HEARTFAID

D45–Clinical testing protocol and validation results

Submission date: 22/06/09
Due date of document: 30/04/09

HEARTFAID

A KNOWLEDGE BASED PLATFORM OF SERVICES FOR SUPPORTING MEDICAL-CLINICAL MANAGEMENT OF THE HEART FAILURE WITHIN THE ELDERLY POPULATION

Project summary	
Project acronym:	HEARTFAID
Project identifier:	IST – 2005 – 027107
Duration of the Project:	01/02/2006 – 30/04/2009
Project Co-ordinator:	UNICAL University of Calabria (Italy)
Thematic Priority:	Information Society Technology
Instrument:	Specific Targeted Research or Innovation Project

Consortium

- UNICAL- Università della Calabria (Italy)
- UNICZ- Università degli studi Magna Graecia di Catanzaro (Italy)
- UNIMIB- Università degli studi di Milano Bicocca (Italy)
- JUMC- Jagiellonian University Medical College (Poland)
- VMWS- Virtual Medical World Solutions Ltd (United Kingdom)
- FORTHNET S. A.- Hellenic Telecommunications and Telematic Applications Company S. A. (Greece)
- SYNAP- Synapsis s.r.l. (Italy)
- CNR- Consiglio Nazionale delle Ricerche (Italy)
- FORTH-Foundation for Research and Technology Hellas (Greece)
- RBI- Rudjer Boskovic Institute (Croatia)
- AUXOL- Istituto Auxologico Italiano (Italy)

D45 – Clinical testing protocol ad validation results

Document summary	
Document title:	Clinical testing protocol and validation results
Document classification:	Deliverable D45
Dissemination level:	PU
Submission date:	22 June 2009
Due date:	30 April 2009
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Work package:	WP7
Report version:	1.1

Short description
The document describes the activities performed by the clinical partners pertaining clinical testing and validation of the HEARTFAID platform in both the hospital and home settings. Acquired experience and future suggestions to complete the final version of the HEARTFAID platform from the end user perspective are summarized.

Change record		
Version number	Changes	Release date
1.0 1.1	First draft of the document Further contributions and final version	30/04/09 22/06/09

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1 Introduction

Chronic heart failure (CHF) is a deadly and disabling syndrome that affects close to 7 million Europeans and 5 million North Americans each year, and it is recognized as a major public health problem. Despite new and more effective pharmacological and non-pharmacological therapeutic strategies, the prognosis of patients with CHF remains very poor. Although patients with CHF often die from a sudden cardiac event, the progressive and unstable nature of the syndrome indicates that many patients require multiple admissions to the hospital in the last 12 months of life. The major component of healthcare costs for CHF is hospital treatment, which accounts for more than two thirds of such expenditure and about 2% of total healthcare expenditure.

Effective pharmacological and non-pharmacological treatments are available for heart failure. Unfortunately, because of suboptimal organization of care, such treatments occasionally are not either fully provided or fully followed. This makes such treatments less effective. Multidisciplinary approaches have been demonstrated to improve outcomes in patients with chronic heart failure. In fact, there is a growing evidence that refining organization of heart failure care with ad hoc programs can have a major impact on reducing hospitalization and/or decreasing deaths. Unfortunately, within most health care systems, because of barriers related to funding or geography, access to these programs is rather limited. Lack of healthcare providers able to provide expert management for heart failure in relation to the number of affected patients plays a big role.

Novel methods for the delivery of quality healthcare have been suggested to increase the effectiveness of heart failure management. Among such methods, some of them imply the involvement of a lower amount of human resources thus allowing to contain costs while offering effective care. In this context, ICT has driven increasing attention, being telemonitoring of hearth failure patients the dedicated application. Remote monitoring models for delivering care range from regular structured telephone contacts to biological signal telemonitoring, i.e. transfer of physiological data through telephone, digital cable, more sophisticated networks from the patient's home to the healthcare providers. Interest in ICT and telemedicine as a way of providing care has been stimulated by the rising costs of hospital treatment, rapid advances in technology, and the wider availability of low-cost, patient-friendly equipment.

In this context, the HEARTFAID consortium has developed the HEARTFAID platform with the ambitious aim to provide the heart failure care providers with a powerful aid supporting a new CHF management model.

The HEARTFAID platform prototype has been tested by the clinical partners participating to the consortium: University "Magna Graecia" of Catanzaro (Italy), Jagiellonian University Medical College (Cracow, Poland), University of Milan-Bicocca (Italy), Istituto Auxologico Italiano (Milan, Italy).

This documents summarizes the experience collected with the HEARTFAID platform prototype by end users "on the field" (hospital and home settings), and

their suggestions for the further development of a final product fully suitable to the needs of the end users.

2 Hospital Care: Clinical Sites Experience

One scenario of testing the HEARTFAID platform services has been the Hospital Care. Hospital Care testing has focused on the use of the platform services available through a PC located in the medical office. In particular, the services mainly refer to 1) a repository of the relevant clinical, hemodynamic, echocardiographic and laboratory parameters listed in Deliverable 5, and 2) a clinical decision support tool providing suggestions to be compared to the clinical decisions taken by the physicians according to current heart failure management guidelines based on the same clinical, hemodynamic, echocardiographic and laboratory data.

Across the clinical sites, some of the patients recruited to test the functionalities of the HEARTFAID platform in the Hospital have also been considered to test the HEARTFAID platform functionalities developed for the Home setting.

2.1 UNICZ

At UNICZ, several outpatients with chronic and stable heart failure (NYHA class II-IV) were enrolled into the platform. After signing the written informed consent, patients were enrolled into the platform and their relevant data were inserted. Medical doctors, accessing the HEARTFAID platform through the front-end by means of their username and password, have filled in the e-CRF with data pertaining to patients' anamnesis, physical examination, medications, ECG parameters, chest X-ray, laboratory tests, echocardiographic parameters, 24h ECG monitoring parameters.
HEARTFAID platform services have been required in case of baseline evaluation and additional successive clinic examinations.

Hospital Care Service
The Hospital Care service has been tested on several patients, with particular attention on the group of patients also evaluated in the Home Care environment.
In particular, the tests performed have provided:

- integration of data stored in the repository of the platform (eCRF) for testing the knowledge base;
- control on the variability and updating of the suggestions offered by the CDSS after the insertion, in eCRF repository, of new data coming from additional visits;
- monitoring and evaluation of the CDSS suggestions based on the clinical status of each patient;
- evaluation of accessibility to services and usability of the front end of the platform.

