Abstract—Chronic heart failure, one of the most remarkable health problems due to its prevalence and morbidity especially in the western world, is characterised by a strong socio-economic impact. Recent studies demonstrate that accurate heart failure (HF) management programs, based on coordinated inpatient and outpatient clinical procedures, might prevent and reduce hospital admissions, improving clinical outcome and reducing costs.

In this paper we present HEARTFAID, a research and development project aiming at defining efficient and effective health care organization models for “optimal” management of care in the field of cardiovascular diseases, and HF in particular. HEARTFAID involves the design, development, and validation of an innovative knowledge-based service platform, that is able to improve early diagnosis and lead to more effective management of heart diseases. HEARTFAID focuses on the following typical settings: health care facilities, home premises and mobile patient. Data collection of HEARTFAID patients will be performed in each of these contexts according to specified protocols.

The long-term goal of the innovative HEARTFAID platform is the improvement of the processes of diagnosis, prognosis, and therapy provision, providing: (a) electronic health record for easy and ubiquitous access to heterogeneous patient data; (b) integrated services for healthcare professionals, including patient telemonitoring, signal and image processing, alert and alarm system; (c) clinical decision support in the HF domain, based on pattern recognition in historical data, knowledge discovery analysis, and inferences on the patients’ clinical data.

I. INTRODUCTION

Heart Failure (HF) is a disorder caused by the impairment of cardiac function which leads to altered peripheral blood flow especially to the kidney and skeletal muscles [1], [2]. Right and left HF refer to syndromes presenting predominantly with congestion of the systemic or the pulmonary veins, respectively. The terms do not necessarily indicate which ventricle is most severely damaged. Most HF is associated with evidence of left ventricular systolic dysfunction (systolic HF) [3]. Diastolic HF is diagnosed when symptoms and signs of HF occur in presence of normal ejection fraction in echocardiography.

Despite wide variations in the results of clinical studies on HF, overall data indicate that prevalence of clinically overt HF increases considerably with age and that the incidence of HF has increased over the past few decades [4]-[6].

In the United States (American Heart Association, 2001) 5 million patients have HF, and nearly half a million of patients are diagnosed with HF for the first time each year. HF is the underlying reason for 12 to 15 million office visits and 6.5 million hospital days each year. During the last 10 years the annual number of hospitalizations has increased from approximately 0.55 to nearly 0.9 millions for HF as a primary diagnosis and from 1.7 to 2.6 millions for HF as a primary or secondary diagnosis. Every year, nearly 0.3 million patients die of HF as a primary or contributory cause and the number of deaths steadily increases despite advances in treatment [7]-[9]. In Europe (guidelines of the European Society of Cardiology, 2001) almost 10 millions suffer from HF. Roughly 78% of the HF patients have at least 2 hospital admissions per year [10]-[11].

The primary aetiology of HF is hard to ascertain in a patient with multiple potential causes (e.g. coronary artery disease, hypertension, valvular heart disease, etc). The aetiology of HF also depends on ethnic origin, socio-economic status and geographic location. The prognosis of HF is uniformly poor. Half of patients carrying a diagnosis of HF will die within 4 years and in patients with severe HF more than 50% will die within 1 year.

HF-related hospital admission rates escalate steadily in all industrialised countries, especially among the elderly. Overall, annual admission rates in 1990 ranged from 10 to
the elderly population. That can be achieved with an efficient and effective management program that effectively improves their quality of life. That can be achieved with an efficient and effective personalized therapeutic treatment that incorporates real-time health monitoring and timely assistance to reduce the risk for adverse events. Such an approach should also reduce the overall socio-economic impact of the disease by reducing hospital admissions and improving coordination of health care in and out of the hospital.

