HEARTFAID

D38 – Investigation on New Models for Health Care 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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D38 – Investigation on New Models for Health Care Delivery

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Short description
This document concerns the assessment and implementation of the organization and management models proposed in the Deliverable D8, by investigating and defining more effective and efficient Heart Failure Care Programs. Legal framework and reimbursement issues have also been addressed.

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1.0	First draft of the document	15/12/08
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Table of contents

Executive Summary

In this deliverable we detail the most relevant issues related to the results of the activities carried out within the Task 8.2.1 of HEARTFAID project.
The deliverable provides a general overview of the investigation and assessment activities concerning the development of innovative models for the organization and management of the health care delivery within the heart failure clinical domain. Issues related to legal framework and reimbursement schemes have also been addressed.

The contents of the document are organized as follows. After some background aspects related to the aims and results of HEARTFAID project, the section 2 presents the model of care, by giving basic motivations, development guiding principles, principal components of the model, implementation and assessment of the model by which the HEARTFAID platform can be effectively embedded. Interesting enough, some "future" HEARTFAID clinical scenarios are also presented.

The section 3 regards some general issues about legal frameworks and the indication of possible legal interventions specifically for the effective management of heart failure.

Finally, section 4 gives some hints on how define suitable reimbursement schemes for the effective deployment and application of the HEARTFAID services delivery.

1 Background

Health care government policy makers, health insurance companies, service providers and users' organizations are changing the face of health care delivery, taking place at different aspects around the world, requesting that the quality and the cost efficiency of the healthcare, the safety and the empowerment of the patients play an ever more crucial role in the management of the national and regional healthcare systems.

In particular, the following issues are increasing the pressure on healthcare systems:

- consumers are more and more demanding for high quality care;
- managers are struggling to deliver health care services at reasonable costs while there is an increasing diffusion of chronic diseases as well as, due to the progressive ageing of the population, a rising number of patients that need long-term continuous health assistance;
- clinicians are placing increasing emphasis on the practice of evidence-based medicine whereas citizens are improving their sensitivity regarding the clinical risk management;
- health care systems are seeking to meet these demands by operating into a framework of continuous quality improvement.

Improving health care quality while reducing costs requires the elimination of unintended and unnecessary overhead in the entire care process (prevention – diagnosis – prognosis – therapy) and the application of new and more accurate procedures for the clinical risk management. To this end, eHealth technologies and applications can play an ever greater and crucial role. In fact, during the last years we have assisted to an increasing development of high technological effective solutions (such as Electronic Medical Records and Clinical Decision Support System prototypes) to foster evidence based medicine and best clinical practices. These solutions have the potentialities to help in reducing unreliability and errors by improving effectiveness and efficiency.

In this context, the great challenge faced by HEARTFAID project consists in providing an integrated and holistic approach based on the continuity and personalization of patient care, in devising and developing optimal health care procedures and workflows based on scientific evidence and yet consistent with best practice, thus defining effective personalized care pathways.

In order to meet these goals, the project has faced the following major issues:

- integration of different Healthcare environments in order to have a unique vision of the patient;

- integration of Wearable and Portable Biomedical Sensors through Wireless Data Communication infrastructure, in order to improve the treatment and management of the diseases outside healthcare centres;
- integration of the Biomedical Knowledge generated from the patient during his/her contacts with different health care environments (implementing technologies such as Biomedical Data Warehousing and Management, Decision Making and Statistical Inference, Knowledge Discovery in Databases, Medical Ontologies and Knowledge Representation);
- definition of new end-user services based on the integrated vision of the patient and on the possibility to recover information from multiple sources (such as Web-based services accessible anywhere and anytime);
- provision to both medical personnel and decision makers of new and advanced mechanisms for decision support (including advanced Biomedical Signal and Image Processing and Decision Support Systems**,** such as computerized clinical practice guidelines).

In general, HEARTFAID strategic impact mainly regards the improvement of the quality of life of Heart Failure patients and the decreasing of the social and economic costs. In particular, HEARTFAID services are mainly finalized to bring substantial increase of the care quality of the individual patient, by ensuring the possibility to personalize the follow-up by having a continuous monitoring and assistance of the patient.

On the other hand, the optimization of the treatment processes may assure the control and reduction of the overall economic and social costs of medical care, mainly by improving the prevention of acute events and support crisis management and, hence, by decreasing the frequency of hospital admissions.

Under this respect, the HEARTFAID platform turns out to be an effective and efficient support of innovative Patient-Centric Heart Failure Care Management Programs. This can be organized by the suitable involvement and competence integration of different health care environments (Home Care, Primary Care, Secondary Care) and operators (patients, care givers, general practitioner, medical doctors, nurses).

In fact, the HEARTFAID platform has been designed following an integrated and holistic approach with the precise goal to implement and activate “virtuous and continuous health care closed-loops” (Fig.1). In particular, the platform support the integration and interoperability, in a cooperative and collaborative “patient centric” context, of the main health care environments, characterized by the relevant health care operators with their roles, responsibilities and functions.

Fig. 1 – Virtuous loops supported by the HEARTFAID platform

On the basis of what has been already proposed and described in the Deliverable D8, it is the main aim of this deliverable to discuss, assess and implement a new model of health care delivery within the heart failure domain, which could easily allow to define more effective and efficient heart failure care programs. This eventually lead to better evaluate the applicability and utility of the HEARTFAID services.
Moreover, some issues about legal framework and reimbursement schemes will also be addressed.

2 Model of Health Care Delivery for Heart Failure

2.1 Motivations

It is well known that heart failure is a complex clinical syndrome with typical symptoms (e.g. dyspnoea, fatigue) that can occur at rest or on effort, and is characterised by objective evidence of an underlying structural abnormality or cardiac dysfunction that impairs the ability of the ventricle to fill with or eject blood (particularly during physical activity). It is important to highlight that the typical trajectory of the condition can be described as cyclical with progressive clinical instability and worsening.

The most common causes of chronic heart failure are coronary heart disease and prior myocardial infarction, hypertension and diabetes. A number of the causes of heart failure, such as coronary heart disease, are preventable. On the other hand, a significant proportion of the burden of coronary heart disease is attributed to the following risk factors: unhealthy diet, physical inactivity, obesity, diabetes, tobacco use and harmful alcohol use. It is important to highlight that hypertension is a major biomedical risk factor for heart failure.

In terms of mobilization of resources and in contrast to other pathological conditions, heart failure is associated with high levels of health service utilisation across the various settings of care (even though, it is quite difficult retrieving reliable data specific to heart failure service provision beyond hospitalisation data). Hospitalisation data does not reflect the true burden of disease or demand for services, particularly in primary care; however, a large component of the cost incurred in treatment of heart failure is expended on hospital-based care.

Very commonly, people with conditions as heart failure access health care services from primary, tertiary and community providers across a range of settings, at different time in the progression of the disease. Moreover, many individuals with heart failure have also comorbidities and effective management of these conditions is an important component of the overall care pathway.