When Hospital Care service is activated (Fig. 1), the medical doctor visualizes CDSS suggestions about diagnosis, additive diagnosis, severity assessment, prognosis, medication status, medication suggestions, medication warnings and other.

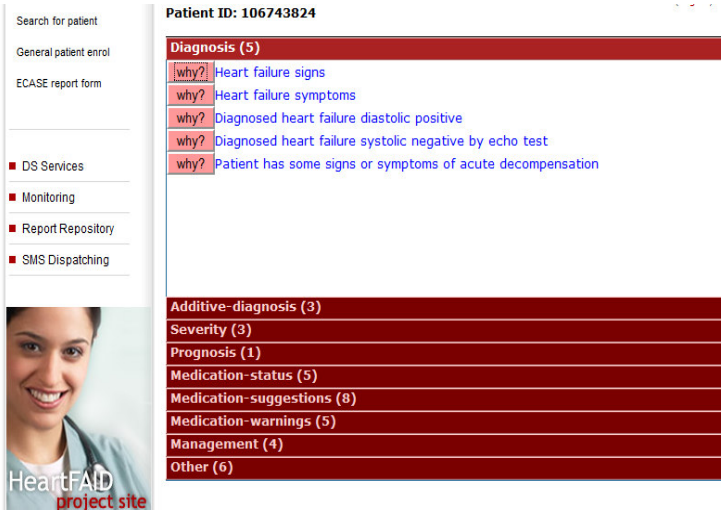

Fig 1. Example of CDSS suggestions for Hospital Care.

By clicking on "Why?" the explanation for every suggestion is provided (Fig. 2).

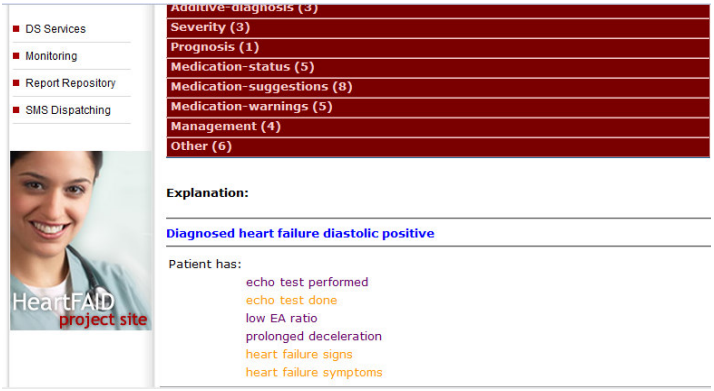

Fig 2. Example of explanations for CDSS suggestions for Hospital Care.

EchocardioLab Service

In order to test the EchocardioLab service, the suitable configuration of the echocardiograph (VIVID 7/Pro VIVID 7, already integrated to the platform) has been carried out. In particular, the specific functionality relates to the HL7 transmission of echo measurements allowing to test the suggestions of CDSS on each patient enrolled. Additionally, echocardiographic images have been automatically sent from the echocardiograph to the DICOM server of the paltform, allowing to evaluate the automatic detection of measurements by an integrated "Echocardiolab " service through the use of the front-end of the

platform. Finally, through an e-mail notification, it is possible to verify the correctness of the procedure for sending the data to the DICOM server.
The CDSS suggestions about echocardiographic parameters and measures (ejection fraction, pulmonary pressure, etc.) (Fig. 3) were also evaluated and confirmed by the clinician.

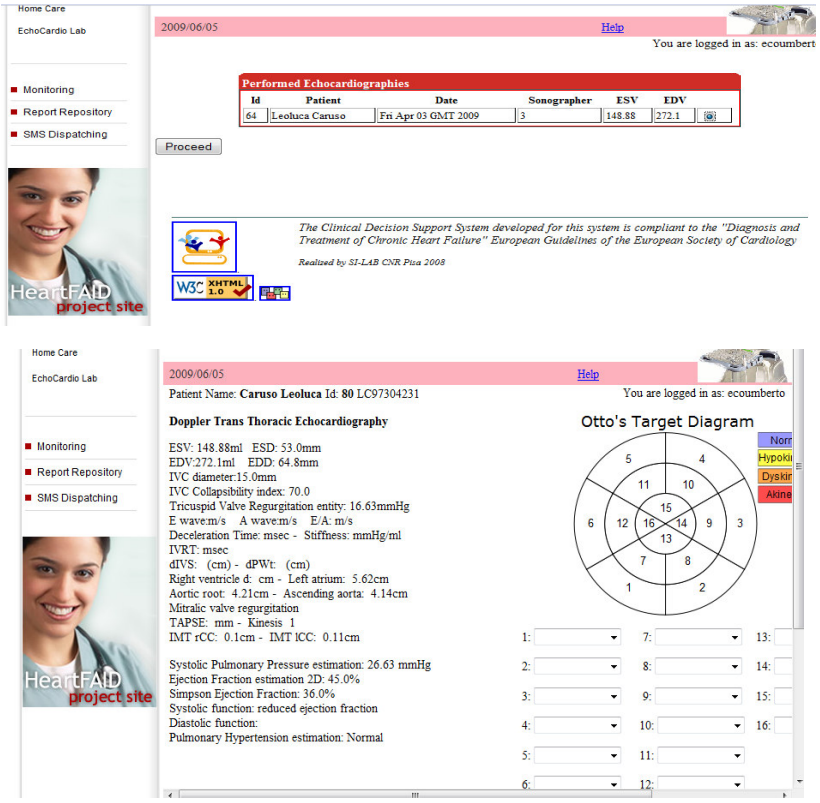

Fig. 3. Echocardiographic parameters and measures.

2.2 UNIMIB/AUXOL

Hospital Care Service

At the joint clinical sites of AUXOL/UNIMIB following the agreed clinical protocol, 7 qualifying individuals with chronic heart failure (NYHA class II-III) referring to the local outpatient heart failure clinic, after having signed written informed consent, were enrolled in the HEARTFAID project.

Clinical data pertaining the baseline evaluation and additional visits were inserted into the eCRF. They overall related to anamnesis, physical examination, medications, ECG, chest X-Ray, laboratory tests, and echocardiography.

Additional 10 historical patients were retrieved among the outpatient clinical records and their data were inserted into the eCRF. This was done with the purpose of enlarging the population of subjects available to test home care

monitoring. For these 10 patients, a 30 day home monitoring was simulated. A daily variation in blood pressure, heart rate, body weight, respiratory rate resembling the most common combinations in most common causes of heart failure decompensation was simulated by the physicians and manually sent to the platform via Nurse@Home.

