HEARTFAID

D8 – Definition and formulation of the organization and management models for the healthcare delivery

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HEARTFAID

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

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Consortium

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D8 – Definition and formulation of the organization and management models for the healthcare delivery

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Short description
This document concerns the devising and development of new organization and management models, on the basis of which define more effective and efficient heart failure care programs.

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1.0	First draft of the document	14/10/2006
1.1	Executive summary completed	18/10/2006
1.2	State of Art and Bibliography added	23/10/2006
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Executive Summary

The deliverable D8, "Definition of the HEARTFAID model for the health care delivery", collects the results of the task T1.3 of the Work Package WP1.

This document describes the proposal of an innovative health care management program for patients with heart failure. The aim is to give a complete and detailed description of the management care programs related to heart failure, with a particular attention to the definition of a new integrated Heart Failure Program, supported by the HEARTFAID platform.

Starting from a deep analysis of the literature and the currently implemented Heart Failure Care Programs (HFCP), we have identified and formulated the most important information relevant to the organization and management models for the heath care delivery within Heart failure context.
In particular, we underlined the differences between an ICT based HFCP and the more traditional ones. Moreover, an analysis about economic issues of HFCP has been carried out.

In the second section of this document, two important issues have been analyzed:

1. the Heart Failure stakeholders;
2. the possible patients trajectories within the HEARTFAID platform levels.

We observe that the above issues are logically necessary in order to design the HEARTFAID Care Management model.
In particular, the Heart Failure stakeholders analysis was aimed to identify and group the principal "actors" (physicians, nurse, and so on) involved in the Heart Failure patient processes. A four groups clustering has been proposed in order to simplify and reduce the "actors" list.

Then, we pointed out the guiding principles followed during the HEARTFAID care model design. The importance of Patient and Care Team empowerment has been particularly emphasized; these two principles have been subsequently used in the management model definition. In fact, two of the main aspects of HEARTFAID care model are the reinforcement of the coordination among care team members and the central role given to the patient during the care process.

In the fourth section, a general high level architecture of the care management models has been provided; in particular, three different levels have been identified, common to every care program:

1. the macro level, related to the country health care policies;
2. the meso level, regarding the medical management issues;
3. the micro level, focused on the interactions between operators.

In relation to the HEARTFAID care model a discussion has been provided about the points of weakness and strength arising from each aforementioned level and from the intersections across distinct dimensions.

In the last section, the HEARTFAID care model is being presented. The principal and new concepts introduced in the model are the Virtual Medical Team and the Care Coordinator.
The Virtual Medical Team is the group of medical and non medical figures that are directly related to the care of the patient. It is "Virtual" because its members could belong to different health environments, and its functions will be assured and supported by ICT tools.
On the other hand, the Care Coordinator is a medical figure in charge of:

1. follow all the phases of patient care process;
2. compose and organize the virtual care team.

The main idea is electing a certain number of Care Coordinators in each health structure; new patients will be assigned to one of the care coordinators, that will decide the composition of the Virtual Medical Team, and will have the responsibility of the whole patient management process.
Through this model, we want to reach two objectives:

1. overcome the main problem in the Heart Failure Care Programs: effectively coordinate all the several care stakeholders. In fact, the Care Coordinator will have the responsibility, and above all the capability, to control every step of the patient care process. This possibility will be assured by the HEARTFAID platform functionalities and services;
2. make official the custom of assigning each chronic patient to a specific physician; in fact, usually in hospital environments chronic patients are followed by the same doctor.

At the end of the document a list of recommendations is given. These recommendations are related to the implementation of the HEARTFAID platform, in order to assure the implementation of the management model described in this document. In particular, the implementation of the functionalities, necessary for the Care Coordinator role, is required.

1 Chronic Heart Failure Care Management Programs: State of the Art

Care Management Program (CMP) are aimed to improve quality of life for individuals with chronic disease, through an integrative care approach, reducing at the same time healthcare costs, via a more rational organization of the resources.

The underlying idea is that with the right tools, experts, and equipment, health expenses can be minimized and health care can be provided more efficiently. Tools include web-based assessment tools, clinical guidelines, health risk assessments, outbound and inbound call – center – based triage, best practices, formularies, and numerous other devices, systems and protocols.

CMP have been widely used in the management of Heart Failure patients. The main reason of CMPs employment in the Heart Failure context is that Heart Failure patients' management requires a great number of medical figures to be involved, distributed in different Health Care Structures. Usually no coordination mechanisms exist nor among medical figures neither among respective structures. From this point of view, CMPs usually provide an organizational model able to coordinate all the actors of the care process. In this way, it is possible to improve planning and implementing therapeutics programs, taking advantage of the synergies created by the mutual interactions.

Moreover Heart Failure Patients management is particularly expensive, due to the frequent re–hospitalizations of HF patients. Consequently, CMPs are widely applied in the field of Heart Failure in order to decrease the number of re–hospitalizations and the associated costs.

After this preamble, it is easy to recognize why an impressive number of projects, aimed to validate the effects of Heart failure CMPs, have been performed in the last years. In a recent study [6] about the diffusion of Heart Failure CMPs in Europe, it has been pointed out that among 26 European countries, seven have CMPs in more than 30% of their hospitals. On 673 hospitals included in the study, 426 (63%) have a HF management programme, half of which (n = 205) is located in an outpatient clinic. In particular, in the UK a combination of hospital and home-based programmes is common (75%).

Due to the chronic nature of HF, the basic structure of HF CMPs is almost always the same, and it is composed by few elements:

1) After the verification of eligible criteria and the informed consensus, the patient is enrolled.
2) A baseline visit is performed.
3) A visits' schedule and a therapeutic programme are decided by the doctors along with the patient's agreement.

4) The patient follows the therapy, keeping in touch with the medical structure.
5) If the patient's status is worsened, the patient is hospitalized and the therapy is reviewed.
6) The whole process finishes at the end of the project, at the death of the patient or if the patient chooses to exit the CMP.

In any way, although the general schema is very simple, large differences subsist among the HF CMPs reported in literature.

In order to examine the different characteristics of the Heart Failure CMPs, we will use the taxonomy proposed from the American Heart Association Disease Management Taxonomy Writing Group [4].
The eight items of this taxonomy collect and represent the main components of each Care Management Program, and they can also be applied to Heart Failure CMPs:

1. **Patient populations:** the common characteristic of patients enrolled in HF CMPs is an ensured diagnosis of Heart Failure. There is a great variability among Heart Failure CMPs in relation to other admission and exclusion criteria: in fact either NYHA class, age and type of cardiac impairment has been considered in order to select patients. However, as investigated in [17], HF CMPs have been applied prevalently to left ventricular Heart Failure patients, with serious illness conditions. This has led to an imbalance in the exploration of Heart Failure CMPs benefits, because aspects of management, such as regular structured review and education, have been preferentially studied only on patients at the later stages of the natural history of the syndrome. Relatively rare, the HF CMPs are also designed in order to consider the presence of other morbidities [3], or the CMPs that investigate interracial difference among HF patients [11].

2. **Intervention recipient:** HF CMPs primary targets are usually patients, relatives/home – care givers, and the Hospital personnel (nurses, cardiologist and eventually other specialists; see [1] for an example). Only a limited number of CMPs involve General Practitioners or non Hospital medical figures (as pointed out in [6]).

3. **Intervention content:** HF CMPs interventions area is particular wide; many CMPs are mainly focused on
   a. medication management, (e.g. drugs titration),
   b. patient/relatives education
   c. management issues.

In particular, the issue concerning patients; education has been resolved in several ways, from the use of very simple brochures (see [10]) to the implementation of complex web based tools [A].
As far as the managerial issues are concerned, almost all of the solutions adopted in HF CMPs can be classified in one of the two following categories:

a. nurse based solution.
b. multidisciplinary medical team approach.

The first solution builds the CMP organization around the relationship between the patient and the nurse; in this kind of CMP nurses can have several responsibilities, regarding the patient follow up, the therapeutic decision making process and so on. A large number of nurse based CMPs exist, for a comprehensive review of the programs to which the reader reffers to [5], [11]. The multidisciplinary team solution employs a certain number of medical figures instead; all of them involved in the Heart Failure care process (see [2]). It should be observed that in the last period a third managerial vision is evolving as well, based on the concept of patient trajectories (more references in [7]). Other more "technological" HF CMPs focus their interventions on data collection and data management activities, EMR (Electronic Medical Records) and telemonitoring implementation, or also on decision supporting issues (see [19] for a very comprehensive example about decision support system and EMR, or [12] for some not exhaustive references on data collection via telemonitoring issues).

4. Delivery personnel: generally, five categories of people are involved in the care providing activities in HF CMPs:

a. Care givers: this category includes relatives, domestic collaborators, and other non medical personnel present at the home of the patient;
b. Specialized nurses: medical personnel usually afferent to a Health Care Provider.
c. General practitioners.
d. Specialized doctors: cardiologists, geriatrics, and all the other specialized medical figures involved in HF patient care process.
e. The patient: several CMPs stress the importance of patient self management [16] as one of the major factor for the outcomes improvements.

5. Methods of communication: before the discussion about the methods of communication, it should be recognized that different, bidirectional communication flows exist: doctor/patient flow, doctor/doctor flow, and all other conceivable flow among the different HF care process actors.

a. Doctor/patient flow has been the most explored and studied one, especially after the introduction of ICT tools. The most basilar implemented method is based on telephonic contacts; usually in this scenario a nurse calls weekly or monthly the patient in order to collect a series of information about the patient's status [13]. But there also exist some cases in which contacts are on a daily base, in order to perform a telephone based telemonitoring. The most advanced telephonic communication methods also include automatic answering system based on knowledge bases. ([C]). Other communication methods have been based on web technologies, as in [15]. In these systems the patient logs in a web portal, and usually sents our data via internet and receives some recommendations from the doctors. In some other examples, the web based communication is performed via a specific device, able to collect and send patient data ([20]). Finally, in the last years, more automatic methods have been developed, able to transmit patient information with a minimal effort request from the patient.. This communication method is based on intelligent, wearable devices, which provide wireless web connection and data transmission. One of the last examples of this communication method implementation is [b].

b. Doctors/doctors communication has not been really deeply explored; generally intra doctors information flow issues are not explicitly faced, except in CMPs that implement a multidisciplinary medical team. However some ICT based CMPs implement teleconsulting systems (as the project defined in [18]).

c. Other communication flows: it seems that a large lack of information exists in medical literature about the possibility of implementing communication systems among hospital specialists and general practitioners, or among different Health Provider environments (as for example between hospital and health care provider structures distributed on the territory).

6. **Intensity and complexity:** the major part of HF CMPs has a limited duration; usually one year's (or less more) follow up. This situation is due to the experimental nature of the majority of HF CMPs, and it is of course a limitation for the evaluation of long term effect of Care Management Programs. During the follow up period, the intensity of the program strictly depends on the frequency of patients'/doctors' feedbacks. Complexity of HF CMPs is widely variable, and it depends strictly on the number of actors involved in the programs and by the amount of resources available. In relation to the effect of the program complexity on the obtained outcome, it is interesting to compare two recent studies, [8] and [14]. Both of them evaluate the relationship about the amount of resources utilized in a HF CMP and the outcome of the

CMP itself, leading to disaccording results. Evidently, more studies are necessary in order to clarify this aspect.

7. **Environments:** usually HF CMPs are implemented in both Home and Hospital environments. Few examples exist about HF CMPs in other settings.