Appropriately supported by the most recent available clinical guidelines and protocols (ESC, ACC/AHA), there is a wide range of heart failure services across the continuity of care, that are delivered by public and private health care providers.

Notwithstanding, the practical clinical experience and the state-of-the-art literature highlight many “open issues” in terms of inefficiency and drawbacks, from patient, health care operators and providers perspectives.

From patient perspective, common issues (among the other) are reported in the following.

- Limited links and interactions between hospitals, General Practitioners and other health professionals, and limited information sharing, communication and coordination.

- Difficulties getting support and advice after hours, and delays getting appointments with General Practitioners and specialists.

- Lack of suitable and effective home care support.

- Delayed referral to appropriate services, as well as limited patient and carer awareness of the services and programs that are available for heart failure management and support.

- Lack of emotional and peer support to enable people with heart failure, carers and their families to come to terms with how to deal with a major illness.

- Variable care coordination and established linkages between heart failure services and peripheral and small hospitals.

- Information, educational and empowerment resources typically difficult to understand.

Yet from patient perspective, some possible areas for improvement can be the following:

- Improve care cooperation and communication between health services and health professionals.

- Provide after hours telephone support and advice, which is available for people who are worried or slightly unwell but not sick enough to go to hospital.

- Expand community-based group rehabilitation programs and include information and support for people with heart failure completing a home based rehabilitation program.

- Improve community awareness of the condition and the symptoms of heart failure, which can be similar to the symptoms of other conditions such as asthma.

- Improve access to quality patient information resources, particularly about medications.

- Provide nurse education sessions mainly in peripheral centres to complement existing specialist clinics.

- Encourage peer support for people with heart failure and carers to address the emotional components of care and facilitate the sharing of ideas and solutions.

From a health professional or provider perspective, typically the following gaps are perceived.

- Late diagnosis of and/or under-treatment of hypertension.
- Variable and poorly accurate levels of health assessment for those at risk.
- Diagnostic delay due to under-recognition of early heart failure symptoms by patients themselves and health professionals. A large proportion are typically diagnosed at hospital presentation requiring admission, but have had symptoms for many months.
- In some cases, late referral for echocardiography and limited capacity to quickly perform public echocardiography.
- Inadequate support for all people with heart failure to reach target doses of heart failure medications and to manage changing requirements for diuretic medication.
- Lack of specialised knowledge on heart failure management resulting from limited educational opportunities and a lack of coordinated clinical leadership. Lack of formalised medical specialist consultancy services for chronic disease with a broad scope of practice which includes heart failure. This may contribute to a lack of consistency in care delivered by health professionals who may deal with people with heart failure including, but not limited to, community health professionals, general practice, geriatricians and general physicians.
- Limited resources and capacity of services providing heart failure care to enable networked and integrated heart failure management across the regional health care system.
- Lack of community programs for people with moderate to severe heart failure.
- Limited capacity for self-management programs promoting lifestyle modification for those with, or at risk of, cardiovascular disease.
- Limited support for people with heart failure who experience barriers accessing care, including those associated with cost, transport and time.
- In many cases, services are concentrated within the metropolitan area, with few programs available in peripheral regions. In addition, there is less frequent use of recommended diagnostic methods and pharmacological treatments among people with heart failure in peripheral areas.
- Lack of care coordination of people with heart failure, particularly those with multiple co-morbidities and for inpatients post discharge. This may result in numerous patient appointments in a given period of time. Variable use of formalised and agreed care management plans, leading to poor understanding of

health professional and patient responsibilities. Variable use of formalised general practice recall registers for monitoring and follow up of people with heart failure.

- Lack of locally endorsed and comprehensive implementation of guidelines for the prevention, detection and management of heart failure. Similarly, lack of awareness of defined guidelines and processes for referral.

- A better understanding of the local epidemiology of heart failure is required to inform planning of services for heart failure and demand management.

- Other examples include, but are not limited to, continuing research into appropriate use of current and new treatment modalities, optimal service delivery and the benefits of echocardiography screening.

The "current" Heart Failure Patient Scenario

Heart failure patients have a wide range of experiences. Using references from actual patient stories, the story of 'George' has been developed to capture some of the common experiences of people with heart failure.

George, a 69 year old man with type II diabetes, was experiencing symptoms of breathing difficulties when he exerted himself.

> *"I decided I had better go and see my GP as when I walked I felt like my breathing was tight. He listened to what I said, put the stethoscope on my chest and back, and to my surprise told me he thought it was my heart. The GP started me on some tablets, gave me advice about salt and exercise, and asked me to make an appointment to get my blood pressure checked soon.*
> *At the beginning the medication seemed to work so I delayed the follow-up appointment because I felt good. I don't have private health insurance and I felt ok so I thought the wait wouldn't hurt; after all, the problem seemed to have improved.*
> *I must say, I was a little worried that he thought it was my heart, however my next- door-neighbour had a heart attack and mine was nothing like that – I had no pain at all and certainly did not need to go to hospital.*
> *Two weeks later I woke up in the middle of the night feeling like I could not get any air. I had never felt like this before and I was scared. I sat up and began to feel a little better after about half an hour. I tried to go back to sleep however every time I lay down the feeling seemed to want to come back, so I propped myself up against some pillows and waited until morning.*
> *My breathing was not any better next morning, and worse still I could feel my heart beating hard in my chest. I called the GP but he was booked up all day. My wife was annoyed I had cancelled the follow-up appointment. I felt breathless when I moved around and even sitting still so I decided to go to emergency."*

George waited for 10 hours in the emergency department before getting a hospital bed. Inpatient assessment included an echocardiogram, cardiac angiogram and

medications and he was given education on how to manage his heart failure on discharge. When George was discharged he went to see his GP for repeat prescriptions. His GP had not received a phone-call or discharge letter from the hospital. George mentioned that the nurses and doctors in hospital had told him that following discharge he would have an increase in the dose of some of his medications. The GP was reluctant to change the dose and advised George that the Cardiologist would do this when George attended the outpatient appointment at the hospital in six week's time.

2.2 Description of the Heart Failure Care Model

On the basis of what has been presented in the Deliverable D8 – "Definition and Formulation of the Organization and Management Models for the Health Care Delivery", and taking into account some practical experiences and results described in the current scientific literature, in the following we investigate on a innovative model of health care delivery for the optimal management of heart failure patients.

The model takes a holistic patient-centred approach to the provision of services for people with heart failure. It outlines best practice through the application of a set of service principles across identified clinical streams and patient flow continuums. In particular, the model aims to ensure people receive the right care, at the right time, by the right team and in the right place.

Guiding Principles

General guiding principles are the following.

- Primary and secondary prevention and health promotion to support healthy lifestyles and risk reduction in support of self-management in the well population. Maximise the opportunities for early identification and modification of risk, with particular attention to identification and treatment of hypertension.

