

HEARTFAID: A Knowledge Based Platform for Supporting the Clinical Management of Elderly Patients with Heart Failure

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ABSTRACT

Chronic heart failure is a major health problem in many developed countries with strong social and economic effects due to its prevalence and morbidity. These effects occur particularly in the elderly who have frequent hospital admissions and utilise significant medical resources. Studies and data have demonstrated that evidence-based heart failure management programs utilising appropriate integration of inpatient and outpatient clinical services, have the potential to prevent and reduce hospital admissions, improve clinical status and reduce healthcare costs. HEARTFAID is a research and development project aimed at creating and validating an innovative knowledge-based platform to improve the early diagnosis and effective management of heart failure. The core of the platform is formalisation of pre-existing clinical knowledge and the discovery of new elicited knowledge. HEARTFAID has been designed to improve the processes of diagnosis, prognosis and therapy by providing the following services:

- Electronic health records for easy and ubiquitous access to heterogeneous patient data
- Integrated services for healthcare professionals, including patient telemonitoring, signal and image processing, alert and alarm systems
- Clinical decision support, based on pattern recognition in historical data, knowledge discovery analysis and inference from patients' clinical data.

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INTRODUCTION

Heart failure is a pathophysiological state in which the heart fails to pump blood at a rate commensurate with tissue needs and/or pumps only from an abnormally elevated diastolic filling pressure. The incidence, prevalence, morbidity, and mortality, and economic costs of heart failure (HF) are considerable¹. In the USA for example the total annual cost of treating heart failure patients is estimated to total \$60 billion.

Although there is some variation in the reported prevalence of HF, overall data demonstrates that the prevalence of clinically overt HF increases considerably with age and that the prevalence of HF has increased over the past few decades²⁻⁴.

In Europe almost 10 million patients have HF, and approximately three-quarters of these will be admitted to hospital at least twice a year^{5,6}. In the United States an estimated 5 million patients have HF, and nearly 500,000 new cases are diagnosed each year⁷. The disorder 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 hospitalisations has increased from approximately 550,000 to nearly 900,000 for HF as a primary diagnosis and from 1.7 to 2.6 million for HF as a primary or secondary diagnosis. Nearly 300,000 patients die of HF as a primary or contributory cause each year, and the number of deaths has increased steadily despite advances in treatment⁸⁻¹¹.

The prognosis of heart failure is uniformly poor. Half of patients carrying a diagnosis of heart failure will die within 4 years and in patients with severe heart failure approximately 50% will die within 1 year¹². In fact data suggests that the mortality associated with heart failure is comparable to cancer. The Framingham studies demonstrated that the probability of someone with a diagnosis of heart failure dying within five years was approximately 70% in men and 40% in women¹³⁻¹⁴. In comparison, five year survival for all cancers among men and women in the USA during the same period was approximately 50%.

With respect to aetiology, coronary artery disease, either alone or in combination with hypertension, is the most common cause of heart failure in developed countries^{11,15}. It may however sometimes be difficult to determine the primary aetiology of heart failure in a patient with multiple potential causes (for example, coronary artery disease, hypertension, diabetes mellitus, atrial fibrillation, etc).

The symptoms of heart failure are related to left ventricular systolic and/or diastolic dysfunction. Failure is commonly assessed using the New York Heart Association (NYHA) functional classification system which relates symptoms to everyday activities and the patient's quality of life¹⁶.

- Class 1 – Ordinary physical activity does not cause breathlessness, fatigue or palpitations.
- Class 2 – Ordinary physical activity such as walking causes breathlessness, fatigue, or palpitations.

- Class 3 – Slight physical activity such as dressing will cause breathlessness, fatigue, or palpitations.
- Class 4 – Patient is unable to carry out any physical activity without developing breathlessness, fatigue, or palpitations. Symptoms are often present even at rest.

Although the diagnosis of heart failure can be made on history and examination, tests are usually performed to confirm the diagnosis¹⁶. These include an echocardiogram, a chest X-ray, an electrocardiogram (ECG) and measurement of natriuretic peptide. Women, the elderly and the obese are often less aggressively investigated and the accuracy of clinical diagnosis in them is often inadequate. However to provide proper prognosis and to optimise treatment, accurate diagnosis of heart failure and establishment of aetiological factors is crucial¹⁷.

Management of heart failure is aimed at treating symptoms and preventing further deterioration in cardiac function. Optimal treatment can improve prognosis and prolong life. A variety of drugs are used in the treatment of heart failure including diuretics, ACE (angiotensin converting enzyme) inhibitors, digoxin, beta-blockers and anticoagulants¹⁶. In selected patients surgery (including transplantation) and other therapeutic interventions, e.g. cardioversion may be beneficial¹⁶.