CDSS suggestions were elicited on these 7 + 10 set of patients following the procedures previously exemplified in Fig. 1 e Fig. 2. Overall results of CDSS performance testing on hospital care done by all the clinical sites on selected patients is summarized in section 3.

Echocardio Lab Service

The echocardio lab service has been tested on the 7 patients actually assigned to home monitoring. Data coming on the echocardiographic examinations performed before the first return visit were manually inserted (Fig. 4).

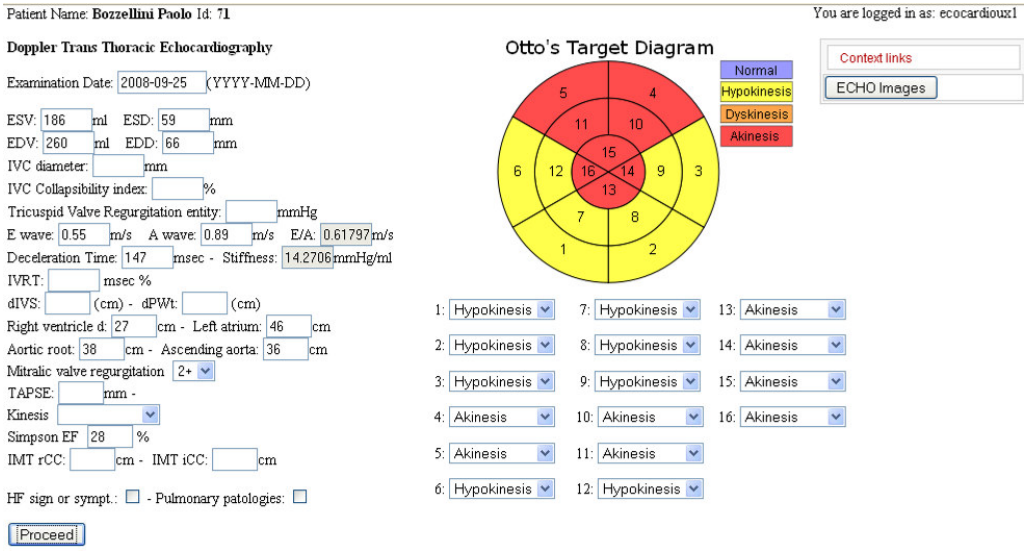

Fig.4. Manual insertion of echocardiographic data.

The CDSS estimations on such data were launched. Data on CDSS performance testing on Echocardiographic Lab done by clinical sites on selected patients are summarized in section 3.

2.3 JUMC

Hospital Care Service

According to the clinical protocol, JUMC selected a group of 7 CHF patients in NYHA class II- III, who have been enrolled into the platform and followed the plan of clinical validation. The elderly patients at age > 65yr, with available internet connection at home and ability to operate PCs, have signed written informed consent and have agreed to participate to the study. The clinical data of

included patients acquired at hospital (anamnesis, physical examination, laboratory tests, echocardiography, 6 MWT, Holter monitoring) were manually inserted into the correspondent sections of the eCRF.

The DS Services at hospital enabled JUMC to confirm the previously made diagnosis of CHF and followed also our management strategy. The system kept JUMC informed about lacking important clinical parameters, and it was helpful in indicating the abnormal values which could be lost very easily in clinical routine. Most relevant to the clinical management, important suggestions were reaffirmed concerning the indications and contraindications to the pharmacological treatment (even though some mistakes were reported to technical partners and corrected in an updated version of the platform) and information about present negative prognostic factors (see the following synoptic table).

Hospital care	**eCRF data**	**Example of platform suggestion**	**Clinical relevance**
Diagnosis	**Anamnesis-symptoms at presentation** **Dyspnoea: YES** **Fatigue: YES** **Distance: 320m** **Anamnesis-cardiovascular history** **Previously diagnosed HF: YES** **Dyspnoea: YES** **Fatigue: YES** **Distance: 200m** **Physical examination:** **-peripheral edema- YES**	**heart failure symptoms (dyspnea) heart failure symptoms (fatigue)** **Patient has some signs or symptoms of acute decompensation** **Patient has:** **-was previously diagnosed with CHF** **-had signs and symptoms of CHFdecompensation** **relevant signs and symptoms (peripheral edema)**	**the HF platform confirmed that the enrolled patient according to the guidelines has the symptoms of heart failure** **the HF platform indicated that the patient has the symptoms and signs which could suggest decompensation and thus the patient requires immediate management**
Additive diagnosis	**Laboratory** **Total cholesterol – 6.48 mmol/l** **LDL- 3.6 mmol/l** **Triglicerydes- 0.87 mmol/l, HDL- 1.2 mmol/l**	**Alternative or additive diagnosis: Hypercholesterolemia**	**the HF platform remembered the doctor about another- parallel to CHF existing pathology which has the impact of further management and treatment CHF patient**
Severity	**Anamnesis-symptoms at presentation:** **Dyspnoea: YES** **Nocturnal**	**dyspnea at rest** **Patient has:** **physical activity sedentary dyspnea**	**The HF platform reminds the doctor the grade of CHF severity based on the data from anamnesis and physical**

	dyspnoea: YES Lifestyle information Physical activity: sedentary		examination
Prognosis	Anamnesis: Atrial fibrillation: not present Pacemaker: NO Physical examination: Third tone- not present SBP- 124 DB-82 HR-76 Anamnesis: Dyspnoea: Yes Irregular heart rhythm: YES Laboratory Na- 126 mmol/l	Good prognosis by HF predictive scale (no coexisting risk factors like third tone, atrial fibrillation, arrhythmia, pacemaker, and low SBP) Very poor prognosis by relevant prognostic markers. The patient has: - hyponatremia - dyspnea at rest or palpitations at rest	The HF platform confirmed that the patient is not characterized by poor prognostic factors The platform reminded the doctor that he should pay more attention in further management of this patient as he has worse prognosis
Medication status	Anamnesis: Atrial fibrillation: not present Physical examination: -HR- 130/min Current therapy: Cardiac glycosides not mentioned Anamnesis: Cardiovascular history: serious ventricular arrhythmias-YES 24-h Holter monitoring: VTach (>=3 beats)- 20 ICD implantation: YES	suggested treatment: Cardiac glycosides Patient has: -atrial fibrillation Patient does not have: -digoxin is contraindicated -takes cardiac glycosides -suggested to prescribe treatment: Cardiac glycosides -cardiac glycoside contraindications suggested prescription: Amiodarone Patient has: -ventricular arrhythmia Patient does not have: -amiodaron contraindications	The platform reminded the doctor about the possibility of controlling fast heart rate in atrial fibrillation in CHF by cardiac glycosides The platform reminded the doctor about the possibility of introducing treatment with amiodaron in case of electrical storm due to frequent ventricular arrhythmias
Management	Physical examination: Weight – 92 kg Height- 164	Weight reduction is recommended Patient is: obese	The HF platform reminded the doctor about non-pharmacological recommendations in

