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TABLE OF CONTENTS

EXECUTIVE SUMMARY	10
1. INTRODUCTION	12
1.1. Exemplificative cases for care systems in Nordic countries, NL and UK.....	13
1.1.1. The Netherlands Care service	14
1.1.2. United Kingdom (Scotland) care services	16
1.2. Exemplificative cases for care systems in Continental countries	18
1.2.1. German care services.....	18
1.2.2. France care services	19
1.3. Exemplificative cases for care systems in Mediterranean countries.....	21
1.3.1. Spanish care services	22
1.3.2. Italian care services.....	24
1.4. Exemplificative cases for care systems in Eastern European countries	27
1.4.1. Polish care system.....	27
1.4.2. Bulgarian care system	29
1.5. Implications for the definition of the health care ecosystems where to implement HEARTEN solution	30
2. USER REQUIREMENT ANALYSIS	34
2.1. Questionnaires.....	34
2.2. In depth interviews	35
2.3. Questionnaires analysis	36
2.3.1. General Framework	36
2.3.2. Patients analysis.....	37
2.3.3. Caregivers analysis	42
2.3.4. Healthcare professional analysis.....	47
2.3.5. Nutritionist/Nurse analysis	53
2.3.6. Conclusions	57
2.4. Methodology overview	59

2.5.	User requirements analysis using NDT	59
2.5.1.	Patients' needs.....	61
2.5.2.	Caregivers' needs.....	69
2.5.3.	Healthcare professionals' needs.....	70
2.5.4.	Secondary actors' needs	76
2.6.	Use case scenarios and definition.....	77
2.6.1.	Patient and healthcare professional interaction case scenario.....	77
2.6.2.	Patient and caregiver interaction case scenario.....	81
2.6.3.	Educational activity scenario	82
3.	USES CASE SCENARIOS	87
3.1.	Patient and healthcare professional interaction case scenario.....	87
3.2.	Patient and caregiver interaction case scenario.....	90
3.3.	Other educational activity scenario	92
4.	LEGAL AND ETHICAL ISSUES	94
4.1.	Ethical and Legal Issues.....	95
5.	CONCLUSIONS.....	96
6.	REFERENCES.....	98
	APPENDIX A. ETHICAL ADVISORY BOARD	102
A.1.	EVERIS.....	102
A.2.	FORTH	102
A.3.	UMR	102
A.4.	UNIPI	103
A.5.	SAS	104
A.6.	CARE.....	105
A.7.	SESA	105
	APPENDIX B. QUESTIONNAIRES.....	106
B.1.	HEALTHCARE PROFESSIONAL QUESTIONNAIRE	106
B.2.	PATIENT QUESTIONNAIRE	110

B.3. CAREGIVER QUESTIONNAIRE	114
B.4. NUTRITIONIST/NURSE QUESTIONNAIRE	118
APPENDIX C. QUESTIONNAIRES RESPONSES	122
C.1. HEALTHCARE PROFESSIONALSRESPONSES	122
C.2. PATIENTS RESPONSES	125
C.3. CAREGIVERSRESPONSES	128
C.4. NUTRITIONISTS/NURSESRESPONSES	130
APPENDIX D. QUESTIONNAIRE ANALISYS ADDITIONAL TABLE.....	133
APPENDIX E.EXTENDED STORYBOARD SCENARIO	134

LIST OF FIGURES

Figure 1: The Netherlands Health System characterisation[Schäfer et al. 2009].	16
Figure 3: France Health system characterisation[Chevreul et al. 2010].	21
Figure 4: Spanish National Care System characterisation[García-Armesto et al. 2010].	22
Figure 5: Shared responsibilities between primary and secondary care in Spanish Care system[García-Armesto et al. 2010].	23
Figure 6: Financial flows across the Spanish Care system[García-Armesto et al. 2010].	24
Figure 7: Overview of the Italian healthcare system[Lo Scalzo et al. 2009].	26
Figure 8: Overview of the Polish healthcare system. Adapted from [Kuszewski et al. 2005]	29
Figure 9: Healthy heart and heart with HF ⁶ .	36
Figure 10: Gender distribution of patients.	37
Figure 11: Age distribution of patients (values in %).	37
Figure 12: Pets owned by patients (values in %).	38
Figure 13: Skills distribution in handling touchscreen computer device.	39
Figure 14: Remote technological device used to monitor HF patients (values in %).	39
Figure 15: Presence of comorbidities in patients with HF (values in %).	40
Figure 16: Health professional consulted for patient treatment (values in %).	41
Figure 17: Gender distribution of caregivers.	42
Figure 18: Age distribution of patients (values in %).	43
Figure 19: Skills distribution in handling touchscreen computer device.	43
Figure 20: Remote technological device used to monitor HF patients (values in %).	44
Figure 21: Presence of comorbidities in caregivers' patients with HF (values in %).	45
Figure 22: Health professional involved in patient treatment (values in %)*.	45
Figure 23: Person responsible for medication administration/adherence of HF patients (values in %).	46
Figure 24: Best way to receive information from healthcare professionals (values in %).	46
Figure 25: Canal of communication in case of blood pressure problem (values in %).	47
Figure 26: Gender distribution of Health professionals.	48
Figure 27: Age distribution of health professionals (values in %).	48
Figure 28: Skills distribution in handling touchscreen computer device.	49
Figure 29: Remote technological device used to monitor HF patients (values in %).	49
Figure 30: Functional scales used to measure patient lifestyle.	50
Figure 31: Health professional consulted for patient treatment (values in %).	51
Figure 32: Person responsible for medication administration/adherence of HF patients, (values in %).	51
Figure 33: Physiological measurements that should be used for patient monitorisation (values in %).	52
Figure 34: Canal of communication in case of blood pressure problem (values in %).	52
Figure 35: Gender distribution of nurses/nutritionist.	53
Figure 36: Age distribution of health professionals (values in %).	54
Figure 37: Skills distribution in handling touchscreen computer device.	54
Figure 38: Remote technological device used to monitor HF patients, (values in %).	55
Figure 39: Health professional consulted for patient treatment (values in %).	56
Figure 40: Person responsible for medication administration/adherence of HF patients (values in %).	56
Figure 41: Physiological measurements suggested.	57
Figure 42: Graphical storyboard of "Patient and healthcare professional interaction scenario II".	81

Figure 43: Graphical storyboard of “Patient and caregiver interaction scenario I” .	82
Figure 44: Graphical storyboard of “Educational scenario I” .	83
Figure 45: Graphical storyboard of “Educational scenario II” .	84
Figure 46: Graphical storyboard of “Educational scenario III” .	85
Figure 47: Graphical storyboard of “Educational scenario IV” .	86
Figure 48: Use Case «Patient registration».....	87
Figure 49: Use Case «Monitoring of patient’s vital signs».....	87
Figure 50: Use Case «Alert sent by the healthcare professional» .	88
Figure 51: Use Case «Healthcare professional provide medication adjustment».....	88
Figure 52: Use Case «Patient registration».....	89
Figure 53: Use Case «Direct communication from patient to healthcare professional» .	89
Figure 54: Patient and healthcare professional use cases.....	90
Figure 55: Use Case «Communication channel through patient and caregiver» .	91
Figure 56: Use Case «Import additional patient information».....	91
Figure 57: Patient and caregiver use cases.....	92
Figure 58: Use Case «Documental content visualization for patients».....	93

LIST OF TABLES

Table 1: National care models in EU28.....	13
Table 2: Key ecosystem actors and their roles.	31
Table 3: Number of questions included in each questionnaire. Total (general + specific).	34
Table 4: Number of questionnaires returned completed by each partner and broken down into end user's role.....	34
Table 5: Number of interviews performed by each partner.....	35
Table 6: Patients' food choices.	38
Table 7: Distribution of patient by Heart Failure Functional Class.	39
Table 8: Distribution of patients HF hospitalisations during the last year.	40
Table 9: Level of autonomy.....	40
Table 10: Types of suggestions received in relation with patient lifestyle.....	41
Table 11: Distribution of caregivers' patient by Heart Failure Functional Class.....	44
Table 12: Types of suggestions received in relation with patient lifestyle.....	46
Table 13: Need to press HF patients to take their medication.....	47
Table 14: Years of health professionals employment.....	49
Table 15: Distribution of health professionals' patient by Heart Failure Functional Class.....	50
Table 16: Notification required in case of patients monitored remotely.....	52
Table 17: Distribution of health professionals' patient by Heart Failure Functional Class.....	55
Table 18: Visits performed in patients with HF (values in %).	56
Table 19: Types of suggestions received in relation with patient lifestyle.....	56
Table 20: Ability of nurses/nutritionist in making changes in the pharmacological treatment plan of HF patients.	57
Table 21: «OBJ01» Changes in the current care model.....	61
Table 22:«OBJ02»Selfcontrol.....	61
Table 23:«OBJ03»Selfcare.	61
Table 24:«OBJ04»Deterioration situations management.	61
Table 25: «OBJ05»Patient and healthcare professionals' relation.....	62
Table 26: «OBJ06»Content.	62
Table 27:«FR01» Communication channels between users.....	63
Table 28: «FR02» Documental content visualization for patients.....	64
Table 29:«FR03» Self-monitoring.	65
Table 30: «FR03.1» Biological variables monitoring.....	66
Table 31: «FR03.2» Treatment management.	66
Table 32: «FR04» Patient decision support.	67
Table 33: «FR05» Alerts, reminders and motivational messages.....	68
Table 34:«OBJ07» Deterioration situations enhance.	70
Table 35:«OBJ08» Survival.....	70
Table 36: «OBJ09» Inter-professional variability.....	70
Table 37: «FR06» Documental content visualization for healthcare professionals.	71
Table 38: «FR07» Patient monitoring management.....	71
Table 39: «FR08» Patient treatment management.	72
Table 40: «FR09» Clinical decision support.	73

Table 41: «FR10» Alerts, reminders and motivational messages management.	74
Table 42:«FR11» Patients follow up module.	75

EXECUTIVE SUMMARY

The HEARTEN vision is to engage all actors related to the management of Heart Failure (HF) patients, including healthcare professionals, caregivers (formal/informal), healthcare providers, nutritionists, fitness experts, and health insurance experts in order to develop a multi-stakeholder patient-centred mHealth ecosystem. The target of HEARTEN is to design, develop and validate an ICT co-operative environment which will enable the HF patients to be adherent and compliant, and the ecosystem actors to be engaged and assist the HF patients' in better disease management.

The target population of HEARTEN are patients with chronic and acute HF, either post-ischemic or with dilated cardiomyopathy, requiring occasionally re-admittance into hospitals. One of the main concepts is to develop biosensors that can detect and quantify novel breath and saliva HF biomarkers that reflect the health status of the patient and identify whether the patient adheres to the administered drugs. These sensors will be integrated into the smartphone and the patient's cup, respectively. Additional sensors will monitor the ECG, the blood pressure, and the physical activity of the patient. Nutrition information, weight monitoring through wireless weight scales, as well as, the patient's profile will complement the input data. These data will be analysed through a knowledge management system to deliver critical information at hand, provide alerts, guidelines, trends and predictive models to the patient and the ecosystem actors. The patients suffering from HF are empowered in self-management through using their smartphones and tracking their medical vital signs, whereas the healthcare professionals and other ecosystem actors can issue warnings, coordinate therapies, improve adherence and intervene before frailty incidences occur.

This document is the first deliverable of WP3 "Ecosystem needs analysis and design of the architecture of the mHealth environment" and represents the result of Task 3.1 "Users needs identification" and Task 3.2 "Ecosystem actors interaction" which run in the first five months of the project (M1-M5). The aim of these tasks is: (i) to review the already available healthcare systems in the EU, (ii) to conduct a user requirement analysis in order to identify and characterise the HEARTEN stakeholders, as well as their needs and expectations of the system, (iii) to define the interaction between the identified stakeholders and final users, (iv) to translate the different scenarios through modelling the interaction objects towards providing an object-oriented design approach, and (v) to present an overview of the legal and ethical issues related to HEARTEN project.

Chapter 1 starts with a detailed description of the various typologies of healthcare system existing in EU28. It then focuses on the Eastern European Countries and the four main existing healthcare delivery models: (i) Nordic, NL and UK model of public services, (ii) Mediterranean model, (iii) Continental model, and (iv) Central Eastern Europe model.

Chapter 2 examines the needs of the stakeholders of the HEARTEN ecosystem. The identified stakeholders and their needs are the key elements in selecting and describing the suitable architectural views and the level of technical details to report for each of them.

Chapter 3 explores the interaction of the different stakeholders and it captures the key elements in this interaction through task flows that will serve as a base for integrating modelling information into the HEARTEN environment and the knowledge management system.

Chapter 4 presents the Ethical and Legal Committee which includes 8 members from 7 different Institutions and companies. Under the main responsibilities of this Committee is to discuss, evaluate and decide regarding the ethical and legal issues related to patients' data protection, confidentiality, regulation compliance and consent need.

1. INTRODUCTION

To understand the various typologies of healthcare system existing in EU28 it would be reductive to use as a proxy the simple typologies of Healthcare system: Beveridge or NHS, Bismarck or Social Insurance SI, and mixed. In fact, the current trend in caring individuals, show as a final goal the integration of health, long term, and social. In order to approach the management of HF patients in different healthcare systems available in EU, a more coherent analysis should include the way in which public funding and support for Care Services are provided to these patients.

According to the various experiences in the EU28 Member States (MSs), the public funding allocation can be provided either universally, simply on the basis of needs, or are means-tested, which means that public support is provided to those deemed to be in need of help whose income or wealth falls below a certain threshold. Social Services in Sweden, Denmark, Austria or Germany are closer to universal, while England is a means-tested system. In practice, differences are not so clear-cut and one can find a combination of universalism and means-testing with different nuance of intensity in each EU28 MS.

Based on this consideration, an initial classification of the EU28 MSs in relation to different care systems underpinning health and social services can be found in [Antonnen et al. 1996], even if it is incomplete and not directly applicable to the new context of the EU28. Following more recent studies (e.g. [Kautto 2002] [Bahale 2003] [Munday 2007] [Simonazzi 2008] [Marmor et al. 2012]) and the more up-to date country profiles consulted (BBI, 2011), for the scope of this study we have defined a classification based on four clusters. The main difference with the other existing classification is that of not considering the traditional Beveridge or Bismarck distinction as fundamental and of not limiting the typology to the distinction between universal or mean-tested systems. We also focused on the main form of provision, at the formal and informal mix, and at whether or not untied and unregulated cash allowances are provided or not. This is important because it shapes the likelihood of the emergence of a formal market for care services. This classification allows us to limit the number of clusters at four, also considering in one separate cluster the Eastern European Countries. The four models are:

1. ***The Nordic and NL and UK model of public services*** (where the clearest cases are: Sweden, Denmark, and Finland – universal-plus Netherlands and UK -mean tested). Nordic healthcare pays serious attention to the principle of universalism, protecting some disadvantaged people such as disabled, elderly, children and offering them services paid with taxes revenues. Strong points of Nordic Model are the good quality of services, such as protections of users' rights which is certainly better than other models (e.g. data protection and a clear definition of rights and obligations related to services offered). On health services, the main role is still played by local government but, since in these years NGOs and for profit organisations are increasing their contribution, we aggregate Nordic countries to United Kingdom and Ireland. Here, the public's hand is decreasing its direct service to the low-income and disadvantaged people and it is drawing upon contracts with service providers such as NGOs and for profit organisations. An example of privatisation applied to Nordic Model is the management of residential care for elderly people committed to the for-profit organisations.
2. ***Mediterranean model.*** This is found in the Mediterranean countries of Greece, Spain, Portugal, Italy, Cyprus and Malta that have traditionally relied on the principle of the social

assistance and on the large roles played by the family. However, they have moved closer to the two other systems and especially to the continental one epitomized by Austria and Germany. Some examples in this direction are the introduction of the ‘Ley de dependencia’ in Spain, the creation of a ‘National fund for dependency’ in Italy, and the Open care (KAPI) and home care programmes initiated by the Greek government with EU funding. These are universal non means-tested cash allowances.

3. **The continental model** (the clearest cases are: Germany, Austria, and – to some extent – France and Belgium). In Germany, the subsidiary principle is particularly strong. NGOs (both very large and long-established and church-based) are the main providers of services. The role of the state is mainly the financing of these NGOs but also families play an important part. Another characteristic is the great variability among the countries of this model: for example, in France children care is a typical state responsibility.
4. **The Central Eastern Europe** (the clearest cases are Hungary, Poland and Bulgaria). This kind of systems is characterized by a limited public intervention in services provision. A strong emphasis is placed on Catholic tradition of families’ interest for care. At the same time, an important role is played by well-established NGOs (e.g. the Red Cross).

In Table 1 we provide a synthesis of the propose classification together with the most representative countries.

Table 1: National care models in EU28.

	Characteristics	Identified cases
Nordic countries, NL, and UK	Both universal non means-tested and mean tested Predominance of in kind formal services or of tied and regulated cash allowances	Sweden, Denmark and Finland (universal); Ireland, UK and Netherlands (mean tested)
Continental	Universal non means-tested Mix of in kind formal services and untied cash allowance	Germany, France
Mediterranean	Base on principle of social assistance Recent introduction of universal non mean tested and untied cash allowances	Italy, Spain
Central-Eastern European	Families legally or implicitly bound to care	Poland, Bulgaria

Source: Our re-elaboration of [Antonnen et al. 1996] [Munday 2007] [Simonazzi 2008] in light of various other sources and country reports (i.e. [BBI 2011]).

So, it is clearly visible that the identified cases cover fairly well the different kind of systems.

Some examples of these systems are provided in section 1.1 for relevant exemplificative EU28 MSs.

1.1. Exemplificative cases for care systems in Nordic countries, NL and UK

As exemplificative cases we provide a description of Netherland (Universal) and UK (mean tested) that are the most representative MSs belonging to this typology of care system. In particular, we have considered the Scotland care system as an exemplificative case of the care service in place in the UK.

1.1.1. The Netherlands Care service

The Dutch healthcare system remained unchanged until the 2006 healthcare reform, which can be seen as a further innovation of the old Bismarckian system. The reform introduced a single compulsory insurance scheme, in which multiple private health insurers compete for insured persons. This reform has radically changed the roles of actors in the healthcare sector, in particular the role of health insurers and patients.

In the current period, Dutch care system offers universal medical care coverage for the whole population, the main responsible entities for the provision of care services are private healthcare providers. There is a single health insurance system in place (Zorgverzekeringswet, ZVW), and it is compulsory for anyone registered in the Netherlands to be insured for healthcare by a Dutch insurer. All regular (short-term) medical treatments are covered by the mandatory health insurance, whereas supplementary care provision (for e.g., dentistry) is largely dependent on the insurance policy paid for, and can therefore be subject to out-of-pocket payments. Individuals can choose among approximately forty health insurers across the country [Schäfer et al. 2009].

The Dutch healthcare system is divided into three 'compartments': long-lasting care for chronic patients, basic and essential medical care supplied by GP visits to day-hospital interventions, and primary care procedures with specialist appointments, supplementary care for e.g., dental work, physiotherapy, and cosmetic procedures [Daley et al. 2011].