- Early detection, assessment and management of heart failure in order to improve quality of life, slow the progression of the condition, and reduce invasive treatments and preventable hospital admissions. Early engagement of appropriate community-based services with seamless transition to specialist services.

- Integration between regional health care systems and health professionals through: agreed heart failure care planning; application of shared care models; ICT support; comprehensive community-based services, in line with an endorsed set of evidence-based guidelines and patient pathways.

- Provision of education to people with heart failure and carers based on self-management principles to enable maximisation of symptom control, health and wellbeing.

- Building the capacity of the workforce to meet the need to manage the complex requirements of people with heart failure within the community. This includes education and training of the health workforce within both the community and health service sectors, with particular attention to peripheral region practitioners.

- Delivery of optimal care in line with evidence-based guidelines, development and implementation of new initiatives to meet service delivery gaps, and future research supported by integrated clinical information systems.

Basically, the model emphasises primary risk reduction and early assessment, detection and management of heart failure.

The key objectives of the primary risk reduction component are to focus on individual and population based approaches:

- to prevent risk factors for heart failure;

- to prevent conditions occurring which lead to heart failure;

- to increase awareness of the causes and risk factors for heart failure;

- to deliver health assessment for those at risk;

- to provide lifestyle modification advice and programs.

Prevention needs to be included across the continuum of care for people at risk of or with chronic diseases such as heart disease. Prevention approaches should target the behavioural and biomedical risk factors for heart disease, many of which are shared with other chronic diseases such as type 2 diabetes, chronic respiratory and renal diseases.

At the population level, to be effective, preventative approaches targeting healthy lifestyle (particularly smoking, poor diet and physical inactivity) and risk factors influenced by lifestyle, should include an integrated comprehensive range of initiatives, including social marketing campaigns, education and skill development, environmental interventions, legislation and organisational policy, sponsorship and community development. Environmental factors such as access to healthy food, food labelling, advertising of unhealthy foods, urban design and access to physical activity opportunities can have a significant impact on people's ability to adopt healthier lifestyles whether well, at risk or with early disease.

At the individual level, interactions should include the provision of preventative advice about the links between lifestyle and risk, early detection of risk (associated with lifestyle, family history and biomedical screening), and early intervention. Systems need to be put in place to support opportunistic and planned screening in line with endorsed evidence-based guidelines such as blood pressure screening for hypertension. By addressing the multiple lifestyle risk factors for people identified as at risk, processes will be in place to support health professional referral to community programs and to access appropriate information.

The key objectives of the assessment, detection and management component are:

- To ensure that persons with elevated risk and/or symptoms of heart failure are screened and assessed.

- To provide a definitive diagnosis of heart failure.

- To provide secondary prevention and rehabilitation services, guided by a personalized care management plan and enable people with heart failure to self-manage their condition.

- To improve the quality of life for people with heart failure, with no avoidable health care utilisation.

Detection and assessment of suspected heart failure is important to identify early people with elevated risk and/or symptoms of heart failure. Echocardiography is recommended for all people with suspected heart failure. Given the emphasis on the echocardiogram, health professionals should be alerted to using echocardiography as an initial assessment tool when suspecting a potential diagnosis of heart failure. Echocardiography providers will ideally also have processes in place to ensure echocardiograms can be undertaken and reported in a timely fashion.

If diagnosis is not clear following initial clinical assessment, and an echocardiogram cannot be performed in a timely fashion, then measurement of B-type natriuretic peptide (BNP) or n-terminal proBNP may be considered.

In terms of clinical management, all people with heart failure should have access to appropriate services that are ideally delivered locally via an integrated and coordinated network that delivers care in line with an endorsed set of evidence-based guidelines and patient pathways. To this end, the model defines the basic elements of heart failure care for service provision.

Services for the management of heart failure will be guided by the care management plan and current evidence-based guidelines and individualised for

people with heart failure's needs. Services for the management of heart failure should comprise:

- General Practitioner - Care planning and coordination, medical management and symptom review.

- Specialist Cardiologists, General Physicians and Geriatricians – Specialist management and symptom review.

- Multi-disciplinary services - Ideally delivered locally, either as a part of a broader community-based chronic disease program or specific community-based heart failure service or a hospital-based program for the smaller group of people with heart failure with more difficult to manage heart failure or complex comorbidities.

The use of Information and Communication Technology for patient-level health information data collection and sharing will underpin communication and care coordination across public hospital and community health providers in the longer term.

Heart failure management is multi-disciplinary in nature, and requires a skilled and sustainable workforce to meet the needs of people with heart failure. Designated heart failure services should be supported to provide a clinical leadership role. Educational opportunities for other members of the care team to improve their specialised knowledge on heart failure management in line with evidence-based guidelines should be in place.

The members of the team working together to provide care for people with heart failure may include but not be limited to: Cardiologists, Community Nurse, Clinical Psychologists, Dieticians, Exercise Physiologists, General Physicians, General Practitioners, Geriatricians, Home care providers, Nurses, Palliative Care Specialists, Physiotherapists, Social Workers.

Under the model each person with heart failure receives appropriate services and care, but there is flexibility in who and where the components are delivered. This allows optimisation of workforce as role definitions change and health professionals gain competencies in new areas. It promotes appropriate upskilling in the smaller groups of health professionals in rural and remote areas.

Fundamental Elements

In the following, we list the basic elements of Heart Failure Care Model.

- **Medical Management and Symptom Review**

People with heart failure require ongoing medical management and symptom review. This may be delivered by General Practitioners, Cardiologists, General

Physicians, Geriatricians, Palliative Care Physicians and/or Nurse Practitioners, and involves:

- Identification and management of reversible cardiac causes of heart failure (where appropriate).
- Medication and symptom review, aiming to achieve target doses of heart failure medication such as ACE/ARB Inhibitors and Beta-Blockers in line with evidence-based guidelines and changing requirements for diuretic medication.
- Referral for investigation.
- Care management plan development.
- Referral to secondary prevention and rehabilitation services.

- **Care Management Planning**

All health professionals, and in particular General Practitioners, should initiate the development of a care management plan to guide heart failure management, in collaboration with the person with heart failure, their carer and family. A care management plan identifies all problems requiring attention (including comorbidities), and outlines the person responsible for addressing each problem. Care management plans are personalized, patient-centred, multi-disciplinary, and written in lay-person terms.

Components of care management plans should include problem types (such as lifestyle changes, personal care, home duties, meal preparation and transport), management goals, treatment plans, the person responsible, relevant contact details and review person and time. When a care management plan is initiated, it should be developed gradually and kept simple and short to ensure that people with heart failure remain motivated to achieve their goals. A copy of the care management plan should be given to the patient and/or carer and circulated to each health care provider identified within the plan.

Hospital based care management planning for inpatients can be supported by automated processes which enable a copy of the care management plan to be sent with the medical discharge letter via email. The medical discharge letter and care management plan complement each other and provide the General Practitioner and other health professionals with a well rounded summary of a patient's needs and treatment plan.