	Anamnesis: lifestyle information **Smoking: YES** **No of cigarettes per day: 20**	**Smoking is always discouraged** **Patient has:** **-smoker**	**CHF which implementation could improve the patient status through weight reduction and refrain from smoking**
Other	**Anamnesis: cardiovascular history** **-Hypertension: YES** **Grade ESH/ESC: III** **-Coronary heart disease: NO**	**Consider hypertension as one of two most probable causes of heart failure**	**The HF platform suggested that hypertension could be the most probable cause of CHF which means that the doctor should concentrate more on the control of blood pressure to slow down the progression of disease**

3 Hospital Care: Clinical Evaluation and Suggestions

The overall evaluation of the HEARTFAID platform as a tool working as a repository of data was positive although further improvements are needed to fasten the procedures on enrolment and data insertion, and to detail the clinical data, i.e. the pharmacological regimen.

The results of the Hospital care CDSS were positive. Pooling the results and impressions of the clinical partners on tested patients, the CDSS overall performance (grading from 1-10) resulted rather accurate for diagnosis (9/10) and severity (8/10); slightly less accurate for additional diagnosis and prognosis (6/10), for medications status, suggestions and warnings (5/10).

4 Home Care: Clinical Sites Experience

4.1 UNICZ

According to Deliverable D5, home care monitoring has focused on telemonitoring of some clinical parameters in order to achieve an early detection of decompensation, rather before its clinical evidence.

According to the protocol, UNICZ selected a group of 10 elderly CHF patients, 9 males and 1 female, already enrolled into the platform. After enrolment, the medical doctor, accessing by the front-end, selects the monitoring services, assigns/changes the decision support services (early detection of decompensation conditions, Minnesota test), assigns/changes the monitoring resources (automatic acquisition of blood pressure and heart rate with UA-767PBT-Oscillometric Blood Pressure Monitor, automatic acquisition of body weight with UC-321PBT Electronic Scale, manually acquisition of body temperature, respiratory rate, and manual acquisition of body weight, blood pressure and heart rate).

The patients enrolled for home care monitoring have been selected with a CHF severity ranging from NYHA class II and NYHA class III. Nurse@Home application has been installed on their personal computer (PC). All patients manually acquired the Minnesota questionnaire, once a week, and every morning body temperature and respiratory rate. In particular, 7 patients every morning manually acquired blood pressure, heart rate and body weight, and for three of them the acquisition was automatic, by the appropriate Bluetooth devices (A&D UA-767PBT and A&D UC-321PBT).

The patient's selection has been made with particular attention; all patients or their relatives had a sufficient ability to use PC. The installation and setting, the preparation of a manual on how to use Bluetooth devices, the development of the application on the patient's PC has been made in the hospital. All the necessary explanations have been subsequently given to health care personnel and to patients or to their relatives on how to send data. A manual in Italian was prepared to this purpose. The control of data from Nurse@Home application was made daily by the care coordinator (a doctor specialized in internal medicine) using the front-end of the platform.

CDSS on Home Monitored data

The decision taken by the medical doctor dedicated to remote home care has been compared with the indications provided by the system, fed by the same tele-transmitted information. The evaluation of data coming from Nurse@ Home has been useful to check possible cases of decompensation. Through the acquisition of data derived from Nurse@Home, an alarm system, implemented using the email and SMS notification, has been able to advice the medical doctor about the clinical condition of the patients enrolled in the platform. An email reports the suggestion of CDSS about a possible risk of patient's decompensation through the indication of a risk level. This comes from the application of the model base and knowledge base rules: in this way, it is possible to obtain from the system a risk level of a current acute decompensation conditions, and the probability level of acute decompensation condition by the next two weeks.

Following, examples of different e-mails are listed: the first and the second are from the same patient, the third from a different patient

CDSS report for Leo…. Car… (male 71)
Request time: Thu May 21 19:49:04 CEST 2009
ALERT level(0) :
Suggestion: no risk of decompensation.
With accuracy: 0,8821

NYHA class:
Old NYHA class : III
Computed NYHA class: III

Minnesota answers : 5 5 4 4 4 4 4 4 4 5 4 5 5 4 4 4 3 4 4 4 4
Minnesota time : 2009-05-18T18:31:31

Home monitoring HM1:
Respiratory Rate change greater than 15%
Respiratory Rate greater than 20
Body Weight change greater than 0.5 Kg
Body Weight change greater than 2 Kg in a 3 days

Input data:
Smoke : -
Alcohol : -
Respiratory rate:22 / -
Systolic BP :122 / -
Heart rate :50 / -
Weight :100.7 / -
Tot. Body Water : - / -

CDSS report for Leo…. Car… (male 71)
Request time: Tue Apr 28 15:28:57 CEST 2009
ALERT level(2) : a probable decompensation condition is early detect for the patient.
Suggestion: very high risk of decompensation.
With accuracy: 0.8821.

NYHA class:
Old NYHA class : III
Computed NYHA class: IV

Home monitoring HM1:
Respiratory Rate change greater than 15%
Respiratory Rate greater than 20
Body Weight change greater than 0.5 Kg
Body Weight change greater than 2 Kg in a 3 days

Input data:
Smoke : -
Alcohol : -
Respiratory rate:28 / -
Systolic BP :165 / -
Heart rate :53 / -
Weight :99.9 / -
Tot. Body Water : - / -

CDSS report for Ado….. Cat…. (male 76)
Request time: Wed Apr 29 09:12:42 CEST 2009

ALERT level(2) : a probable decompensation condition is early detect for the patient.
Suggestion: very high risk of decompensation.
With accuracy: 0.8821.