A distinction is made between preventive care, primary care, secondary care, and long-term care for chronic conditions. Primary care has a strong foundation in the Netherlands, with GPs functioning as gatekeepers for healthcare access. In fact, every Dutch person is required to register to a GP. Many GP practices are solo practices, but support each other through 'cooperatives' to provide out-of-hours care, usually with in one of the 105 regionally distributed out-of-hours centres [Schoen et al. 2007]. Nurses are usually employed into the practices/cooperatives to perform check-ups on the critically ill. The rationale underlying the strong position of primary care is to prevent unnecessary costs as secondary care is more expensive, and to promote consistency and coordination of individual care. This is why patients have access to hospital and specialist care only in case of referrals by the GPs, while access to dentists or midwives, and since 2006 also physiotherapists, is exempted from this provision. Provided patients get a referral from their GP, they are able to choose which hospital they prefer. Hospitals provide inpatient and outpatient care services, and have emergency departments. Specialised health professionals of hospitals are mostly organised in partnerships. As more than 90% of the hospitals are managed and owned on a private, not-for-profit basis, specialists are generally self-employed.

Public health services are the main providers of preventive care, whereby the municipalities take care of disease prevention, health promotion and health protection. There are 403 municipalities in total in the Netherlands and altogether 29 municipal health services (Gemeentelijke Gezondheidsdiensten, GGDs) performing these services on their behalf. Long-term care provision lies with nursing homes, residential homes or home care organisations. In addition, a lot of people provide informal care visiting the elderly on a voluntary basis, providing emotional support, and assisting with household work or assistance [Schäfer et al. 2009].

A regulatory reform was implemented in 2006, which introduced extensive changes in terms of regulatory mechanisms and structures governing healthcare. This means that health insurers, healthcare providers and the insured became market players, which would interact within the new legislative framework. A single compulsory insurance scheme was introduced, which enabled multiple private health insurers to compete for policy holders. It also enabled health insurers to negotiate price, volume and quality of care with healthcare providers, allowing them to make a profit and share dividends with shareholders. The Dutch Care Authority, however, controls the quality of the services provided so as to ensure accessibility and affordability for citizens. Health insurance companies are obliged to accept anyone asking for the standard package of healthcare services (basisverzekering), which is determined by the government and revised in accordance with population needs. Generally, the standard package that must be offered by insurers under reasonable costs must include: medical care including GP appointments, hospital care, prescribed specialist care, dentistry (<18 years), ambulance services, post-natal care and midwifery, certain medications, rehabilitation care, and smoking cessation schemes [Daley et al. 2011].

Provisos attached to this basic package help to ensure healthcare is universal [WHO 2007]: all individuals are required to purchase the basic package of health insurance or face a fine worth 130% of the premium; an 'open enrolment' system obligates insurers to accept any application for insurance; they cannot "risk assess" to deny coverage to individuals deemed to be 'high-risk' on account of their age, gender or health profile; tax credits make the package affordable to those on low income.

The regulatory changes further had an impact on long-term care services, with increased competition among healthcare providers for outpatient services. With the responsibility for domestic services delegated to the municipalities, a range of different care arrangements was established. Since the reform of 2006, the funding of healthcare providers has changed considerably. GPs are paid through a combination of capitation fees and fees-for-service, whereas long-term care providers are paid in relation to an assessment of the intensity of care required for a given patient. Hospital and mental care follow a sophisticated diagnosis-related groups (DRG) type of system called Diagnosis and Treatment Combinations (Diagnose BehandelCombinaties, DBCs) which links prices to real costs and increasingly allows insurers to negotiate prices for the services offered by hospitals [Schäfer et al. 2009].

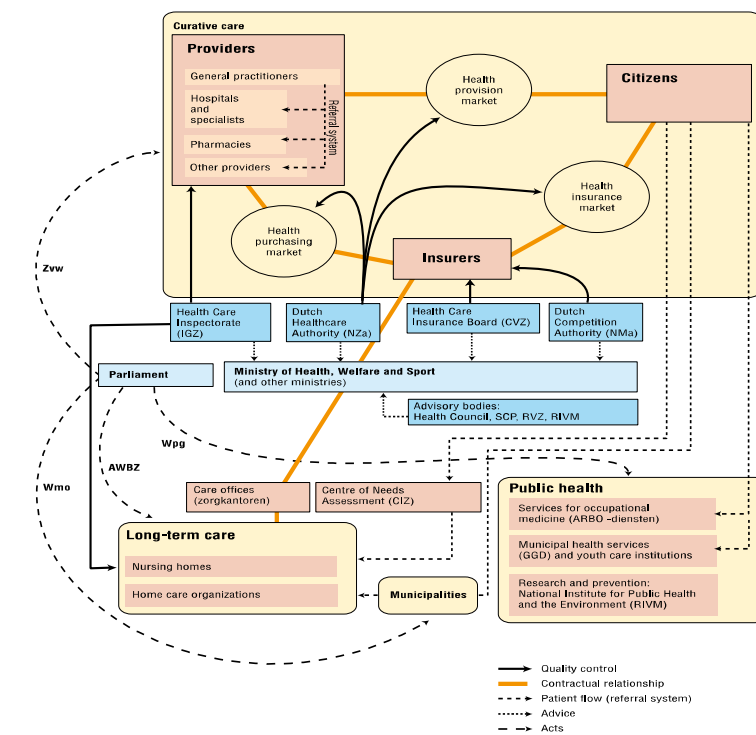


Figure 1: The Netherlands Health System characterisation[Schäfer et al. 2009].

1.1.2. United Kingdom (Scotland) care services

Healthcare services in Scotland (NHC Scotland) are financed almost entirely out of general taxation and are, thus, largely free of the point of need and available to all the inhabitants. Many functions are delegated to 14 integrated territorial NHS boards responsible for planning and delivering all health services – acute, primary and community services – to the population in their areas. There are also nine national health bodies responsible for services that are best provided by a single organisation, such as ambulance transport, information, education and training, and quality improvement. There is no purchaser–provider split. NHS boards directly employ on a salaried basis the staff working in hospitals and the community. They also manage, through Community of Health Partnerships (CHPs), the contracts of independent contractors in primary care such as GPs, dentists and community pharmacists, reimbursing them for the work they do for the NHS [Steele et al. 2012].

Next to the National Health System, there is a private non-for-profit healthcare sector, which is independent and financed through private contributions. It comprises of 7 acute medical and surgical hospitals, 10 mental health hospitals and clinics, 15 voluntary hospices, and 2 specialist clinics.

The Scottish Government determines the allocation of the budget between the NHS and other social services, such as education and sport. The Scottish Government directorates for health and social care have responsibility for health and social care policy, the management of the NHS and oversight of social care services (provided by local authorities and the private and third sectors). In relation to health, the Government determines national objectives and policies for health protection, health improvement and, in general, health services, indicating clearly targets and offering guarantees for patients. At the same time, it provides a clear statutory and financial framework for the NHS and control the NHS in order to perform in accordance to national priorities and targets. 22 Health systems

in transition in Scotland intervene in case of serious problems or deficiencies in service, impossible to be solved quickly enough at local level [Steele et al. 2012].

The majority of the health budget is distributed among 14 geographically based NHS boards that are in charge of the planning and delivery of services in order to meet the healthcare needs of the population living in each region. The NHS boards retain significant powers in terms of patterns of local care provision and the setting of local priorities. Distribution of spending by 14 territorial NHS [Steele et al. 2012] is as follows: 53.7% for hospital services; 24% for family health services; 15.3% for community services; and 3.4% for resource transfer (to local authorities).

To bridge the gap between primary and secondary care, the NHS Reform (Scotland) Act 2004 required to establish CHPs. They also fill the gap between health and social care. They are in charge for coordinating the planning and provision of a wide range of primary and community health services in the area of their competences [AS 2011]. This includes GP services; general dental services; all community-related health services; mental health services; and community-based integrated teams, such as rapid response and hospital at home services. NHS boards were also given flexibility to devolve any other function or service to the CHP [SE 2004].

Complementary, there are nine national bodies in charge of services provided to the entire country, which are in turn supported by territorial boards. These focus on delivering services best provided by a single entity, for e.g., ambulance transport, information, education and training, as well as quality improvement.

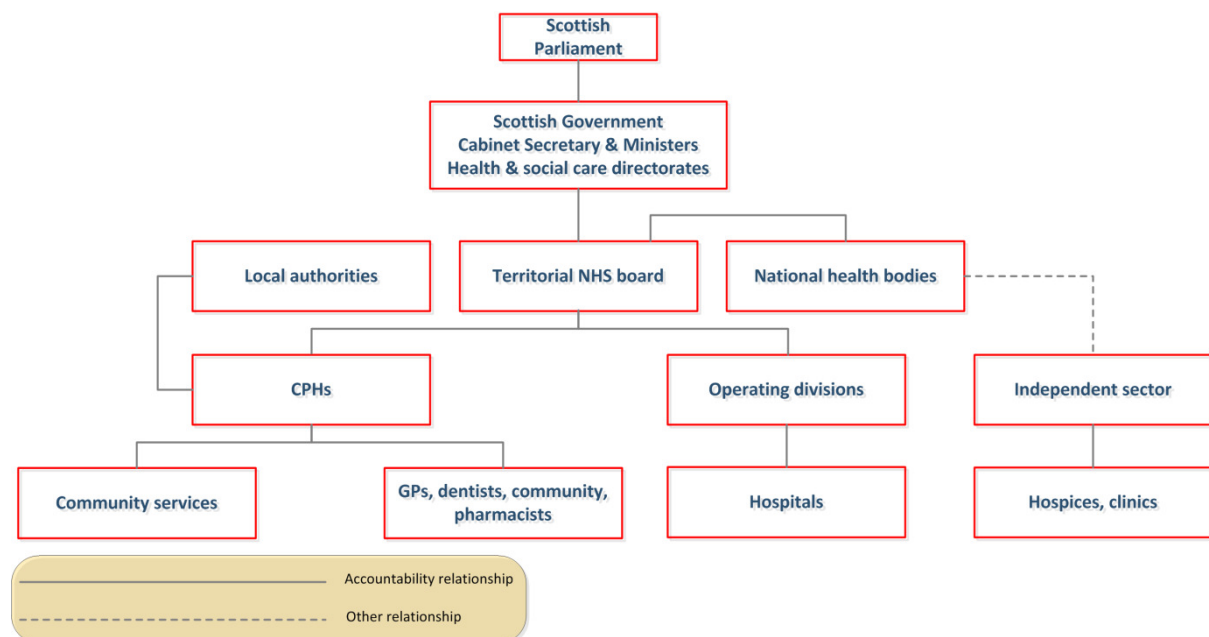


Figure 2: Scottish National Health System characterisation[Steele et al. 2012].

The NHS is financed mainly through general taxation (76.2%) with a further 18.4% coming from the NHS element of National Insurance Contributions (NICs), both of which are levied by the United Kingdom Government. Most NHS healthcare in Scotland is free at the point of use. However, some services are subject to user charges in the form of co-payments or are not covered by the NHS and patients therefore have to pay themselves (direct payments) [Steele et al. 2012].

1.2. Exemplificative cases for care systems in Continental countries

As exemplificative cases, we provide a description of Germany and France that are the most representative MSs belonging to this typology of care system.

1.2.1. German care services

German healthcare system is funded for the 75% of total expenditure by public resources and the remaining part is covered by private contributions (half of them are covered with out-of-pocket expenses). The majority of public resources used to finance the HC system derives from contributions based on wages, while the rest is financed with government funds.

Public ("social") health insurance (SHI) has been mandatory since 2007 with 154 competing Statutory Health insurers (SHI – "sickness funds") providing self-administered bases services. They are established on the bases of 5 statutory health principles: solidarity; benefits in kind (i.e. beneficiaries receive direct treatment, they don't have to pay upfront), financing from employers and employees, self-administration, plurality (i.e. patients can choose amongst hospitals and private providers). SHI covers about 88% of the population, about 12% has private health insurance (PHI), and less than 1% has no coverage [Deloitte 2014]. Private insurer option is possible only if the individual's income is above a certain annual adjusted level (>58.850 €) [Obermann et al. 2013]. These individuals may also opt to remain in SHI on a voluntary base (this is the situation that is currently chosen by the majority of the citizens having this possibility).

Cities and counties are the main actors of Public healthcare activities (for e.g., surveillance of communicable diseases, health reporting, supervision of hygiene in hospitals; physical examination of schoolchildren and certain other groups; provision of community oriented psychiatric services, health education and promotion), while the German federal state is not directly involved in the provision of healthcare.

Healthcare services are delivered by non-profit and non-government SHIs and PHIs on a competitive basis. University hospitals are owned by the State, while acute care hospitals are owned by different typologies of public and private organizations, such as: municipalities, local foundations, private companies and churches. Primary care is delivered, on a competitive base, by association of GPs or private companies constituted by GPs associations and health management organizations. These organisations usually have contracts with SHIs and PHIs in order to provide the service.

Out of pocket payments of healthcare services constitute to 14% of the overall healthcare expenses in German healthcare system [Busse et al. 2014]. The other main sources of finance are: the SHIs (57% of the total expenses), PHIs that contribute for the 9% of the expenses and the statutory long-term care insurances that contributes for the 8%. The remaining 12% of the expenses are shared amongst: taxes (5%), employers (4%), statutory accident insurance (2%), and statutory retirement insurance (1%).

German infrastructures show a much better quality, compared to some other countries. In fact, in Germany the ratio doctor per 1,000 is stable and is equal to 3.8, higher than the OECD average. Even the ratio of nurses to population is one of the highest among OECD countries. However, during last years, the number of healthcare graduates is decreasing, creating some problems in the recruitment process. To deal with this, Germany has recruited a number of foreign physicians (about 33,000), showing an increase of 15% in the period 2011-2012.

In the recent year, several driving forces (i.e. the decrease of the number of persons liable to compulsory insurance and migration of higher income groups towards private insurance; income portfolio of household less wage dependent; demographic change into ageing society; progress of medical technologies; inefficient structure in the public health system; rising of cost) are pushing German healthcare systems into a new reform which bases are constituted by a combination of both the traditional approach and the new paradigm via congruent incentive systems for all relevant participants in the healthcare system.

As a consequence of these changes, general practitioners and specialists that were usually reimbursed on the basis of a fee-for-services, with fees negotiated between the sickness funds and the physicians, in the recent period have started to negotiate, in an increasing number, shared contracts between SHIs and PHIs and the service providers (mainly GPs associations and service companies). This new approach to service provisioning follows the logic of the “triple aims” (i.e. better quality of the services at a lower cost, with the engagement of the patients), and it foresees incentives in addition to the fee-for service reimbursement. The rate of incentive is accounted on the bases of the national average cost of service and the current cost of the service provided by the GP practice [Hildebrandt 2012].

1.2.2. France care services

As already discussed in the general overview of the healthcare systems in Europe, the French healthcare system could be described as a mixed model that is structurally based on a Bismarckian approach with Beveridge goals such as universality and unity, which has led towards an increasingly Beveridgian type system. In particular, the French care system is characterised by universal coverage, with all residents entitled to access publicly financed healthcare through non-competitive statutory health insurance (SHI) funds. Three major SHI funds cover more than 90% of the French population working as salaried employees, rural workers or self-employed. The state covers health insurance costs of residents not eligible for SHI [Chevreul et al. 2010].

The delivery of healthcare services is shared among private, fee-for-service physicians, private hospitals (both profit and non-profit making) and public hospitals. Next to the healthcare and social sector, the French health system also covers a third sector providing care and services to the elderly and disabled. The health system is largely regulated by the state through the Parliament, Government and Administration of Health and Social Affairs, the SHI and to some extent also at the regional level through local communities. In 2009, a regional health agency (ARS) was established so as to ensure that healthcare provision corresponds to population needs by means of improved coordination among ambulatory and hospital sectors, in line with national health expenditure objectives. However, in some recent publications of EC¹ there is a clear evidence of shortage of resources available to provide social services under this organisational structure.

¹Source:<http://ec.europa.eu/social/keyDocuments.jsp?advSearchKey=ESPNSocInv&mode=advancedSubmit&langId=en&search.x=15&search.y=8>

The SHI covers a broad range of services provided by GPs and specialists, but does not cover all expenditures [Green et al. 2013] (for e.g., hospital treatments are typically covered up to 80%, although there is a daily charge of €18 for stays over 24 hours; GP visits is covered between 50-75%, depending on compliance with recently introduced gate keeping system; vaccination is covered between 65-100%; prescriptions is covered between 35-100% depending on the medical necessity and effectiveness).

About 90% of the population can contract complementary or supplementary voluntary health insurance (VHI) either through employers or means-tested vouchers to cover services not addressed by the SHI. The level of both contributions made to and benefits received from each fund vary. The contracts can also differ in terms of level of coverage of the costs that patients have to bear after SHI reimbursement. In general terms, the VHI provides reimbursement for additional or co-payments made by patients and includes a better coverage of medical goods and services that are poorly covered by the SHI.

In terms of service provision², the SHI funds cover hospital care and treatment in public or private Hospital care and treatment in public or private institutions providing healthcare. In particular they cover: rehabilitation and/or physiotherapy; outpatient care provided by GPs, specialists, dentists and/or midwives. Furthermore, it comprises of; diagnostic services, prescription of drugs and care prescribed by doctors and carried out by laboratories and paramedical professionals (nurses, physiotherapists, speech therapists, etc.); pharmaceutical products, medical appliances and prostheses prescribed and included in the positive lists of products eligible for reimbursement; prescribed healthcare-related transport.

Since 2004, the Ministry of Health defines the benefit package of the SHI, its price and the cost-sharing levels together with the statutory health insurers. The benefits provided under the SHI are defined, however, differently for outpatient and inpatient care. Outpatient services that are covered by the SHI are determined at the national level and applied throughout all regional authorities. The coverage of medical devices and drugs is determined by the Ministry of Health and the SHI determines the procedures applicable to it. As concerns inpatient hospital care, there is a range of services that are provided to patients under a diagnose-related reimbursement scheme.

The SHI is financed by employer and employee payroll taxes (43%), a national earmarked income tax (33%), revenue taxes levied on tobacco and alcohol (8%), transfers from other branches (8%) and state subsidies (2%). The funds are pooled on the national level and allocated through the national budgets determined by the Parliament. Within each budget, a regional allocation is decided upon and distributed by regional health agency. Healthcare costs account for about 85% of SHI expenditure,

²Source: L'Assurance Maladie government website <http://www.ameli.fr/assures/soins-et-remboursements/comment-etre-rembourse/le-parcours-de-soinscoordonnes/choisir-et-declarer-votre-medecin-traitant.php>

while around 15% are spent as cash benefits through daily allowances for maternity, sickness, or occupational accident leave or disability pensions [Green et al. 2013].

Most physicians in France are working on a self-employed basis, with more GPs than specialists being self-employed and most of them working in solo practice. The providers are paid by the SHI or directly by patients and the statutory tariffs are established through negotiations between providers and the SHI with prior approval of the Ministry of Health.