Optimal management particularly in elderly patients requires an effective and integrated disease management program, capable of:

- Making treatment more effective, appropriate and personalised
- Reducing the risk for adverse events by creating real-time monitoring and assistance to HF patients
- Controlling and reducing the overall economic and social costs of medical care by decreasing the frequency of hospital admissions

This requires in-depth knowledge of an individual patient and early detection of the signs and symptoms related to heart failure accompanied by prompt treatment. To achieve these objectives, requires the identification, collection, integration and processing of a large and complex amount of biomedical data and information from the patient on several levels: molecular, cellular, tissue, organ and personal/clinical levels (relevant patient history, pertinent signs and symptoms, risk factors, life style, etc). This is aided by the current availability of several advanced mathematical and information technologies including Knowledge Discovery and Machine Learning, Wearable Sensors, Wireless Communication, and Decision Support Systems, which provide advanced problem representation and solving capabilities. Finally, new advances in genomics and proteomics research related to HF, by acquiring relevant biomedical data on molecular and cellular level, offer the potential of a better understanding of the pathophysiology of HF, early diagnosis of the disease, and the development of new treatment strategies, based on individualised gene and cell-based therapies.

HEARTFAID aims to achieve these objectives by developing and deploying an innovative computerised system. The technological platform provides information

and decision support to make diagnosis, and management of individual patients more personalised and effective. It does this by exploiting computational modelling, knowledge discovery methodologies, visualisation and imaging techniques, medical domain knowledge, and effectively integrating and processing biomedical data and information at different levels. In addition it will help develop and define new healthcare delivery organisation and management models for heart failure, to produce more effective and efficient use of available resources (healthcare staff, healthcare equipment and financial resources).

GENERAL DESCRIPTION OF HEARTFAID PLATFORM

The main goal of HEARTFAID is to support clinicians in the management of patients with heart failure and in particular to improve the quality of life for elderly patients, and reduce the number of their hospitalisations.

To achieve these objectives, the following requirements must be met:

- Easy access to heterogeneous patient data
- A common user interface of integrated and easy-to-use services for healthcare professionals
- Easy access to formalised clinical knowledge (declarative knowledge, procedural knowledge, and newly discovered knowledge)

The third requirement is of crucial importance as highlighted by the OpenClinical organisation: *“It is now humanly impossible for unaided healthcare professionals to*

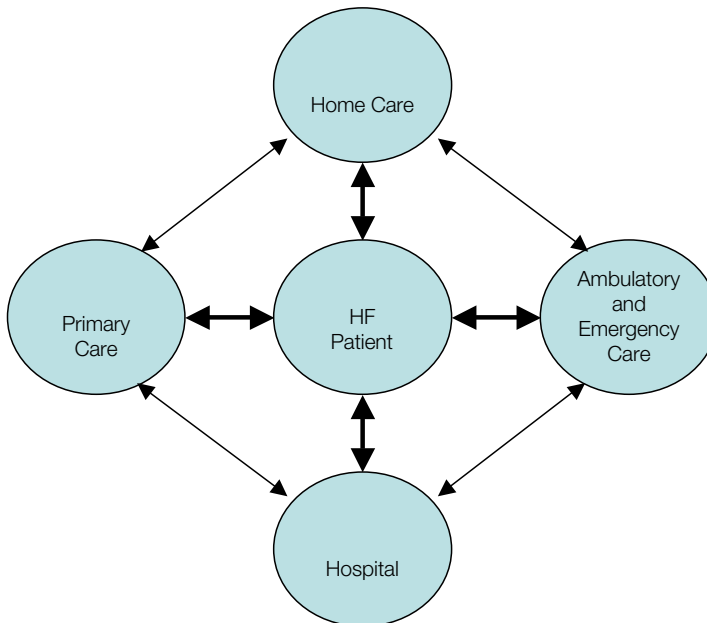


Figure 1. *The patient centric vision of HEARTFAID*

*possess all the knowledge needed to deliver medical care with the efficacy and safety made possible by current scientific knowledge. This can only get worse in the post-genomic era. A potential solution to the knowledge crisis is the adoption of rigorous methods and technologies for knowledge management*¹⁸.