8. **Outcomes measurements:** multiple indicators have been defined, in order to measure cost reduction and patient status improvement in HF CMPs (for a general model on HF CMPs evaluation, see [21]). In particular, regarding the patient's status improvement, the most commonly used are:
   a. number of re– hospitalization: it is considered as a clinical outcome and as an indicator of cost reduction.
   b. Death ratio in patient population.
   c. Clinical indicators of patient's status: CMPs usually measure the evolution of the patient's status during the follow up period; each CMP defines a useful set of measurements, in order to track the evolution of the patient, and in order to compare the patient's initial status with their conditions at the discharge. This set of indicators is always defined as "ad hoc", in order to fulfil the objectives of the study. Common used indicators can be strictly clinical, as for example NYHA class, weight, blood pressure, blood serum values, or more functional, as for example in [22], where the "Minnesota Living with Heart Failure Questionnaire" has been used in order to evaluate the functional capabilities of the patients.
   d. Number of acute events (as AMI, syncope, etc).
   e. Number of decompensation.
   f. Number of acute decompensation.

   Cost decrement measurement in HF CMPs represents a more challenging task. In fact, the number of re hospitalization is more often used as an indicator of cost reduction, but it is clearly not sufficient, and more financial parameters have to be considered. Several studies report evidence in cost savings, but it is difficult to evaluate the methods used in this studies in order to calculate the total costs, before and after the CMP application. Recently the Return On Investment (ROI) has been used as CMP effectiveness indicator (see [D] for a comparative study), but also the ROI measurement presents several difficulties.
   Regarding the number of re– hospitalizations, its validity has recently contested in [23]. In this work the authors argue that, in order to save costs, reducing the number of re–hospitalizations too much is not the best strategy, because re–hospitalization can also have a preventive role, overall in order to avoid the costs related to the treatment of acute events.

Once the common points and the most relevant differences among the HF CMPs are defined, it is worth while to analyze the evidence of CMPs effectiveness in

cost reduction and patient status improvement as reported in literature. Numerous recent articles are focused on the simultaneous comparative examination of different HF CMPs results (see [9], [12], [23], [24], [25], [26], [27], [D]).

Summarizing, all the comparative studies agree that HF CMPs are effective, regarding the improvement of patients' conditions. In any case, due to the complexity and variety of CMPs, it is still not clear which actions performed during HF CMPs are more relevant, in order to achieve the desired results. Moreover, the small size of patients' groups involved, don't permit to assert the validity of HF CMPs with an absolute and definitive evidence.
Similar conclusions can be drawn for the financial and economic aspects; each singular study about a specific HF CMP reports a certain advantage in using HF CMPs (in terms of ROI, financial savings, reduced re– hospitalizations), but comparative studies stress the importance of having larger and controlled trials, in order to validate the findings of singular projects.

In conclusion, although no evidence of widespread positive impact of the programmes have been reported across the world, the World Health Organization [28], acknowledges the potential of the programmes' impact in the management and control of chronic Heart Failure condition.

2 Building the HEARTFAID Care Management Program

A major challenge for heart failure programs is to identify the combination of effective treatments within a given care program. Since there have been no studies that compare the relative effectiveness of different programs or compare individual components within programs, a suitable approach seems to be the identification of those components which are common to successful programs and the appropriate coordination and integration of these common and suitable components.

Components of successful Healthcare delivery Models for Heart Failure
Physicians directed care with assistance from nurse coordinators in patient management or nurse-managed care by experienced advanced practice cardiovascular nurses with access to a cardiologist for consultation.
Intensive patient and family/caregiver education about heart failure with emphasis on a low-salt diet, medications, symptoms that signal worsening heart failure, weighing, and management strategies for problems.
Vigilant, frequent follow-up after hospital discharge
Optimization of medical therapy with published guidelines based on large scale randomized, controlled clinical trials.
Increased access to healthcare professionals for problems by telephone or walk-in appointment.
Early attention to signs and symptoms of fluid overload.
Supplementation of in-hospital education with outpatient education
Coordination with homecare health agencies when appropriate
Attention to behavioural strategies to increase compliance
Emphasis on addressing personal, financial and social barriers to compliance
Assessment and assistance in management of social and financial concerns

Table 1: Components of successful Healthcare delivery Models

In any case, by making decisions about which components to include into a program, the specific features of the target population must be examined.
For example, in the HEARTFAID setting, in which the targeted population consists of elderly patients, the inclusion of some component of home care environment is likely to be more successful, given the transportation and mobility difficulties experienced in many elderly patients.

Integration of medical care and patient education, with close communication between inpatient and outpatient care providers, is essential.
An integrated and innovative approach to the management of heart failure patients, based on consensus recommendations, can contribute to improved patient outcomes, including reduced morbidity rate, improved functional status and quality of life, enhanced compliance, reduced rates of re hospitalization, reduced costs, and prolonged survival.

2.1 The HF stakeholders

In the HF context, a stakeholder could be defined as a Health Operator that acts directly for implementing the HF patient care process.
From an organizational point of view, an impressive number of stakeholders are involved in the HF patient care process. Multiple reasons are below this phenomenon: firstly, the complexity of HF syndrome requests very different medical capabilities and knowledge, and thus several health professionals have to be involved during the whole care process.
In fact HF presents various levels of severity, and in each level different care actors should be employed; furthermore, the variability along the course of the pathology is a complexity factor that could require a health setting shift.
As an example, consider the case of an acute decompensation: during this kind of event, the HF patient is initially stable, without symptoms suggesting any worsening, often located at his home. In this initial phase, General Practioners or his relatives are his stakeholders. During the acute decompensation onset, the HF patient has to be moved rapidly in a different health setting, usually a hospital emergency room, and he starts being monitored by specialized physicians and cardiologists.
Moreover, the presence of several comorbidities and the average age of the HF patients contribute to the increased number of health actors in the HF patient care process. As an example, not only cardiologists, but also lung and kidney specialists have to be involved in the health process; moreover, due to the HF patient's age, there could be an admission to a dedicated ward.
Last but not least, considering the whole European health infrastructure, several differences could exist among the countries health systems, multiplying the number of stakeholder that a European project, like HEARTFAID, should consider. The principal problem arising from the numerosity of the heath care operators is the possibility of "blind" actions. In fact, the operators who are often involved in the HF care process don't have any mechanism devoted to the mutual coordination. Only the patient memory and sometimes the clinical notes represent the coordination tools among the different health actors. In this way, a synergic and integrated approach to the patient treatment is not possible. Instead, each health operator acts in a blind way, ignoring a lot of information possessed by the care process actors. In order to define a Care management program able to manage the HF patient in his totality and complexity, it is necessary to order and cluster the various health care operators and settings. Firstly, we can define three different levels, characterizing the HF care process organization:

1. Health Environments: is the highest organizational level, describing the characteristics of the environment in which the patient could be treated.. In the HF care process it is possible to recognize three different Health Environments:
   - Home Environment: it includes the settings where the patient lives during his usual live.
   - Hospital Environment: the ensemble of public/private hospital structures.
   - Primary/Office Environment: the huge ensemble of health structures distributed on the territory (e.g. Primary Care Trust centers) that are able to give primary care but don't have the possibility to provide specialized treatment.
2. For each Health Environment, there could be listed different Health Settings:
   - In the Home Environment, the main setting is of course the patient's house. But, if the HF patient leads an active life, other possible settings related to the Home Environment could be defined as:
     i. Work Setting;
     ii. On move Setting;
     iii. endless list…
   - For the Hospital Environment, the settings are the patients' reference hospitals. In fact the HF patient could change his reference hospital for several reasons, for example change of address.
   - The Primary/Office Environment collects a great number of settings. The first one is the patient GP office, but in every European country is possible to recognize at least a web of Primary Care Trust centres and a system of pharmacies. It would be not useful to list all the possible settings belonging to the Primary/Office Environment, but instead it should be more useful to note that all these settings are devoted to provide generic and primary assistance but not specialized treatment.
3. Last but not least, in each Health Environment and in each Health Settings, different kind of people exist and interact; a possible taxonomy, sufficiently detailed in order to examine the HF care process, could be the following:
   - Care givers: in particular, they could be the patient relatives, social assistants, domestic collaborators.
   - Specialized nurse: a medical figure with an apposite degree;
   - Medical Doctors: a generic physician, e.g. the General Practitioner;
   - Specialized Doctors: each specialized physician, e.g. the Cardiologist.
   - The patient.

It is worth while to describe more in detail the role and the characteristics of each actor involved in the HF care process.

2.1.1 Care Givers:

Under this definition is collected all the non medical personnel, devoted to the care of the HF patient. Usually the care giver is a relative of the patient, who lives with him. But also some social organization providing care givers services, especially for elderly people. In any case, the principal dues of this figure are the following:

- Assist the HF patient during his normal life; HF usually limits the freedom of the patient, so often an assistant is needed;
- Assure the patient's compliance to the therapy. Aged HF patients don't follow the therapy for multiple reasons: dementia, because they have problems in reminding medications, or simply because far away the decompensation phase they feel so healthy that they believe they don't need medications or for the appearance of depression, so they haven't the will to take medications.
- Keep in touch with the physicians if the patient is not able to.

Generally, the role of the care giver becomes more important when the patient losses his independence; in fact, especially for patients with NYHA II or NYHA III, re hospitalization is not necessary, but the patient needs a continuous assistance in his Home Environment. So the only possibilities are the presence of a care giver or the hospitalization in a private structure. Some town councils have organized a home assistance for elderly patients, this is supported by volunteers that, without profit, help and assist elderly patients in their daily life.

2.1.2 Specialized nurse:

This figure is present in every Environment and Setting previously examined. In particular, in the Hospital and Primary/Ambulatory Environment the specialized nurse assists the physicians, providing the basilar care treatments to the patients. Specialized nurses in the Home Environment instead have been employed in several HF Care Program (see section 2). During the home visit the specialized nurse collects various vital parameters (e.g. electrocardiogram) that the patient would not be able to collect himself. Moreover a specialized nurse can also judge the state of the patient, and act consequently. Generally, a specialized nurse service at the home of the patient is very expensive, even if it has been demonstrated that this kind of service improves the medical outcomes. A particular case of specialized nurses is represented by the emergency operator employed in the ambulance; in fact their principal role is to succour the HF patient during an acute event (e.g. acute decompensation, arrhythmic event, and so on).

2.1.3 General Practitioners

The role of the GP regarding the HF treatment, is defined as the following:

- Screen suspected cases of HF among his patients
- Address suspected HF case to a specialized centre (usually the local hospital department of cardiology) for further assessments.

- ollow the patient during the HF treatment, providing recommendations on therapy and lifestyle, and monitoring the patient status.
- Refer to a specialized centre in case of decompensation.
- Educate the patient regarding the correct behaviour that a HF patient should have.

2.1.4 Specialized Doctors

All the physician specialists in a particular field fall in this class. A long list of medical figures falls in this general definition, including geriatrics, internists, cardiologists, laboratory physicians, radiologists, pneumologists, diabetologists, etc. For the aim of the model defined in this document, it should be sufficient to collect all this figures under the generic definition "specialized doctors". Specialized doctors' dues are mainly related to the care of the specific illness of the patient. Of course, cardiologists have a primary role in the treatment of the HF. In particular the cardiologists:

- Have to identify exactly the HF patients among the suspected HF cases.
- Prescribe the therapy according to the most recent guidelines and assess effectiveness and patient's compliance to it
- Follow the progresses of the patient during the therapy
- Are responsible with the "Medical Doctors" of the patient education.