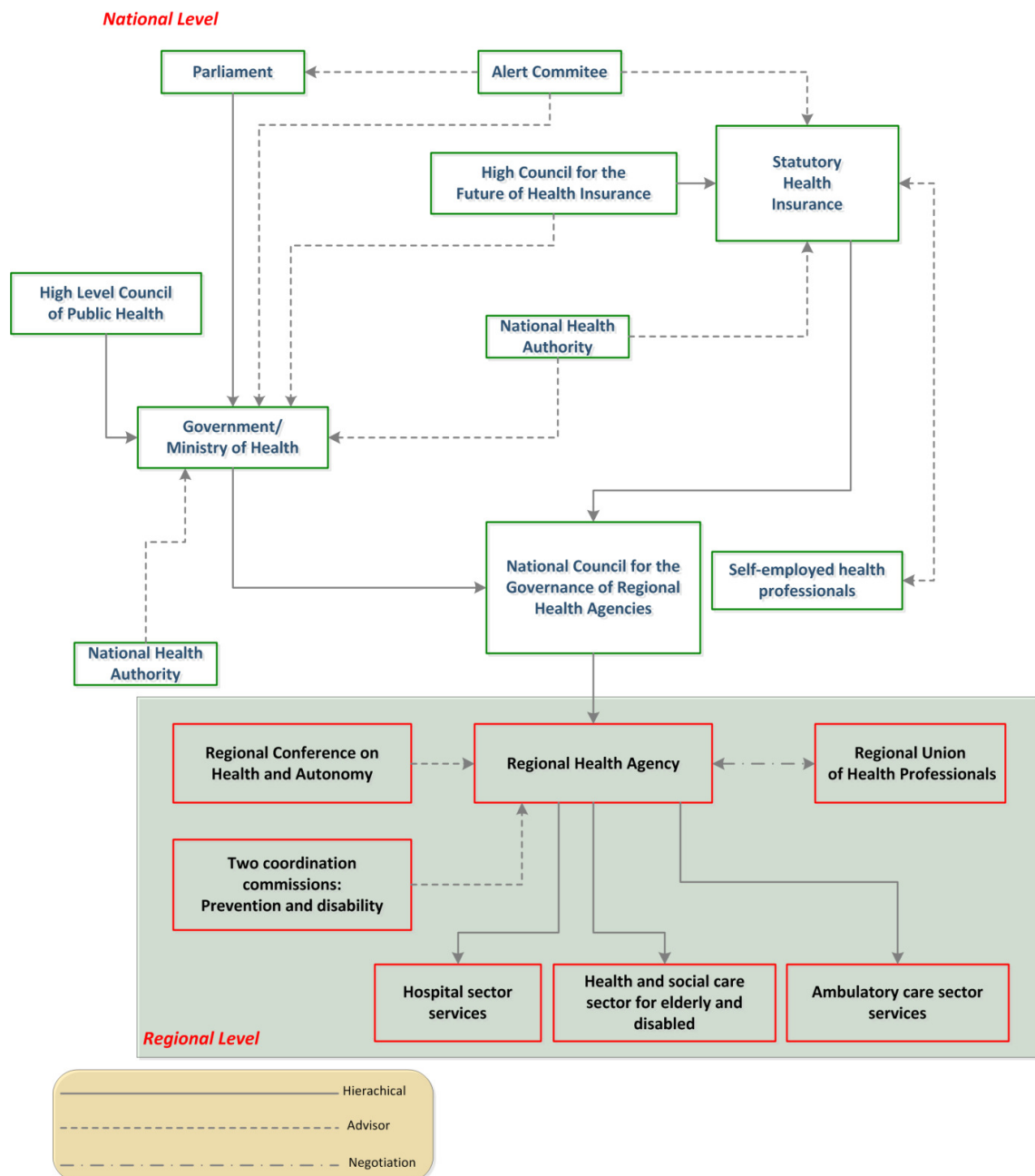


Figure 3: France Health system characterisation [Chevreul et al. 2010].

1.3. Exemplificative cases for care systems in Mediterranean countries

As exemplificative cases we provide a description of Spain and Italy that are the most representative MSs belonging to this typology of care system.

1.3.1. Spanish care services

The Spanish Constitution of 1978 established the right to health protection and healthcare for all citizens. The Spanish National Health System (SNS) is universal coverage-wise, funded from taxes and predominantly operates within the public sector. Private voluntary insurance (OVI) plays only a minor role in the Spanish health system.

Provision of HC services in Spain is free, except for pharmaceuticals prescribe to people aged under 65: in this case, a co-payment of 40% is, with few exceptions, required. HC competences are xtotally devolved to regional governments (ACs): since 2002 there exist 17 regional health ministries, responsible for primary delivering and organizing health services at local level.

Especially after 2009 reforms, the ACs' financing system is based on regional autonomy both in expenditure and in funding.

The Ministry of Health and Social Policy (MSPS), active at national level, coordinates some strategic areas, in particular pharmaceuticals' legislation, and is in charge for guarantee an equitable supplying of health services across the country. The highest body for SNS coordination is the CISNS, composed by 17 regional ministers of health, chaired by the national minister. Decisions in the CISNS must be adopted by consensus and they can only take the form of recommendations, as they involves matters that have been transferred [García-Armesto et al. 2010].

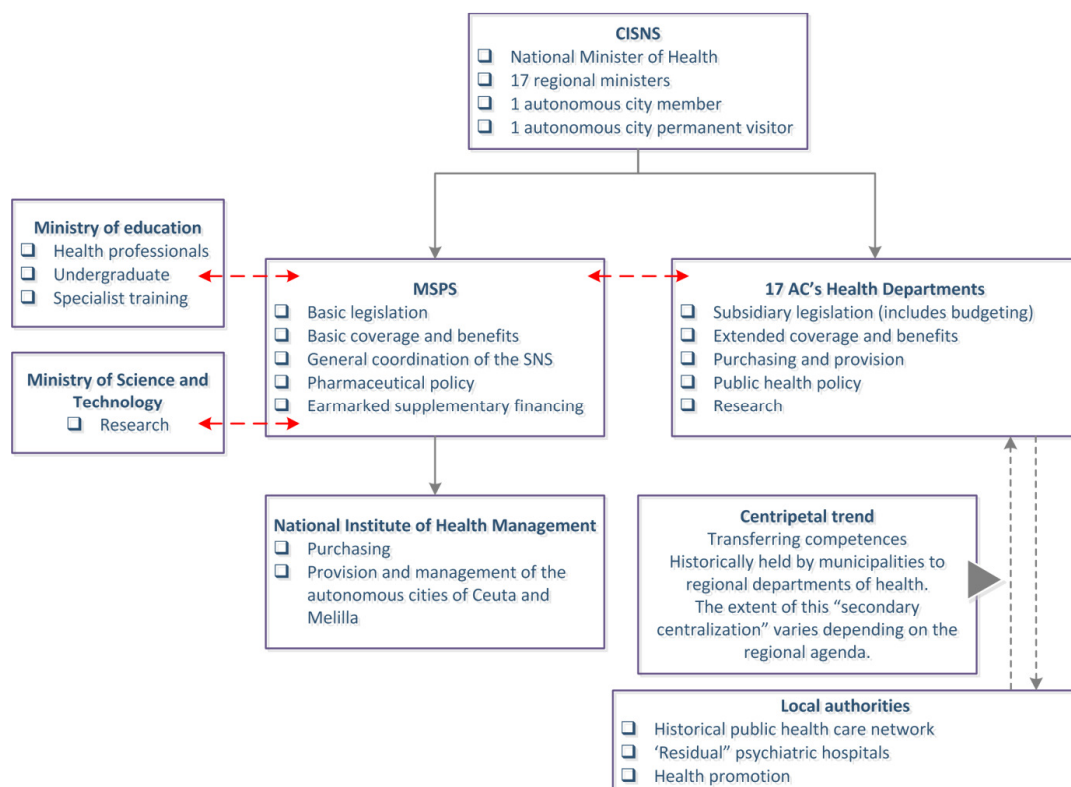


Figure 4: Spanish National Care System characterisation[García-Armesto et al. 2010].

There are 17 regional health ministries across Spain, which each being in charge of primary jurisdiction over the organisation and delivery of health services within the respective region. They are in charge for: basic legislation and general coordination of the SNS; international health issues; pharmaceutical policies; management of INGESA (The body in charge of healthcare for the two autonomous cities in the north of Africa, Ceuta and Melilla).

The Inter-territorial Board of the National Health System is the body responsible for the coordination, cooperation and liaison among the central and autonomous region public health administrations.

The regional ministry organises and structures the health service within the region. Usually, it takes form of two executive organisations that provide primary care or specialist care which responsibilities are shared as described in the figure below.

	Primary Care	Specialist Care
Feature	Accessibility	Technical Complexity
Activities	Health promotion and disease prevention, and sufficient technical resources to properly deal with common health problems	More complex and costly diagnostic and treatment resources that have to be concentrated to be efficient
Access	Spontaneous	By referral from primary health care professionals
Facilities	Health care centres and local clinics	Specialist care centres and hospitals
Place of health care provision	In a health care centre and at patient's home	Outpatient and inpatient

Figure 5: Shared responsibilities between primary and secondary care in Spanish Care system[García-Armesto et al. 2010].

Most of the public health expenditure in Spain is financed through general taxation (>94%), supplemented by contributions from payroll tax and employers contribution, as well as the mutual funds for civil servants.

Public health expenditure relates mainly to both in-and outpatient specialist care (54%), primary healthcare (16%), pharmaceuticals (19.8%), as well as prevention measures and general public health (1.4%), transportation, prosthesis and therapeutic products (1.8%) and capital expenditure (4.3%)³.

Figure 6sketches the financial flows across the Spanish NHS. The allocation formula is based on a per capita criterion, weighted by population structure, dispersion, extension and insularity of the territory.

³Ministry of Health and Social Policy, General Directorate for Professional Regulation, National Health System Cohesion and High-Level Inspection.Public Healthcare Expenditure Statistics. Advance of figures for 2002-2007.

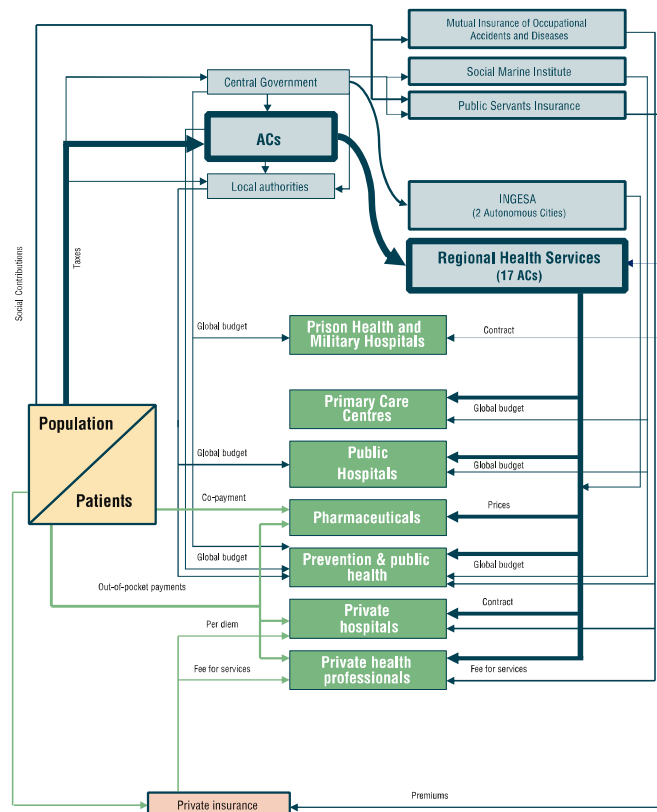


Figure 6: Financial flows across the Spanish Care system[García-Armesto et al. 2010].

1.3.2. Italian care services

The Italian care system is characterised by a universal access to a uniform level of care throughout Italy, as established through the Servizio Sanitario Nazionale (Italian National Health Service, INHS) in 1978.

Italy's healthcare system is a regionally based national health service (Servizio Sanitario Nazionale (SSN), in the following INHS) that provides universal coverage free of charge at the point of service. The national level is responsible for ensuring the general objectives and fundamental principles of the national healthcare system. Regional governments, through the regional health departments, are responsible for ensuring the delivery of a benefits package through a network of population-based health management organizations (Azienda Sanitaria Locale, 'local health enterprises' (ASLs)) and public and private accredited hospitals. There is considerable variation between the north and south in the quality of healthcare facilities and services provided to the population, with significant cross-regional patient flows, particularly to receive high-level care in tertiary hospitals [Lo Scalzo et al. 2009].

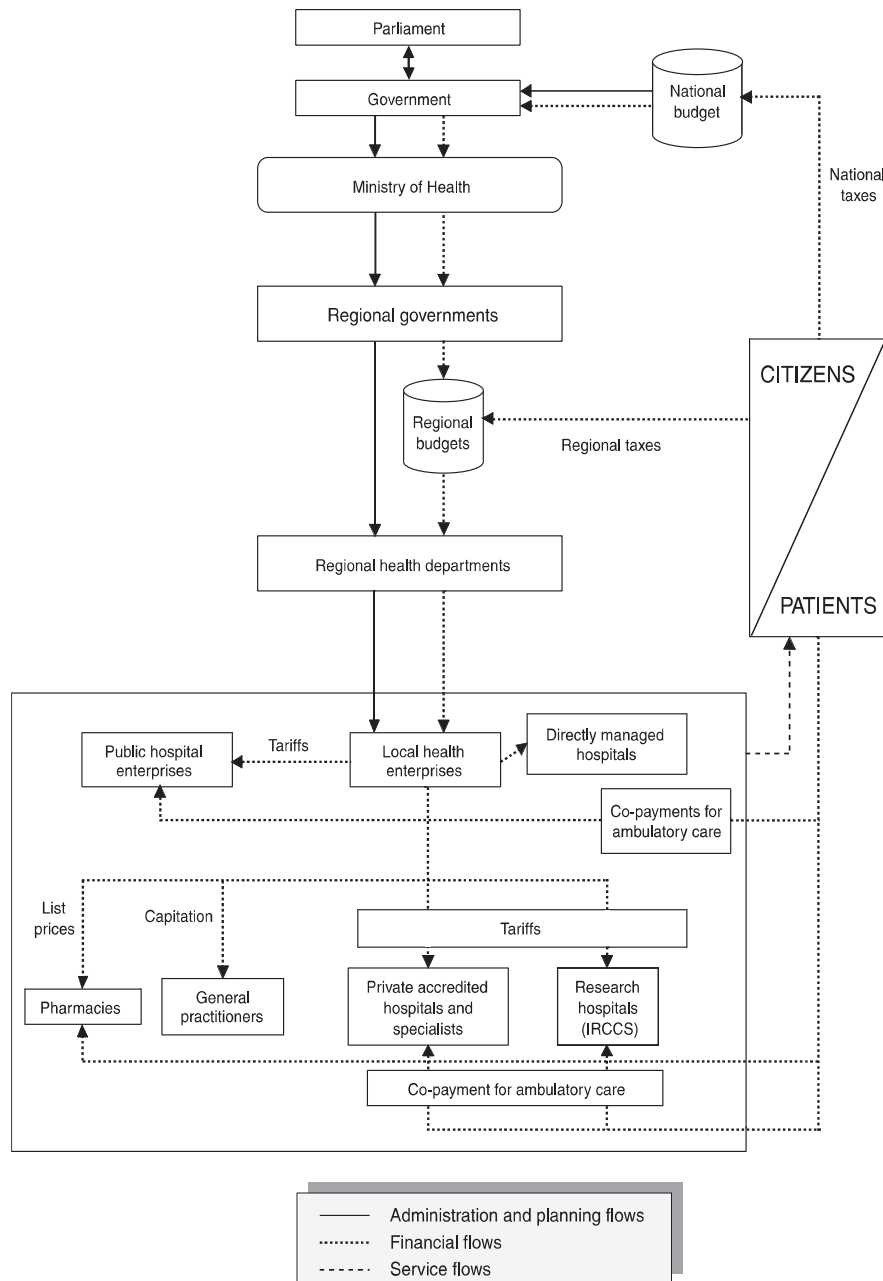
The system provides for a full spectrum of services, ranging from visits to GPs, specialised in-patient treatments, post-operative rehabilitation to ambulatory care and outpatient treatment. Drugs and medicines are covered to a considerable extent by the INHS.

A decisive change of the Healthcare System took place when a major reform of the Constitution (Constitutional Law No. 3 of October 18th 2001) altered the roles and responsibilities of the State and the Regions. This reform is aimed at controlling healthcare spending, that it has been enforced in 2005, with the so known 'Pact for Health' between the state and the regions (France 2007). Amongst

other things, the pact defines a greater role for the state in financially supporting the regions, which, in turn, are to be held highly accountable for the efficient usage of funds granted by the state and the balancing of regional budgets [Doetter et al. 2011]. Both national and regional authorities enact major policy decisions in inter-institutional “State-Regions Conferences” [Ceccherini 2009], in which representatives from both authorities participate to deliberate on relevant issues.

IHHS is organised on three levels (see figure below): national, regional and local. At national level the Ministry of Health is the central body of the INHS in charge of coordination of the services covering human health, occupational health and safety, and food hygiene and safety. The Ministry has the authority to pass laws concurrently with the Regions, and it has regulatory authority towards the Regions with regard to safeguarding health, and to occupational health and safety, regulation of the professions, nutrition and scientific research. Agreements between the State and the Regions establish the financial resources for a three-year period and the essential levels of care [Lo Scalzo et al. 2009]⁴.

⁴Source: http://www.euro.who.int/__data/assets/pdf_file/0006/87225/E93666.pdf



Note: IRCCS: National Institutes for Scientific Research.

Figure 7: Overview of the Italian healthcare system[Lo Scalzo et al. 2009].

At regional level, according to national laws and general indications of the Ministry of Health, there are 19 regions and two autonomous provinces, which have responsibility for the organisation and delivery of health services in its areas as regards to health education and promotion and disease prevention and care.

At local level, the health system is organised in Local Health Units (Aziende Sanitarie Locali, ASL), which are bodies with public juridical status that operate autonomously with regard to organisation, administration, management of assets, accounts, management and technology. They are responsible for the health services provision to the citizens. To this end they are organised in Districts which provides the following services: health education; information and advice to help residents make

informed choices; primary healthcare; home healthcare; health certificates; prevention and control of infectious diseases; hygiene in confined environments; food hygiene; and protection of mother's and child's health assessment of interventions for the disabled.

Health expenditures in the IHNS represents the 9.2% of the overall Italian GDP (2012), with an health expenditure per capita of about 3000 €/year and a pharmaceutical expenditure per capita of about 500€/year.

Public health expenditure⁵ represents the 77.3% of the overall cost of health, while pharmaceutical expenditure are about 16.9%, the remaining 6.4% are capital expenditure and other services. Of the total expenditure in healthcare services and products, out-of-pocket payments are about 18.8%.

1.4. Exemplificative cases for care systems in Eastern European countries

As exemplificative cases we provide a description of Poland and Bulgaria that are some of the most representative MSs belonging to this typology of care system.

1.4.1. Polish care system

Before the start of gradual public sector devolution in 1989, the Polish care system was strongly hierarchical and predominantly funded from the central budget. In the course of the political and economic reorganisation that followed the collapse of communism, the strongly centralised system based on the Soviet model of healthcare (the so-called Semashko model) was replaced with a decentralized system of mandatory health insurance, complemented with financing from central and local budgets. During the 1990s, the administration of most healthcare services and the ownership of most public healthcare facilities were transferred from the Ministry of Health initially to the *voivodeships* and *gminas* and *later also* to *powiats*, which were re-established as an intermediate level of public administration in 1999. According to Article 68 of the 1997 Constitution of the Republic of Poland, all citizens, regardless of their financial circumstances, have the right to equal access to health services that are financed from public funds. Approximately 98% of the population is covered by the system of compulsory health insurance, including family members of persons paying insurance contributions and some vulnerable groups whose contributions are financed from the state budget. Furthermore, the system's legal framework is based on the 2004 Law on Healthcare Services Financed from Public Sources, on the 2011 Law on Therapeutic Activity and on legislation harmonising Polish law with that of the EU.

The stewardship, management and financing functions in the Polish healthcare system are divided between the Ministry of Health, the NFZ and territorial self-governments. The NFZ is charged with financing of healthcare services provided to the insured population. It manages the process of contracting health services with public and non-public service providers. The operations of the NFZ are supervised by the Ministry of Health, while its finances are entrusted to the Ministry of Finance.