The HEARTFAID platform is an effective distributed and heterogeneous infrastructure with its core implemented as a multi-functional middleware layer. This layer is responsible for the data exchange among the different platform modules and for guaranteeing interoperability both within the platform and with the external end-user world. In addition, this layer certifies that all incoming, outgoing and exchanged information are compliant with data representation standards, and that all communications performed between the internal systems of the platform and the external applications meet HL7 (Health Level 7) requirements¹⁹. The middleware is implemented using standard interoperability tools and makes the distributed platform easily portable on GRID enabling infrastructures. All the functionalities and services provided by the HEARTFAID platform are developed and implemented with careful regard to the security and privacy of patient data. In particular, the following key issues have been identified and addressed during the project implementation phase: authentication, confidentiality, integrity and validation of the data.

In terms of healthcare delivery, the management program is centred around the patient and involves and integrates different healthcare personnel and organisations (Figure 1):

- The home care environment with community nurses, patients themselves and their families as active participants
- The primary care environment involving principally general practitioners
- Ambulatory and emergency care involving community and hospital staff
- Hospital environment (coronary care units, cardiology, geriatric and internal medicine wards) involving cardiologists, nurses, physiotherapists, etc.

According to the characteristics of the individual environment, healthcare personnel can collect different types of biomedical data from the patient, and observe and treat the patient. Personnel can interact to exchange data and information, share decisions and reach consensus on the treatment of an individual patient. A key feature of the program is continuous home monitoring of the patient. This is aimed at improving the quality of patient care within their own environment and reducing the number of home nursing visits and hospitalisations.

Technological Innovations

In terms of scientific and technological advances, compared to other projects devoted to the management of heart failure patients, HEARTFAID is characterised by the following innovations:

- Integration of relevant biomedical data, of varying structure and complexity and obtained from several different sources

- Integration of several approaches for coding the relevant medical knowledge and extracting new knowledge:
 - a knowledge based approach (deductive knowledge) for coding clinical guidelines and clinical best practice
 - a data mining approach (inductive knowledge) for extracting new knowledge from the practical clinical experience of suitable case sets
- Medical decision support of all the key steps in the clinical management of HF patients, i.e. diagnosis, prognosis, and treatment.

Functional Aspects of the HEARTFAID Platform

The macro components of the HEARTFAID platform are:

- Multi-channel data acquisition
- Medical and clinical knowledge generation and management (Knowledge engine)
- Decision support services
- Interoperability/Integration middleware and use of clinical data representation and communication standards
- End-user services and applications

Figure 2 shows the interactions among these components including the flow of data and information, the roles of the involved actors and the services to be provided to end-users.

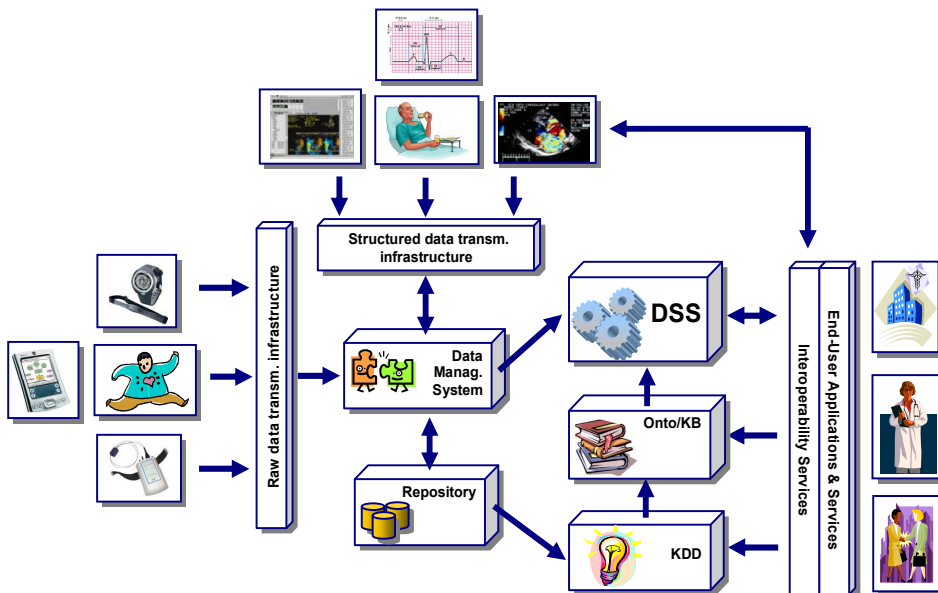


Figure 2. HEARTFAID System Functionalities and Services

DSS = Decision Support System, KDD = Knowledge Discovery in Databases, Onto/KB = Ontology/ Knowledge Base System.