The other specialists take care of the other pathologies that the patient may have. A not completed list, regarding the other specialists, comprises of lung specialists, kidneys specialists, geriatrics, and so on.

2.1.5 The Patient

Last but absolutely not least, the patient plays a central role in the whole care process. In particular he should:

- Educate himself about all the aspects of his condition, in order to recognize preventively each symptom and sign of worsening or decompensation;
- Discuss therapy options with the physicians in order to reach an agreement on the optimal therapy programme
- Follow strictly the therapy programme
- Control his behaviour, especially about the aspects that are relevant for the HF (smoking, food, etc.) in order to adhere to the medical recommendations.

Moreover it is worthwhile to remember that the importance of the patient in the care process is strictly related to his self care capability; the more the patient is independent and able to live without assistance, the more his behaviour influences the medical outcomes. Finally, it is necessary to remember that this classification is not very binding. In particular, there could be some existing settings belonging to multiple environments. E.g., private cardiologist offices belong to the Primary/Office Environment, but often they can provide examinations that are usually provided only in a Hospital Environment.

2.2 The trajectory of the patients

The concept of trajectory was introduced over 30 years ago, in order to capture and describe the experience of chronic illness. Illness trajectory encompasses the total organization of work done over the course of illness, and the impact that this work has on those involved in the work and its organization. Within life-course theory, trajectories, as well as transitions and turning points, are core concepts. Trajectories are sequences of long-term patterns within a focal area (family, health) or across different areas and are formed by examining states and transitions across successive years. Trajectories are not individual events in time but are embedded in health care pathways that are defined by health care institutions and stakeholders. Heart failure patients frequently have coexisting conditions, for which they take many medications. Often they may have cognitive and/ or functional limitations, and may be isolated with poor social support. Many will have financial concerns, and psychological conditions such as anxiety and depression are common. Heart failure patients frequently have inadequate access to health care personnel, receive poor follow up, and are poor compliers with medications. From the patient's perspective, the disease is characterised by a vicious cycle of worsening symptoms, acute decompensation, hospitalisation, and subsequent stabilisation and discharge (fig 1).

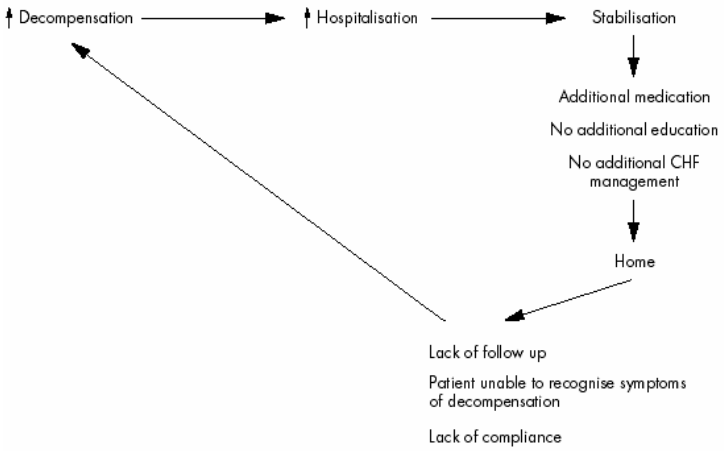

Figure 1 The vicious cycle of repeat hospitalisation that may occur with the traditional approach to heart failure management.

Figure 1:Vicious cycle of worsening symptoms

Moreover, since patients often feel substantially better after hospitalisation, they do not understand the need to take so many tablets. Poor compliance with medication means the patient is more likely to decompensate, leading to re-hospitalisation and the need to re-stabilise the patient.
As outlined in the deliverable D5 with the current project we plan on developing a tool capable of, breaking this vicious cycle by instituting a structured system of care delivery involving a multidisciplinary team that provides the patient with education about their condition, medications, and when to seek help for worsening symptoms (fig 2).

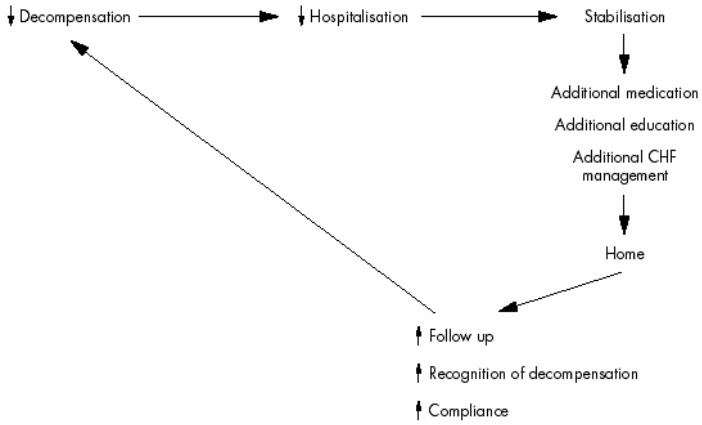

Figure 2 How specialist intervention can break the vicious cycle of repeat hospitalisation.

Figure 2: Breaking vicious cycle of worsening symptoms

This will be accomplished by collecting, integrating, and processing relevant biomedical data and information coming from the main settings actually encountered by patients with CHF.
These settings include:

- the *medical environment*, corresponding to HFP level of functioning 1 (i.e. office of the general practitioner), and HFP level 2 (i.e. specialized hospital, with cardiologists involved in outpatient and inpatient care);
- the *patient environment*, (i.e. patient's home) corresponding to HFP level 3;
- the medical and technological *research environment*, corresponding to HFP level 4.

HFP level 5 represents a future development where data coming from a number of platforms (levels 1-4) might be integrated at the national or international level (i.e. randomized clinical trials, public health). The new integrated care pathways can make a major difference in the course-life of patient as depicted in figure 3. Here various workflows can be articulated depending o the characteristic of the patient.

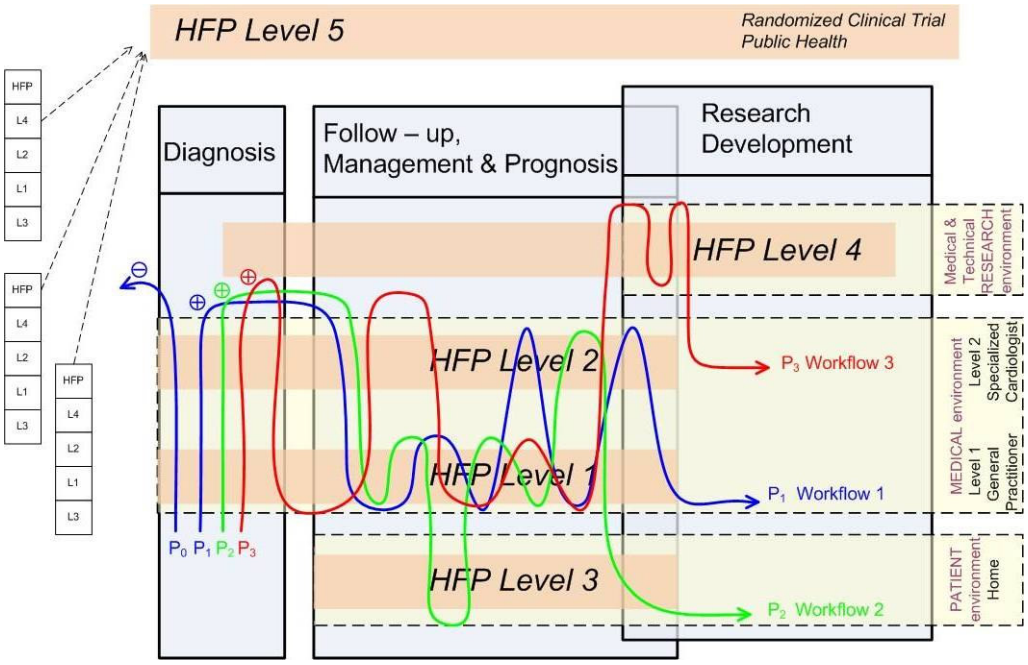

Figure 3: HF patients paths

- **Workflow 1: medical environment.**

In Fig 3. HFP level 1 and 2 and patient n. 0 and n. 1.

Trajectory of patient of type 0 is a degenerate trajectory corresponding to the case of a false positive, i.e. a patient suspected to have HF but not actually without heart failure. Trajectory of patient of type 1 depicts a care delivery process in which the diagnosis, management and prognosis assessment are provided with patients' data collected and medical recommendations provided both in the office of the family physician and in the specialized cardiology setting. The patient deserving this treatment is a patient with a modest severity of illness and a good transportation and mobility capabilities.

- **Workflow 2: medical environment and patient's home.**

In Fig 3. HFP level 1, 2 and 3 and patient n. 2.

Trajectory of patient of type 2 depicts a care delivery process in which the diagnosis, management and prognosis assessment are provided with patients' data collected and medical recommendations provided both in the office of the family physician, in the specialized cardiology setting and in patients' home. Biomedical parameters, relevant symptoms and compliance to prescribed pharmacological and non pharmacological regimens will be monitored by HFP level 3 in patients' homes. Serial measurements of selected biological parameters will be collected by the patients and by their relatives and will enter HFP level 3. Furthermore, HFP level 3 will engage with the patients by providing informative material, reminders on medications' schedule,

reminders on biomedical measurements. The patient deserving this treatment is a patient with a higher severity of illness and limited transportation and mobility capabilities.

- Workflow 3: medical environment (HFP level 1 and 2) and research environment (either medical or technical) (HFP level 4).

Processes of diagnosis, management, prognosis assessment with patients' data collected (and medical recommendations provided) in the office of the family physician, in the specialized cardiology setting, and in the ultraspecialized research setting.
As stated above, in workflow 3, while supporting the standard CHF management and prognosis assessment, the HEARTFAID program will assist in collecting biomedical information for research and development purposes.

3 Guiding Principles of the Framework

The HEARTFAID care model is based upon a set of guiding principles. Each of the principles is fundamental in the development of the system.

3.1 Evidence-based decision making

Evidence should be the basis for all decisions in policy-making, service planning, and clinical management. Evidence includes the available information about the magnitude of heart failure conditions, effective and efficient interventions to reduce the associated burden, current and anticipated resource needs, and the appropriate mix of skilled health care personnel. Evidence-based information includes what is known about clinical processes of care and patient outcomes.

3.2 Quality focus

Quality control ensures that resources are used properly, that providers are accountable for providing effective and efficient care, and that patient outcomes are the best possible given any limitations. Quality is not only a health care delivery issue. A quality focus that begins at the organizational level ensures better quality at the organization and patient levels of the system.

3.3 Integration

Integration, coordination, and continuity should occur across time and health care settings, including primary health care, speciality care, inpatient care and home care. Patients with chronic conditions need services that are coordinated across levels of care – primary, secondary, and tertiary care – and across providers. Health care workers who care for the same patients need to communicate with each other. There is strength in the collective knowledge, information, and skills of multiple health care workers that far surpass that of a single provider. Where possible, an identified "**care coordinator**" can serve as the over-seer and director of a patient's care ensuring that efforts of all involved health care workers are integrated and coordinated.
Continuity of care also is critical. Care must be planned over the course of the condition. Follow-up visits should be scheduled and organizations must be proactive in caring for patients.