NYHA class:
Old NYHA class : III
Computed NYHA class: IV
Minnesota answers : 4 4 3 3 3 4 2 4 3 3 3 3 3 0 3 4 4 4 4 4 4
Minnesota time : 2009-04-27T09:40:30

Home monitoring HM1:
Respiratory Rate change greater than 15%
Respiratory Rate greater than 20
Body Weight change greater than 0.5 Kg
Body Weight change greater than 2 Kg in a 3 days

Input data:
Smoke : -
Alcohol : -
Respiratory rate:21 / -
Systolic BP :135 / -
Heart rate :76 / -
Weight :71.5 / -
Tot. Body Water : - / -

In case of a high risk of decompensation, in addition to an e-mail notification, an alert SMS reaches the mobile phone of the care team coordinator with the following message:

Ado….. Cat…. (Patient's name and surname)
"Very High Risk of Decompensation"
Wed Apr 29 – 09:12:42 CEST 2009
From EDCC ALERT

After these messages the care team coordinator can contact the patient by phone to perform immediately a hospital visit.
We had alert notifications about "very high risk of decompensation" for 4 patients.
For two patients the changes of clinical parameters (blood pressure, heart and respiratory rate, body weight and temperature) were not associated with a clinically significant worsening of the patients' status. But for the other two patients, the evaluation of data coming from Nurse@Home has been useful to check two possible cases of decompensation, for example, the employment of anti-inflammatory drugs for a patient who had consequently a dangerous increase in systolic pressure. In another case the home monitoring service has been useful

to discovery that a patient, who showed an increase in body weight, had suspended the diuretic therapy.

4.2 AUXOL/UNIMIB

Seven patients enrolled in the HEARTFAID platform (on whom the Hospital care test has been completed) performed a one month daily monitoring of selected biological parameters. Three patients completed the home monitoring by means of an integration of the MagIC System and the related MagIC-Monitor software in the Nurse@Home software. Another subgroup of 4 patients completed the data collection in the home setting by means of either the "Manual" acquisition procedures, or "Automatic" acquisition devices (using the blood pressure recorders and scales). Three of them were daily contacted by phone by the healthcare providers that manually entered their measurement from the hospital.

Home monitoring by integration of the MagIC System in the Nurse@Home software.

A subgroup of 3 patients completed the testing phase of the Nurse@Home application by means of home self collected biological parameters in combination with parameters collected by the MagIC vest and the related software developed by Polo Tecnologico, Fondazione D. Gnocchi (Milan, Italy: Ing. Marco Di Rienzo, Ing. Paolo Meriggi) and clinically tested in conjunction with AUXOL and UNIMIB. The MagIC textile-based monitoring system has been selected as a test acquisition device because of its suitability and simplicity of use. Indeed, all sensors and wires are embedded in an underwear garment that only requires to be worn by the patient without any further setup procedure. This system can detect ECG, respiratory-driven thorax movement and subject's accelerations (details have been provided in the deliverable D19). In this validation, the HEARTFAID platform derives the respiratory rate from the respiratory signal flowing from the MagIC vest.

According to the protocol, the three patients using the MagIC vest were asked to perform a session, every morning between 8:00 and 10.00 a.m., which consisted in the following steps:

1. Measuring: blood pressure twice (by an automatic oscillometric device), weight (by a normal scale) and the breathing rate (by simply counting the number of respiratory efforts in a given minute). The Minnesota questionnaire was completed once a week.
2. Writing the obtained measurements on a diary provided by the investigators.
3. Turning on the HEARTFAID home gateway where the MagIC Heartfaid Bridge (MHB) and the N@H are running.
4. Wearing the MagIC vest, and letting the system to acquire data from the vest for three minutes according to the instructions provided by the software.
5. Filling in the fields of the Nurse@Home (N@H) computerized questionnaire.

6. Activating data transfer from the home gateway to the Heartfaid Portal via an internet connection.
7. Completing the acquisition, turning off the device and unwearing the MagIC vest.

More precisely, the core of the HEARTFAID home gateway has been the Nurse@Home software that was responsible for the whole data collection and data transmission to the remote HEARTFAID server. Thus, in close cooperation with the technical partners, specific procedures have been developed to allow the MagIC system to send data measured by the textile sensors directly to the Nurse@Home through a Bluetooth connection.

In more details:

1. The MagIC-Monitor (MM), previously developed by the WestLab, Polo Tecnologico, allowed us:
    a. to guide the patients to perform correctly the acquisition from the MagIC vest,
    b. to collect data from the vest for 3 minutes,
    c. to pack all data in an XML file,
    d. to send an email containing two strips of signals to the caregiver/s (see details hereafter).

    For the test phase of the project this procedure was slightly modified in order to transfer the XML file to MagIc Vest Server via a TCP/IP connection and the updated software was called MagIC Heartfaid Bridge (MHB).
2. The MagIC Vest Server (MVS), developed by FORTH, receives the XML file provided by MHB, processes and transfers the selected information to the N@H, without any additional user interaction.

The scheme of the interactions among MagIC system, MHB and MVS programs and the Nurse@Home software are illustrated in Fig. 5. An example of the whole system implemented in one patients' homes is represented in Fig. 6.
An example of the content of the E-mail daily received by the healthcare providers in charge of monitoring patients assigned to Nurse@Home + MagIC vest protocol is represented in Fig. 7.