The HEARTFAID platform of services is sustained by the continuous flow of data acquired from biomedical devices, and the structured information collected from clinical and medical applications. The continuous monitoring of patients allows healthcare personnel to effortlessly monitor their health status and to react promptly when signs of deterioration appear. The system can also analyse the clinical conditions of monitored patients using historical data contained in the central “Repository” of the platform and alert healthcare staff if parameters deviate significantly from the patient’s baseline. This again facilitates early intervention by medical personnel and can play an important role in decreasing hospitalisations.

Continuous monitoring is based on the use of wearable devices that transmit biological data such as heart rate, blood pressure, ECG, etc. The information acquired by the wearable devices is transmitted to the HEARTFAID platform using the “Raw Data Transmission Infrastructure” and utilises different communication technologies, including PSTN (Public Switched Telephone Network), GPRS (General Packet Radio Service), and UMTS (Universal Mobile Telecommunications System). This data is then managed by the “Data Management System” to ensure the adoption of appropriate data codification standards prior to storing the acquired information in the Data Repository. Complex data acquired during a patient hospitalisation, for example structured data produced by laboratory investigations, unstructured data such as clinical reports, and multimedia data such as a chest X-ray or an echocardiogram, are transferred to the Data Management System using the “Structured Data Transmission Infrastructure” and utilising Bluetooth, Wi-Fi, or Intranet technologies.

The Data Management System, the Transmission Infrastructures and the Repository represent the architectural core for data collection, storing and organisation. The Repository is the general data storage component. It is composed of one or more physical/virtual databases where data are structured for both transactional applications (e.g. electronic health records) and data analysis in knowledge discovery processes. 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. Security and privacy issues are comprehensively addressed at both data storage and communication/exchange levels (including Authentication, Authorisation and Data Encryption).

Regarding knowledge generation and management, the “KDD” component has the goal of supporting the implementation of Knowledge Discovery in Databases by processing and extracting valid, new, potentially useful and understandable knowledge from information acquired. This component guides users through the iterative phases of the process: data preparation, data transformation, data visualisation and data mining with the application of innovative algorithms.

The discovered knowledge is validated by domain experts and is opportunely coded in order to extend the “Ontology/Knowledge Base System” (Onto/KB). This component represents the knowledge repository of the HEARTFAID platform,

where concepts, constraints and relations, as well as clinical protocols are formalised in a machine understandable manner. The platform allows users to maintain the knowledge base, i.e. to insert new rules/constraints or to modify/delete existing ones using an editing tool.

The Decision support service is supplied by the DSS component. It represents the ‘brain’ of the platform by exploiting the knowledge base in order to perform inference reasoning on data from a specific patient. The main goal of the DSS is to support medical personnel in their daily decision making.

Development Methodologies and Technologies

In order to develop an integrated and interoperable system, that is capable of providing a variety of services ranging from the acquisition and management of raw data to