⁵<http://www.oecd.org/els/health-systems/Briefing-Note-ITALY-2014.pdf>

The Ministry of Health is also responsible for national health policy, financing of long-term public health programmes and selected highly specialized medical services, major capital investments and medical science and education. It is tasked with implementing national public health programmes and has a number of supervisory and direct managerial functions.

At each administrative level, territorial health authorities are responsible for the identification of the health needs of their respective populations, for planning of health services delivery, health promotion and the management of public healthcare institutions. The Polish system of social insurance provides income security (monetary benefits) for old age, disability, sickness and maternity, and for accidents at the workplace and occupational diseases. Key social insurance benefits are old-age and disability pensions. Healthcare in Poland is a separate part of the social insurance system with its own insurance fund (NFZ). The involvement of ZUS in the sphere of health is limited to collection of health insurance contributions from people earning their income outside the agricultural sector. The KRUS collects health insurance contributions from people getting their income from the agriculture sector. The NFZ pays ZUS and KRUS for collecting health insurance contributions. A simplified overview of the structure of the Polish health system is given in following figure.

Therapeutic Activity is one of the latest law for the Polish care system. It comes into force on 1 July, 2011 with the aim of transforming public hospitals (and other public healthcare providers) into Commercial Code companies. It represents a continuation of earlier efforts to commercialise public hospitals with the intention of improving financial efficiency of hospital management and reduction of hospital debts. The 2011 Law on Therapeutic Activity replaces the term healthcare unit with therapeutic entity.

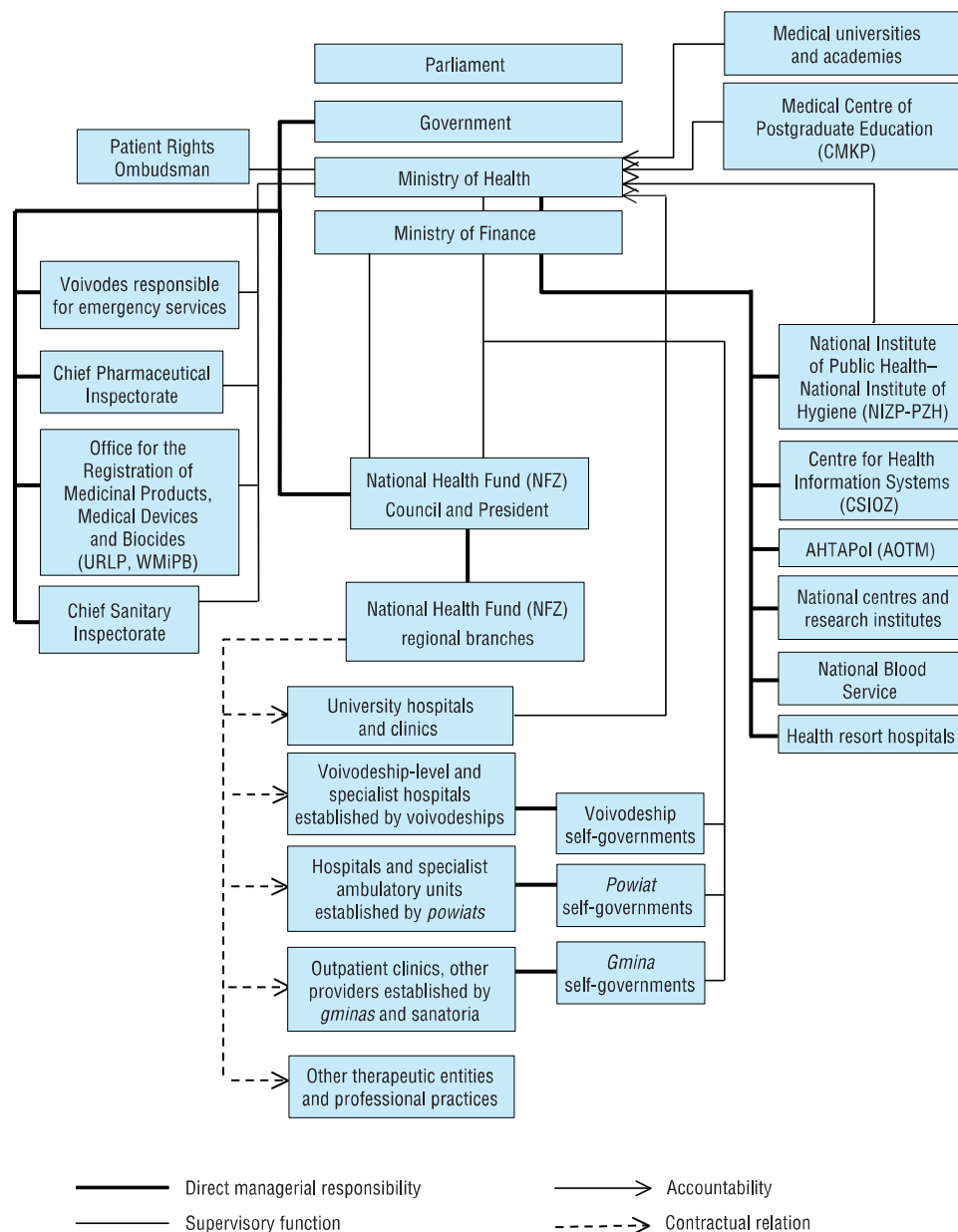


Figure 8: Overview of the Polish healthcare system. Adapted from [Kuszewski et al. 2005]

1.4.2. Bulgarian care system

In the Bulgarian Care system, care policy priorities are determined by the Ministry of Health through the National Health Strategy (NHS). At the district level, state health policy is organised and implemented by the Regional Health Inspections (RHI). The Bulgarian health system is based on an insurance model consisting of compulsory SHI and VHI. SHI is administered by a single payer, the National Health Insurance Fund (NHIF) while VHI is solely provided by for-profit joint stock companies. The insurance system (SHI and VHI) covers diagnostic, treatment and rehabilitation services as well as medications for the insured individuals. Public health services, inpatient services for people with mental disorders, emergency care, transplantations, and transfusion haematology are organised and financed by the Ministry of Health. The SHI system was created with the 1998 Health Insurance Act; the National Health Insurance Fund (NHIF) was established as an autonomous public institution

independent from the executive power (the government). The NHIF is the only responsible organisation for SHI and thus, in effect, a monopolist by law. Its organisation includes one central office located in Sofia, 28 branches (one in each district and called Regional Health Insurance Funds), and 105 municipal offices. The supreme governing body of the NHIF includes representatives of the government, insured individuals and employers. The main purpose of the NHIF is to guarantee equal access to the health system for those insured. The NHIF finances medical and dental services as well as medications included in a basic benefit package. The benefit package and prices of services are negotiated between the NHIF and the professional associations of physicians and dentists in Bulgaria. The negotiation takes place every year and ends with the signing of the NFC. The NFC also defines rights and obligations of the NHIF, healthcare providers and insured individuals, organisational procedures and control mechanisms. Based on the NFC, providers sign individual contracts with the Regional Health Insurance Funds (RHIF). The RHIF contract all public or private healthcare providers operating in their territory that meet criteria stipulated in the NFC. This means that the RHIF cannot selectively contract. In accordance with the 1999 Healthcare Establishments Act, healthcare providers are autonomous market players. The act distinguishes three types of healthcare providers: (1) outpatient care providers (single and group primary and specialised medical and dental practices, medical and dental centres, diagnostic laboratories), (2) inpatient care providers (specialised and multi-profile hospitals, for active or long-term treatment and rehabilitation), and (3) a group encompassing emergency care centres, mental health centres, comprehensive cancer centres, centres for dermato–venereal diseases, homes for medical–social care, hospices, dialysis centres and cell banks. Irrespective of ownership form, that is, public or private, all healthcare providers have to be registered according to the act as well as the Trade Law or Cooperation Law. As of 2011, the private sector encompasses primary care, much of the specialised outpatient medical and dental care, pharmacies and some hospitals. All healthcare providers except emergency care centres can contract with the NHIF and VHICs. They can also receive OOP payments for services not covered by the insurers, or in case providers have no contractual relations with a third-party payer. State and municipal healthcare providers may receive payments from the Ministry of Health and municipalities in addition to the NHIF and OOP payments.

Emergency care as well as public health services are organized and financed by the Ministry of Health. There are 28 regional centres for emergency care, one in each district, which have branches in the smaller towns in the district. In 1999, the public health system was restructured to 28 Regional Centres for Protection and Control of Public Health (RCPCPH). At the beginning of 2011, the RCPCPH merged with the Ministry of Health's representative bodies at the district level – the Regional Health Centres (RHC) – forming the new Regional Health Inspections (RHI). The RHI combine functions of the former two institutions. The public health network also includes the National Centre of Radiobiology and Radiation Protection, the National Centre for Infectious Diseases, the National Centre of Drug Addictions, the National Centre of Health Informatics and the National Centre of Public Health Protection. The latter two merged in 2011.

1.5. Implications for the definition of the health care ecosystems where to implement HEARTEN solution

The analysis of the characteristics of the European health care systems allows us to better understand the ecosystem which exists in European Countries, and to highlight the key differences and similarities that we have to consider in the definition of the HEARTEN use cases and implementation processes.

Later on these characteristics will also help us in better define our exploitation strategy as well as to raise consideration on the overall sustainability of the service underpinning HEARTEN solution.

To this aims in this paragraph, per each of the four typologies of health care system we are going to define the key ecosystem actors and their roles. It is important to underline that, whereas the four ecosystems described below provide a clear picture of the configuration of the health care services based on the main characteristics of the health systems within each cluster, however each countries presents peculiarities and specificities that cannot completely encompasses in this analysis.

To help in the comparison of the four ecosystems we consider the following typologies of roles:

- **Health Governance actor:** i.e. the actor that is in charge for the decisions of the characteristics of the health service to be provided and that is in charge for the overall evaluation of health care performances.
- **Responsible of public health care activities:** i.e. the actor responsible of the public health policies and initiatives supporting population health services.
- **Responsible of the funds collections:** i.e. the actor that is in charge for the collection of the financial and economic resources needed for the management of the health care services.
- **Responsible for the funds allocation:** i.e. the actor that is in charge for the decisions related to the use of financial and economical resources for the management of the health care services.
- **Getkeeper:** i.e. the actor in charge for the first identification of the patient' needs and that is in charge for the preliminary assessment of the patient's health status to decide if he/she has to be a potential user of HEARTEN solution and related service.
- **Health services governance actor:** i.e. the actor that is part of the health decision makers in relation to the provision of the HEARTEN service to the patient.
- **Health services provider:** i.e. the actor that is in charge for the provision of the health care service.
- **eHealth services provider:** i.e. the actor that is in charge for the provision of the ICT services enabling the health care processes.
- **Other relevant actors:** i.e. specific actor that is not in the previous categories by that has a relevant role in the ecosystem.
- **Beneficiaries:** i.e. the individuals that are the direct receivers of the health care service and therefore that could directly get benefit from the use of HEARTEN solution.
- **Indirect beneficiaries:** i.e. the individuals that provide support to the direct beneficiaries and that could receive indirect benefits from the use of HEARTEN.
- **Investors:** i.e. the actors that are interested in investing on innovative health care services.
- **Other Relevant stakeholders:** i.e. the actors that can leverage the voice of specific groups of individual and/or organizations and provide suggestions and stimuli for health care services improvements. They are common in all type of ecosystems.
- **Research providers:** i.e. actors that can contribute to the improvement of health care product and services. They are common in all types of ecosystems.

Table 2: Key ecosystem actors and their roles.

Nordic countries, NL, UK and IRL	Continental	Mediterranean	Central-Eastern Europe
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Health Governance actor	National Government	National Government	National Government	National Government
Responsible of public health care activities	National, regional and Local authorities	Local authorities	National, regional and Local authorities	National and Local authorities
Responsible of the funds collections	National and Local Government and health insurance with different importance according to the country	Public and private insurances	National and Local Government	Public and private insurances
Responsible for the funds allocation	Local authorities	Public and private insurance	Regional and local authorities	National health insurance funds organization
Getkeeper	GPs with a clear role	General Practitioners and hospitals, not explicit role is foreseen in this ecosystem	General Practitioners	Not explicit role is foreseen in this ecosystem
Health services governance actor	Communities of health practices	Local Authorities, Hospitals units, gps associations	Local Authorities, Hospitals units, gps associations	Local Authorities, Hospitals units, gps associations
Health services provider	Primary care providers, secondary care providers, specialists	GP practices, hospital units, specialists, nurses, caregivers, etc.	GP practices, hospital units, specialists, nurses, caregivers, etc.	Primary care providers, hospital units, specialists
eHealth services provider	Telecare providers, telecom operators, biosensors producers, producers of other eHealth equipment	Telecare providers, telecom operators, biosensors producers, producers of other equipment	Telecare providers, telecom operators, biosensors producers, producers of other equipment	Telecare providers, telecom operators, producers of e-health equipment

Other relevant actors	Charities	Health management companies	Not specifically present in this ecosystem	Mainly hospitals, not specifically present in this ecosystem
Beneficiaries	Patients	Patients	Patients	Patients
Indirect beneficiaries	Patient's families, informal caregivers	Patient's families, informal caregivers	Patient's families, informal caregivers	Patient's families, informal caregivers
Investors	Private funds	Relevant in this ecosystem such as local foundation, private companies and churches	Not specifically present in this ecosystem	Relevant in this ecosystem such as local foundation, private companies and churches
Other relevant stakeholders	Patient and families' patients associations, health care associations, health care unions, etc.	Patient and families' patients associations, health care associations, health care unions, etc.	Patient and families' patients associations, health care associations, health care unions, etc.	Patient and families' patients associations, health care associations, health care unions, etc.
Research providers	Universities, research centers	Universities, research centers	Universities, research centers	Universities, research centers

2. USER REQUIREMENT ANALYSIS

2.1. Questionnaires

Within the T3.1 framework, a set of questionnaires have been designed in order to gather the point of view from end users of the HEARTEN ecosystem regarding to HF and the expected functionalities that this project intends to address.

This set of questionnaires was first proposed by FORTH, taking into account the end user's role by including 4 different questionnaires addressed to patients, caregivers, healthcare professionals and nutritionists/nurses. Subsequently, all the members of the HEARTEN consortium reviewed them and proposed improvements on them. SAS was the partner on charge for gathering suggestions, improvements and updates on the questionnaires.

These 4 questionnaires follow a similar structure: the first questions are related to general and demographic information and the others are questions specific of the HEARTEN project. The final number of questions included in these questionnaires is shown in the following table.

Table 3: Number of questions included in each questionnaire. Total (general + specific).

Q Patients	Q Caregivers	Q Healthcare Professionals	Q Nutritionists/Nurses
19 (7+12)	15 (5+10)	18 (7+11)	17 (7+10)

After its validation, this set of questionnaires has been forwarded to all members of the HEARTEN consortium in order to perform the survey among the involved end users. The following table shows the number of questionnaires returned completed by each partner.

Table 4: Number of questionnaires returned completed by each partner and broken down into end user's role.

Partner	Q Patients	Q Caregivers	Q Healthcare Professionals	Q Nutritionists/Nurses	Q Total
CARE	2	0	0	2	4
SAS	4	4	10	5	23
UMR	0	0	4	1	5
UNIFI	7	5	12	9	33
TOTAL	13	9	26	17	65

Appendix B includes the final (validated) version of the questionnaires. Appendix C includes a spreadsheet accounting the gathered responses for each questionnaire. Section 4.5 addresses the analysis of the survey outcomes, including the regarded conclusions.

2.2. In depth interviews

The interviews define the needs and expectations of the product and are the basic tool to define the requirements, if they are made in a structured way and easily documented and if they are understandable for the actors of the ecosystem. The requirements help to define what needs to be designed so that the needs of the user are met. After the clear identification of the purpose of the interview, the possible interviewees have been identified among the different potential actors of the system: patients, carers, nurses, nutritionists and healthcare professionals. Apart from the patients, we interviewed the main actors in the different stages of therapeutic diagnostic of patients with HF, with emphasis on the decompensation phase, when patients really have more doubts that need to be solved, problems, self-care, difficulties accomplishing with the treatment, etc. In our environment, given the level of functional and cognitive dependency, with the corresponding limitations of the patients, has made it impossible to focus on interviews to patients. Thus, we have focused more on carers and healthcare professionals.

In order to perform the survey, personal interviews have shown to be the best approach when addressing some of the end user's roles (specifically when dealing with patients and caregivers) given that the following barriers arose:

- Difficulty to understand the questionnaire due to the language. Difficulty to understand the questionnaire due to a low cultural level.
- Difficulty to understand the questionnaire due to the severity of patient's conditions.
- Lack of knowledge on the disease. Lack of criteria to answer questions on the development and evolution of the disease.
- Lack of confidence on the utility of questionnaires.

The following table shows the number of interviews performed by each partner.

Table 5: Number of interviews performed by each partner.

Partner	I Patients	I Caregivers	I Healthcare Professionals	I Nutritionists/Nurses	I Total
CARE	2	0	0	2	4
SAS	4	4	5	5	18
UMR	0	0	4	1	5
UNIP	7	5	12	9	33
TOTAL	13	9	21	17	60

2.3. Questionnaires analysis

2.3.1. General Framework

HF is a complex syndrome in which abnormal heart function results in clinical symptoms and signs of low cardiac output and/or pulmonary or systemic congestion [Arnold et al. 2006].

It is a chronic and progressive condition which is associated with high morbidity and mortality rates [Hawkins et al. 2009].

Projections show that the prevalence of HF will increase 46% from 2012 to 2030, resulting in more than 8 million people ≥ 18 years of age with HF. In 2012, the total cost for HF was estimated to be \$30.7 billion. Of this, 68% was attributable to direct medical costs [Heidenreich et al. 2013].

For all these reasons, it is important to increase early diagnosis and improve access to care and quality of care for patients with HF.

Recent international recommendations for the treatment of patients with HF include not only medical therapy, but also comprehensive care with diet, physical activity and patient and caregivers education [Remme et al. 2001] [Hunt et al. 2005]. Even though these strategies have been shown to be effective, patients with HF often have poor treatment adherence.

HEARTEN is a new approach that will enable patients to achieve sustainable behaviour change regarding their compliance to treatments. Additionally, HEARTEN will target all the actors related to the management of patients suffering from HF, including healthcare professionals and caregivers (formal and informal).

We believe that HEARTEN will significantly improve HF patients' functional capacity and quality of life. However, it is crucial to provide policy makers with evidence-based data on the HEARTEN significance to result in its successful adoption by the HF patients.

In the following pages, we will illustrate the preliminary project data. All the data were collected through questionnaires filled by patients, caregivers or healthcare professionals after their consent.