The main objectives of a HF therapy can be summarised as follows: slow down the progression of the disease, alleviate symptoms, and minimize risk factors. A HF disease management program able to attain these objectives requires the identification, collection, integration and processing of a huge and complete amount of biomedical data and information from the patient on several levels: molecular, cellular, tissue, organ and personal/clinical levels (relevant signs and symptoms, anamnesis, risk factors, life style). This wide-ranging individualized knowledge of HF patients, achieved through the collection of biomedical data gives the possibility to personalise and improve the effectiveness of the therapies.

HEARTFAID will design, develop and validate an advanced and innovative technological service platform and end-user applications for the optimization of the clinical management of HF and the reduction of the socio-economic costs by collecting, integrating and processing all types of relevant biomedical data and clinical information. In this way it will contribute to the available medical knowledge and at the same time it will improve health care processes related to diagnosis, prognosis, treatment and personalization of health care of the HF elderly patients [12]. In terms of health care delivery processes, the HEARTFAID platform (HFP) supports a patient-centric management program, which will be organized by the suitable involvement and competence integration of different health care environments and operators. Regarding health care facilities, HEARTFAID will involve: (a) ambulatory care with internist physicians; (b) primary care focusing of the interaction of the patient and the GP; (c) hospital care including cardiology, geriatric and internal medicine wards. In the home care environment, the patients and their family are considered as active users, while professional nurses assist them in home care. Finally, mobile patients are monitored and alarms/warnings are sent to the patient and/or the specialist.

The HFP will comprise a distributed and heterogeneous infrastructure and its core will be implemented with a multifunctional middleware layer. This layer will be responsible for data exchange among the different modules and for guaranteeing the interoperability both inside the platform and with the external end-user world. In addition, this layer will certify that all the incoming and outgoing information are compliant with established data representation standards. Moreover, all the communications among the internal systems and external applications reflect the HL7 requirements [13] and interoperability tools will facilitate portability of the platform to a Grid-enabling infrastructure. The services of HEARTFAID will be developed and implemented respecting the aspects of security and privacy of patient data specifically addressing authentication, confidentiality, integrity and non-repudiation.

The HFP will act as an informative and decision support infrastructure, on the basis of which efficient and effective health care delivery organization and management models and new clinical approaches can be defined and developed. A key issue in HEARTFAID is the continuous monitoring of the patient at home, aiming at improving the quality of patient care in the patient environment and at reducing the number of skilled home nursing visits and hospitalization.

A HEARTFAID operative scenario

It should be noted that all characters in the scenario described below are fictitious.

During his normal life Mr. Vito Gattuso, a 68-year-old man, smoked, had a normal intake of alcohol, practiced sport regularly, and disregarded the quantity of fat and salt in his diet. During the five-a-side soccer matches that Vito used to play regularly, he started to show breathlessness, ankle swelling and fatigue. Dr. Caputo, his local GP, was alerted by the symptoms described by Vito and prescribed him a set of exams to assess his health status. The results of the tests carried out in a specialized centre provided evidence of HF. After consulting Dr. Caputo, Vito went to the local university hospital that provided support for HF patients.

Dr. Amenta, a specialist at the hospital, reviewed the symptoms and the exam results and prescribed to Vito a set of additional exams. A follow-up visit was scheduled for two days later when the results of additional exams would be ready. In the next visit the results of the additional exams fully confirmed the HF diagnosis of HF and Vito’s
eligibility for the HEARTFAID program. Dr. Amenta explained carefully to Vito and to his wife Maria, all the details of HEARTFAID, and Vito accepted to participate in this program signing the informed consent form. Thus Dr. Amenta started a HEARTFAID session at his PC, entering all the required data. Then HEARTFAID elaborated for Vito a clinical pathway that included a therapeutic plan, specific vital sign monitoring and a schedule for follow-up visits if no complications arise till that date. Dr. Amenta reviewed, corrected, approved, and saved the plan. The necessary devices for the out-of-hospital monitoring with instructions on the clinical and biomedical data acquisition protocol were given to Vito and his wife that were also trained on their proper use.