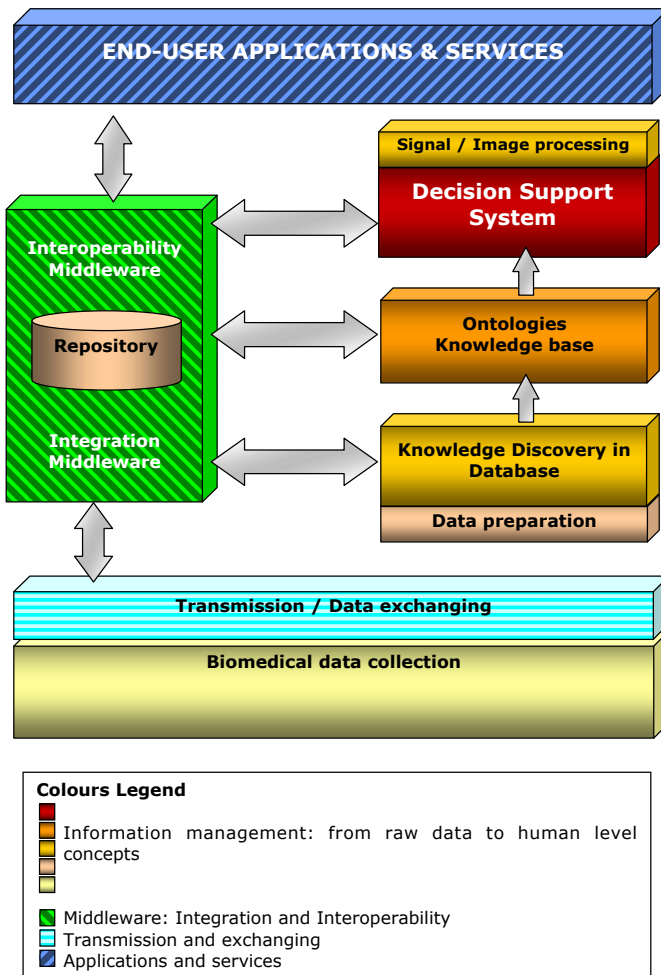


Figure 3. HEARTFAID Architecture

the provision of effective diagnostic support to clinicians, a multi-level heterogeneous and distributed architecture is proposed. In this model, each level has different responsibilities and provides different functionalities. The levels are (Figure 3):

- Biomedical Data level
- Middleware level (Interoperability/Integration Middleware and Repository).
- Knowledge level (Data preparation, Knowledge Discovery in Databases and Ontologies)
- Decision Support level (Decision Support System and Signals/Images processing)
- End-user level

Biomedical Data Level

This is the lower level, concerned with heart failure related biomedical data. This part of the platform is responsible for collecting all data that can be exchanged with the external world, including raw data, structured and laboratory data, non-structured information and multimedia data.

The Biomedical Data level has as its main goal the acquisition of external information, including both raw and complex data. This level includes personal homecare devices implemented for monitoring patients and the modules that are in charge of interacting with external systems to acquire structured data (e.g. laboratory investigations), non-structured data (e.g. clinical reports) and multimedia data (radiology images, ultrasound scans, etc). This level also includes a data transmission and exchange infrastructure that guarantees the secure transmission of relevant data from the external world to the Middleware of the platform.

Regarding the monitoring support and biosensors, traditional patient monitoring is typically limited to simple data acquisition (e.g. 24 hour Holter recordings) of specific signals such as ECGs. The analysis of the recorded signals is usually performed off-line using dedicated diagnostic systems. Increased intelligence of monitoring devices coupled with the low power consumption of the new generations of microcontrollers/digital signal processors combined with wireless technologies, makes possible a wide range of intelligent monitoring applications, providing the possibility to analyse data remotely and in real time.

In HEARTFAID, the communication infrastructure is developed taking into account state of art technologies and solutions to support wireless medical devices (e.g. Bluetooth enabled devices for blood pressure monitoring, ECG monitoring, electronic weighing scales and pulse oximeters).

The Middleware: Data Integration, Standards and Interoperability

The Middleware level is the component of the HEARTFAID platform responsible for providing efficient access and exchange of all the patient's clinical data acquired both during home monitoring (raw data) and during his/her contacts with healthcare facilities (complex information).

The issue of interoperability, including data access, exchange, and integration, is of profound relevance due to the heterogeneity of medical information systems. The HEARTFAID platform addresses this by implementing both established and developing clinical standards such as Health Level 7 (HL7) and Clinical Document Architecture (CDA). The latter is an extensible markup language (XML)-based document standard that specifies the structure and semantics of clinical documents for the purpose of exchange. Being a part of the emerging HL7 version 3 family of standards, CDA derives its semantic content from the shared HL7 Reference Information Model. The document specification however is independent of the transport, i.e. HL7 version 3 messaging is not required. A document can be sent inside an HL7 message or through various different transport mechanisms, including (but not limited to) HTTP (hypertext transfer protocol) POST with XML payload, Web Services over HTTP, FTP (file transfer protocol), SMTP (simple mail transfer protocol), IBM MQ (message queuing) Series Messaging and Microsoft message queuing (MSMQ).

This standard, thanks to the use of XML, sets itself as a fulcrum in the process of communication between different entities belonging to the same environment of interoperability, allowing the exchange of clinical documents from and to existing applications without requesting the total re-engineering of information systems already installed.

The problem is more complex than simply adopting standard languages to communicate among different applications. Institutions working on these issues are also addressing the problem of defining standard roles and workflows in order to accurately describe typical interactions inside healthcare structures and across different facilities. It is necessary to create a totally interoperable and integrated environment for healthcare structures, that are able to exchange clinical data, to access distributed and shared repositories of both raw data and complex information, as well as the ability to access computer databases, medical expertise, etc.

In the HEARTFAID context, a suitable Middleware is designed and developed, to guarantee interoperability at the project level. As shown in Figure 4, the Middleware level is divided into two main layers: the Integration Middleware and the Interoperability Middleware. These two layers represent two different abstraction levels of the functionalities of the Middleware.