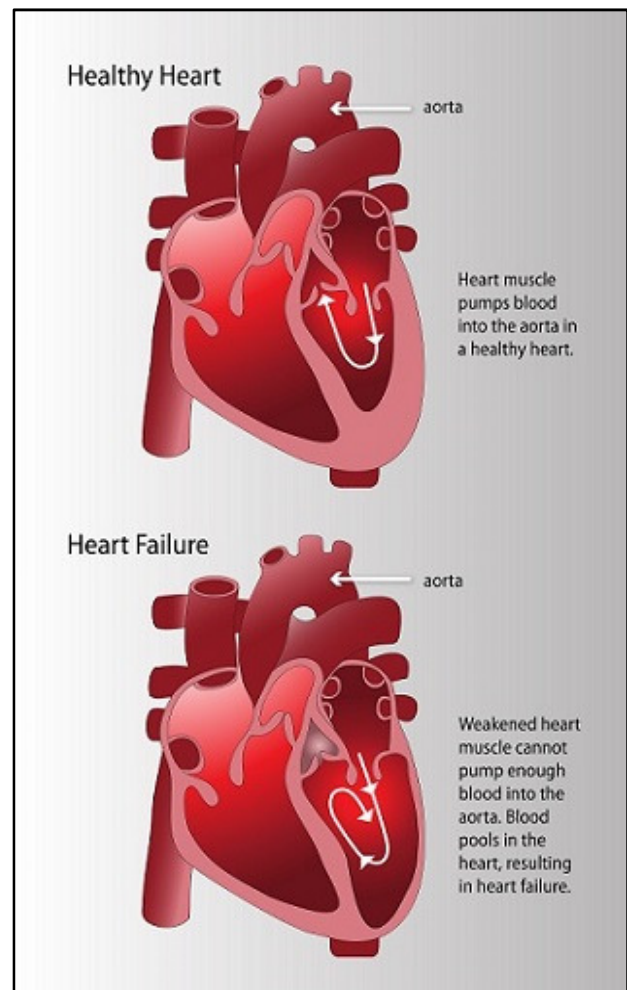


Figure 9: Healthy heart and heart with HF⁶.

⁶Source: http://www.cdc.gov/dhds/data_statistics/fact_sheets/fs_heart_failure.htm

2.3.2. Patients analysis

General Information

In this section we analyse the demographic characteristics of patient with HF. A total of 13 questionnaires have been filled.

In Figure 10, we show patient distribution by gender. Most patients are male, accounting for 54% of the population sample.

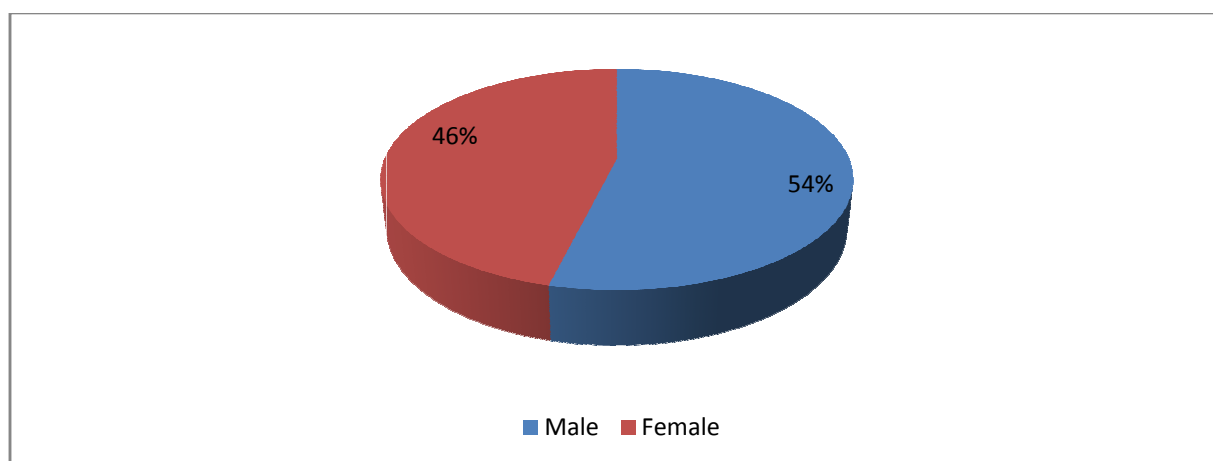


Figure 10: Gender distribution of patients.

Figure 11 includes the distribution of our patients for specific age categories. It is clear that roughly 61% of these patients are between 70-79 years old. In addition, regarding patient residual status, we can say that 84.6% of them live with somebody (for e.g., spouse, partners, and so on).

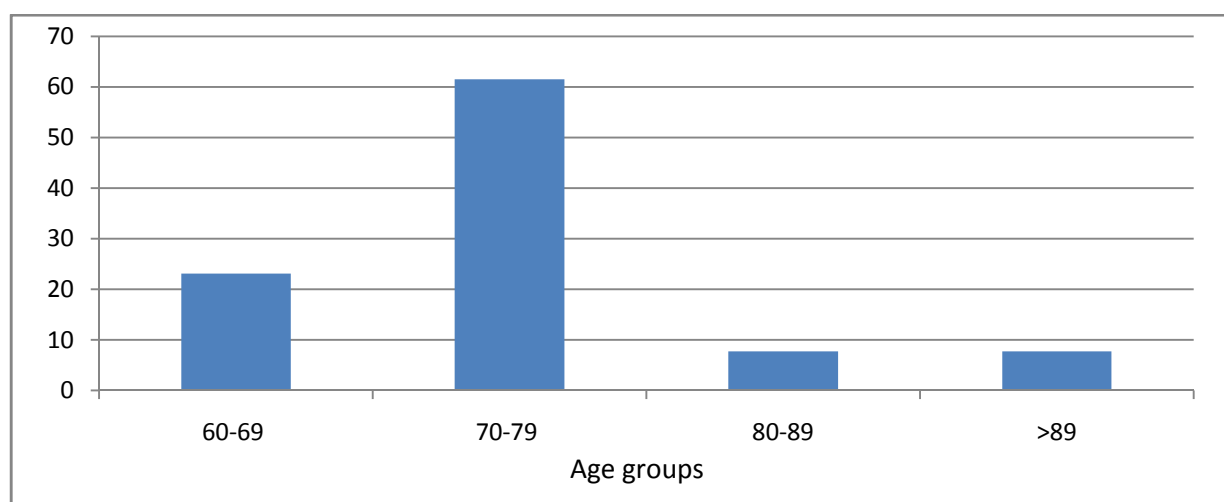


Figure 11: Age distribution of patients (values in %).

Animals can be used to help patients with HF to improve their functional, physicals and cognitive functions as well as in reducing pain. Figure 12 indicates that 84.6% of patients do not have any pet.

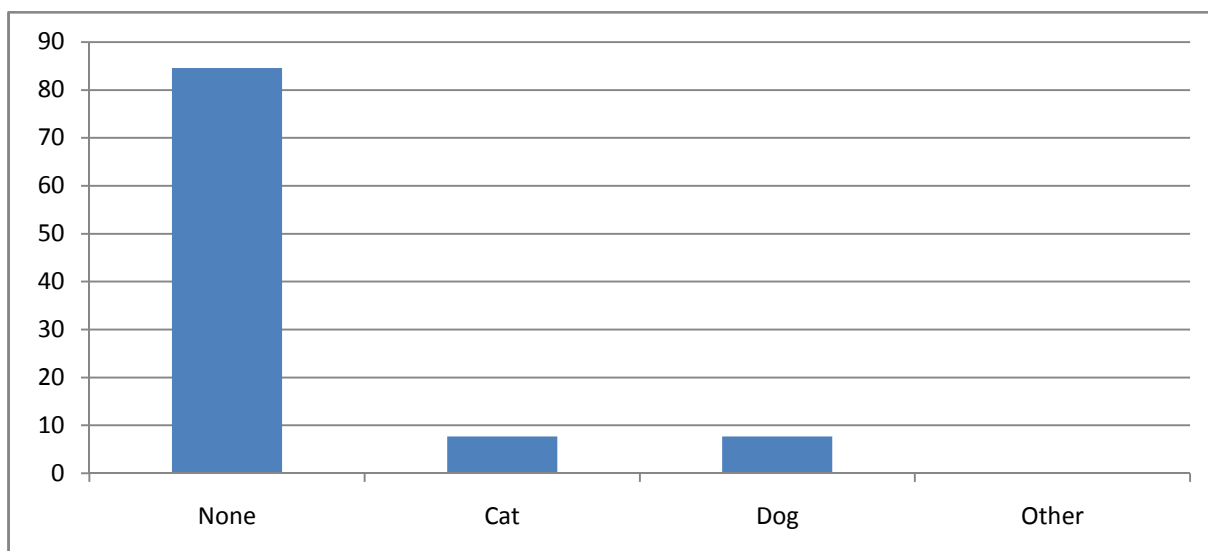


Figure 12: Pets owned by patients (values in %).

Looking at Table 6, 46.2% of patients declare to choose alone the food that they eat, while 30.8% chose most of the food and 23.1% are on a prescribed diet.

Table 6: Patients' food choices.

	Freq.	%
I choose all the food that I eat	6	46.2
I choose most of the food that I eat	4	30.8
I receive a meal service at home	0	0.0
I am on a prescribed diet from a medical professional	3	23.1
Total	13	100.0

Since the use of a technological device could improve functional capabilities of HF patients for the purpose of this project, it is interesting to focus particularly on patient abilities in using touchscreen computer device. We found that 77% of these patients own poor skills, 23% are beginner and no one rates himself as an expert or an advanced user (Figure 13).

Although patients have low skills in handling touchscreen device, our results show that 90% of them think that smartphones are the best technological instruments for monitoring remotely their HF symptoms (Figure 14).

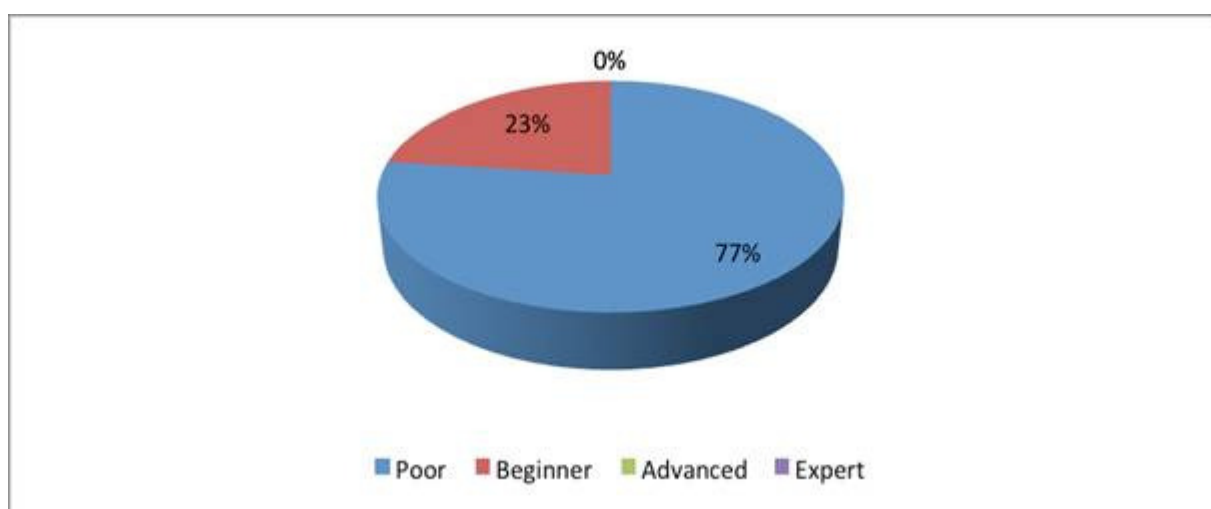


Figure 13: Skills distribution in handling touchscreen computer device.

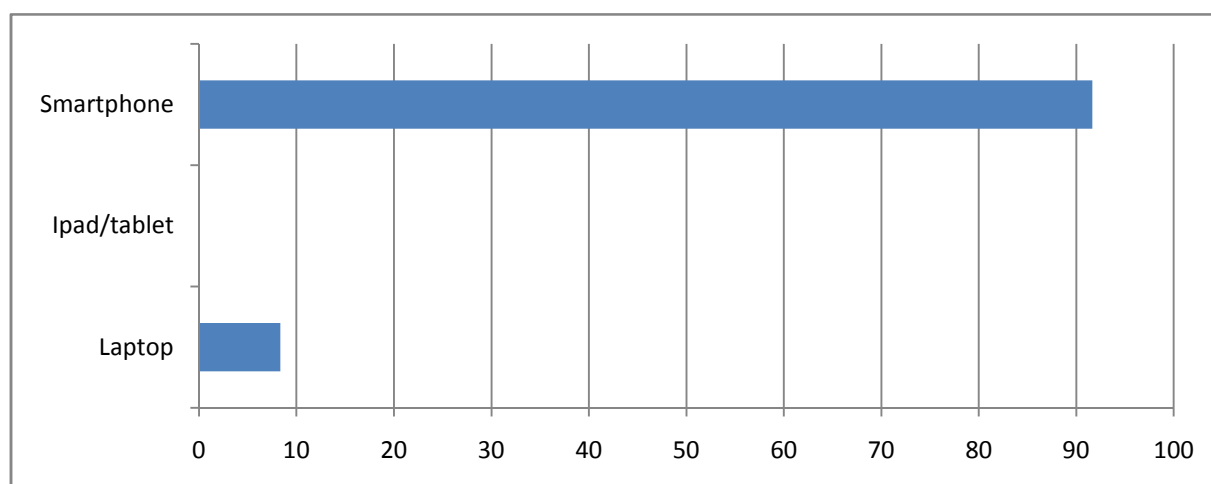


Figure 14: Remote technological device used to monitor HF patients (values in %).

Patients' health status

In this section, data from questionnaires are used in order to provide a brief description of patient health status and to understand how they rate their abilities in managing their treatments, lifestyle and symptoms at home.

Table 7 provides data about the impact of HF in patient daily activities using the New York Heart Association (NYHA) Functional Class [NYHA 1979]. This classification was introduced in 1928 as a way to provide a common instrument to rank patients. It classifies HF patients in one of the four categories based on the severity of the symptoms and limitation in physical activity [Holland et al. 2010].

According to the NYHA Functional Classification, 53.8% of patients belong to the Functional class II observing mild symptoms and slight limitation during ordinary activity. In addition, more than 46% of patients have further limitation: 38.5% go through marked limitation in activity whereas 7.7% show more severe limitation.

Table 7: Distribution of patient by Heart Failure Functional Class.

	Freq.	%
Functional Class I	0	0.0
Functional Class II	7	53.8
Functional Class III	5	38.5
Functional Class IV	1	7.7
Total	13	100

Nowadays, HF is one of the common causes of hospitalisation and readmissions. For these reasons, it seems useful to show the information in Table 8 in which we can easily see that 53.6% of patients experience hospitalisation once a year, while 23.1% have been hospitalised between 2 and 5 times during the last year.

Table 8: Distribution of patients HF hospitalisations during the last year.

	Freq.	%
Zero	2	15.4
Once a year	7	53.8
Between 2 and 5 times	3	23.1
More than 5 times	1	7.7
Total	13	100

In most patients, a variety of concomitant disorders may appear and contribute in the progression of the disease. Of all patients, 61.5% have four or more comorbidities. Figure 15 (below) shows that hypertension, dyslipidemia and diabetes are the most common comorbidities in our patients with HF.

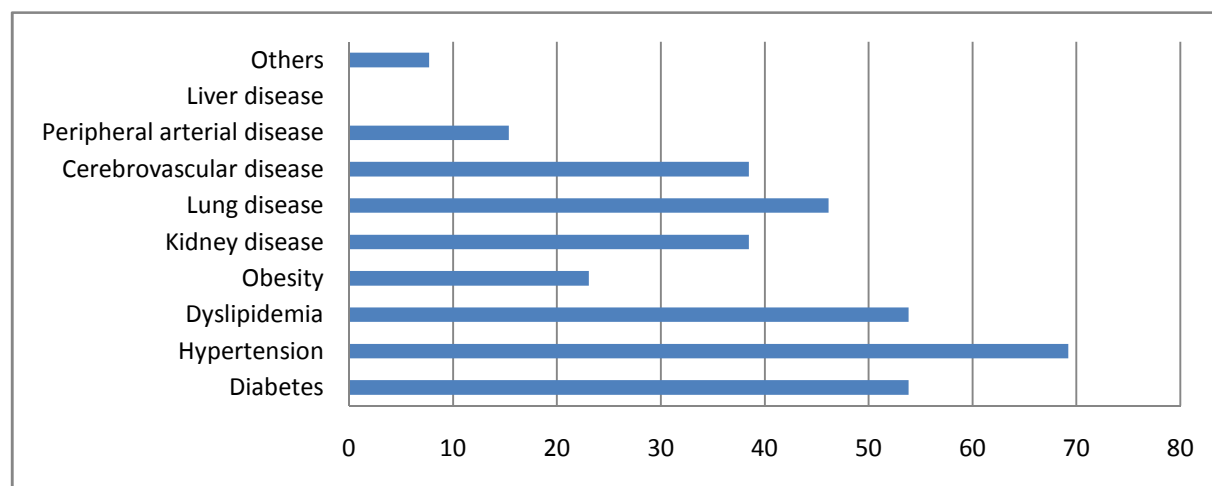


Figure 15: Presence of comorbidities in patients with HF (values in %).

Considering our sample, 53.8% of patients can live alone depending on their clinical condition while 30% think that they will never be able to live by themselves (Table 9). Furthermore, 92.3% of these patients have a family caregiver.

Table 9: Level of autonomy.

	Freq.	%
Always	0	0.0

During long periods of time	2	15.4
Depending on clinical situations	7	53.9
Never	4	30.8
Total	13	

As we can observe in Figure 16, it comes to light that General practitioners, Cardiologist, Internal Medicine doctors are the health professionals more involved in patients monitoring and treatment.

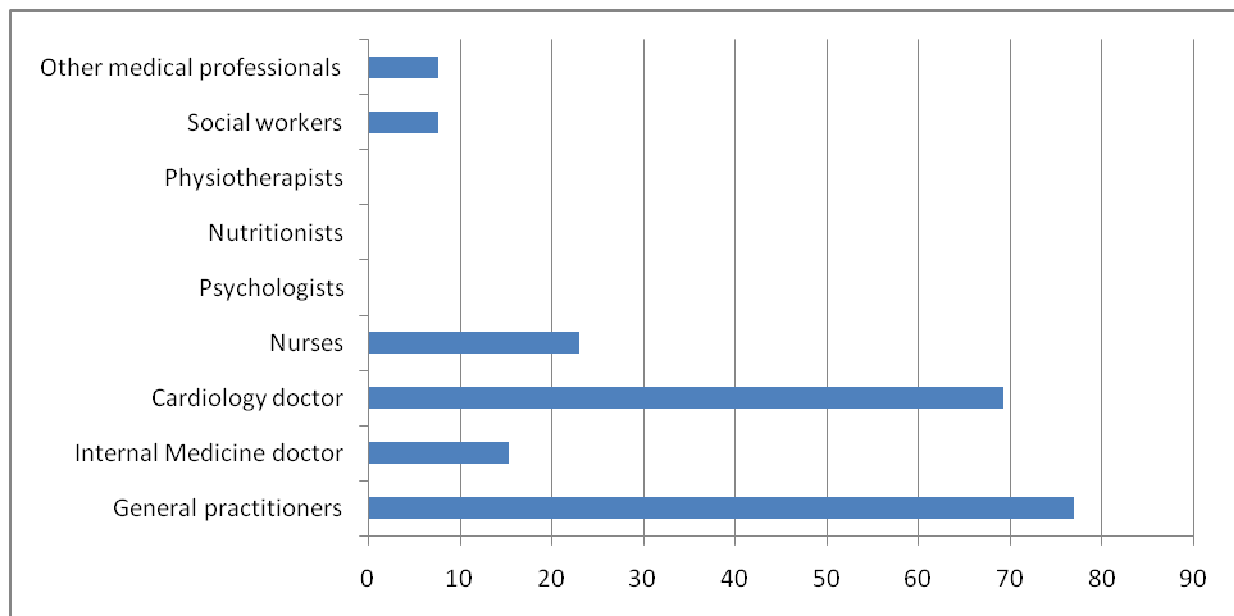


Figure 16: Health professional consulted for patient treatment (values in %).