3.4 Flexibility/adaptability

The HEARTFAID care model need to be prepared to adapt to changing situations, new information, and unforeseen events. Changes in disease rates and burden, as well as unpredicted disease crises can be assimilated into systems that are designed to adapt to change.

Routine surveillance, monitoring, and evaluation are keys for systems, in order to be able to adapt to changing contexts. When these processes are embedded within a health care system, it has the potential to become a constantly evolving, adapting "learning system" that foresees and responds flexibly to changes.

3.5 Patient empowerment

When the components of each level of the system are integrated and working optimally, the patient and family become active participants in care, supported by their health care team.
The patients should feel empowered, capable, and supported to self-manage their chronic problems.
Patients and their caregivers need to be informed about self-management strategies and to be motivated to implement them on a daily basis over the course of time. Self-management training (for example, to improve adherence to medications, consistent exercise, proper nutrition, regular sleep, and tobacco cessation) can reduce the frequency of follow-up visits and will prove cost-effective with time.
Health care workers are crucial in educating patients and families about self-management. They are instrumental in helping patients initiate new behaviours. However, more importantly, health care workers must support patients' self-management efforts over time. Attention to self-management and prevention of acute conditions should occur at every patient encounter.

3.6 Health care team empowerment

The team includes multiple categories of care providers, from each level of care (including specialists), and within all clinical settings.
Health care teams need to be equipped to manage chronic conditions. They need necessary supplies, medical equipment, laboratory access, and essential medications to provide care that is informed by scientific evidence. Teams require support to make optimal decisions, including written guidelines of care, and diagnostic and treatment algorithms.
Health care teams need special skills and knowledge that extend traditional biomedical training. Effective communication abilities are important to promote information exchange, open questioning, and shared decision-making with patients. In addition, health care workers need expertise in behavioural interventions to help patients initiate new self-management techniques, adhere to complex regimens, and make lifestyle changes. Even more importantly, workers need the skills to support patients in their efforts to maintain change over the long-term course of the condition.
Physicians and other health care workers need skills that enable them to work cooperatively. The traditional independent practice model is not optimal in heart failure setting. In contrast, teams made up of multiple health care workers must learn to work collaboratively and share patient responsibilities.

Team members accept roles and responsibilities for tasks according to their professional strengths and capacities.
The traditional hierarchy flattens and moves away from physician dominated models because each team member is valued for his or her unique skills in the management of the heart failure conditions. Innovations in the team concept may be necessary. For example, virtual teams, linked through information technology, would be implemented in the project.

4. The HEARTFAID care model

4.1 Overview

Our HEARTFAID Care Model identifies the essential elements of a system that encourages high-quality heart failure disease management.
These include:
-the community;
-the health system;
-self-management support;
-delivery system design;
-decision support and clinical information systems.

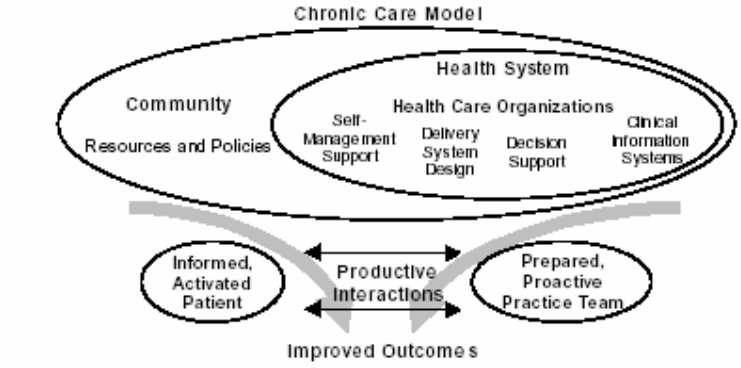

Figure 4: Chronic Care Model

One strategy to organize thinking about the model is to divide it into strata or levels.
Micro-, meso-, and macro-levels provide a reasonable framework and refer to the patient interaction level, the health care organization and community level, and the policy level, respectively. Each of these levels interacts with and dynamically influences the other two. For example, consider the levels as linked by interactive feedback loops in which events at one level influence actions and events at another level, and so on. In this scheme, patients respond to the system in which they receive care, and health care organizations and communities are responsive to policies that in turn influence patients. And, the feed-back loops perpetuate.

Figure 5: CMP levels

Delineation between micro-, meso-, and macro- levels is not always clear. For example, when health care personnel are not prepared to manage chronic conditions because of training deficiencies, the problem could be considered a micro-level problem because it affects patients. Training deficiencies could be considered a meso-level problem because it is the responsibility of the health care organization to ensure providers have the expertise and tools to care for patients.
In the HEARTFAID project we will consider only two levels: the micro-level and the meso-level.
Before going into details concerning the model, we give an overview of the issues involved in each level and of the potential weakness and strength arising from intersections across distinct dimensions.

4.2 Micro-Level: Patient Interaction Problems

Within the micro-level, problems that may arise are evident. The system may fail to recognize the extraordinary importance of patients' behaviours and the value of quality interactions with health care workers in influencing the outcomes of health care. There is ample scientific evidence regarding efficacious strategies for the micro-level (e.g., interventions for changing patient behaviours, techniques for increasing medication adherence, or methods for improving health care worker communication).
This evidence must be integrated into daily clinical practice. Two common problems at the micro-level are the failure to empower patients to improve health outcomes and the lack of emphasis on quality interactions with health care personnel.

4.2.1 Failure to Empower Patients

Heart failure problems are enduring, necessitating a care strategy that reflects a protracted time frame and clarifies for patients their roles and responsibilities in managing their health problems. Appropriate clinical care is necessary; however, it is not sufficient for optimal health outcomes. Patients have to make changes in their lifestyles, must develop new skills, and must learn to interact with health care organizations to successfully manage their conditions. They no longer can be viewed as, nor see themselves as, passive recipients of health care services.
Patients have to participate in their care and health care personnel must support their efforts. In fact, there is substantial evidence from more than 400 published articles that interventions designed to promote patients' roles in the management of chronic conditions are associated with improved outcomes. What patients do for themselves on a daily basis (e.g., adhere to medication regimens, exercise, eat properly, sleep regularly, interact with health care organizations, and cease tobacco use) influences their health far more than medical interventions alone.

4.2.2 Failure to Value Patient Interactions

It becomes imperative that patients develop quality relationships with health care personnel and that these relationships persist across time. Health care workers

must ensure that patients have adequate information and skills to manage their conditions. For this to occur, patients need a context in which they can freely ask questions, and they need an environment that initiates and supports their self-management behaviours.
The HEARTFAID model will create an environment that promotes quality interactions and partnerships with patients. Self-management, medication adherence, functional abilities, knowledge, or personal responsibilities will be discussed in the clinical context.

4.2.3 Addressing Prevention

Given information about making appropriate choices, patients and their families have the option to act to improve their health. With the help of Heartfaid care model personnel, patients can engage in behaviours that prevent or delay complications of conditions they have already developed. Moreover, they receive knowledge, motivation, and skills to change hazardous work environments, to stop using tobacco products, to practice safe sex, to eat healthy foods etc.. Prevention and health promotion should be part of every health care encounter, but this is far from routine clinical care.

4.3 Meso-Level

4.3.1 Organizing Care

The face-to-face visits with health care workers whose purpose is to diagnose and treat a patient's presenting complaint is a typical visit format that may be inadequate to HF conditions. One problem is the discrete nature of the interactions, which belies the importance of promoting a continuous, thoughtful, and high quality relationship between patients and health care workers. Clearly, Heart failure conditions are not a series of disconnected complaints.
A planned programme of care must be set across time. The plan of care will be update and modified every time a new event will occur. A new event can be, for instance, a change in clinical or psychological conditions. Providing top quality care necessitates close collaboration, secure, easy and timely exchange of information, and coordination of the team activities. This should be achieved irrespective of the physical presence of the individual members of the team, or even if different doctors treat the patient, for possibly different symptoms at different hospitals, or visit him at home. It is of course obvious, that the *concurrent physical presence* at the *point of care* of all members of the team is rarely possible. This creates serious difficulties for providing the quality care that heart failure patients deserve to obtain in a friendly (to them) home environment. Through this project we expect to assist in the delivery of better home-care, by offering the health-care team services that are aimed in achieving a continuum of health and health-related services, despite the structural problems of home-care, as compared to facility based care, as for example the geographic proximity and geographic separation between the team members and the patient.
The HEARTFAID care model aims to overcome these difficulties by maintaining a ***dynamic collaborative virtual healthcare team***, as well as secure, easy, and

timely access to the **unified Electronic Medical Record** database (see section 6.3) for the continuous home treatment of patients. The dynamic virtual healthcare team is created explicitly to satisfy the needs of each particular patient at a point in time.

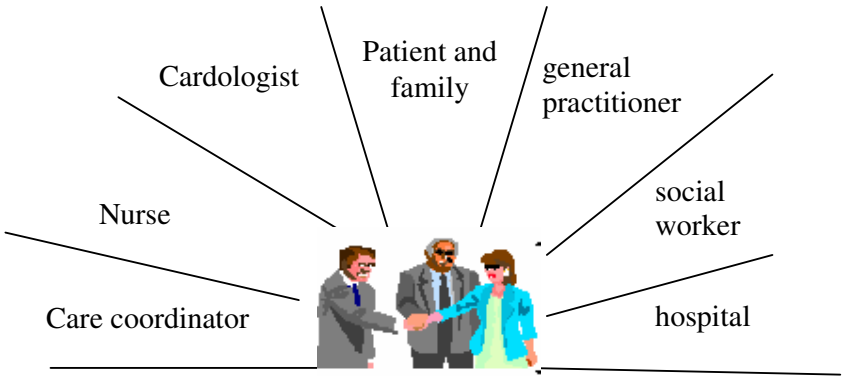

Figure 6: HEARTFAID Care Team

As a result the following **clinical objectives** are addressed:
• To provide the presence of the (virtual) team by the patient at any given time, irrespective of locality, or cross country movement.
• To improve communication within the dynamic (virtual) home care team and between the home care team and the hospital (locally, or cross country), through a **care team coordinator** which will play a central role in the model. In particular the care team coordinator should be a medical figure (e.g. specialized nurse or general practitioner) able to follow the whole HF patient trajectory.
• To provide flexible and secure access and management of healthcare records at any time and from anywhere, to improve continuity of care.
• To improve collection of statistical data for further audit and research within home care setting, enhancing knowledge and offering possibility of evidence-based care. Guidelines based on the available scientific evidence for the management of heart failure conditions are well established. This important information will systematically reach HEARTFAID care model personnel; thus, interventions known to be effective will be provided routinely
• Provide continuation of care for heart failure via Virtual Collaborative Medical Teams.