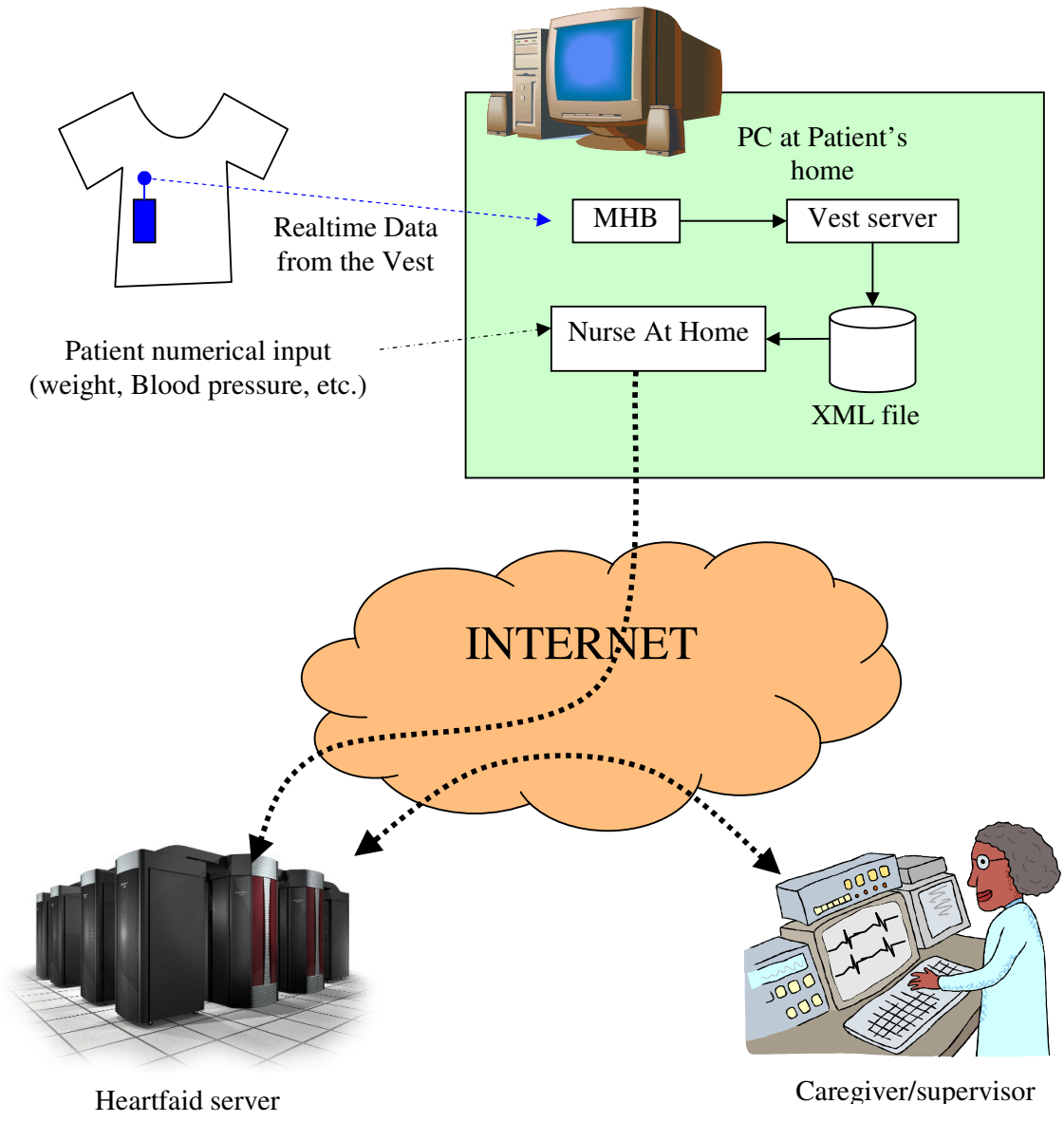

Fig. 6. Graphical representation of the interaction among the several components of the Heartfaid platform.

Fig. 6. Example of system implementation in one patients' home.

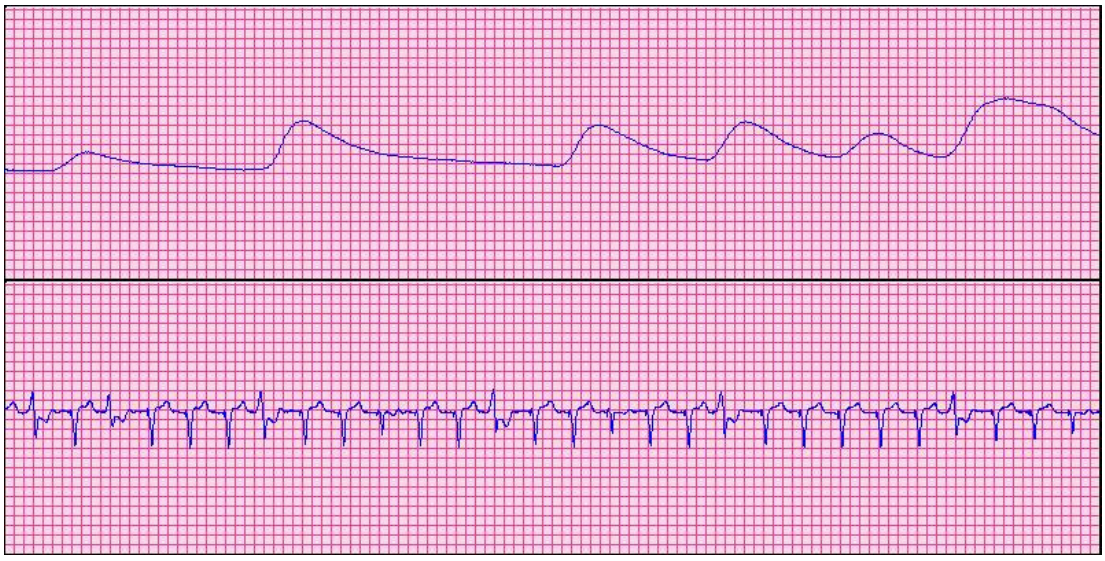

Fig. 7. Example of the content of the E-mail daily received by the healthcare providers in charge of monitoring patients assigned to Nurse@Home + MagIC vest protocol.

Results.
All of the three patients positively complied with the protocol. The system behaved correctly in 85 out of 90 sessions (94%), while in 5 cases a second session was required due to internet traffic congestion. In only three sessions, caregivers asked the patient to repeat the acquisition, because of movement artefacts. All patients found the smart garment comfortable, and the platform easy to use. They also reported to feel themselves "safely supervised" and asked to continue the monitoring for a longer period.

Manual and automatic home monitoring.
Another subgroup of 4 patients have completed the data collection in the home setting by means of either the "Manual" acquisition procedures, or "Automatic" acquisition devices (using the blood pressure recorders and scales). The technical components of our team, that had worked on installing the HEARTFAID software on the PC located in the medical environment and on the PCs used at home by the patients, have continued verifying the correct functioning of data transmission from the home environment which was successfully completed.
Finally, both the clinical and technical components have performed the validation of the CDSS of the platform with respect to the Home environment.

Simulated patients.
In 10 real patients, whose clinical data (enrolment and subsequent visit) were inserted via the portal, a paradigmatic variation of home monitored parameters were simulated and subsequently entered via Nurse@Home, and also included in the validation. Their simulation went from the simplest (1 parameter) to the most complex simulation one (up to 4 parameters). Practical examples include the following:

↑ BP	→ decompensation
↑ fluid retention	→ decompensation
↑ BP + ↑ fluid retention	→ decompensation
↓ FC + ↓ BP	→ ↑ wt → decompensation
Acute COPD with ↑ RR	→ ↑ wt → decompensation
Drug overdosing ↓ PA + ↑ FC	→ ↑ wt → decompensation
Dehydration ↓ PA + ↑ FC + ↓ wt + ↑ RR	→ decompensation

CDSS on home data.
The CDSS "on demand" on home data has been tested on the 7 + 10 patients. Overall, as the 7 real patients kept rather stable clinical conditions, the CDSS gave the correct suggestion that there was no risk of incipient decompensation (Fig.8). Regarding the real 10 patients for whom the home monitoring was simulated, a sufficient agreement between the clinical impressions and the suggestion of decompensation provided by the on demand CDSS was detected for the patients with concomitant variation in 2 or more home monitored parameters.