The Integration layer uses an information-oriented integration approach to communicate and exchange data with all sources. Moreover the building of a middleware at data level will act as an open system, where existing external applications or systems like electronic health records, laboratory information systems, electrocardiographs, holter devices, etc. and also new future data sources systems could be easily integrated providing adapters or gateways modules, based on common standards in healthcare information systems, such as HL7 and CDA.

At the Integration layer, the Repository acts as a centralised data storage. Adequate approaches based on “data replication” are implemented to ensure better data

availability and to improve the performance of analysis and processing activities. Moreover, data federation solutions is taken into account, i.e. the integration of a set of database schema offering a unified view of data by means of a virtual database, that maps calling and requests to the physical databases, and interface processing solutions – information importing by means of API (application programming interfaces) defined by external packaged applications.

The more external Middleware layer, the Interoperability Middleware, will guarantee the interoperability of the system components and, using the approach of service-oriented integration, will integrate the functionalities that the HEARTFAID platform will provide to end users.

The Knowledge Level

This level focuses on the selection, acquisition and formalisation of expert knowledge and experience. It deals with the management of domain expertise and know-how, both explicit (i.e. formal ‘know-how’ already represented using a formal approach, e.g. a clinical protocol) and implicit (i.e. derived from the daily practice of the clinicians and their experience), as well as with the extraction of novel, useful and non-trivial knowledge from the project repository by using innovative knowledge discovery processes. Relevant knowledge for the effective monitoring and prevention of cardiovascular diseases is individualised with the help of clinical partners. Both the explicit and implicit expertise of clinicians are taken into account and exploited for the definition of suitable ontologies able to model specific scenarios under consideration.

This level also includes the implementation of a process for Knowledge Discovery in Databases (KDD). The KDD process provides intelligent analysis of the large amount of data, contained in the Repository, resulting in construction of models applicable to the decision making process and presents potentially novel and useful knowledge. When the models are in an explicit form of rules, they can be analysed and evaluated by medical experts.

This process adopts standard Data Mining algorithms as well as innovative methods for the elaboration of cardiovascular data. This level also includes a data preparation phase that focuses on the extraction of information to be analysed from the repository and the application of data cleansing and simplification techniques for the implementation of selected data mining methods. The outcomes of the knowledge discovery process are used to extend the expertise coded in the knowledge base.

We plan to use recently developed subgroup discovery methodology for building class descriptions in the form of short, conjunctive rules. The methodology has already been successfully applied to a few medical domains, including building descriptions of coronary heart disease risk groups. The methodology can be iteratively used on the same patient data for differently defined target classes resulting in many potentially useful relations that can be included into the knowledge base. Supporting features, necessary for reliable inference, can be generated

either by statistical analysis of generated subgroups, or by induction of additional rules after elimination of patient features used in previously induced subgroup descriptions.

Specifically, activities will focus on:

- Collecting relevant medical data
- Analysing the collected information
- Transforming the results into effective medical knowledge

The first task in this activity is the design and development of a data warehouse system that should, besides standard database functionality enable implementation of diverse knowledge based techniques, including integration of existing expert medical knowledge. The quality of decision making strongly depends on the quality of collected data and significant effort is devoted to data preparation including the application of intelligent methods for data cleansing and outlier detection. Detection of medical or procedural outliers can itself be a relevant result for increasing healthcare quality.

A central task is knowledge discovery aimed at analysing patient data and building a decision support system. Attention is given to approaches delivering human understandable interpretations and those which can be integrated with existing human expert knowledge. Rule induction approaches, especially those based on subgroup discovery is analysed and implemented. Insightful data analysis is the ultimate goal hopefully leading to effective novel decision support systems. In addition, approaches leading to automatic generation of medium layer features that can help in decision making process are analysed. Among others, development and tuning activity is carried out on the Kernel Support Vector Machine algorithms, with the definition of several categories of kernels. Other approaches like regression models, artificial neural networks, fuzzy logic, genetic algorithms are also analysed in the context of heart disease and included when appropriate.

Using ontology technologies, the ultimate task is the presentation of knowledge collected from medical experts and gathered during data analysis in a form appropriate for diagnosis, explanation and decision making processes.

Building ontologies is a combination of two approaches. On a higher level ontology classes represent existing medical knowledge are defined by experts in a process of interviews. On a lower level additional ontology classes, including relations among the high and low level classes, are defined using data-driven induction methodology. The latter stage is less well defined and strongly related to the data collected during execution of the project. Iterative repetition and improvements of building ontologies will eventually lead to a structure enriched by the quantitative description of classes, subclasses and their mutual relations. For this task recently developed techniques for semantic Web analysis as well as methodology applied in constructing gene ontologies has been adapted. The starting point for building ontologies is a knowledge base consisting of expert knowledge and models automatically or semi-automatically constructed from patient data using knowledge

discovery tools and evaluated by medical experts. When necessary, the knowledge base will contain patient data in the form of relevant exceptions.