Vito then went home and continued his normal daily life following accurately Dr. Amenta’s suggestions on lifestyle avoiding stress, wearing sports and taking regularly the prescribed drugs. According to the specified protocol, Vito is reminded to acquire the vital sign measurements. The acquired measurements are then transmitted through a specific gateway (fixed or mobile) to the HEARTFAID server and some checks are performed for artefacts detection. If an artefact is detected Vito is requested to repeat the test, otherwise the measurements are collected and processed as part of Vito’s HEARTFAID record. These measurements can provide precious indications about Vito’s health status and the HFP is able to early identify and immediately report to specialists, critical situations. Whenever necessary, Vito is alerted to go to the hospital and perform additional tests such as an electrocardiogram, a chest X-ray, an echocardiography, etc. If the result of the processing suggests some changes in the treatment (different drug treatment, different schedule for the measurement acquisition or different schedule for the next visit) then the specialist is alerted and after confirmation (or modification) of the proposed new plan, this is stored and sent to Vito for its immediately adoption.

B. Analysis of the operative scenario

Vito’s life from the HEARTFAID point of view can be divided into the following important states/events:

1) normal life before the suspect of a cardiac dysfunction was raised by his GP, Dr. Caputo;
2) the first contact with a specialized cardiac centre where HF was diagnosed;
3) the personalized clinical pathway and the new lifestyle that Vito should follow;
4) follow-up of the therapy and of the compliance to treatment (monitor progress);
5) if monitored conditions are worsening (slowly or rapidly), patient is checked for potential precipitating and exacerbating factors of decompensated chronic HF and clinical pathway is changed;
6) stable or improved condition.

Points from 3 to 6 should be considered iterative (see Figure 1). In fact, the initial clinical pathway identified after the first contact may not be the most adequate for Vito and his health conditions may not improve. In this case it will be necessary to analyse again the data available, revise, and fine-tune the plan accordingly. Achieving stable or improved condition does not imply that the health parameters of Vito should no longer be monitored; on the contrary, Vito should follow regularly his parameters and if necessary revise his health plan.

![Figure 1: States/events in the HEARTFAID platform.](image)
scheduled tasks foreseen in the plan, such as exercises, exams, medication and their prescribed dosage, etc. At the same time the experts will have the possibility to add new tasks or modify the initial plan according the measurements acquired by the platform. However, the platform will provide vital educational support to the patient and his relatives about the procedures of the planned therapy, the modalities for operating the acquisition devices, instruction about the use of the platform itself, general information on the disease, as well as more dynamic information such as the effects of the ongoing therapy, the meaning of the measurements acquired with respect to the normal values, what are the expected values for the specific patient, and so on. The provision of this sensitive information will be mediated and authorized by the clinical experts.

Using the platform will be a great support for the new lifestyle of Vito since it will make easier for Vito to follow all the prescriptions of the doctors. In this phase, the patients should acquire new habits and should get used to a new way of living that includes alimentary restrictions, medical visits, regular exams, and so on. The platform will support all these prescriptions by reducing the number of times Vito has to move to the hospital for a measurement and, at the same time, by simplifying the procedures he should follow that might have a negative effect on the mood of the patient, especially at the beginning.

III. RESULTS

A. Architecture of the HEARTFAID platform

A multi-layer heterogeneous and distributed architecture will support the development of an integrated and interoperable service platform enabling a multitude of services ranging from the acquisition and management of biomedical data to the provision of effective diagnostic support to clinicians and patients in the HF domain. Figure 2 provides an overview of the HEARTFAID architecture.

The five layers of the architecture, namely biomedical data collection, middleware, knowledge, decision support, and end user, provide distinct functionalities outlined below.

**Biomedical Data layer.** Biomedical data collection and Transmission/Data exchanging is concerned with acquisition of HF related biomedical data. It is the part responsible for collecting all data to be exchanged with the external world, including raw data, structured and laboratories data, non-structured information and multimedia data.