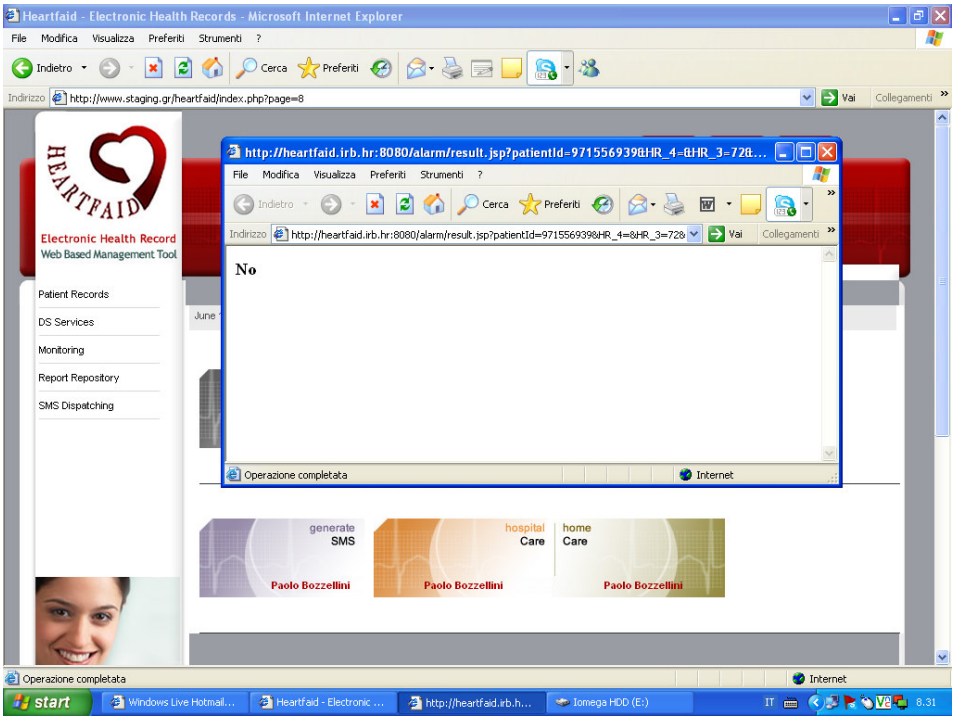

Fig 8. Example of CDSS on demand on home monitored data in 7 patients.

4.3 JUMC

DS Services concerning home care allowed daily monitoring of patient's status. During the follow-up none of the selected patients had decompensation episode so we did not receive any notification. This might be explained by the fact that the system improves the patient' compliance to both pharmacological and nonpharmacological recommendations thus extending the elapsed time between subsequent decompensation episodes.

5. Home Care: Clinical Evaluation and Suggestions

In the Home setting the system prototype has been tested to transmit, by various sensors, most commonly monitored home data in heart failure patients. The service has been useful to keep the health care providers informed about the patient's status. Additionally, this experience indicates that, besides routinely used sensors, the MagIC system is fully compatible with the Heartfaid architecture. This implies that such textile-based system can be used, in a possible future upgrade of the HEARTFAID platform, to monitor also additional signals, apart from respiration, i.e. ECG and patient movement. The CDSS on home monitored data was overall helpful in identifying most unstable patients. Some limitations must be acknowledged. In current times, elderly people are not often computer literate, mostly do not live with younger relatives capable of using PCs, erratically faulty Internet connection can make home monitoring intermittent.

6. Metrics of Success

In terms of metrics of success, different sets of indicators have been considered as suitable indices for measuring the effectiveness of HEARTFAID platform. In detail, we have considered:

Patient centered indicators

- registered outcomes;
- clinical stabilization at home of the HF patients and incidence of acute exacerbations at home;
- generic and condition-specific quality of life;
- satisfaction with care and acceptance of the new ICT based care model.

At UNICZ, during the phase of testing and validation, for two patients, the data coming from Nurse@Home have been useful to check two possible cases of decompensation. In one case the employment of anti-inflammatory drugs for a patient caused a dangerous increase in systolic pressure. Thus, the medical doctor has contacted the patient, informing him to stop the anti-inflammatory drugs and improving the antihypertensive therapy. In another case, the home monitoring service has been useful to discover that a patient, who showed an increase in body weight, had discontinued the diuretic therapy. In this case the medical doctor has redefined the diuretic therapy. Through this service we had the possibility to avoid two possible hospitalizations. With home care monitoring, we observed improvement at patient's care through an easier and better management of the disease. In addition the HEARTFAID platform increased interest towards a better care and awareness of the disease among CHF patients improving self control. Also quality of life evaluated by Minnesota questionnaire has been positively influenced. Moreover, telemonitoring of clinical parameters at home was found acceptable and highly useable by the patients, with good patient satisfaction. Only 4 patients had to seek the help of a relative. Only in one case there was a technical problem about Internet connection, but it has been solved in the same day.

At AUXOL/UNIMIB the 7 patients monitored by means of Nurse@Home (with or without the MagIc vest) at home did not exhibit, according to both the clinical judgment based on daily checking of home data and the HEARTFAID platform, a risk of incipient decompensation. Daily home data on blood pressure prompted fine titration of pertaining medications by the physicians in two patients. In agreement with the clinicians' impressions, the HEARTFAID platform sent no notifications about an immediate risk of decompensation. Several explanations can be given about the fact that such patients kept overall stable clinical conditions during the home monitoring phase despite being at high risk of decompensation. It might depend on the fact that, due to the tight time frame, perhaps the duration of follow up phase has been too short. An alternative explanation could be that patients were involved in a research study pertaining the daily practice of self monitoring. It is likely that this improved the patients' compliance to the pharmacological regimen. Even with the most complex form of

transmission architecture patients demonstrated a good acceptance and relatively quick familiarization with the system although it must be admitted that during the screening phase patients were selected only if having some experience with computers.