4.3.2 Information Systems

Information systems are essential components for coordinated, integrated, and evidence-informed health care. In the HEARTFAID care model process model of care delivery extends from the home of the patient to the care facilities and back to the home covering the whole care cycle. Continuity of care is necessary for high quality care with optimal resources. This means that several service providers have agreed to collaborate seamlessly in solving the problem of the patient. This implies the need for an information network integrating the service providers, the individual care plans and patient data. In the information system

will be used to monitor health trends, the implementation of standards and regulations, and clinical guidelines for processes of care. In HEARTFAID model the solving of the problem of a patient can be seen as a process: a chain of partly sequential and partly parallel diagnostic and therapeutic actions. The challenge is to manage these events in order to optimize the outcome and the use of resources needed during that process. The process paradigm leads to a new organizational structure for care delivery. Resources are reorganized to serve the main activity of problem solving. The core activity is the clinical service line which uses the skills of service units. The process approach and the need to manage care jointly are pushing service providers towards collaboration in order to meet the needs of their customers and solve the problems of their patients effectively and efficiently. Information Technology (IT) can integrate data and make it and medical knowledge available in the right format anywhere and at any time. From the IT viewpoint health care will become 'virtual' and 'transparent'. The development of the information system that is transportable and integrable naturally starts by identifying user needs. The concept of a user needs to be viewed as widely as possible. This means that one should include all categories of users (nurses, doctors, cardiologists, care coordinator, patient, family and so on). In the following section the user needs will be described using the UML language.
In the figure below a care scenario combining care processes, plans and clinical guidelines and with quality improvement both at the organizational and medical research levels is reported.

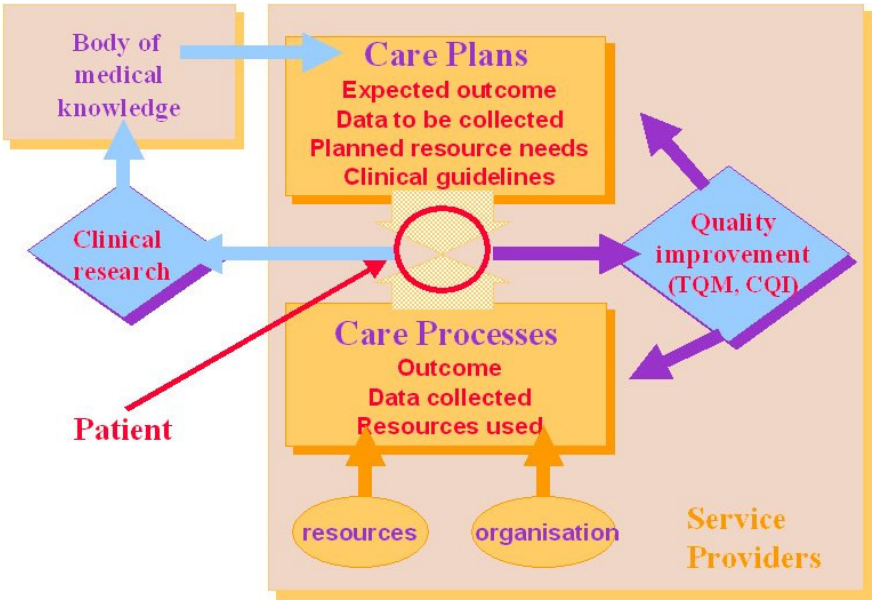

Figure 7: Care Scenario

5. Implementing the model: A New Way of Thinking about Heart Failure Conditions

HEARTFAID care model is the devise and integration of methods and programmes (of proved effectiveness), with the aim to improve the clinical management of heart failure conditions.
The innovative characterization of the model consists in the integration of fundamental components from each of the micro-, meso- levels of the heart failure system, but first, a re-conceptualization of heart failure conditions is needed to create a necessary foundation from which to build.
From a health care perspective, it is no longer advantageous to view heart failure conditions as discrete health problems.
Innovative care is based on the demands that the heart failure problems places on the health care system.

In new conceptualizations of heart failure conditions, the quality of life of the patient and family is thought an important outcome, and the role of the patient in producing this outcome is emphasized.
The patient is not an inactive participant in care; rather, he/she is considered a "health producer."
Innovative care means re-orienting the systems such that outcomes valued by the system are the ones that actually are produced.
Patients with heart failure problems need broader support. They need planned care; they need care that anticipates their needs. Patients need integrated care that cuts across time, settings, and providers and self-care skills for managing problems at home.
Innovative care elevates the roles of the integration among different levels and settings.
All levels need to be linked and each is integrally important to the other. Each component of each level has important roles to play in improving outcomes for chronic problems.

5.1 Identification of the HEARTFAID team, their roles and collaboration scenarios

The HEARTFAID team includes cardiologists who are based in the cardiology centre, treating doctors who are usually located in the community or in the hospital, home care nurses who regularly visit the patient at home, care coordinators and a number of other professionals called in as the demand arises.
The care coordinators are in charge of the patient, and thus the analysis has initially focused on them and their interactions with the rest of the healthcare team.

5.1.1 HEARTFAID functionality trough scenarios

With the following plausible scenarios we illustrate aspects of HEARTFAID functionality.

Scenario 1

*Care coordinator Mary wakes up early in the morning. She connects (**with her Mobile Computing Unit, MCU**, such as a Smart Phone, Pocket PC etc…) to the central office web server to check in and acquire day's visit schedule of her patients. For each patient in her list, Mary receives regularly important biomedical data via telemonitoring.*

Mr. P., a nice sweet old man who while enjoying the comfort of his home regularly receives attention (due to the seriousness of his situation) is in the pool of patients followed by Mary. When an extreme change in his condition happens, the telemonitoring system alerts immediately Mary about the severity of patient conditions.

*The system records (**into the electronic medical record of the patient in the database**) the new data. Mary, first examines the situation and, given the seriousness of event chooses to contact the care team.*

*She decides which members of the team to contact and transmits messages (**via the mobile agents**) to the selected members of the team alerting them and requesting their services.*

*Each member of the team contacted extracts (**via MCU**) from the patient registry only the needed (and authorised) parts of the information concerning not only the data of the triggering incident (i.e., patient P experiences pain in the heart) but also relevant patient history.*

The virtual team around patient P. has now been set in motion.

The team evaluates the information submitted to it and discusses the specific clinical protocol that team members should carry out.

Also a new appointment is scheduled for patient P. with the cardiologist.

The nurse performs her/his tasks immediately at home of Mr P. and goes to her next appointment.

Scenario 2:

Care coordinator Mary reviews the tests attached to the chart, the registry-generated data sheet, the home monitoring results of Ms. Jones.

Mary reviews Ms. Jones' chart and the self-management checklist that they agreed upon at the last visit.

After noting that Ms. Jones' weight has increased she contacts Ms. Jones and congratulates her on how well she is keeping track of her home testing results.

Mary and Ms. Jones briefly discuss nutrition, exercise and she asks Ms. Jones if she would like to speak to a Certified Educator.

After some initial hesitation, Ms. Jones agrees to have contact with the educator. Mary asks Ms. Jones if she has any questions. They also review her self-management goals and agree to set up a telephone visit every two weeks for the next 6 weeks so that Mary can answer her questions and provide encouragement for Ms. Jones.

The platform arranges a contact with the educator for Ms. Jones and schedules a reminder alert for her next appointment.

In the meanwhile as usual the system provides access for Ms. Jones online to request appointments, referrals, and medication refills. The practice website also includes a link to the Personal Health Record program

Scenario 3

Mr. Smith is a 42-year-old man with heart failure and fairly erratic medical care because of his busy schedule. Approximately six months ago he had a pretty severe exacerbation of his HF that required a visit to the local emergency department for several hours. Once he was stable, the emergency department physician gave him Mary's office number and encouraged him to call to establish himself with Mary.

Mr. Smith typically was able to manage his HF fairly well on his own, but this visit to the emergency department was his third one in the past 4 months. Mr. Smith calls Mary expecting to be told that the next available appointment is in two months. He is very surprised when Mary, after a brief description of the program in which he could be enrolled, asks if he could come in later that day. When Mr Smith arrives, Mary asks him a few questions about his health.

Mary , via touch screen, enters the information provided previously. Shortly thereafter he is escorted to an examination room.

Mary asks whether Mr. Smith monitors his blood pressure at home. Mr. Smith indicates that he used to do that but didn't understand what to do with the information – so he just stopped doing it.

Mary takes the opportunity to coach Mr. Smith on the proper technique and how to properly use the gathered information.

She also provides Mr. Smith with a copy of a generic HF action plan to review while he waits for Dr. Y. Dr. Y has been contacted by Mary and is now part of the care team of Mr. Smith.

Dr. Y acquires all the relevant information of Mr. Smith and makes a deep examination of his health status.

While Dr. Y enters the additional data collected during the visit in the patients' record, the clinical decision support module generates an alert indicating that a recent study suggested that a component in a drug taken by Mr. Smith might cause HF exacerbations in some patients.

Dr. Y recommends that Mr. Smith discontinue the drug and after a telephonic contact with Mr. Smith GP, prescribes a new medication regimen.

Dr. Y provides Mr. Smith with information about the practices' website and personal health record. With Mr. Smith's permission, Dr. Y is able to send key clinical information to Mr. Smith's personal health record including treatment recommendations, medications prescribed through the e-prescribing module in the electronic health record, and health maintenance reminders. Dr. Y also encourages Mr. Smith to email Mary any non-urgent questions or concerns. Mr. Smith agrees to send his home-monitoring results via email but to call if his symptoms get worse despite following the action plan. Dr. Y enrols Mr. Smith in a remote monitoring program whereby his home-monitoring results will be transmitted electronically to the platform. However, Dr. Y does review a self-management checklist with Mr. Smith that includes the need for Mr. Smith to assess his home environment, do daily aerobic exercise, and commit to using the

action plan guide. An appointment with Mary is fixed to provide Mr. smith with the home-monitoring equipment.
During the subsequent week, Mary is very worried about the alert of the platform indicating worsening of Mr. Smith symptoms . Mary schedules a telephone consultation with Mr. Smith an the care team to review his medication regimen and to discuss Mr. Smith's evaluation of his home environment.
Based on Mr. Smith's worsening condition and the absence of an identifiable cause, Dr. Y recommends to Mr. Smith a referral to a specialist t to help identify potential environmental triggers for the exacerbation of his condition. Though Mr. The specialist will receive an electronic summary of Mr. Smith's records in advance of his visit which will be incorporated into the electronic health record for review. The report of Mr. Smith's visit will likewise be sent securely back to Dr. Y for his electronic health record so that the follow-up management of Mr. Smith's can be coordinated after consultation is complete.
Scenario 4: *Mrs. Murphy is an 85-year-old woman enrolled in the Heartfaid program with several chronic medical problems including Type II diabetes mellitus, congestive heart failure, atrial fibrillation, and based on a recent assessment, mild dementia. For these conditions, Mrs. Murphy takes several medications including oral medication for diabetes, an anticoagulant (warfarin) and digoxin for her atrial fibrillation, a diuretic ("water pill") and a beta-blocker for her congestive heart failure, and an angiotensin converting enzyme inhibitor. While Mrs. Murphy has been generally compliant with her visits, Mary is somewhat concerned because she missed an appointment with him today – and as his assistant reviewed the practice management system, she noted that Mrs. Murphy also missed a telephone follow-up visit with the cardiologist, and a laboratory visit at which time a test for her anticoagulation status (ordered by the GP) and a chemistry profile (ordered by the cardiologist) were to be done. Mary reviews the most recent cardiology visit and becomes even more concerned when he sees that the cardiologist increased the dose of Mrs. Murphy's diuretic because of some shortness of breath, weight gain, and swelling during the last visit. Mary also notes that Mrs. Murphy was seen by the GP five days previously with a fever and a cough and was prescribed an antibiotic. The GP coordinated the anticoagulation test with the scheduled visit to Mary since she could see the appointment in the system and was prompted to consider the test by the clinical decision support program which reminded her of the potential for antibiotics to interact with anticoagulation medication. Mary calls Mrs. Murphy – and after several rings she picks up the phone. Mrs. Murphy is clearly somewhat out of breath but professes to be doing well. She indicates that her cough is better, but doesn't recall her appointment today or the scheduled laboratory tests. Mary knows that the practice management system automatically calls to remind patients one day in advance for every appointment – including important scheduled laboratory tests such as anticoagulation monitoring. The platform confirms that Mrs. Murphy was called and answered the phone yesterday afternoon.*
Mary decides that rather than upset her by calling an ambulance he will ask her granddaughter, who is her primary family caregiver, to take arrange a tele-visit in the afternoon at 3:00pm.