In order to reduce HF, behavioural changes should be promoted. Exercise training is encouraged in 92.3% of the patients and at the same time dietary sodium restriction and weight loss are suggested in 76.9% of the cases (see Table 10).

Table 10: Types of suggestions received in relation with patient lifestyle.

	Freq.	%
Dietary sodium restriction	10	76.9
Weight loss	10	76.9
Exercise training	12	92.3
Cardiac rehabilitation	0	0.0
Others	2	15.4

Patients seem to be aware about the lifestyle changes recommended. In fact, only 7.7% of patients sample declare to have a poor knowledge on that. However, patients believe that, even though they make changes in diet and exercise recommended, it will not change anything in their health status (46.15%).

Variability is shown in patients' level of confidence about their skills in carrying out self-treatment; only 7.7% think to be fully confident in performing this task. Similar results are shown with refer to their level of confidence in taking actions that may help, prevent HF symptoms.

To conclude, 38.5% of patients with HF condition give a medium score on their abilities to handle symptoms alone (see Table D.1 in Appendix D for more details).

Identified Requirements

Considering patients' profile, it seems that the system must use a clear and comprehensive language to communicate medical information to them. HF patients have poor skills in managing computer devices even they consider smartphones as the best option to communicate with health professionals. Therefore we should take into account this characteristic in the phase of user interface design so as to provide them with an easy to use technological device. Videoconference, instant messaging systems and phone call should be proposed as specific communication channels by HEARTEN platform.

Weight loss and dietary restrictions appeared to be encouraged by health professionals, therefore the system should allow communication with the other ecosystem actors (caregivers, healthcare professional) in a daily basis and provide reminders and motivational messages to alert HF patients and empower them in carrying out self-treatment.

2.3.3. Caregivers analysis

General Information

Managing HF is not a simple task, and people experiencing this problem may need the help of somebody to perform daily activities. In this context, caregivers play an important role not only in helping people with HF to overcome their difficulties, but also in monitoring their health condition.

In the following pages we will analyse data from 9 caregivers. As shown in Figure 17, caregivers are mainly female (89%) and 44.4% are between 40 to 49 years old (see Figure 18). Moreover, 62.5% of them are patients' relatives (for e.g., wife, son/daughter), while 25% are professionals' caregivers.

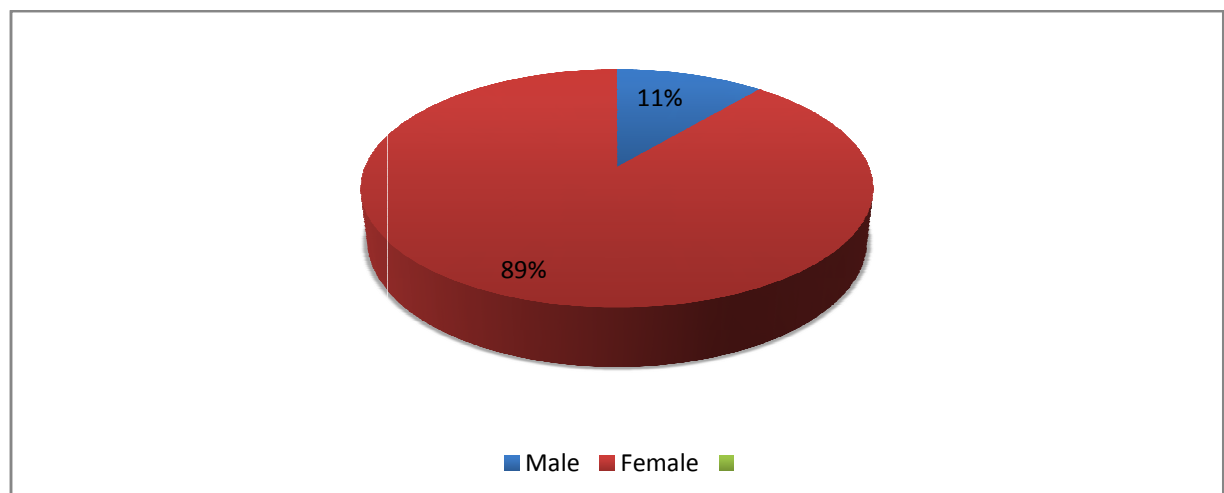


Figure 17: Gender distribution of caregivers.

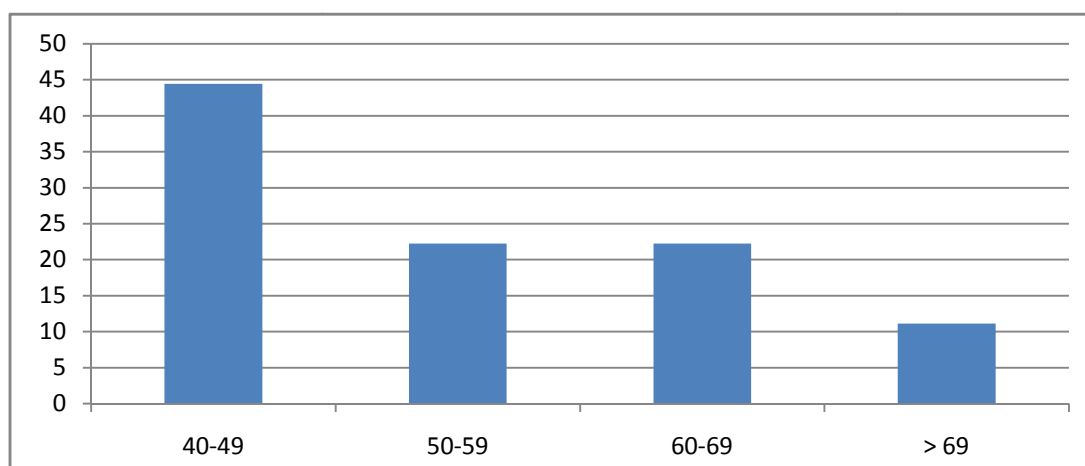


Figure 18: Age distribution of patients (values in %).

Data reported in Figure 19 shows variability in caregivers' skills in using touchscreen devices. Some of them have poor and beginner abilities (22% and 45%, respectively). Nevertheless, others owned an advanced knowledge. In general, there seems to be a positive correlation between young age and advance use of ICT devices.

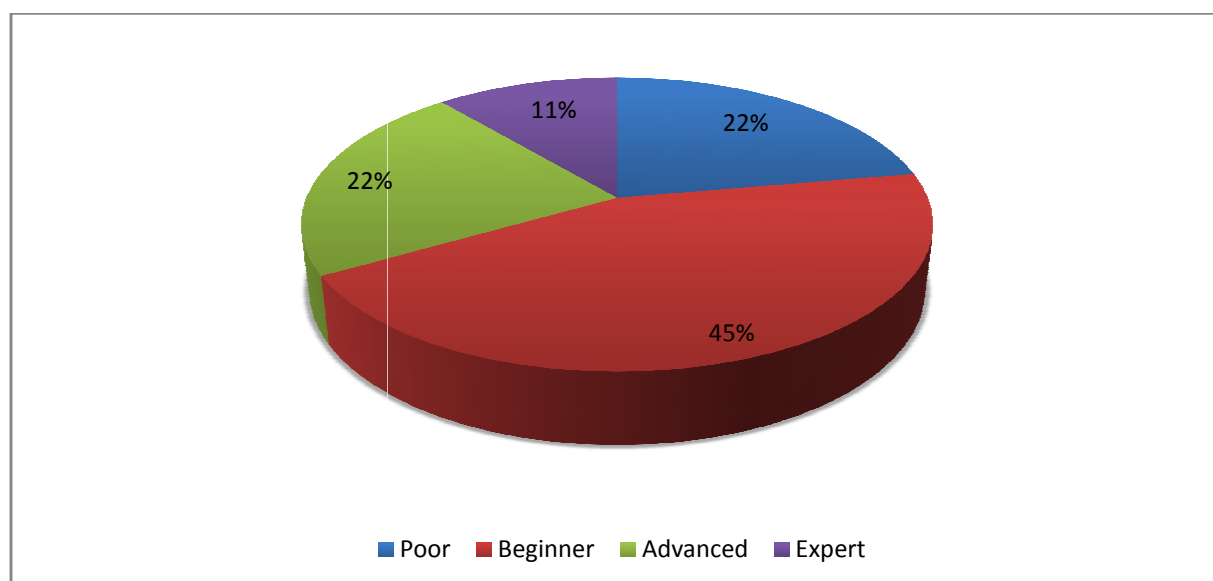


Figure 19: Skills distribution in handling touchscreen computer device.

Caregivers consider smartphones the best technological instrument to get information on HF patients (44.5%); only 11% think that laptop may be useful for this goal (Figure 20).

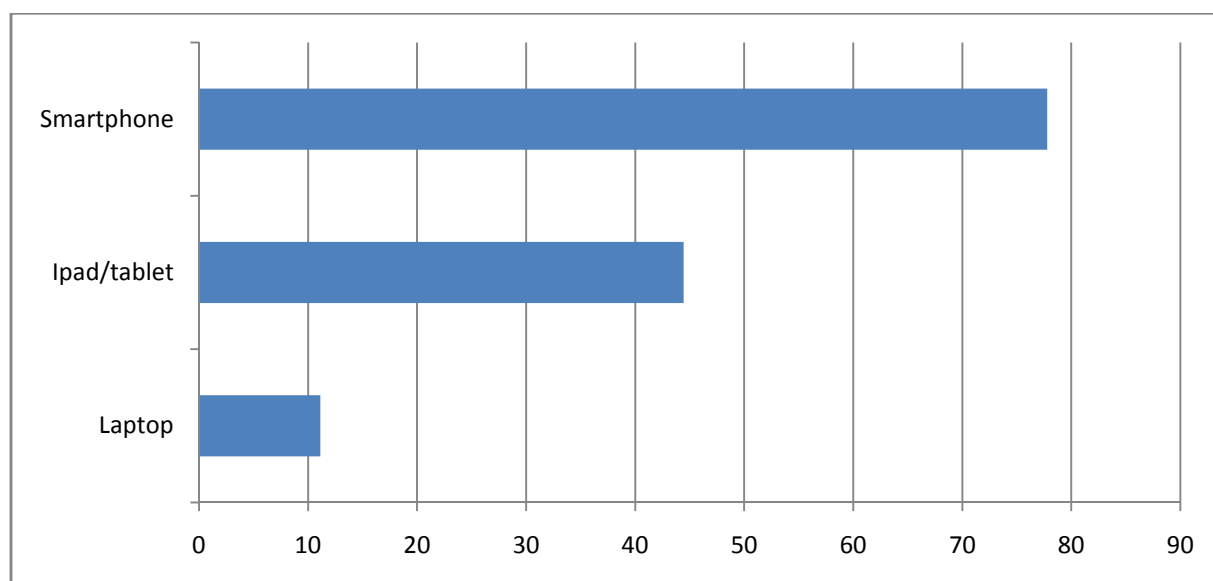


Figure 20: Remote technological device used to monitor HF patients (values in %).

Caregivers - patients' needs and interaction

As mentioned above, caregivers use to take care of relatives with chronic medical conditions trying to simplify their daily life.

Table 11 lists the distribution of NYHA Functional class for caregivers' patients. Caregivers report that most patients have NYHA class II (33.3%) or class III (66.7%) showing marked limitation in activity due to symptoms.

Table 11: Distribution of caregivers' patient by Heart Failure Functional Class.

	Freq.	%
Functional Class I	0	0.0
Functional Class II	3	33.3
Functional Class III	6	66.7
Functional Class IV	0	0.0
Total	9	

Common comorbidities in HF patients are represented by diabetes, kidney and chronic pulmonary disease. Data on Figure21 show that diabetes, hypertension and obesity are the most common comorbidities. Other important conditions to be considered are renal dysfunction (77.8%), peripheral arterial disease (77.8%) and dyslipidemia (66.7%).

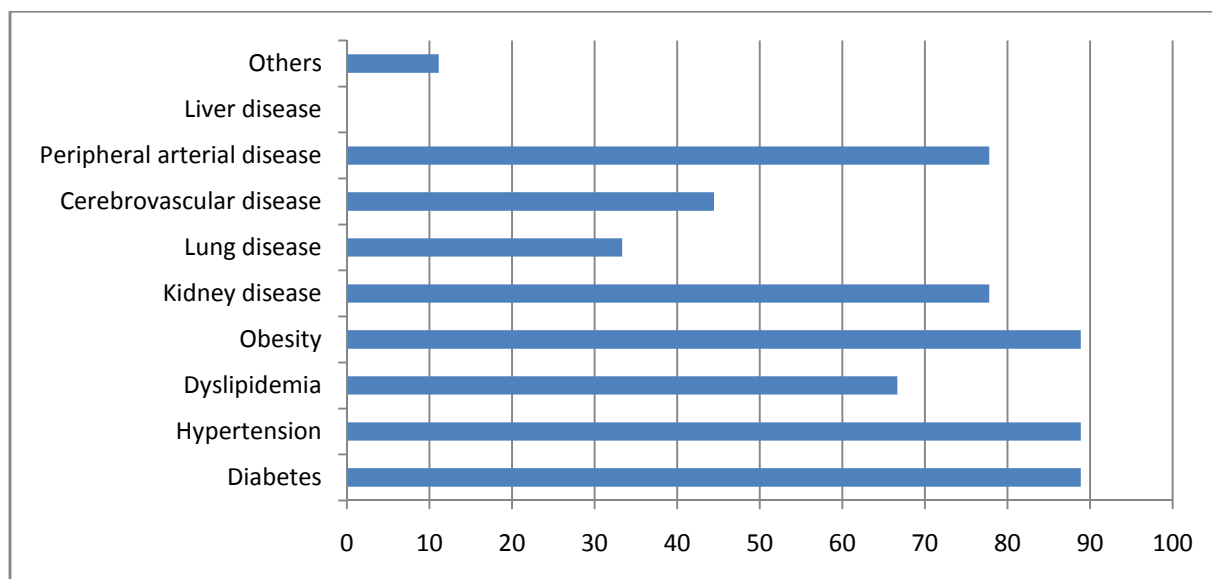


Figure 21: Presence of comorbidities in caregivers' patients with HF (values in %).

Patient with HF conditions may need different healthcare professionals. To manage their condition all caregivers' patients consult General Practitioners (GPs), whereas 55.6% of them communicate with a Cardiologist (see Figure22).

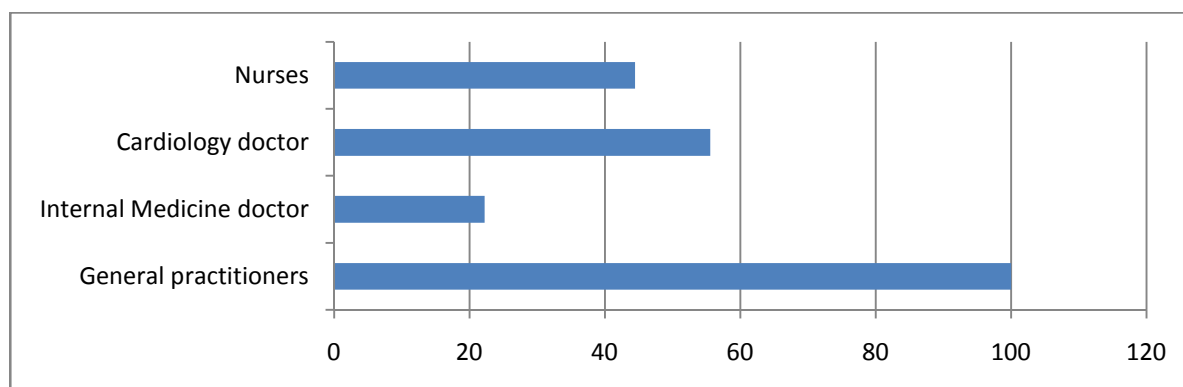


Figure 22: Health professional involved in patient treatment (values in %)*.

**Psychologists, Nutritionist, Physiotherapists, Social workers are not involved in monitoring/treating HF patients*

Care is important in patients with HF disease. It is clear from Figure 23, that caregivers are more responsible for medication administration in HF patients (88.9%).

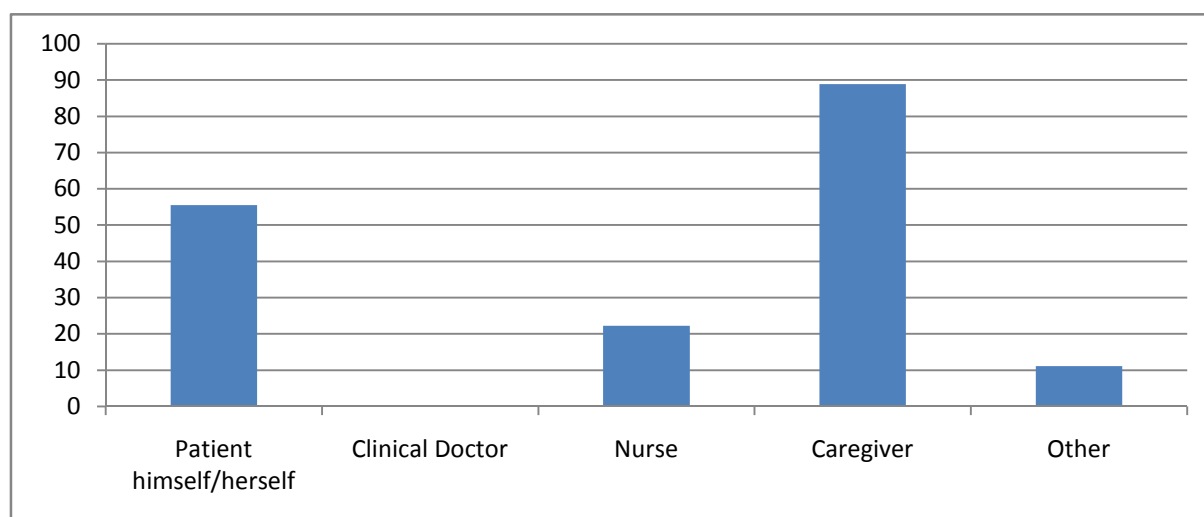


Figure 23: Person responsible for medication administration/adherence of HF patients (values in %).

All caregivers have received suggestion on dietary sodium restriction in order to improve patient health status. Furthermore, weight loss (88.9%) and exercise training (77.8%) are others advice given to caregivers as a way to take care of their patients (Table 12).

Table 12: Types of suggestions received in relation with patient lifestyle.

	Freq.	%
Dietary sodium restriction	9	100.0
Weight loss	8	88.9
Exercise training	7	77.8
Cardiac rehabilitation	1	11.1
Others	0	0.0

As shown in Figure24, there are different ways to get information from healthcare professionals, but caregivers think that direct contact (88.9%) is the best one.