- **Patient, Carer and Family Education**

Information should be provided to people with heart failure, and their carers, to enable them to be informed and to self-manage their condition. Patient education should include information on the condition; lifestyle changes; medications, treatments and devices; potential course of the condition and the service directory for heart failure services. The carers and family of people with heart failure should also receive tailored education with a focus on additional supports and services available. To meet the educational objectives of people with heart failure and carers, there should be standardised heart failure educational resources available. Complementary education sessions should be flexible and available after hours for people with heart failure and carers that work. The development of educational

resources should be done with input from people with heart failure and carers to ensure relevance.

- **Self-Management**

Self-management involves people with heart failure engaging in activities that protect and promote health, and is relevant to people with heart failure. Self-management entails engaging in activities that promote health; managing a chronic condition by monitoring signs and symptoms; dealing with the effect of a chronic condition on personal well-being and interpersonal relationships; and following a treatment plan.

- **Management of Comorbidities**

Many people with heart failure have comorbid conditions such as atrial fibrillation, diabetes, obesity and renal diseases, just to name a few. Recognition and management of comorbidities is an important component of overall care. All members of the team providing care for heart failure, including the person with heart failure's GP, should be aware of comorbidities, management goals and the health professionals involved in the person with heart failure's care. Good communication and care management planning underpins this. Likewise health professionals treating people with heart failure for other conditions need to be aware of the heart failure diagnosis, care management plan and to liaise with members of the heart failure care team appropriately.
All components of care for people with heart failure with comorbidities should be coordinated. Opportunities to combine generic chronic disease care exist and these should be maximised to best use a person with heart failure's time, ability and desire to access programs.

- **Exercise Options**

It is recommended that when medically stable, all people with heart failure should be referred to a specifically designed physical activity program. Hospital- and community-based exercise options should be available for people with heart failure depending on their level of risk.

- **Telephone Support, Coaching and Medication Titration**

Telephone support, coaching and medication titration complements other components of care and provides people with heart failure with additional support. Telephone support, coaching and medication titration should be nurse led and be delivered within operating hours with some coverage out of hours. Designated heart failure services will provide tailored telephone support for enrolled people with heart failure, including medication titration and advice for those with increasing symptoms.

- **Home Medication Reviews**

People with heart failure, particularly those with comorbidities, may take a number of medications and may benefit from Home Medication Reviews. The goal of Home Medication Reviews is to maximise an individual person with heart

failure's benefit from their medication regimen through a team approach involving the GP and the person with heart failure's preferred community pharmacy. The Home Medication Review process involves the person with heart failure and their carer, the GP, the pharmacist from the person with heart failure's preferred community pharmacy and other members of the health care team that are identified as appropriate.

- **Psychosocial and Carers Support**

Heart failure places enormous stress on people with heart failure and their carers, family and significant others. People with heart failure occasionally suffer from depression and anxiety, and the provision of psychosocial support aims to improve mental health, which may also improve heart failure prognosis. During an informal or formal health professional assessment of people with heart failure, psychosocial issues should be identified, and people with heart failure should be educated on coping mechanisms and undergo additional therapies. Some people may benefit from specific Clinical Psychologist input.

- **ICT infrastructures, Electronic Devices, Remote Monitoring (Tele-Health)**

Typically, heart failure conditions last for a long period of time or is marked by frequent recurrence. According to the Information Technology Association of America E-Health Committee "Today, 45% of the American population is affected by one or more chronic illnesses. Studies show that caring for people with chronic disease consumes approximately 78% of all healthcare spending in the United States-more than $1 trillion annually". The World Health Organization projects that chronic disease will be the leading cause of disability by 2020 and will be the most expensive problem facing healthcare systems. Researchers have begun to conclude that ICT infrastructures, electronic devices and remote monitoring work best with those patients who need the most frequent contact, such as those with chronic diseases.

Patients with chronic diseases require more frequent visits to the emergency room, incur a higher rate of hospitalizations, have a higher risk of being institutionalized, and are financially more costly than the 'average' patient. On discharge from the hospital to their homes, patients with chronic disease often need a great deal of support including compliance with medications and treatments, improved health behavior coaching, and symptom management.

Tele-Health technology allows care providers to monitor the patient daily and make real-time identifications and interventions in the care of their patients. These early interventions are vital to the improvement of symptom management and reduction in unnecessary health care encounters such as hospitalization or emergency room visits. Remote monitoring can lead to better symptom management, improved health behaviors, and compliance with medications and treatments.

However, it is important to point out that a proper business model for Tele-Health technologies will be about much more than just vital parameters measurements. It is essential that telehealthcare involve regular communications be it over

videoconferencing or teleconferencing or other methods. Particularly for older people, maintenance of the doctor/patient relationship needs to be kept as 'personal' as possible and not become a barrier to the human to human interface.

The Patient Scenario under the Model of Health Care Delivery

The implementation of the principles and elements of the model will make direct improvements to the experiences of people with heart failure. The patient journey will be individual depending on the evidence-based guidelines applied at the time, the severity of heart failure, the response to treatment, services available locally and patient preferences.

The story of 'George', has been revised to demonstrate how his experience and outcomes could have improved within the proposed model of care.

George, a 69 year old man with type II diabetes, was experiencing symptoms of breathing difficulties when he exerted himself.
George was seen by his GP who treated his symptoms, ordered relevant tests including an echocardiogram and after reviewing these results, referred him to a Cardiologist for advice.
Following assessment the Cardiologist talked to him about the diagnosis of heart failure, added more medications to his treatment, discussed the plan for further investigations and communicated this promptly to George's GP via secure electronic means.
George was admitted to hospital for an angiogram and the heart failure service nurse visited him and talked to him about how he was feeling with this new diagnosis, as well as options for education and exercise in the community. The option of telephone support and follow-up, through a coaching service, was discussed; however, George wished to attend a group as he wanted to meet others with the same heart condition as himself.
George was referred to a community-based service delivering heart failure care following his discharge from hospital to help monitor his progress, ensure that his cardiac medications were at appropriate doses, and develop a management plan for George's heart failure and diabetes in consultation with his GP and Cardiologist. George was also told that he was able to bring his wife along to appointments and education sessions and that his wife could be provided with support if she needed it.
Within weeks of discharge he underwent assessment to determine his physical and psychosocial health needs, attended education sessions about heart failure and also type 2 diabetes and entered an exercise program. George's GP was regularly updated. On completion of the exercise program George did not feel ready to exercise independently so the community physiotherapist suggested referral to the Community Physiotherapy Service to see him weekly while he built up his own home exercise regime.