At 3:00 pm Mary clicks on the video link to Mrs. Murphy's home. She can see immediately on the screen that Mrs. Murphy has a high temperature, has gained and has an elevated blood pressure. Mary ask Mrs. Murphy and her granddaughter, to measure the whole blood glucose with the tool kit provided at the beginning of the Heartfaid program and following her instructions.
The recorded the whole blood glucose is significantly higher than her usual random glucose. Mary pans the video cam to Mrs. Murphy sitting on the edge of her bed, leaning forward and points out that Mrs. Murphy has some bruising on her arms and lower extremities and raises the potential that Mrs. Murphy may be over-anticoagulated. Murphy's condition has deteriorated in the past few hours. Mary decides that the best and safest way to quickly manage Mrs. Murphy multiple medical problems is to admit her to the hospital.
Mary documents her assessment and plan in the platform and then sends a clinical record summary to the hospital admitting department with his initial admitting orders via secure email. The email is also sent to the cardiologist and endocrinologist in the care team to alert them that Mrs. Murphy is to be admitted and requesting that the cardiologist assist in the management of what he expects to be complications related to worsening congestive heart failure. Mary is sent a secure email when Mrs. Murphy arrives at the hospital. Mrs. Murphy is taken to an assessment area where laboratory tests, an electrocardiogram and a chest x-ray are completed per Mary's orders. Shortly thereafter, Mary arrives to see Mrs. Murphy and accompanies her up to the hospital room. Murphy is treated for pneumonia, congestive heart failure and excess anticoagulation. The morning after her admission, a hospital discharge planner visits her and reviews her clinical record.
Mary informs the whole care team that Mrs. Murphy lives alone and sees the recent diagnosis of mild dementia suggesting a revise of care. The care team meeting will take place that afternoon, Mrs. Murphy's case is discussed and the team members decide to recommend a new remote monitoring program for Mrs. Murphy. At the time of discharge, Mrs. Murphy is accompanied home by Mary. When they arrive at Mrs. Murphy's apartment, a technician from the remote monitoring program is already waiting for them. While Mary reviews Mrs. Murphy's medication and self-management goals, the technician installs a wireless network hooked up to a secure internet connection. He places a scale in Mrs. Murphy's bathroom, a docking station for Mrs. Murphy's pill bottles, and a home glucose monitor – all connected wirelessly to the computer. Mary explains to Mrs. Murphy that the platform will monitor her condition through the computer. Mrs. Murphy doesn't understand how it all works, but she agrees to weigh herself in the morning, take her pills when she hears the reminder from the pill bottle docking station, and check her sugar in the morning. Mrs. Murphy agrees that her granddaughter will be informed about these new interventions.
A couple of days later, Mary get an automated alert via secure email that Mrs. Murphy has gained weight in the past two days.
Mary call Mrs. Murphy and after consulting the team, asks Mrs. Murphy to take an extra diuretic pill now and one at 6pm tonight. Via the internet, Mary is able to re-program the medication reminder system to prompt Mrs. Murphy to take the

correct dose at the correct time. At 6:30pm, Mary receives a notification from Mrs. Murphy's computer that the diuretic pill bottle has not been opened or moved since noon.Mary calls Mrs. Murphy who admits that she has been entertaining a friend and hadn't taken her pill yet, but promises to do so in the next few minutes.

These four scenarios illustrate how patient-centered care could be provided through the platform based on the advanced medical care model. In the above examples, patient-centered care is provided through a combination of face-to-face visits, telephone and e-mail consultations, and referrals to other health professionals as appropriate. Evidence-based clinical decision-making is aided by utilization of health information technology, a web-based decision-support tool that provides physicians with rapid, up-to-date, evidence-based guidance at the point of care. Electronic medical records, electronic prescribing, and open scheduling further add to the improvement of patient care and enable care to be provided more efficiently and in a manner that values the time of patient and physicians. This markedly contrasts with traditional patient care where patients often must schedule multiple office visits, evidence-based care is not always provided, avoidable errors occur, and where the time of patients and physicians is wasted.
All this is made possible by HEARTFAID which provides a distributed web based database with direct wireless connectivity and mobile agents linking all members of the virtual medical team.
In addition, thank to the empowered role of the care coordinator, less urgent situations can be solved without resorting to the cardiologist or other specialists.
This is made possible by guidelines that the collaborative care team has set up ex-ante.

5.2 The Integrated HEARTFAID Care model

The UML (Unified Modelling Language) has been used to identify roles and analyse and formalise collaboration scenario between virtual healthcare team members.
Using results of the analysis the collaborative system software will be developed.
To illustrate the process of care of Heart failure patients in the HEARTFAID setting, we present a simplified UML class diagram which identifies macro-processes and possible interactions.

Macro-processes:

– Referral of a new patient to home-care and relative assessment of the seriousness of the disease.
–Virtual care team creation / addition of members and Communication with the virtual team members (the team creation will account for the personal characteristic of the patient as supposed compliance, autonomy etc..)
– Given the severity of the disease, creation of the plan of care.
– Training and education of the patient enrolled in the program
– Follow-up

The relevant characteristic to take into account in the planning of the care model is the severity of the patients' conditions. With respect to the condition of the patient, the model will suggest an integration of actions and environments in which to deliver high quality care.
Figure 4 presents a simplified version of the three dimensions that should guide the care delivery plan.

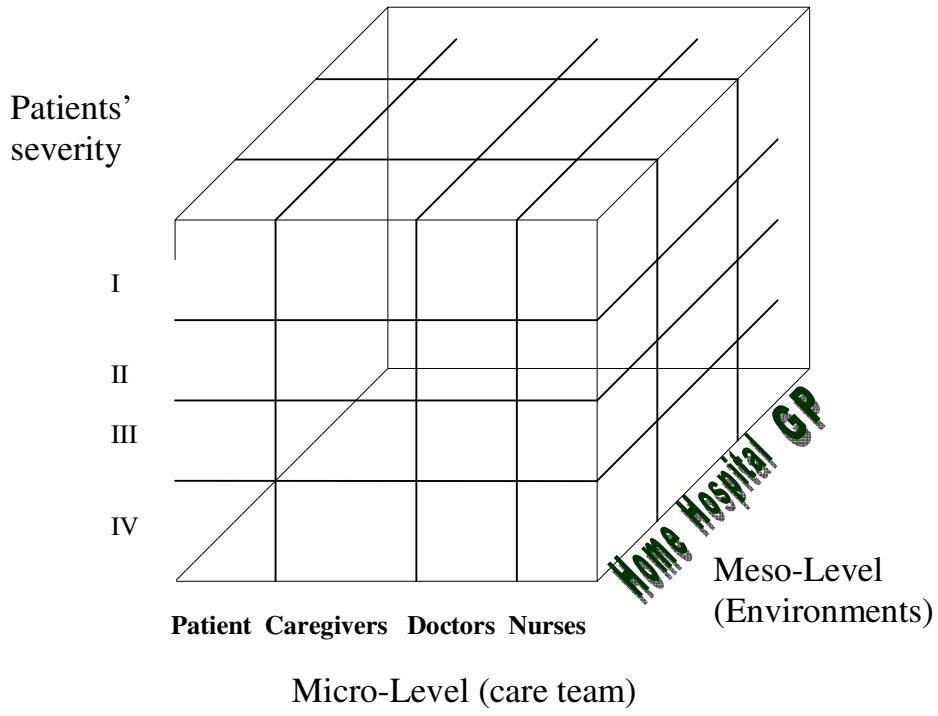

Figure 8: The cube of care

The aim of this deliverable is to clarify the framework and to give suggestions for effective implementation of this conceptual framework. In particular, the assessing process will put the patient in the proper class of disease, the creations of the plan of care will determine the environment in which to deliver care (meso-level) and the team creation will decide the importance of each component of the micro-level in the care team. The combination of the results of the first three processes will lead to a point in the cube of care. For each possible position in the aforementioned cube, the HEARTFAID project will standardize a plan of care.In the follow-up phase different pathways can occur. Thank to the flexibility and adaptability of the HEARTFAID care model, the plan of care will be update accordingly.