The Decision Support Level

The Decision Support System's main goal is to offer intelligent support to clinicians in their daily practice. The DSS uses the knowledge base to provide inference-reasoning functionalities on the information acquired, to offer intelligent support to clinicians. Moreover image and signal processing methods are studied and implemented on the data acquired in the cardiovascular context. These methods and tools are available to end-users as services of the platform and can be implemented by clinicians on data to be examined.

The Inference engine is the main part of the DSS, and gives predictions about class memberships based on the available domain knowledge contained in the knowledge base and real, new patient data. The quality of the inference engine is measured by its reliability and robustness. The major problem in its design is performing an effective search over all available ontologies. In addition it must be able to solve the problems of contradicting and undefined predictions, as well the problem of recognised rule exceptions. In the process of the inference engine design we use methodology based on confirmation rules developed in previous machine learning research, and the methodology of redundant structures whenever this is possible. The latter in particular is very challenging for medical applications because the use of redundant knowledge and supporting features are key properties of human decision making that should be implemented in automatic classification systems.

Another ambitious long-term objective of the DSS level is the study and development of adequate mathematical models and algorithms aimed at processing the images and signals acquired during investigations of cardiovascular patients. A different model needs to be identified for each medical problem considered, and should be opportunely tuned on the acquired data to provide valid support for specific issues addressed.

The results of this activity together with the complementary hardware components and software tools, integrated with the middleware layers of the platform and extended with the adequate end-users interfaces, will represent a prototype of the DSS for testing on clinical cases. This prototype will be employed in the validation and assessment process by clinical partners.

End-User Services and Application Level

This is the highest level of the platform and interacts with external users, both human beings and software applications. The level provides specific services and applications to exploit the functionalities of the developed platform. Technological components of the platform are integrated to provide the following set of functionalities:

- Electronic Health Record
- Patient Telemonitoring

- Alert and Alarm System
- Pattern recognition in historical patients' data
- Signal and image processing
- Inferences on patients' data, using the knowledge base
- Knowledge base editing
- Support to knowledge discovery analysis

Electronic Health Record

A web-based Electronic Health Record (EHR) will enable both access and insertion of cardiovascular related data. This tool should not be considered as a standard Digital Patient Record but as a specific integrated service of the platform that other external applications can exploit to gather, display and use an individual patient's data.

In addition, this tool should provide filtering of the data stored in the repository with two main goals:

1. Organise the patient's data according to active pathologies and past medical history, and highlighting any open patient problems
2. Permit access to a subset of the patient's data according to the authorising credentials and the profile of the user.

The EHR and the underlying Repository and middleware layer is compliant with the IHE Technical Frameworks and in particular with the Integration Profiles for Cardiac and IT-Infrastructure.

Patient Telemonitoring

Specific personal devices are employed to provide homecare to meet the specific needs of patients and to reduce the number of hospitalisations. This service requires the provision of daily monitoring functionalities to collect and process the data acquired by the home medical devices. The information monitored can be both raw data (heart rate, ECG, blood pressure, etc.) and calculated data (signal processing, data variability indexes, etc.). The monitored data is stored in the central repository of the platform, which allows real time visualisation of the information acquired in case of emergencies or whenever it is required by authorised medical personnel.

Alert and Alarm System

The Decision Support System can be used to detect specific conditions or patterns in the monitored data that may lead to critical health situations. In these cases the system can provide alert or alarm functionalities to appropriate healthcare personnel according to the gravity of the situation detected and the patient risks.

Pattern Recognition in Historical Patients' Data

The Decision Support System is able to provide clinicians with pattern recognition functionalities in the historical data of the central repository. In this way it is possible

to obtain from the repository specific information and clinical cases similar to a pre-defined pattern specified by the user. Using this service clinicians are able to visualise all the clinical information of patients with similar characteristics to the specific case they are dealing with. Alternatively, it is possible to define a set of constraints to identify the information to be recovered from the repository, e.g. recover all clinical data related to patients with a specific disease and following a selected therapy.

Signal and Image Processing

Specific algorithms and methods for image and signal processing are being developed. The developed algorithms will be integrated in the Decision Support system to achieve an integrated platform capable of combining an alarm/alert generation module, a pattern searching engine and innovative data processing algorithms to efficiently support clinicians in their daily decision making.