George's GP arranged a Home Medicine Review in which an accredited community pharmacist visited George and his wife at home to review his medication therapy and reported recommendations back to his GP.
George continues to have regular check ups with his GP and six monthly reviews with his Cardiologist, who are both aware of the continuing management plan and responsibilities via the care plan and can communicate changes efficiently. Although he has ceased contact with the community-based service following maximisation of his medical therapy and completion of his sessions, he knows how he can easily access assistance if he develops any further heart failure signs or symptoms, concerns or worries.

2.3 Implementing and Assessing the Model with the support of HEARTFAID platform

The proposed model of care with the support of HEARTFAID platform implies the suitable integration of methods, programmes and ICT technologies (of proved effectiveness), with the aim to improve the clinical management of heart failure conditions. The innovative implementation of the model consists in the integration of the described fundamental elements effectively supported by the services provided by the technological platform.

Moreover, within a new conceptualizations of heart failure conditions, the quality of life of patient is thought as 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 of care. All settings need to be linked and each is integrally important to the other. Each component of each settings has important roles to play in improving outcomes for chronic problems.

Possible strategies for implementation of the model of care differ in terms of resource requirements and expected timeframe. Given this, a possible three phases strategy for implementation is defined as the following:

Phase 1: Achievable within existing resources and current service provision.

Phase 2: Require further planning and development.

Phase 3: Require additional human resources, funding and endorsement.

Phase 1: Achievable within current service delivery model and existing resources

- Endorse the Model of Care for Heart Failure.
- Review patient pathways between general practitioners, specialists and allied heath professionals.
- Review current evidence-based protocols and patient pathways for the prevention, detection and management of heart failure within the regional health systems.
- Promote the use of care management planning, particularly within General Practice.
- Promote the use of Home Medication Reviews for people with heart failure, particularly those with comorbidities.
- Review existing telephone support services available for people with heart failure and health professionals within the regional health systems.
- Review of current information, education and resource materials for people with heart failure and their families.
- Formalise current linkages and networks between designated heart failure services and the regional health care systems, with a view to improving communication, staff development and support, and shared care models.
- Promote self-management training for health professionals working with people with heart failure.
- Review current population health and health promotion initiatives for hypertension management.
- Identify research needs to inform and enhance heart failure care within the local regional health system.

Phase 2: Require further planning and development

- Endorse and implement appropriate current evidence-based protocols and patient pathways for the prevention, detection and management of heart failure within the regional health systems.

- Formalise partnerships or links between services and organisations in order to develop an integrated network with agreed heart failure care planning, consistent use of current and evidence-based protocols and patient pathways, and seamless transfer as appropriate.

- Support the development of Information and Communication Technology to enable multi-disciplinary care planning.

- Develop a strategy for the prevention of cardiovascular disease to guide integrated program and service planning.

Phase 3: Require additional human resources, funding and endorsement

Ensure that all people with heart failure have access to appropriate, multi-disciplinary services, ideally delivered locally, including:

- Delivery of community-based services to people with heart failure throughout the regional health systems. In particular, areas of high prevalence of heart failure should be considered priority areas.

- Formalised partnerships or links between services and organisations in order to develop an integrated network with agreed heart failure care planning, consistent use of evidence-based guidelines and patient pathways, and seamless transfer as appropriate.

- A structured system of seven days per week, extended hours telephone advice for people with heart failure, carers and health professionals.

- Adequate and suitable community-based exercise options.

- The provision of clinical leadership and ongoing support to health professionals in diagnosis and long term care, including adequate resources to enable designated heart failure service staff to deliver education to other health care professionals.

Establish a central resource directory for heart failure services within each local regional health system. The scope of this directory will include service options and information on risk modification, diagnostic services, long term care services and advanced heart failure services.

The life of an heart failure patient with respect to the model of care supported by HEARTFAID platform can be divided into the following important states/events:

1) **Usual life**, before a cardiac dysfunction is suspected. The typical heart failure patient likely did not follow an healthy lifestyle and had some behaviors or

medical conditions that exposed him/her to an increased risk of developing heart failure. Usually because of some precipitating factor, after an asymptomatic phase (of variable length), heart failure becomes symptomatic thus urging the patient to seek medical attention.

2) **The diagnosis of Heart Failure**, which coincides with the first contact with the Cardiology centre where the necessary specialized diagnostic tests are performed. The diagnostic process coincides also with the first contact with the HEARTFAID platform with the expectation that such support would decrease both falsely negative and the falsely positive diagnosis, and that it would help with the difficult task of diagnosing the presence and determining the prevalence of heart failure with preserved left ventricular ejection fraction.

3) **The follow-up as a patient** affected by a rather complex heart condition calling for a rather complex management. The Cardiologist, based on the heart failure etiology and symptoms' severity will select, according to the most recent European Society of Cardiology (ESC) guidelines, the most appropriate clinical management approach. During the follow-up phase, the progress made by the patient will be carefully monitored by the Cardiologist and the GP with the support of the HEARTFAID platform. The patient's symptoms and signs with/without the results of selected tests will be followed by either the medical personnel alone or by such personnel supported by specific functionalities of the platform. In fact, the platform will allow to convey serial readings of selected biological parameters measured both by the medical personnel and patient himself (or his/her relatives) from nearly every environment, including home. These parameters will be acquired, stored and examined in real-time and without the need for the patient to move from his home environment. This will save time to both the patient and the health professionals and will provide a more detailed control of the patient's health status. During the follow-up phase, thanks to the strict monitoring implemented by the platform, any time the patient's clinical conditions are about to worsen or have already worsened, the medical personnel will be immediately informed and either the appropriate changes in pharmacological and non pharmacological regiment will be proposed by the platform and confirmed by the medical personnel, or the patient will be referred to the outpatient or inpatient Cardiology services for testing, consultation or admission. This way, potential precipitating and exacerbating factors of decompensated heart failure will be identified and management will be changed accordingly.

   Stable or improving clinical conditions do not imply any change in frequency and quality of monitoring in health parameters. Data demonstrating stable or improving condition may themselves prompt management changes.

   The platform monitoring functionality implies that some of the patients will be provided with a set of devices that they will operate from home. The measurements acquired will be sent automatically to the central system. Such measurements, providing precious indications about the patient's conditions, will enable the platform to early identify critical situations that needs to be

immediately reported to the specialists. In particular, such close monitoring aims at identifying a decompensation of heart failure before this is clinically manifest. Earlier detection of patient's decompensation allows a better optimization of therapy, a better outcome and a reduction of the health care costs.

During the follow-up phase of a patient with chronic heart failure conditions, the platform will assist the medical personnel in devising the most suited clinical management procedures. In detail, this will take place not only during the scheduled visits but also in the usual patient's environment, and to monitor the patient during his daily life and the scheduled visits. The general activity of the HEARTFAID platform can be synthesized as an iterative closed-loop cycle with the following steps: measurement; analysis; decision; action.