5.2.1 HEARTFAID Care Program UML diagrams

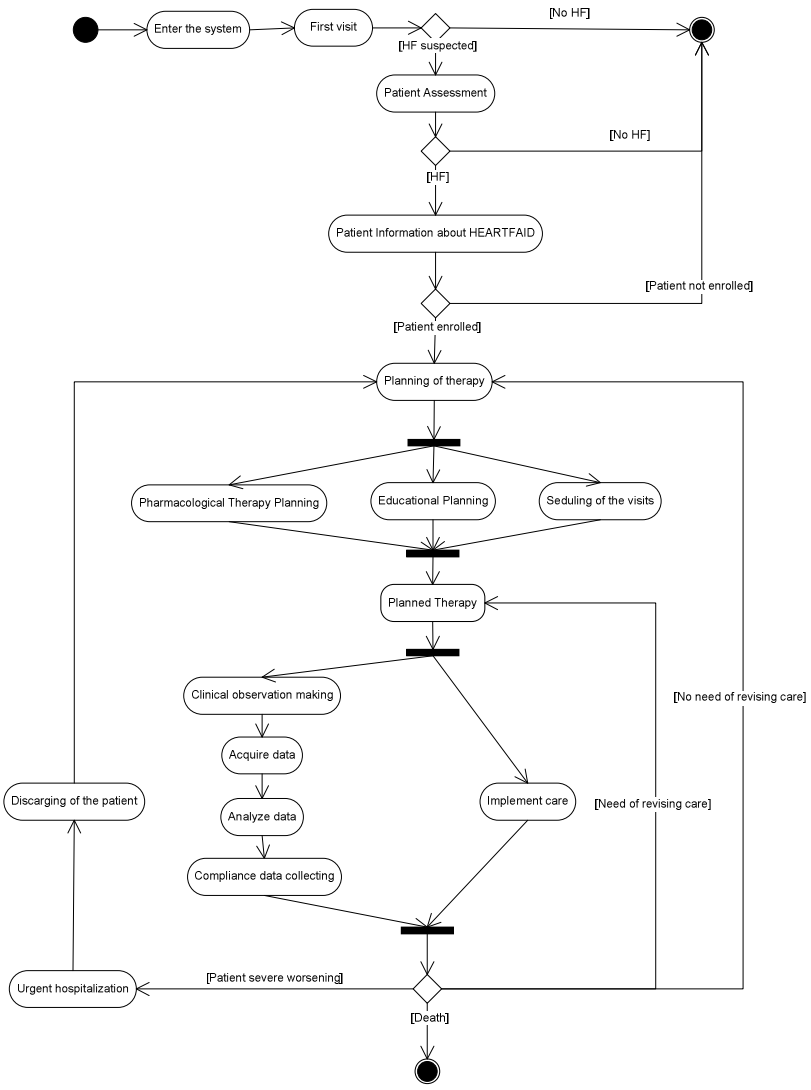

Figure 9: HEARTFAID Care Program Activity Diagram

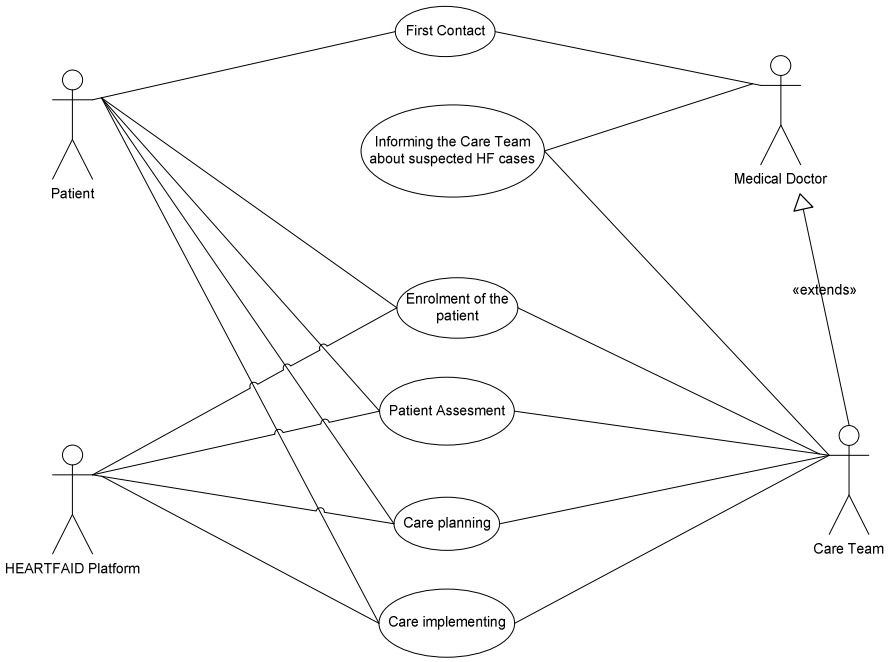

Figure 10: HEARTFAID Care Program General Use Case Diagram

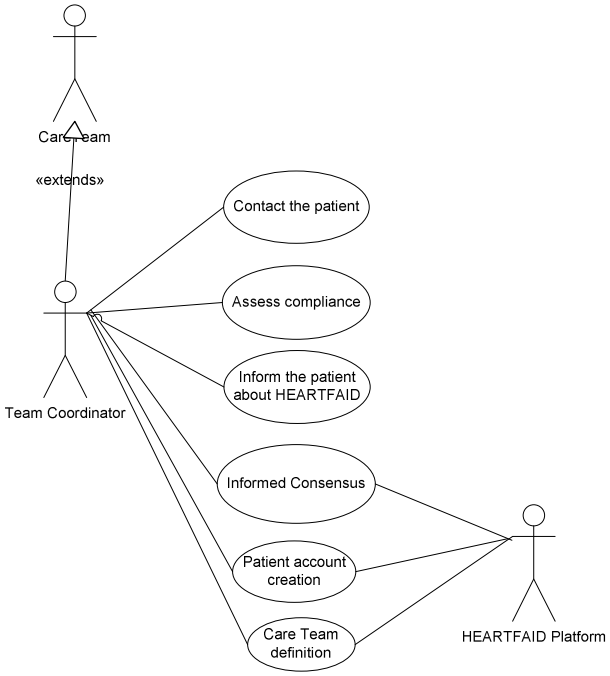

Figure 11: HEARTFAID Care Program Patient Enrolment

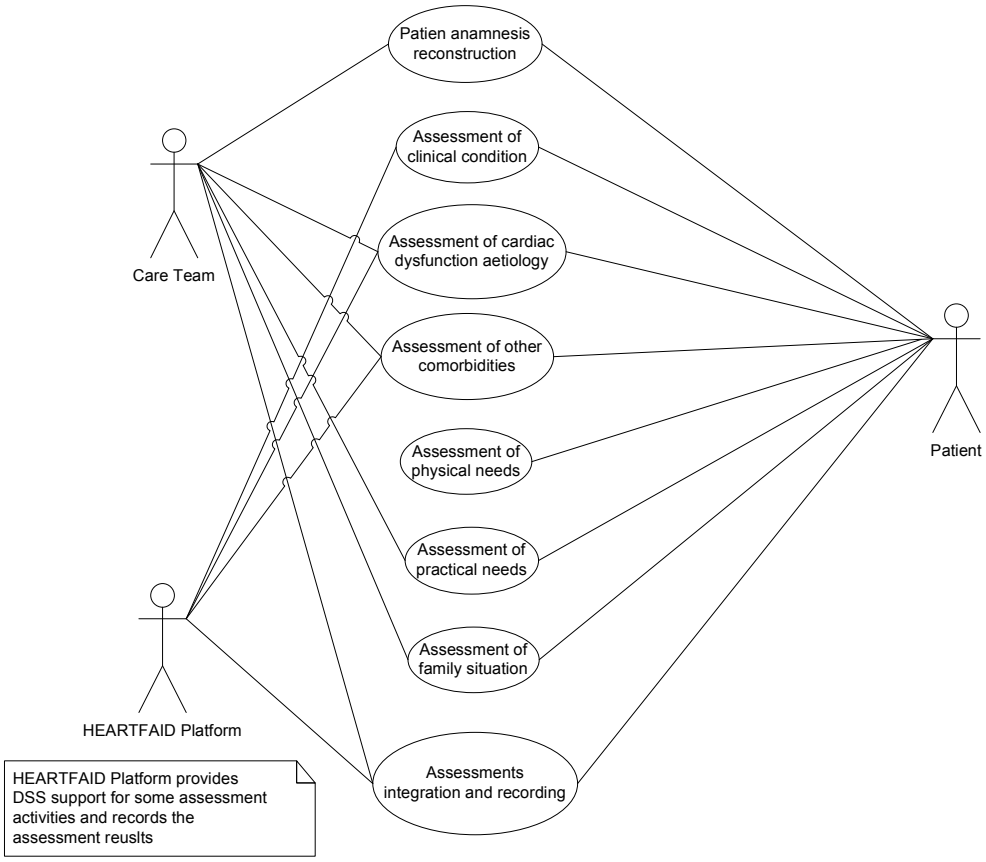

Figure 12: HEARTFAID Care Program Patient Assessment

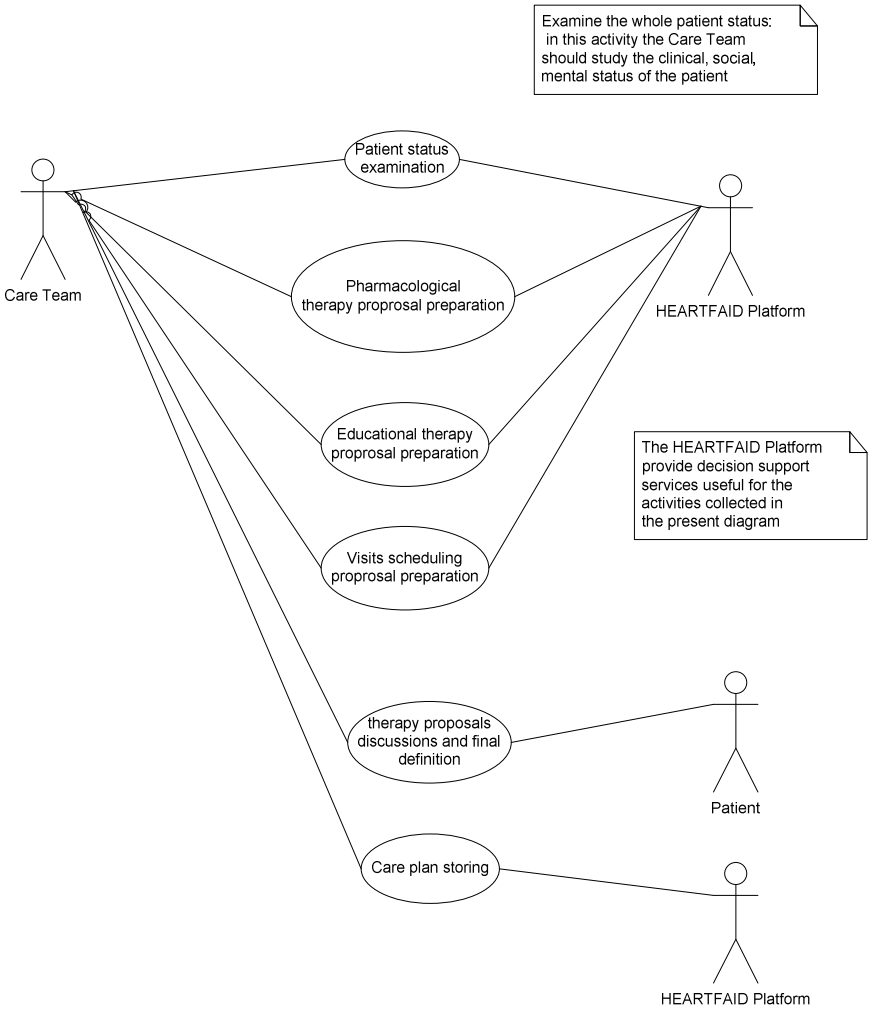

Figure 13: HEARTFAID Care Program Care Planning

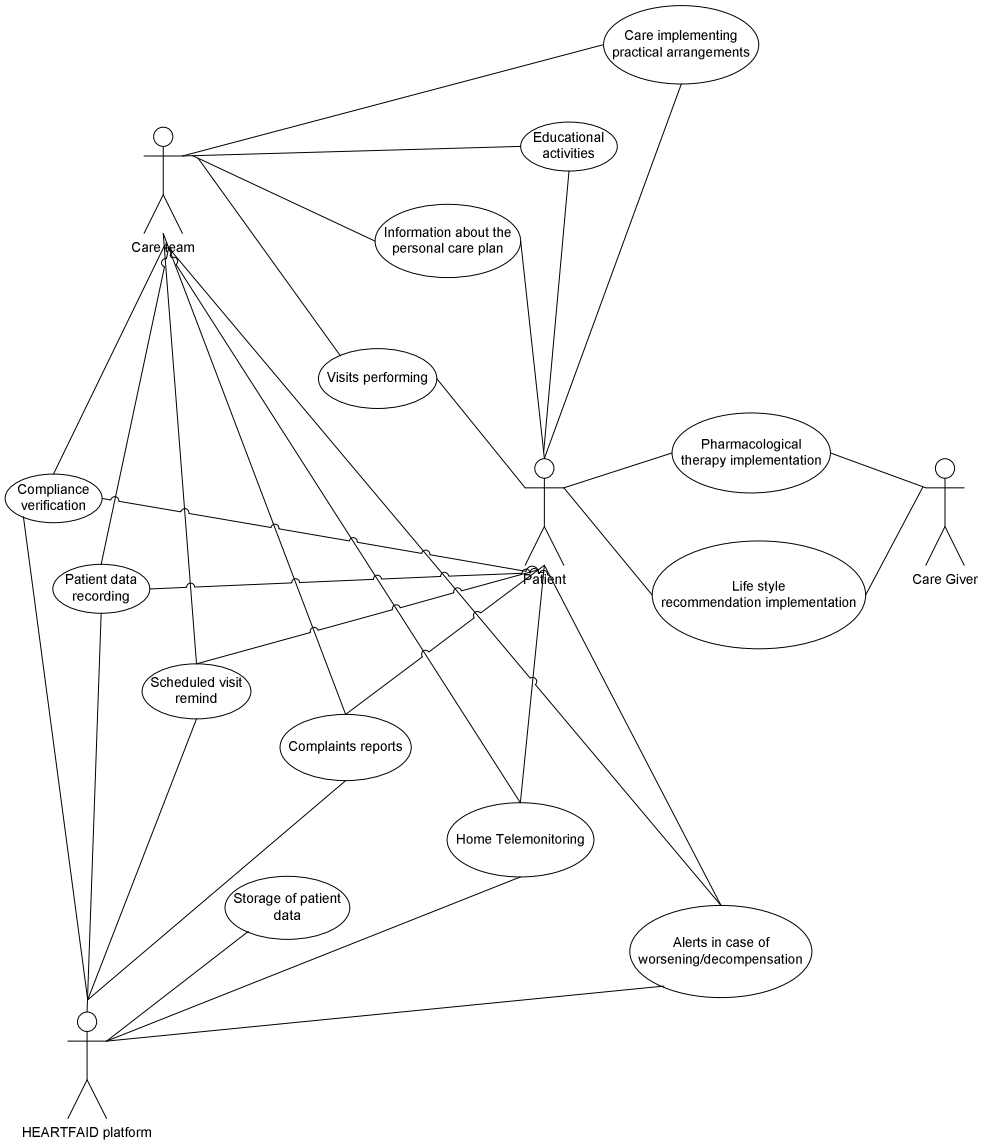

Figure 14: HEARTFAID Care Program Care Implementing

5.2.2 Referral of a new patient to home-care and relative assessment of the seriousness of the disease.

By the time a patient is enrolled in the heart failure management program, the diagnosis of heart failure, the first decisions about diagnostic procedures, and the initiations of standard therapies have usually been completed.
The essence of chronic heart failure management lies in the systematic approach to serial assessment and response to change on patient status.

The care team must alert to factors that may exacerbate underlying cardiac dysfunction.
As a patient is followed in the heart failure management program, there should be explicit assessment of a composite clinical stability.
The degree of instability influences decisions regarding further medical therapy and investigational protocols. Some heart failure patients simply require follow-up at regularly scheduled clinic visit, whereas others require additional follow-up via telephone or home visits.
Patients who demonstrate favourable clinical and psychological profiles will require less intensive follow-up to maximize outcomes. Other may require more intensive or high-level follow-up.
Therefore, patients must be identified early so that resources can be allocated appropriately.
Last, factors associated with a greater risk of heart failure exacerbation and hospital readmission must be identified.
The assessment of HF symptoms' severity (see also section 5.1 of D5) can be done following the New York Heart Association (NYHA) classification:

NYHA Class I → No limitation: ordinary physical exercise does not cause undue fatigue, dyspnoea, or palpitations.
NYHA Class II → Slight limitation of physical activity: comfortable at rest but ordinary activity results in fatigue, palpitations or dyspnoea.
NYHA Class III → Marked limitation of physical activity: comfortable at rest but less than ordinary activity results in symptoms.
NYHA Class IV → Unable to carry out any physical activity without discomfort: symptoms of heart failure are present even at rest with increased discomfort with any physical activity.

Irrespective of baseline status, by monitoring NYHA class (or HF symptoms/signs), patients conditions can be defined as being:
e.1 stable.
e.2 improving.
e.3 rapidly worsening (usually need hospital admission).
e.4 slowly worsening.

During the follow-up phase, patients' progress will be monitored by reassessing:
. NYHA Class
. symptoms and signs.
For the assessment of HF symptoms' severity see section 5.1 and 8.2.1 of D5.

5.2.3 Virtual team creation and management

In this part we discuss virtual teams and the dynamic virtual healthcare team creation for HEARTFAID.
The human-to-human computer-mediated interaction is particularly important since virtual teams are effective not only because of technological advancements

but also and most importantly because individuals are able to interact and thus constructively engage in knowledge sharing and creation in the increasingly emergent virtual work environments. In particular, we focus on interactivity among the key actors in medical virtual teams. In such virtual teams, where effective and quality patient management care are the expected outcomes, high levels of interactivity often need to be developed quickly and it is important that they last throughout the short duration of the interaction. During the last few years there is an increasing volume of literature on virtual organisations and virtual teams. This body of research generally agrees that virtual teams consist of a collection of geographically dispersed individuals who work on a joint project or common tasks and communicate electronically.

The building of a virtual team around a patient will normally start with the arrival of a referral form for a new patient. We emphasize that the patient registry contains not only clinical information but also personal, psychological and social information.

Once the care coordinator is assigned, the virtual team can be progressive and dynamically created, following the evolving needs. The care coordinator should have the major responsibility in the virtual team creation ad management. In particular during the HEARTFAID project the coordinator should contact, enrol and registry in the platform the patient relatives and, when possible, the patient general practitioner. In the table below is shown an example of creation of care team. The relative importance of each component of the team is indicated by a number from 1 to 5.

Patient Type	Self-management level	Care-coordinator	Caregivers	GP	Cardiologist	Nurse
I	good					
	bad					
II	good					
	bad					
III	good					
	bad					
IV	good					
	bad					

Table 2: Example of Care Team creation

To ensure shared information across settings and providers, and across time (from the initial patient contact, forward) integration and coordination are compulsory

Action Examples

a) Ensure that policies and plans are up to date and reflect consistent messages about heart failure conditions.

b) Develop patient registry and an information systems.

c) Develop information sharing strategies across HEARTFAID care model team.
d) Link different health care settings via a common information system.
e) Promote skills training for health care workers.
f) Where there are multipurpose health workers, study possibilities of reinforcing their decision-making via linkages with specialists.

5.2.4 Creation of the plan of care

It should be questioned what the optimal intensity of a heart failure management programme should be. Intensive education with only one follow-up visit does not seem sufficient to significantly reduce hospitalization or improve quality of life. The choice must be made by also considering the costs associated with the programme. The best strategy to adopt in any case seems to perform interventions based on the severity of the patient's condition.
In particular, there should be explicit assessment of a composite clinical stability. The degree of instability influences decisions regarding further medical therapy, such as drugs, referral back to a heart failure specialty program, and consideration of investigational protocols. In addition, the components of both physiological and psychosocial stability influence the allocation of valuable personnel time for further education, frequent telephone calls, and home visits.

5.2.5 Training and education