**Middleware layer.** Interoperability/Integration Middleware and Repository is the layer responsible for data exchange guaranteeing interoperability among its modules and with the external end-user world. In addition, this layer certifies that all the incoming and outgoing information, as well as all the communications performed among the internal modules of the platform and between the platform and the external applications are compliant with clinical data representation and communication standards.

**Knowledge layer.** Data preparation, Knowledge Discovery in Database and Ontologies/Knowledge-base at this layer, deal with the management of the domain expertise and know-how, both explicit (i.e. formal know-how already represented using a formal approach) and implicit (i.e. derived from the daily practice of the clinicians and their experience), and with the knowledge extraction from the Repository with innovative knowledge discovery processes.

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**Figure 2: The HEARTFAID architecture.**

**Decision Support layer.** Decision Support System and Signal/Image processing at this layer, provide an effective support to the daily practice of the clinicians in the field of cardiovascular diseases by implementing adequate data processing algorithms, providing guidelines to medical protocols as well as access to the knowledge base, alarms in case of critical situations and diagnostic suggestions.

**End-users layer.** It is the higher layer of the platform and interacts with the external users (human being and software application). This layer provides specific services and applications to exploit the functionalities of the platform.

**B. System functionalities and services**

The macro components of the HFP are: (a) multi-channel data acquisition; (b) medical and clinical knowledge generation and management (knowledge engine); (c) decision support services; (d) interoperability/integration middleware; (e) end-user services and applications. Figure 3 shows the interaction among components, the flow of data/information, the roles of the actors involved, and the end-users services.

The HFP will be sustained by the continuous flows of data acquired by biomedical devices, and the structured
information collected from clinical and medical applications. Continuous patient monitoring allows the health care operators to observe the health status of their patients and to react promptly. The system could perform provisions on the clinical conditions of the monitored patients using historical data contained in the central “Repository” of the HFP, thus allowing the early interventions of the doctors and avoiding, if possible, the hospitalisation of the patient himself. The continuous monitoring will be based on the use of portable/wearable devices transmitting biological data. The information acquired by the medical devices will be transmitted to the HFP using the “Raw Data Transmission Infrastructure” that will implement up-to-date communication technologies, such as GPRS, or UMTS. These data will be then managed by the “Data Management System” that will be in charge to guarantee the adoption of appropriate data codification standards to store the acquired information into the “Repository”.

![Figure 3: The HEARTFAID system functionalities and services.](image)

Data collection outside health care facilities, involves the selection of the sensors to be used, data acquisition from those, sensors, association of the measured values with information pertaining to the patient, measurement conditions and device identification. It also involves adoption of a standard format for the transmission of information, data encryption and encoding, data transmission, reception, data quality check and storage. The role of the OpenECG network will be central in selecting standard format for the communication and storage of data that is widely available and facilitates interoperability [14].

The HEARTFAID server will have to provide manual and automated data insertion mechanisms. The Web-based Electronic Health Record (EHR) application will be a front end which will allow remote users to manually add new data to the system by filling in the fields in a web page. However, when an automated scenario is considered, the HEARTFAID server has to be able to establish IP communication channels with mobile or home gateways and accept the transferred data. The “Data Management System”, the “Transmission Infrastructures” and the “Repository” represent the architectural core for data collection, storing and organization. The “Repository” will be the general data storage component. In particular, it will be composed by one or more physical/virtual databases where data are structured for both transactional applications and data analysis in knowledge discovery processes. Any access to the “Repository” is controlled by the “Data Management System” that guarantees the use of data coding and communication standards in any information exchange.