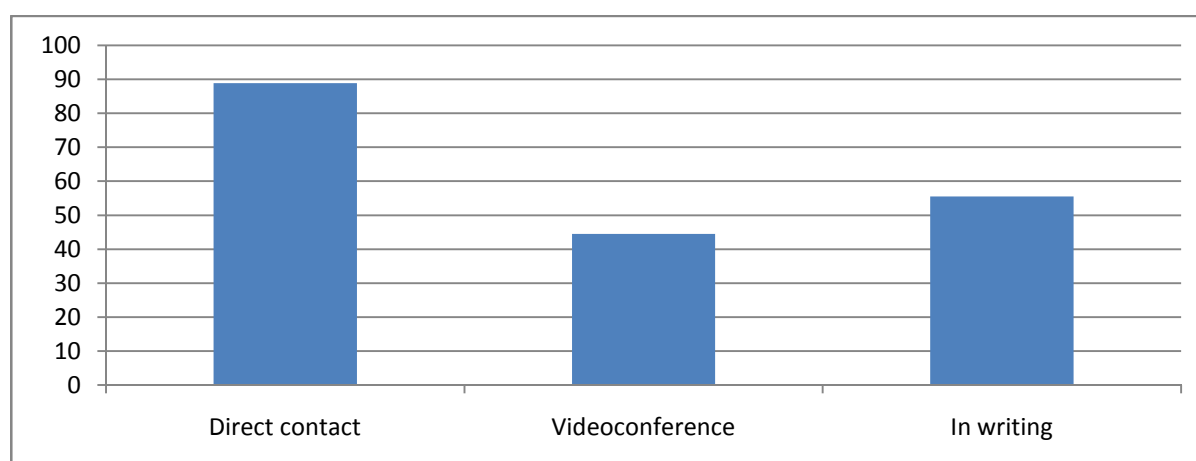


Figure 24: Best way to receive information from healthcare professionals (values in %).

Despite the presence of more technological instruments to receive information, caregivers prefer to get information by telephone call in case of a blood pressure problem (88.9%). However, 66.6% of these patients think that information may be sent using an alert through the Hearten App (Figure25).

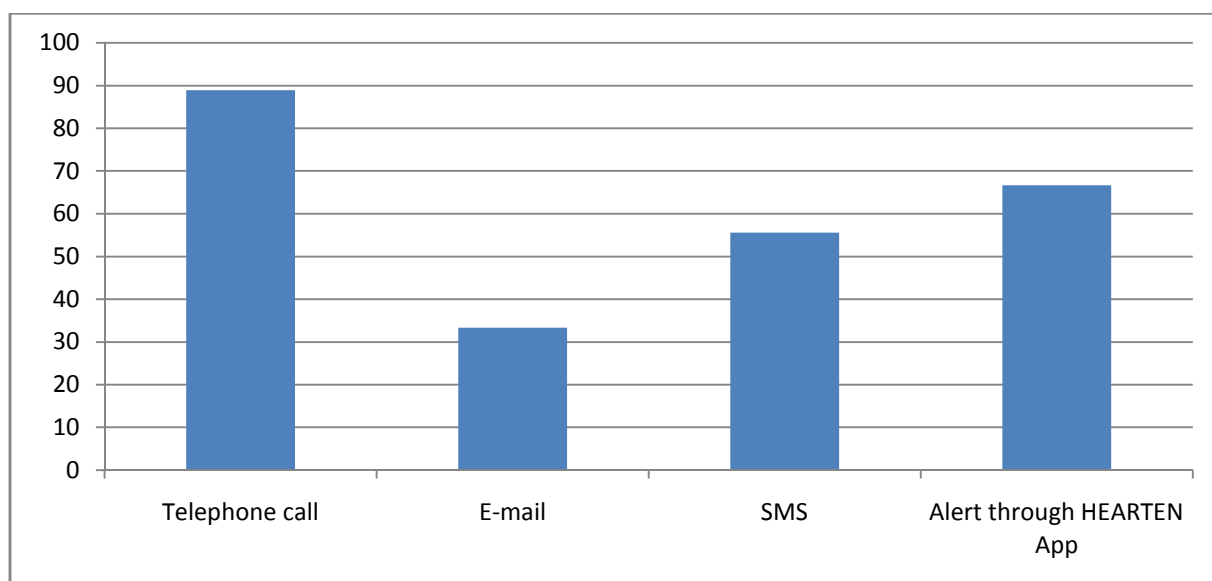


Figure 25: Canal of communication in case of blood pressure problem (values in %).

Caregivers believe that in case of an exacerbation or adverse effect, health professionals should respond instantly or in the following hours. In addition, 55.6% of them assert that they often need to press patients to take their medication (Table 13).

Table 13: Need to press HF patients to take their medication.

	Freq.	%
Always	1	11.1
Often	5	55.6
Sometimes	1	11.1
Never	2	22.2
Depends on the clinical situation	0	0.0

Identified Requirements

In contrast with patients, caregivers seem to have more advanced skills in the use of technological devices. In their opinion, direct contact is the best way to receive information from healthcare professionals. Consequently, the system should propose specific communication channels as videoconference or instant messaging, given patients symptoms.

As shown above, caregivers' patients have different comorbidities. For this reason, the system should provide a self-monitoring module as a way to take into account biological variables and other lifestyle issues and to manage a possible communication between patients and professionals.

In addition, the caregivers should be able to import the nutrition habits of the patients in a daily basis, in case they live together, as well as provide them with direct communication with the patients in case of emergency issues.

2.3.4. Healthcare professional analysis

General Information

Healthcare professionals may play a central role in the treatment of patients with HF. It is important notice that care may be delivered not only on a clinic, but also at patients' homes. The advantage of home-based treatment is that healthcare professional can help sick people, who might not be able to reach a hospital [Holland et al. 2010].

Different health professionals are involved in patient HF treatments: GPs, cardiologists, internal medicine doctors, psychologists and nutritionists. In our sample of 26 health professionals, 46.1% of them are Cardiologists, 38.5% Internal medicine doctors and 15.4% Anaesthesiologists.

As depicted in Figure 26, 54% of health professionals are male. In addition, the age distribution data show that the majority of health professionals are between 30-39 years old (Figure 27).

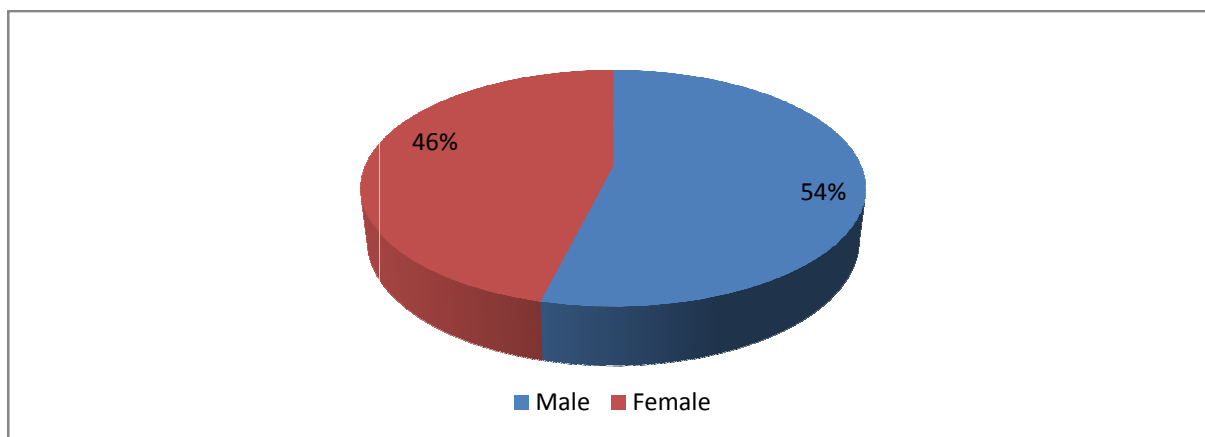


Figure 26: Gender distribution of Health professionals.

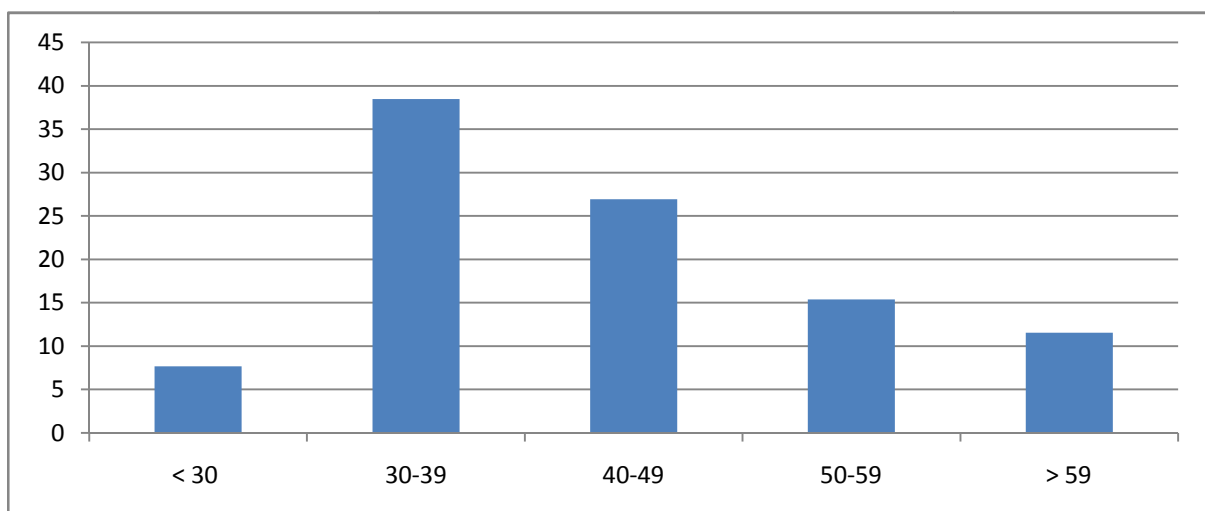


Figure 27: Age distribution of health professionals (values in %).

Among health professionals, 42.3% have less than 10 years of employment, while 26.9% register more than 20 years of experience (see Table 14 below). Moreover, 53.8% declare to treat 5-10 HF patients per week, while very few of them examine more than 20 patients.

Most of the health professionals have high skills in the use of touchscreen device, just 15% are beginner and no one have poor skills (Figure 28 below).

Table 14: Years of health professionals employment.

	Freq.	%
< 10	11	42.3
10-19	8	30.8
20-29	1	3.9
30-39	5	19.2
> 39	1	3.9
Total	26	

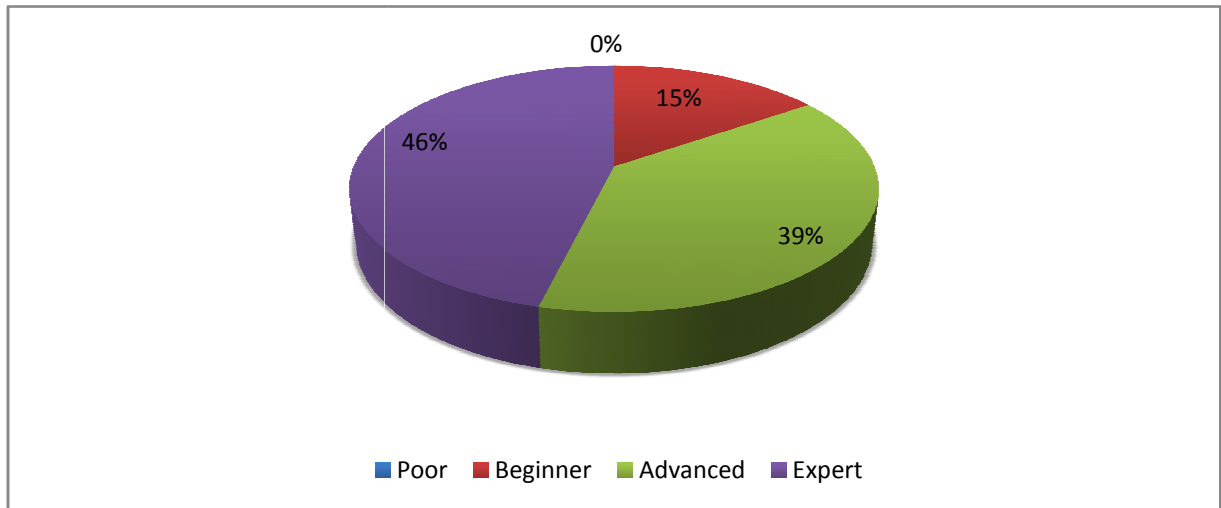


Figure 28: Skills distribution in handling touchscreen computer device.

As shown in Figure 29 healthcare professionals seem to prefer an Ipad and/or a tablet to monitor HF patients remotely (57.7%) as well as smartphones (46.1%).

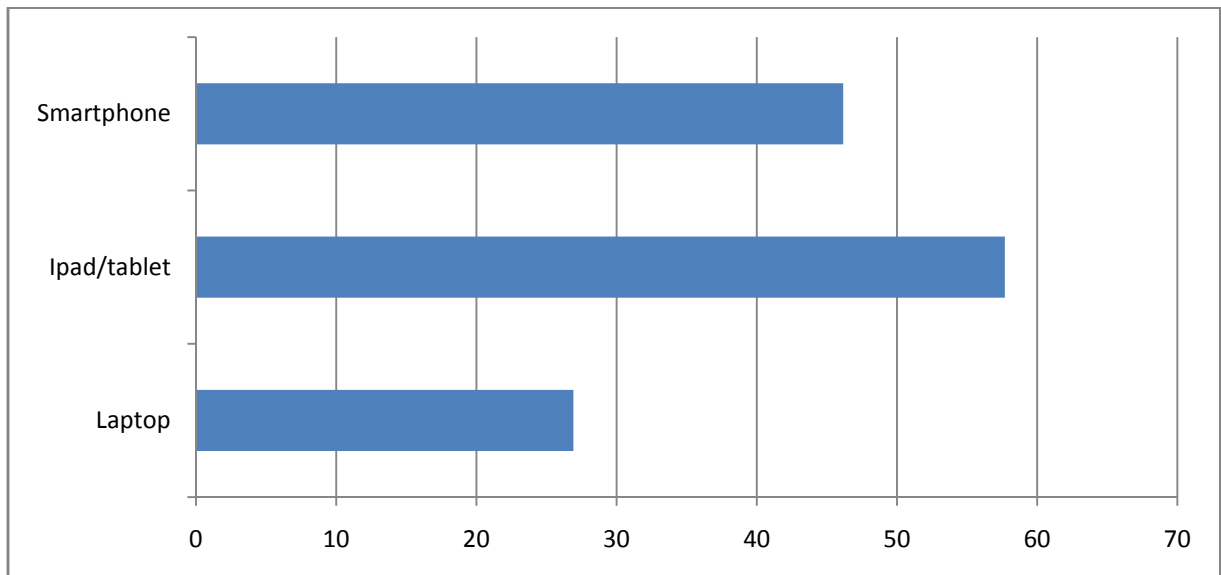


Figure 29: Remote technological device used to monitor HF patients (values in %).

Healthcare professionals - patients' needs and interaction

In Table 15, we examine the extent of HF on patient's daily life using NYHA functional class. Few patients are classified as Functional class II (26.9%), while a higher number of them are ranked in Functional class III and IV (50.0% and 23.1% respectively).

Most of these health professionals' patients are hospitalised once a year (72%), whereas low percentages are hospitalized once a month (12%) or a week (8%).

Table 15: Distribution of health professionals' patient by Heart Failure Functional Class.

	Freq.	%
Functional class I	0	0.0
Functional class II	7	26.9
Functional class III	13	50.0
Functional class IV	6	23.1
Total	26	

Functional status scales are commonly used to assess the physical and cognitive capacities required to be independent [Russel et al. 1994].As we can see from Figure 30, we can use different scales to measure patients' independence. However, patients' lifestyles are usually measured by Barthel (42.3%) and Minnesota scales (19.2%).

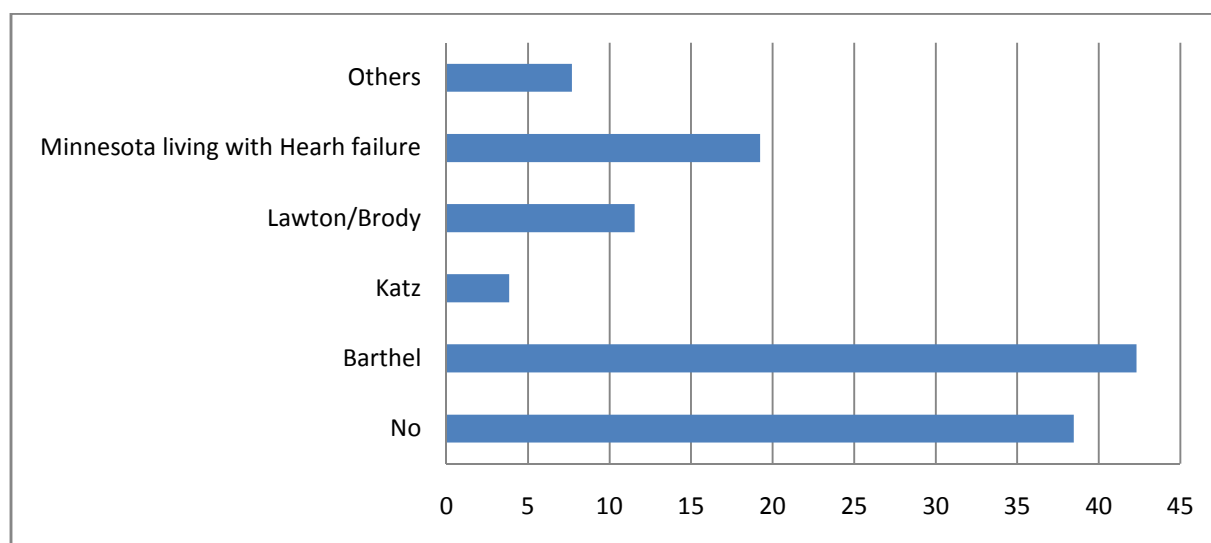


Figure 30: Functional scales used to measure patient lifestyle.

Receiving care at home is often desirable, not only from an economic point of view but also to patients' wellbeing. Caregivers are commonly used to help people with chronic disease, managing treatments or talk with healthcare professionals. According with physicians' experience in HF treatment, patients' caregivers are wife and husband (88.5%) or/and son and daughter (69.2%).

Figure31 shows that General practitioners, cardiologists, nurses and internal medicine doctors are the healthcare professionals more involved in monitoring/treating patients with HF.

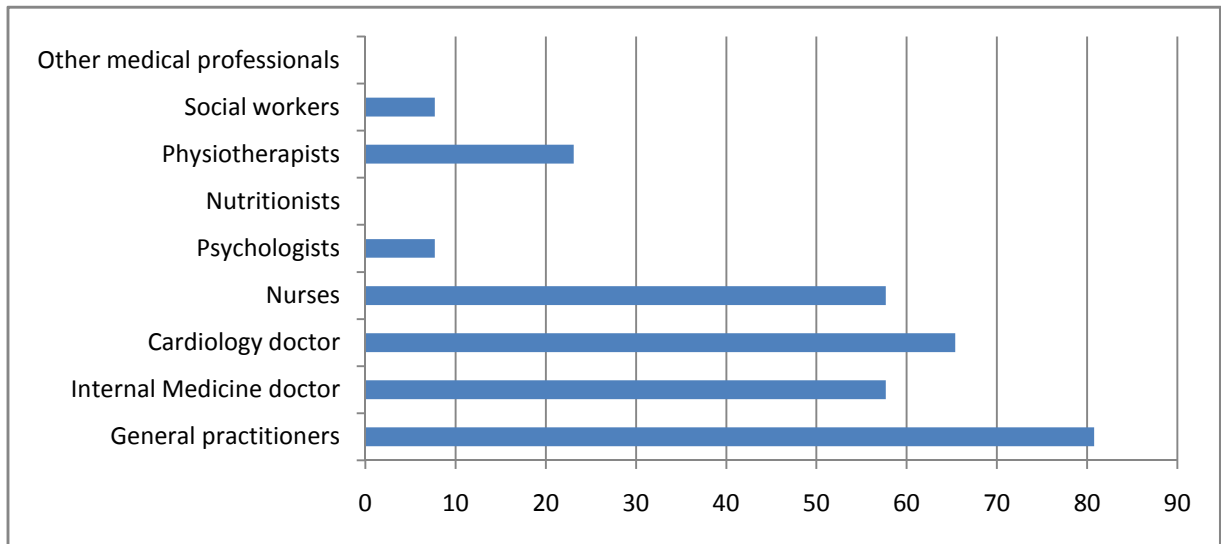


Figure 31: Health professional consulted for patient treatment (values in %).