Because the management of heart failure conditions requires lifestyle and daily behaviour change, emphasis must be upon the patient's central role and responsibility in health care. Focusing on the patient in this way constitutes an important shift in current clinical practice.

Action Examples

a) Provide information about chronic conditions management to patients and families.
b) Include self-management support instruction during health care interactions.
c) Develop educational and skill-building workshops for patients and families on the management of heart failure conditions.
d) Use written educational materials to supplement self-management messages.
e) Provide patients and families access to information and self-management support outside the health care setting, via telephone or Internet.
f) Use computerized patient self-assessment for the generation of individualized self-management materials.
g) Provide accessible information and advice to patients on self-monitoring.
h) Implement NICE guidelines on drugs.

5.3 Technology platform design and implementation

Once the HEARTFAID model of care has been defined, it is worthwhile to point out some specific issues regarding the implementation of the HEARTFAD technology platform.
Firstly, since the team cannot be physically present at the point-of-care at all times, the technology platform has to ensure the communications among virtual team members via an internet based communication network solution. The philosophy adopted for modelling the networked solution should incorporate the paradigm shift in computing toward network centric, based on the observations that Internet offers global connectivity, and the World Wide Web offers access to distributed information. The system should employ this capability in conjunction with today's wireless connectivity for the realization of the virtual "always" present medical team. Mobility and Tele-presence come however, with certain cost. This cost is the limitations of wireless link; expensive, low bandwidth and low reliability (e.g. poor mobile network coverage). The cumulative effect of these limitations can be frequent disconnection and weak connectivity.
Secondly, the implementation of the technology platform should remark the HEARTFAID model of care organization, giving a central role to the team coordinator (e.g. the possibility to manage the accounts of the other team components) and reflecting the characteristics of patients trajectories (e.g. temporarily stratifying the patients visits, and so on).
Moreover the HEARTFAID platform should be adaptable to different devices, via several web interfaces studied in order to be visualized and used on smart phone, PDAs, PCs, etc.
It is also extremely important that the HEARTFAID platform supports the asynchronous and synchronous communication among the team members. In particular, a teleconsulting system should be provided, e.g. an email system structured in order to request a suggestion from an other team member about a specific patient; moreover, a service for real time communications should be also provided, e.g. a chat system.
Finally, an alert service should be also implemented in order to advise immediately the team coordinator or a specific team component if an event occurs. This service should be able to trace the physicians on mobile device as well, e.g. mobile phone.

5.3.1 Some open issues

• The improvement of the secure transaction, process and data archiving with the users being able to access only the levels that they have been authorized for, in a dependable, secure, legal, and trustworthy way.
• Improve TRUST, not only between the (virtual) team members, but also between the team members and the technology.
• Improving robustness of system (to commercial levels suitable for application), whilst ensuring that the open design of the HEARTFAID model of care is interoperable and compatible with other European systems, for data exchange.

• The expansion of the system, to be used from all healthcare providers that work on heart failure.
• Assess fully the national and European legal framework with e-health records, as well as prescription.
• Minimise system management costs.
• Adapt, customize and validate a sound clinical model and a service delivery model which is financially viable, secure, and legally acceptable, at a Pan-European basis.
• The expansion of the collaborative system for usage in other settings and its eventual commercialisation.
• Disseminate/promote at government and national policy-making level.

5.4 Sustainability of the Program

As it should be clear, the HEARTFAID care model is built up on a virtual organization framework. Organizations are formed, not for the sake of establishing organizations, but originate from having a common purpose of doing something.
The first things within the minds of those who establish the organizations are the objectives, as well as the ways to achieve these objectives.
The basic variables for the new model of organization are people, technology and processes of care. Once a common technology basis has been established, the virtual organization can be set up within any existing organization, irrespective of the country in which the structures involved in the virtual framework are placed.
The issue concerning the sustainability of the program is different.
One of the most important challenges facing any care management programme is how to fund and sustain the programme over the long term.
We strongly believe that the advanced medical home model presented so far offers an opportunity to demonstrate the widespread value of coordinated, patient-centred care, that is enabled by health information technology. Nevertheless, we are also convinced that a funding model is essential, in order the HEARTFAID program to be widely adopted.
In some countries, the government could be responsible for funding the program, in others countries, the primary sources of funding may be international or national donor agencies and faith-based organizations. Funding partnerships might also be developed between the government and nongovernmental donor agencies.
An analysis of potential funding mechanisms should be the subject of a deeper discussion of a policy level in each European country,
In light of these issues and depending on the country-specific health policy, the following questions should be addressed.
• Will funds be provided through general taxation from the national government?
• Will a form of prepaid financing be established? For example, will a social insurance scheme or other forms of community-based insurance mechanisms be put in place?

• Will a special premium be applied to clinical stakeholders, in order to contribute to the programme?
• Will community-based insurance schemes be introduced and, if so, how will they be managed and maintained?

Whatever the system will be, such a system should start with the identification of physicians and practices that can demonstrate consistent application of the key attributes described for the HEARTFAID care program, as well as accomplishment of training in the principles of the patient-centred based care.

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