This cycle will be instantiated and adapted to each of the three typical scenarios addressed by the HEARTFAID platform: Hospital environment; Home Care; Patient on the move

2.4 The future HEARTFAID scenarios

We consider Antonio, a 70 years old italian patient, former smoker, suffering from hypertension from several years. Five years ago, he had an Acute Myocardial Infraction and he underwent to aorto-coronary bypass. The patient had a post ischaemic dilated cardiomyopathy, with a systolic dysfunction.
Antonio was convinced by his medical doctor to use the telemonitoring services of the HEARTFAID platform. He was enrolled six months ago and during this period he has been automatically telemonitored (level of physical activity, blood pressure, heart rate, respiratory rate, weight, peripheral oedemas or other decompensation signs). He referred slight limitation of physical activity, comfortable at rest but ordinary activity resulted in fatigue and dyspnoea and an Heart Failure diagnosis was confirmed with NYHA class II. A transthoracic echocardiography performed before the enrollment showed an LVEF (left ventricle ejection fraction) of 40%. The patient was treated with ACE-inhibitor, beta-blockers, spironolactone, aspirin and statin.
During telemonitoring, clinical symptoms (fatigue, breathlessness, confusion), clinical signs and parameters (presence of peripheral oedemas, weight, heart rate, blood pressure) and the pharmacological therapy has been followed with care. To this end, Antonio is aiding by his family (his wife and sons), mainly controlling the compliance of the therapy. All monitored data are periodically and automatically sent to the Decision Support system in order to early detect unexpected trends and further complications. At the same time, suddenly, the patient observes a worsening of his symptoms, with a marked limitation of physical activity, an increase of heart rate and a decrease of systolic blood

pressure, this situation is detected by the HEARTFAID platform and the cardiologist is contacted. Thus, with the decision support of the HEARTFAID platform, the doctor decides to activate other monitoring devices for monitoring Antonio, in particular 1 lead ECG and BNP measurements. The platform underlines the worsening of ECG and the increase in BNP values, thus alerts the medical doctor to perform a medical visit immediately.

Mark is a coronary heart disease patient from 3 years, he is 66 years old worker, overweight (BMI = 27). He goes to his GP because he accuses chest pain and fatigue. He had a myocardial infraction 2 years ago and now he is really scarred. Doctor accesses to HEARTFAID web portal section developed for GPs and selects signs and symptoms reported by Mark, selecting them from a list. Mark is not enrolled into HEARTFAID, so platform asks for some additional data (e.g. laboratory exams or echo and ECG and stress test). Signs and symptoms provides a very low myocardial infarction risk (mainly due to Mark clinical history), but platform suggests to prescribes a specialist visit and some exams, because data could be not enough to provides a reliable suggestion.
After a month, Mark returns to his GP reporting same signs and symptoms. At the specialist visit (about 20 days before) cardiologist did not detect any Mark health worsening, but GP doctor decides to accesses to HEARTFAID web portal again, listing signs and symptoms reported by Mark. Since Mark is still not enrolled in HEARTFAID project, so platform asks for more data and GP inserts data about ECG and the other laboratory exams. Then platform asks for Mark treatments and life style and does not suggest a myocardial infraction but a really early diagnosis of heart failure (high risk). Platform suggests to GP to regularly check Mark health condition (e.g. 2 days a week) and contact cardiologist if diagnosis will be confirmed in the next days.

Max is a 60 years old man affected by heart failure and diabetes. He goes to his GP for a check and he reports fatigue and tachycardia during last days. GP doctor is worried about such symptoms and accesses to HEARTFAID web portal because he knows that Max was enrolled in HEARTFAID project, so he accesses to site section relative to past exams. About a month ago, in fact, Max was visited by his cardiologist and made some laboratory exams, echo and ECG. Doctor accesses to the images repository for examining echo and ECG and he asks for HEARTFAID service for extracting some clinical measures from the echo. After this checks doctor thinks there is not risk for Max. However, today is 5th check for Max to his GP, who inserts Max signs and symptoms, heart rate and blood pressure. HEARTFAID platform (today) asks also for respiratory rate, and after a multi-parametric analysis (that takes into account also last laboratory exams, echo, ECG and evolution of data acquired by GP during this month) suggests a health condition worsening for Max and a high risk for a myocardial infraction. Finally GP suggests a specialist visit to Max as soon as possible.

Nick is a 63 years old mathematician. Nick was a heavy smoker, although has a medical history of hypertension and coronary artery disease for over than 15 years. Nick was recently diagnosed with congestive heart failure (CHF). Since then, his condition has been worsened and he has been admitted in the cardiology department 2 times. He also suffers from arrhythmia.

During his last visit to the hospital Emergency Department, his condition was severe. He was admitted to the cardiology ward, where he was treated for the exacerbation and his condition improved in the next two days. The attending cardiology informed him that there is a conventional way to remain at the hospital a few days and a new alternative approach, returning home and stay in touch with the medical personnel through a pioneer HEARTFAID technology. Nick was very interested to learn more about this new potential. The doctor discussed with Nick about early discharge and the continuity of his care at home. Nick thought this would be a very good opportunity to remain at his home, away from the stressful hospital environment, having the opportunity to edit his manuscripts of a new book he prepares. In addition, he remembered that during his last hospitalization, a hospital-acquired infection was the reason for significant longer length of stay and complications. A special trained nurse visited Nick and educated him on the basic aspects of CHF, mainly focused on early detection of CHF exacerbation signs and informed him how to be involved in his disease management. The nurse also suggested that Nick could watch additional video material though HEARTFAID platform when we would be back at his home. Finally, Nick was instructed how to use a number of medical devices (blood pressure monitor, weight scale and one-lead ECG monitor) in order to transmit his biosignals to HEARTFAID platform, where his doctor has access to. Nick was discharged from the ward the next day, three days earlier than the average patient with similar condition who receives traditional care and return to his home. He started transmitted his measurements according to his tailor-made, personalized care plan and he downloaded additional educational video material from HEARTFAID platform.

Within the next 48 hours, Nick received a scheduled visit from a specialized home care nurse according to his care plan, to ensure his cardiologist that his condition was improved. Nick's condition was getting better and he received significant fewer scheduled nurse visits, in comparison with patients without HEARTFAID platform.

Five week later, the care manager recognized early signs of an exacerbation, based on data received from Nick's medical devices. The care manager contacted Nick, detect early signs of dyspnoea and informed his cardiology, who suggested that Nick was candidate for Home Hospitalization concept, with nurse visits at his home twice a day and more intensive telemonitoring schedule. With this approach, Nick managed to stay at home and to overcome this exacerbation, with a more intensive care plan and a change at his medication. Nick's condition was improved 4 days later and Nick felt that his role in his disease management was critical since his involvement in HEARTFAID solution.