Concerning the knowledge generation and management, the “KDD” component supports the implementation of knowledge discovery in databases processes to extract valid, novel, potentially useful and understandable knowledge from the information acquired during the project lifetime. This component will guide the users through the iterative phases of the process: data preparation, data transformation, data visualization and data mining applying innovative algorithms. The discovered knowledge will be validated by the domain experts and will be opportunely coded in order to extend the ontology/knowledge based system (“Onto/KB”). This component represents the knowledge repository of the HFP, where concepts, constraints and relations, as well as clinical protocols will be formalised in a machine understandable manner. The decision support services that support the medical personnel in their daily activities will be supplied by the “DSS” component. It will represent the central intelligence of the platform by exploiting the knowledge base to perform inference reasoning on the specific patients’ data.

Summarizing, the HFP will provide services that will be exposed by the Web-based “End-User Applications & Services” level. These services include EHR, patient telemonitoring, alert and alarm system, pattern recognition in historical data, signal and image processing, inferences on patients’ data, knowledge base editing, and support to knowledge discovery analysis.

IV. DISCUSSION

The objective of the HFP is to support decision makers and clinicians operating in the field of heart diseases in the processes of diagnosis, prognosis, treatment and personalization of healthcare assistance to the elderly population. The widespread implementation of the proposed services will guarantee a better quality of life to HF patients and will also reduce hospitalizations. The HFP emphasizes easy access to heterogeneous patient data, a common user interface to easy-to-use services for healthcare professionals, as well as easy access to formalised clinical knowledge.

Other information and communication technology projects that focus on the management of HF patients take a less holistic approach addressing just one of the aspects covered by HEARTFAID namely, knowledge based systems, machine learning, or telemonitoring. Knowledge based systems aim to support the physicians in the clinical decision making comparing the data of an EHR with the rules contained in a knowledge base and pointing out errors
of commission or omission [15]-[16]. In the last years Machine Learning (ML) has been used also in the health environments, according to the principles of evidence based medicine. The literature reports several ML applications in the HF domain concerning with prognosis [17]-[18], therapy [19], diagnosis [20], and text mining [21]. Monitoring the condition of HF patients requires continuous feedback to assess the health status and this need translates to hospital admissions, inconvenience, and costs. A home monitoring program for HF patients can fill this need and may result in a great savings in terms of resources and costs and a better service for the patients [22]-[23].

The main innovations introduced by HEARTFAID in the management of HF patients are: (a) integration of biomedical data with different structure and from different sources; (b) integration of deductive and inductive knowledge approaches for coding the relevant medical knowledge and extract new knowledge; (c) medical decision support characterized by assistance in diagnosis, prognosis, and therapy planning of HF patients.

In order to minimize problems/drawbacks during the implementation of the HFP, special care will be devoted to the security and privacy of the biomedical data. In such respect all the ethical issues related to the adult volunteers, human biological samples, personal data and genetic information will be treated according to the ethic regulations stated by the European Community laws (directives 93/42/EEc, 95/46/EC, 97/66EC, 2001/20/EC). Special care will be devoted to the treatment of in-home patients. In particular, the possibility of a sudden worsening of telemonitored patients, e.g. a respiratory crisis, is a scenario that needs the implementation of adequate measures and strategies since in-home patients cannot receive the same assistance given to inpatients.

V. CONCLUSIONS

In the health care delivery sector, advanced and innovative information technologies enable new services and novel ways of service delivery that address to needs and requirements of an aging population while at the same time contributing to the reduction of costs. The application of an approach like the one proposed by HEARTFAID capitalizes on recent developments and assures process optimization, increase of the treatment quality of the individual patient as well as a remarkable reduction of health care costs.

ACKNOWLEDGMENT

This research work is supported by the European Community, under the Sixth Framework Programme, Information Society Technology – ICT for Health, within the STREP project “HEARTFAID: a Knowledge based Platform of Services for supporting Medical-Clinical Management of the Heart Failure within the Elderly Population”, 2006-2009. The authors would like to thank all the partners of the HEARTFAID consortium for their support and help in the work on which this paper is based.

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