Inferences on Patients' Data, Using the Knowledge Base

The system will be able to perform inference reasoning on processed data by using the rules, constraints and clinical protocols coded in the knowledge base. The declarative knowledge, the procedural knowledge, and newly discovered knowledge is opportunely coded into the knowledge base using formulas, and then exploited by the Decision Support System by processing the individual patient data to provide valid decision support to clinicians.

Knowledge Base Editing

The platform will provide a set of functionalities aimed at managing the information contained in the knowledge base. These functionalities include the possibility of modifying the existing data, inserting new rules/constraints, deleting existing rules, as well as changing, creating or updating the clinical protocols.

Support for Knowledge Discovery Analysis

An appropriate knowledge discovery process will be implemented on the data acquired to extract valid, novel, potentially useful and understandable knowledge. In addition, a specific web-enabled tool will be implemented to allow on-line analysis of the available data. This will provide "advanced" users with the capability of applying common statistical analysis methods, as well as innovative approaches based on machine learning algorithms.

DISCUSSION

In healthcare advanced and innovative information technologies are necessary to enable services to be delivered more efficiently and effectively, as well as to provide new services that correspond to people's evolving needs and requirements. Information technologies offer new solutions with the potential to meet societal demands

and solve societal problems. The application of quantitative methodologies and advanced ICT tools within clinical settings can reduce the time and effort that clinicians spend in providing care.

The problems and potential solutions are well illustrated by the heart failure domain. HF represents a major and escalating public health problem. It is the leading cause of frailty and disability in late life and more Medicare dollars are spent on the diagnosis and treatment of HF than for any other diagnosis. The overall prevalence of clinically identified HF is estimated to be 3–20 cases/1000 population, but rises to greater than 100 cases/1000 population in those aged 65 years or older²⁰. Approximately 6% to 10% of people older than 65 years have HF, and approximately 80% of patients hospitalised with HF are more than 65 years. Hospital admission rates are steadily increasing in developed countries, particular for older individuals in whom, the rate of hospitalisations for HF has increased by 159% over the past decade.

Hospital admissions for heart failure are frequently prolonged and in many cases followed by readmission within a short period of time. For example, in the UK during 1990, the mean length of stay for a heart failure related admission was 11.4 days on acute medical wards and 28.5 days on acute geriatric wards²¹. Within the UK about one third of patients are readmitted within 12 months of discharge, while the same proportion are reportedly readmitted within six months in the USA²². These readmission rates are higher than those associated with other major causes of hospitalisation, including stroke, hip fracture, and respiratory disease.

In any healthcare system, hospital admissions represent a disproportionate component of total healthcare expenditure, and as a consequence heart failure consumes a significant amount of healthcare expenditure. In many industrialised countries this is estimated to amount to 1–2% of healthcare expenditure. In the USA the total inpatient and outpatient costs for HF in 1991 were approximately \$38.1 billion, which was approximately 5.4% of the total healthcare budget that year. This is now estimated to exceed \$60 billion per year²³.

HEARTFAID is an innovative solution that aims to address many of the problems associated with the management of heart failure. It is based on the hypothesis that optimal management of heart failure will produce better patient outcomes and reduce hospitalisations. Crucial to these aims are accurate diagnosis, effective treatment to prevent deterioration in cardiac function, and the ability to continuously monitor patients for early signs and symptoms of deterioration and to respond rapidly and effectively.

HEARTFAID aims to achieve this through the creation of a medical platform that combines intelligent data retrieval and acquisition with sophisticated decision support systems. The platform processes data from both primary and secondary care and knowledge bases. In particular it can capture and analyse data transmitted by biological sensors worn by a patient in their own home.

Many of the technologies used within HEARTFAID are not new. Knowledge based systems, machine learning and telemonitoring in the context of heart failure

patients have all been previously evaluated in several projects²⁴⁻³⁰. HEARTFAID however represents the first attempt to integrate all these different technologies. This is a crucial factor to its success.

Measurable benefits that HEARTFAID is expected to provide include:

- Improved patient quality of life and survival. This is related to its ability to personalise treatment coupled with real-time patient monitoring and rapid response.
- Decreased medical care costs. This is primarily related to a reduction in hospital admissions that use of the application is expected to achieve.

These benefits and other potential benefits, e.g. the discovery of new knowledge related to the epidemiology or pathophysiology of heart failure by capturing and analysing data from several thousand patients, remain to be demonstrated.

ACKNOWLEDGEMENT

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.

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