4. Legal Framework

Legal frameworks can help to achieve broad public health goals. In particular, legal frameworks can be developed to assist in decreasing chronic diseases as major public health threats, using a comprehensive framework to make sure that all avenues are appropriately considered. For example, under a comprehensive structure, law can assist in monitoring various interventions for their appropriateness and their efficacy.
It can also be used to ensure new laws are implemented and enforced. Core program strategy includes system level changes to reach public health goals, increasing behavioural change, decreasing risk factors, achieving a higher quality of life, and decreasing disparities. If we determine and use the appropriate legal frameworks, we can achieve these goals more effectively. Such legal tools are meant to enhance, enable and facilitate conventional approaches; the law serves to complement and support rather than replace the traditional tools of public health.

It is well known that Cardiovascular Diseases, and in particular heart failure, are major contributors to death, disability, disparities and reduced quality of life all over the world. On the other hand, it is well recognized that environmental and policy changes are crucial in the efforts to effectively prevent, manage and control heart failure. Under this respect, the following broad goals have been identified:

- prevention of risk factors;
- detection and treatment of risk factors;
- early diagnosis and treatment ;
- prevention of recurrent adverse events.

Achieving these goals will require changes in individual behavior and modifications to the broader social and physical environment. For example, the major modifiable risk factors for Heart Failure are directly affected by individual behaviors. However, individuals' decisions concerning their behaviors that affect Heart Failure are all made against the backdrop of the physical and social environment. For example, exercise may depend on how easy or hard it is to walk or bike in one's neighborhood, and a healthy diet may depend on the ease of access to nutritious food. Similarly, increased detection, treatment, and control of Heart Failure will require a combination of changed behavior and changed institutional and social conditions.

One technique for achieving some of the desired policy goals is changing the law. Law can be a potent tool for redirecting both private and government activities, and well-designed legal interventions can be an important part of improving public health. Laws have been shown to be effective in reducing the burden of a variety of public health problems, including alcohol-related motor vehicle crashes, micronutrient deficiency diseases, and exposure to environmental tobacco smoke.

The impact of laws on these problems suggests roles for a comprehensive legal strategy for the prevention and management of Heart Failure.

In the following, taking into account what is currently proposed in the scientific literature, we highlight a conceptual overview of legal strategies for addressing the public health burden of Heart Failure. Several different techniques of legal intervention can be analyzed and tested, each of which has advantages and disadvantages. These techniques are:

- direct regulation through command and coercion;
- economic incentives and disincentives to encourage parties to behave in a particular way;
- indirect regulation through private enforcement such as tort law;
- altering the informational environment;
- directly providing services or infrastructure to the public;
- government acting as a "model citizen" with respect to its employees and facilities;
- inducing other levels of government to take appropriate steps.

Direct Regulation

The most obvious technique of government intervention is direct regulation. Direct regulation is used extensively to improve public health by protecting and modifying the environment. The strategy of direct regulation can be used in several ways to address Heart Failure prevention and control. Some examples are the following:

- Prohibition of smoking in entire work sites and public places.
- Insurance coverage mandates for essential Heart Failure preventive services.
- Change zoning and land use laws to require more compact, pedestrian oriented development.
- Dietary interventions can be enhanced by requiring food providers to include clearer nutrition labelling.
- Insurance coverage mandates may improve the diagnosis and treatment of chronic heart failure and contributory risk factors (e.g., mandated coverage for nutrition counselling and for weight-reduction programs).
- Definition new regulatory framework for the acknowledgment of remote data control as a medical activity, not equivalent but similar to the face-to-face visit.
- Enforcement for the integration of different Health Care environments: Home Care, On-the-move Care, Primary Care, Secondary Care.
- New organization of the medical doctors and nurses work activities, related to the integration of the Heath Care environments.

Economic Incentives and Disincentives

Government also may alter private behaviors through the use of economic incentives or subsidies that encourage some behaviors and discourage others by altering the costs to private parties of particular actions and decisions.

There are a variety of ways that incentives and subsidies could be used to decrease Heart Failure and its risk factors.

- Incentives for developers to provide fitness centers and recreational facilities.
- Incentives for employees to walk, ride bicycles, or use public transportation.
- Incentives to encourage full-service grocery stores in under served areas.
- Increased sales taxes on tobacco products.
- Economic incentives for obese people to participate in weight reduction programs.

Indirect Regulation through Private Enforcement

Government can regulate conduct directly, but it can also do so indirectly through the liability rules that apply in private lawsuits, primarily for tort or breach of contract, brought by individuals. The risk of private lawsuits and accompanying damage awards provide an incentive to individuals to reshape their conduct. Law shapes and delineates these risks by providing the rules for liability and the level of damages.

Some examples are:

- Tort liability, based on tobacco litigation model, to encourage restaurants to provide healthier food alternatives.
- Provision of legal protection or immunity for worksites and facilities that install automatic external defibrillator.
- Imposition of liabilities on practices that contribute to the Heart Failure burden.

Information Provider

Government can be an important source of information about health, and can use information campaigns to discourage risky behavior and encourage healthier choices. Moreover, law plays a key role in these campaigns by providing the funding and sometimes delineating the allowable scope of the message. Information can be part of a broader strategy to alter the social environment. Public information campaigns attempt to persuade, but are generally less coercive than either mandates or economic incentives. As a result, they may be seen as less intrusive than other possible strategies.

- Public campaigns to encourage physical activity targeted at various age groups.
- Public campaigns on benefits of proper nutrition, including fruit and vegetable intake.
- Public campaigns on signs and symptoms awareness and need to call emergencies.

- Screening of major heart failure risk factors and referral for care.
- Improved school curricula on health, nutrition, and physical activity.

Direct Provider of Facilities and Services

Governments provide a broad range of facilities, infrastructure, and services that directly affect the public health environment and medical care. Some of this basic infrastructure (such as roads, sidewalks, parks, and schools) can be designed to encourage healthy behaviors. In addition, government can provide clinical and preventive services, as well as critical emergency response services. Government also may purchase services that directly benefit individuals, such as programs that reimburse medical providers to the elderly and the disabled.

Government as Employer and Landlord

In addition to providing public infrastructure and services, government also performs many functions that are comparable to most private businesses. Government employs millions of workers and occupies numerous buildings and facilities. The steps that government takes in its role as employer and facilities manager not only affect its employees and customers, but also provide an important model to private enterprise of the successful implementation of such programs.

- Prohibit smoking in and near all government facilities
- More nutritious food options in government cafeterias
- On-site health and fitness programming in government facilities

Laws Directed at other Levels of Government

Within the system of government of many countries in the world, there are multiple levels of law—national, regional, and local. Many of the public health approaches to preventing Heart Failure will need to be addressed at the regional and local levels, and the legal interventions will similarly need to focus on regional and local laws. One technique to facilitate change at these levels is first to seek changes at a higher level.

Some examples are:

- Condition receipt of national transportation money on regional and local improvements in pedestrian and bike facilities
- Condition receipt of national school lunch money on improved nutrition in schools
- Condition receipt of national education money on improved physical education programming and health education
- Condition receipt of national health care system money on improved preventive medicine programs and requirements

5. Reimbursement Scheme

Heart failure is a deadly disease and one of the primary causes of hospital admissions. Once a person has been hospitalized with heart failure, there is a 25% chance that he or she will die or be re-hospitalized within three months. Nevertheless, careful management of heart failure, including careful reporting of changes in weight and symptoms, can extend lives and improve quality of life.