JUMC shared the same experience occurred at AUXOL/UNIMIB. DS Services concerning home care allowed to perform daily monitoring of patients' status, increasing interest in better care and awareness of the disease among CHF patients and improving the independency of the patient. Also quality of life assessed by Minnesota questionnaire has improved. During the home follow-up none of the selected patients had decompensation episode and no alert notifications were received by the healthcare providers. In one case we noted an increased body temperature which was followed also by increase of the heart rate and respiratory frequency. We have contacted the patient- he reported also cough and sweating- and scheduled for him ambulatory visit. After the laboratory tests, chest X ray and general assessment also according to CRB scale he was released home with diagnosis of community acquired pneumonia given the treatment with antibiotic. After 24 h he felt better and recovered completely within 4 days. Early detection of the symptoms allowed on immediate diagnosis and treatment introduction thus avoiding the hospitalization and complications of delayed treatment (CHF decompensation, pleuritis, respiratory insufficiency, septal shock etc).
Implementation of the platform after initial difficulties (manual insertion of the data into PC, learning of proper measurements performance) has been accepted by patients and except from short periods in which patients were outside from the home for traveling, measurements have been regularly taken in the majority of cases. All patients at the beginning required the help of third person (usually relatives) even though all instructions and written manual have been provided by the doctor and informatics experts. After several weeks all patients were able to took all measurements and to do the manual insertion of the data themselves.

It is likely that the system allowed an improvement of patients' compliance to both to pharmacological and nonpharmacological recommendations thus prolonging the time to next decompensation episode.

Physician centered indicators

- adherence with the recommendations given by the system prototypes
- physicians' attitudes toward guidelines

The DS Services at hospital enabled us to confirm our previously made diagnosis of CHF and showed to be generally in line with our management strategy. The system kept us informed about the lack of important clinical parameters, it provided indication on abnormal values which could be disregarded very easily in clinical routines. Reminding suggestions concerning a possible alternative diagnosis, indications and contraindications for the pharmacological treatment and information about existing negative prognostic factors turned out to be very important. Moreover, it was common experience at UNICZ, AUXOL/UNIMIB,

JUMC that home telemonitoring allowed early detection of worsening symptoms and of changes in clinical parameters, thus preventing late complications, avoiding delayed modification of treatment and making it possible a better scheduling of hospitalization. Planned re-hospitalization is likely to be much less stressful for a patient and less costly than an emergency readmission, which is often out-of-hours and not necessarily under the care of the heart failure team. The Hospital care service has contributed to build the CDSS suggestions about diagnosis, severity, prognosis, medication status and suggestions and medication warnings about CHF. The system prototype has been tested by comparison with the routine clinical protocols used in the management of heart failure patients, in line with current interpretation of recent CHF management guidelines. Indeed, this activity has also allowed to verify the physicians' attitudes toward guidelines and their adherence to the available recommendations. Overall, the service provided by the platform was approved and found to be useful to support the doctor in the management of HF patients.

Indicators about costs and productivity

- health care costs per patients
- number of unplanned hospitalizations
- number of home visits needed

At UNICZ a preliminary cost/effectiveness analysis has been made. About the health related costs for patients telemonitoring, if we hypothesize that the patient has already a personal computer (PC) with Bluetooth interface and Internet connection (this should be the case in 70% of patients), the cost is only limited to Bluetooth devices (weight scale and blood pressure monitor) and Nurse@Home application.

According to this, the following costs should be considered with good approximation:

- Bluetooth blood pressure monitor: 165 Euro;
- Bluetooth Electronic Weight Scale: 240 Euro;
- Nurse@Home: 180 Euro (with installation & configuration)
- Nurse@Home: 80 Euro (without installation & configuration)
- Nurse@Home: 100 Euro (assistance for one year).

If patient does not have a PC with Bluetooth interface and Internet connection already available, the additive costs should be slightly lower than 1.000 Euro.

We remark that in Italy the cost for one day of hospitalization (DRG 127 Heart failure) is about Euro 250 and that, for day-hospital admission, this cost should be multiplied for the number of times that patient returns to the hospital. However, for ordinary admission the costs increase in an exponential manner, in fact the first day of hospitalization costs Euro 250, the cost of the second day is double (Euro 500) and for the third day the cost is three times greater. During the validation phase we had the possibility to avoid two possible hospitalizations, and

considering that the duration of the hospitalization is not inferior to three days, we hypothesize to have saved about Euro 1.500 for patient. Thus, considering these very simple observations, the incremental cost per patient in relation to telemonitoring seems to be practically not-significant.

For JUMC only a manual data insertion was foreseen, no specific home devices has been used. About the health related costs for patients in relation to telemonitoring, if we hypothesize that the patient has already a personal computer (PC) with Internet connection (in Poland it should be less than 50% of elderly patients), the cost is only limited to Nurse@Home application.
According to this, the approximate costs should be:

- Nurse@Home: 150 Euro (with installation & configuration)
- Nurse@Home: 50 Euro (without installation & configuration)
- Nurse@Home: 100 Euro (technical assistance for one year)
- Nurse@Home: 300 Euro (medical assistance for one year)

If patient does not have PC with Internet connection, the additive costs should be about 300 euro (PC) + 1.000 Euro per year (Internet connection).
We consider that in our country the cost for every day of hospitalization is about Euro 100 and that, for day-hospital admission, this cost should be multiplied for the number of times that patient returns to the hospital. However, for ordinary admission the costs increase in an exponential manner, in fact the first day of hospitalization costs Euro 100, the cost of the second day is double (Euro 200) and for the third day the cost is three times greater. During the validation phase we had the possibility to avoid one possible hospitalization (early symptoms detection allowed on ambulatory treatment) and costs related to possible complications of non-treated pneumonia. Considering that the medium duration of the hospitalization in pneumonia cases is about 7 days, we hypothesize to have saved about 1500 Euro for the patient and the cost is still high when considering the expenses of ambulatory treatment .
Taking into consideration these very simple calculations, combined with the limited patients number and the short validation time, it appears that the cost per patient for home telemonitoring with Nurse@Home application was not significant.

7. Conclusions

The results obtained by the clinical partners in a small sample of patients suggest that the HEARTFAID platform exerts an impact on the timelines of medical interventions in response to changes of the parameters monitored and this could be very important to prevent hospital readmission and to reduce health care related costs. In fact, after evaluating the accuracy of acquired data, the physician may modify a pharmacological treatment according to clinical findings in order to improve the clinical conditions of heart failure patients, to increase the time free from hospitalization and/or to reduce hospitalization days. In addition, the support

by the platform on hospital care of CHF patients can improve the management of the disease, favouring correct behaviors according to current guidelines, with the aim to promote the best care and to reduce the medical errors. This approach may in the end allow to reduce the social and economic costs of CHF management.
Overall, the tests performed by clinical partners support the feasibility and applicability of a platform of services supporting management of CHF patients. In particular, home monitoring facilities, facilities for remote transmission of data obtained in Hospital and facilities for an automatic feedback by the system seems to be applicable and to be able to provide clinically relevant information. This represents an encouraging start, although additional improvement is still necessary to make the platform fully functional. These pilot observations strongly emphasize the need of these observations to be confirmed by large scale randomized intervention trials.