/</u>.
- 4. Greenbaum Joan and Morten King (eds): Design At Work Cooperative design of Computer Systems, Lawrence Erlbaum 1 Ed. 1991.
- Leone, A., Rescio, G., Siciliano, P., Supervised machine learning scheme for tri-axial accelerometer-based fall detector, IEEE International Conference on Sensors, 2013, pp.1-4
- 6. Omniacare official website: <u>http://www.omniaplace.it/en-us/Solutions/OmniaCare</u> .
- 7. Rubin, Jeffrey, Handbook of Usability Testing: How to Plan, Design, and Conduct Effective Tests, John Wiley and Sons, Inc., 1984.