Two recent randomized controlled clinical trials show that remote monitoring can be a useful component in achieving these goals.

A study of 426 patients found that remote monitoring, in which an electronic device recorded and reported blood pressure, pulse, heart rhythm and weight and transmitted them to a Web site, substantially reduced the mean duration of hospital admissions and the number of home or office visits when compared to monthly follow-up phone calls from nurses. The duration of each hospital stay for the remote monitoring patients was 10.9 days versus 14.8 days for patients who only received telephone calls from nurses. Office visits were reduced 10% and home visits were reduced 65% for the remote monitoring group versus the nurse telephone call group.

In another study, a randomized trial of 280 patients from 16 USA heart failure centers found that a home monitoring device that captured and transmitted weight of heart failure patients reduced the six-month mortality rate 56.2%, as compared with a group of patients who did not use home monitoring. The study concluded that, "Despite aggressive medical management in both arms of the study, this non-drug, daily monitoring technology intervention provided an additional mortality benefit beyond guideline-recommended care for patients with advanced heart failure." According to the authors, daily monitoring and evaluation of symptoms by trained nurses via remote monitoring allowed for rapid assessment and action when warning signals appeared. This included immediate notification and action by physicians when necessary.

These and other applications have produced reductions in hospital admissions, emergency department visits and the overall cost of the heart failure patient's care.

A study that tracked data on 281 veterans who received telehomecare found significant reductions in resource consumption. After 12 months, hospital admissions for the usual care group increased 27% (in contrast to a 60% reduction for the telehomecare group). Emergency room visits increased 22 percent in the usual care group, while they decreased 66% for telehomecare. Also, the usual care group experienced a 37% increase in pharmacy utilization, versus a 59% decrease for those receiving telehomecare.

Delivering remote monitoring and telehomecare will have its own associated costs in terms of equipment, supplies and personnel time. This must be accounted for in the context of both the overall cost of care and the business expenses of the individual physician office or agency delivering the care.

Of course, providers will continue to be the final source of care in this environment of telehomecare and remote monitoring, but a new and potentially time-consuming function is added to their workload: that of real-time advisor.
This emerges from the fact that patients will monitor themselves during the course of daily living at home, at work or at school. Real-time or bundled data uploaded to databases to which both the patient and the provider will have access require manual or automated review and interpretation by the medical provider, and may require action.

In particular, providers will likely experience some increased costs because of their responsibility to monitor the in-coming data. Wherever possible, they will want that monitoring to be automated so that normal monitoring results can be recorded and filed for future reference, but out-of-target-range data will be brought to their attention. In the best case, these latter data will require cautionary messages to patients that can be automated and copied to the provider.

However, the data may signal a need for an intervention, a preventative change in management, a follow-up call of further inquiry, or the need for an earlier in-person appointment. These responsibilities will add to the workload of the provider office, whether that is the office of a physician, a community health center or a home health agency.

At the same time, it is clear that many benefits come from remote monitoring and telehomecare, with the potential for many more. They accrue to the patient, the community and the health care system. Patients using telehomecare and remote monitoring can remain in their homes and communities, thereby avoiding travel, job interruption and inconvenience.

As noted earlier, it is believed that increased disease monitoring and management will lead to better patient health, along with reduction in complications and less need for hospitalization and emergency room visits. That such results are occurring in costly chronic diseases, such as heart failure, holds promise for reducing long-term costs of chronic disease. With such costs currently at about $1.5 trillion annually (in USA), better management of chronic disease through careful monitoring, prompt intervention/adjustment and better patient adherence to treatment regimens represents clear economic benefits for patients, public and private payers and health care systems. In fact, the operational efficiencies created by telehealth can have a financial benefit to the care agency (often the taxpayer in the case of public health services).

In terms of reimbursement schemes for remote health care services, it is worth while to point out that very poor experiences have been reported in Europe. Most efforts are part of 'pilot' programs and are often governed by local authorities within the member states. The reimbursement landscape is very much operated on a region-by-region and program-by-program basis which indicates the need for an overall structure and clear EU-wide policy.

Some examples of experiences are the following:

- German law allows direct contracts between providers and statutory health insurances. Telemonitoring services for patients with heart failure or diabetes have been implemented by many health insurances. These services are free of charge for patients insured by the health insurance offering the service. GPs get reimbursed for payments for telephone or similar contacts after initial examination in the physician's office and only GPs who are participating in the particular programme get reimbursed. For smart home solutions, no reimbursement schemes are in place yet.

- In Sweden, for home care telemonitoring, an application could be made to the local county council for a telehealth installation and these would be assessed on a case-by-case basis. There are no standard eligibility criteria set. In general, such services would be free-of-charge although this might vary as each county council sets its own policy on this issue. This means that at some point in the future telemonitoring may be charged for (e.g. through some level of co-payment in the same manner as for other health services), but this is currently not the case. Some telehealth services are used throughout Sweden, like online patient journals and digital prescriptions. Also, some home telehealth pilot projects have been carried out, but usually have not been incorporated into mainstream medical care for older people.

- Home care telemonitoring for older people and others with chronic conditions is beginning to take off in the UK, even if such services are currently only available in some localities and are typically tied to specific hospital services (trusts) and medical conditions. As an example, Northern Ireland's Department of Health and Social Services is getting set to issue a tender for the supply of telehealth services to cover 5,000 people by 2011. Northern Ireland will invest £46m in telemedicine services to support chronic disease management. For home telehealth services, to the extent that they have been mainstreamed in principle at least, services are free to the end-user under the National Health Service.

As far as the HEARTFAID platform services deployment and applications are concerned, some possible reimbursement schemes are the following:

- Assessed the appropriateness of the prescription of the HEARTFAID services to the right patient by the medical doctor (in particular by the

Team Care Coordinator), all the services are free to the patient and all the costs are covered by the National/Regional Health Care system. The needed financial resources come from the substantial reduction of the current expenses for the management of chronic heart failure patients obtained by the applications of the telemonitoring services.

- On the basis of specific agreements between health care providers and private health insurances, the prescribed HEARTFAID services are delivered to the insured patient. Health care providers and operators get reimbursed on the basis of the specific services delivered and according the related DRG code.

- Fee-for-service is a standard business model where services are unbundled and paid for separately. In health insurance and the health care industry fee-for-service involves when doctors and other health care providers receive a fee for each service such as an office visit, test, procedure, or other health care service. Fee-for-service health insurance plans typically allow patients to obtain care from doctors or hospitals of their choosing, but in return for this flexibility they may pay higher copayments or deductibles. Patients frequently pay providers directly for services, then submit claims to their insurance company for reimbursement.

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