Patient himself (92.3%), caregivers (80.7%) and clinical doctor and nurse (11.5%) are the people involved in medication administration/adherence of HF patients (Figure 32).

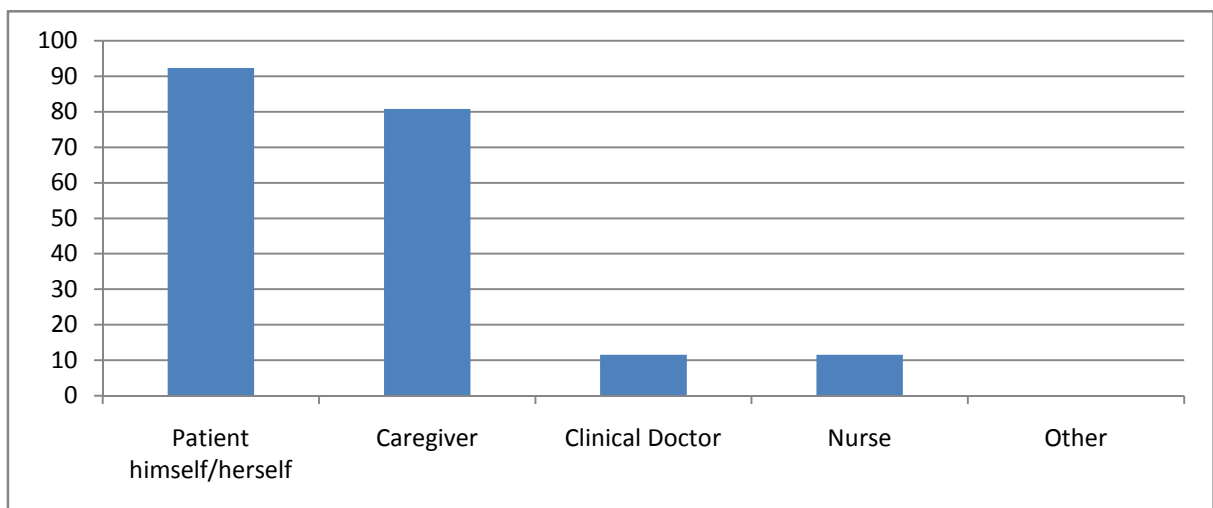


Figure32: Person responsible for medication administration/adherence of HF patients, (values in %).

Weight measure is recommended by healthcare professionals as a way for patients' monitoring. Furthermore, blood pressure and cardiac frequency should be taken to support patients' health observation (Figure33).

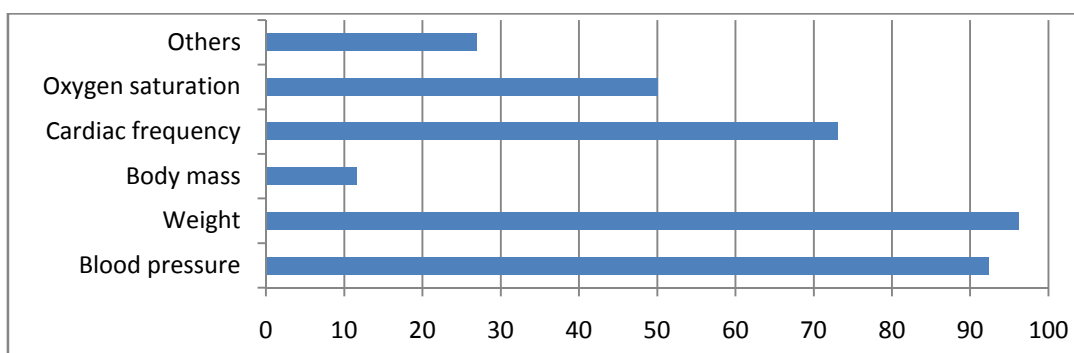


Figure 33: Physiological measurements that should be used for patient monitorisation (values in %).

Commonly, those measures are required in the same day (41.7%) or weekly (33.3%). However, if patients are monitored remotely, data seems do not change significantly. In fact, 56.5% of healthcare professionals expect to receive information about their clinical situation in the same day (see Table 16). In addition, they should take part to a treatment linked to an exacerbation or adverse event in the same day (50.0%) or instantly (45.5%).

Table 16: Notification required in case of patients monitored remotely.

	Freq.	%
Instantly	1	4.3
In the same day	13	56.5
Weekly	9	39.1
At request	0	0.0
Total	23	

In healthcare professionals' opinion, caregivers should use SMS (42.3%) or telephone call (38.5%) to communicate with them in case of blood pressure problems (Figure34).

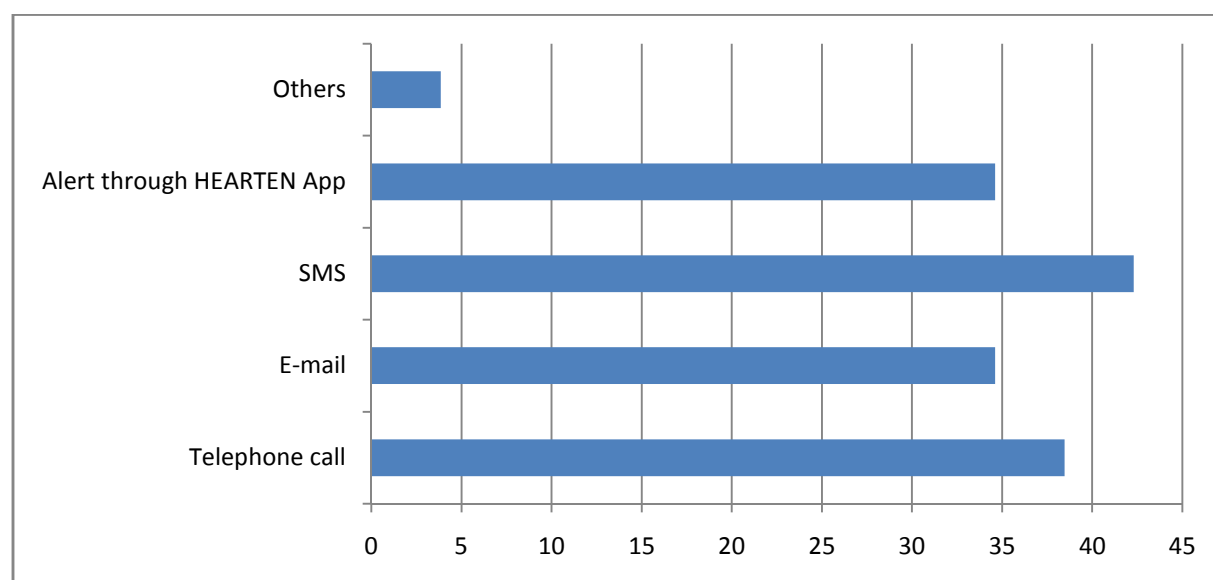


Figure 34: Canal of communication in case of blood pressure problem (values in %).

Identified Requirements

Healthcare professionals present in general advanced or high skills in the use of electronic devices. Since SMS are considered the best option to keep healthcare professional informed about patient conditions, the system should offer more information and assistance on how to use the Hearten app.

Although there are different functional scales, patients' lifestyle is usually measured by Barthel and/or Minnesota scales. For these reasons, the system must provide prognostic evaluation scales and therapeutic decisions algorithms using the information registered by the patients and caregivers. In addition, considering professional requirements in case of a patient monitored remotely, the system must offer a module to simplify the follow up of patients.

Healthcare professionals should communicate both with the patient and the caregiver. They should be able to provide alerts and recommendations to the patients while with the caregivers they should notify them for further assisting the patients in a specific field of HF treatment (e.g. medication) or even provide extended messages or alerts in case of a critical patient's status.

2.3.5. Nutritionist/Nurse analysis

General Information

Despite medical progress, the prevalence of HF will increase quickly in the next years [Heidenreich et al. 2013]. For this reason, managing care for heart failure patients is an important path not only to reduce health costs but also to improve patient quality of life.

Nowadays, HF nurses and nutritionist carry out important roles in helping patients and families with cardiac conditions. Usually, nurses and nutritionists have a degree qualification with knowledge in family and patient education. In addition, the use of specialised nurses may help patients to learn how to monitor symptoms and keep actions in case of exacerbation [Jaarsma 2005]. Given that, it is useful analyze our sample of twenty-seven nurses and nutritionists.

As shown in Figure35, 76% of nurses/nutritionist are female. Furthermore, almost 41% of them are between 40 to 49 years old (Figure36).

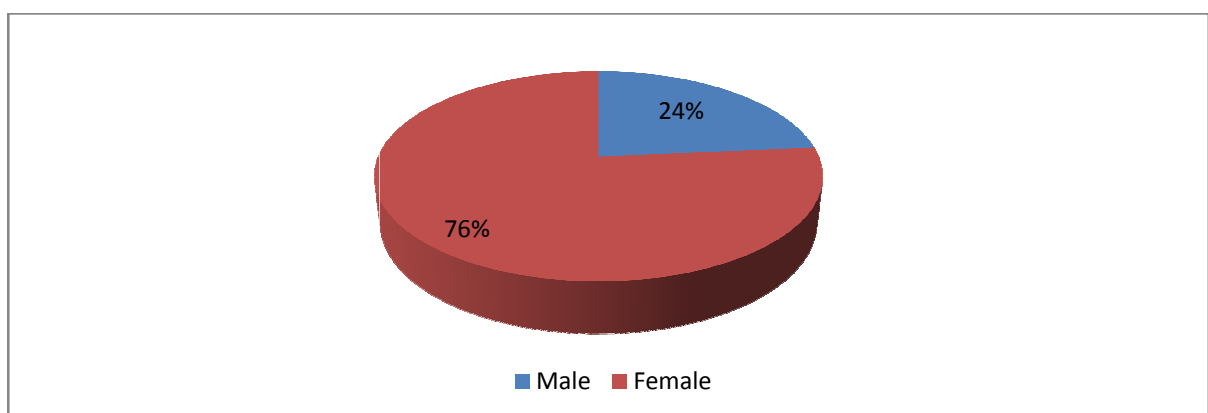


Figure 35: Gender distribution of nurses/nutritionist.

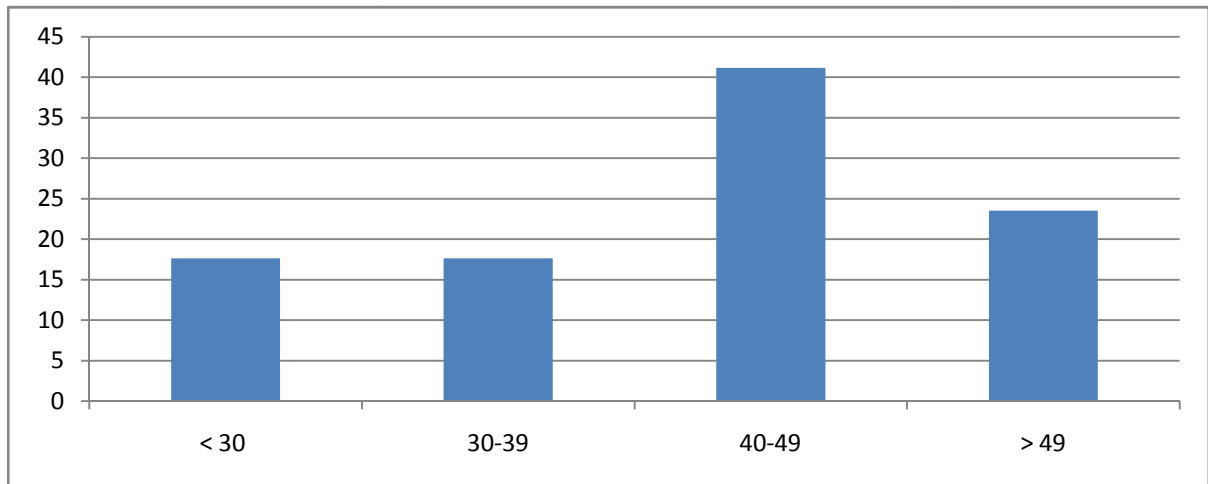


Figure 36: Age distribution of health professionals (values in %).

Among nurses/nutritionists, 47.1% have between ten to nineteen years of employment, while 41.2% has been working for more than 20 years. In addition, 47.1% handle 5-10 heart failure patients per week.

As in the case of health professionals, nurses and nutritionists show high abilities in the use of touchscreen computer device, even though 24% of them classify themselves as a beginner (Figure37). Finally, Ipad and Tablet appear to be the technological device preferred by nurses and nutritionist to monitor HF patient remotely (Figure38).

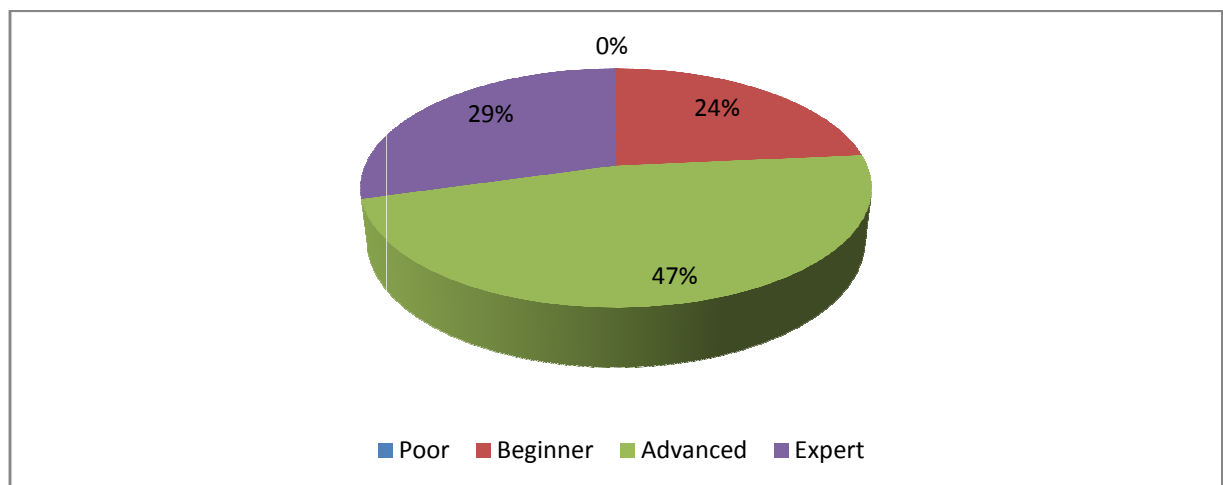


Figure 37: Skills distribution in handling touchscreen computer device.

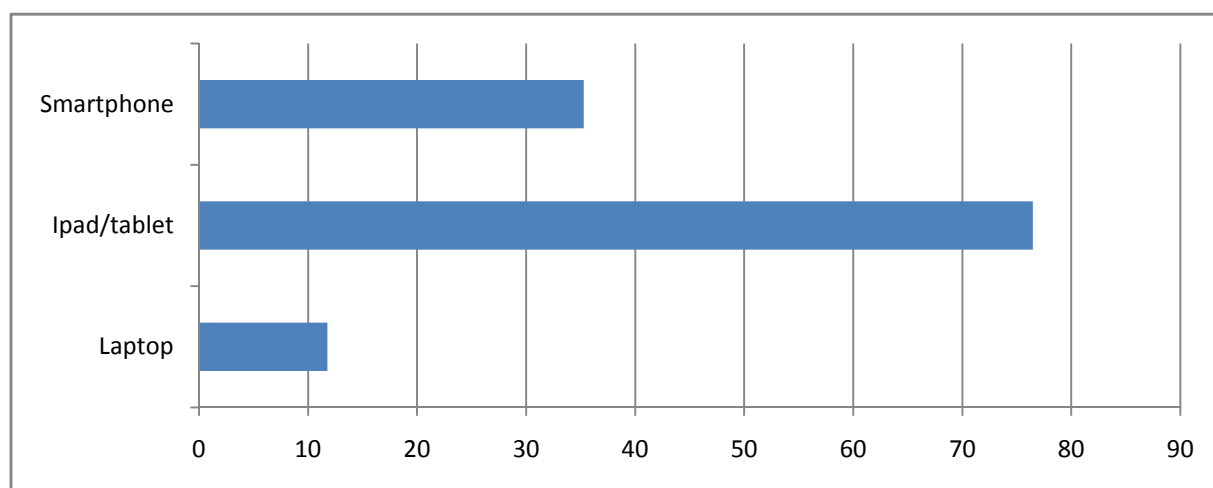


Figure 38: Remote technological device used to monitor HF patients, (values in %).

Nutritionists - patients' needs and interaction

According with data presented in Table 17 below, 64.7% of patients had a functional class II, while 23.5% are placed in the more severe class. In addition, these patients are hospitalised once a year in 58.8% of the cases analysed.

Table 17: Distribution of health professionals' patient by Heart Failure Functional Class.

	Freq.	%
Functional class I	0	0.0
Functional class II	2	11.8
Functional class III	11	64.7
Functional class IV	4	23.5
Total	17	

Although a variety of specialists can be contacted to handle patients with HF, nurses and nutritionists report that most patients use to consult nurses, cardiologist, internal medicine doctors in order to monitoring their health conditions (Figure 39).

Looking at Table 18, we can say that 41.2% of nurses/nutritionists think that visits should be performed once a day.

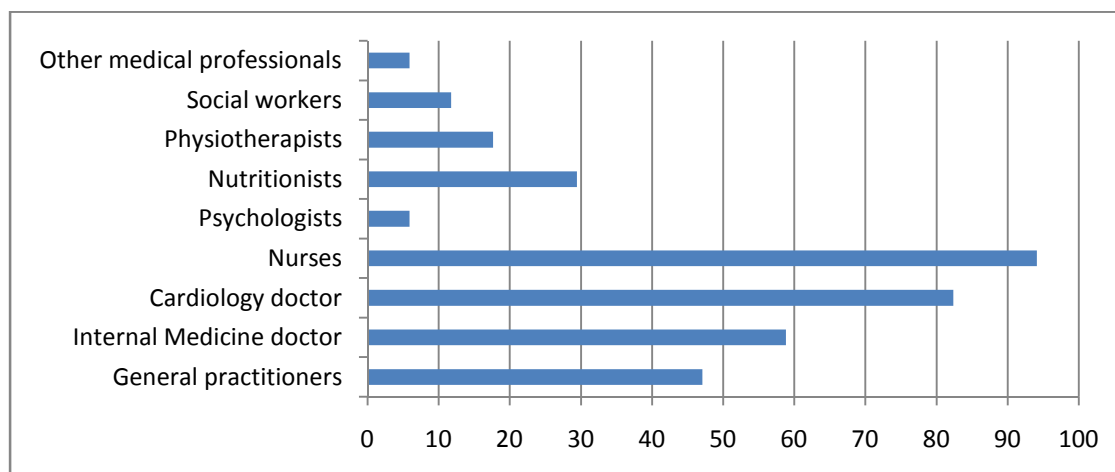


Figure 39: Health professional consulted for patient treatment (values in %).

Table 18: Visits performed in patients with HF (values in %).

	Freq.	%
One a day	7	41.2
Twice at week	2	11.8
Weekly	2	11.8
At request	6	35.3

It is interesting notice that nurses seems to be responsible for patients' medication in 88.2% of the cases.

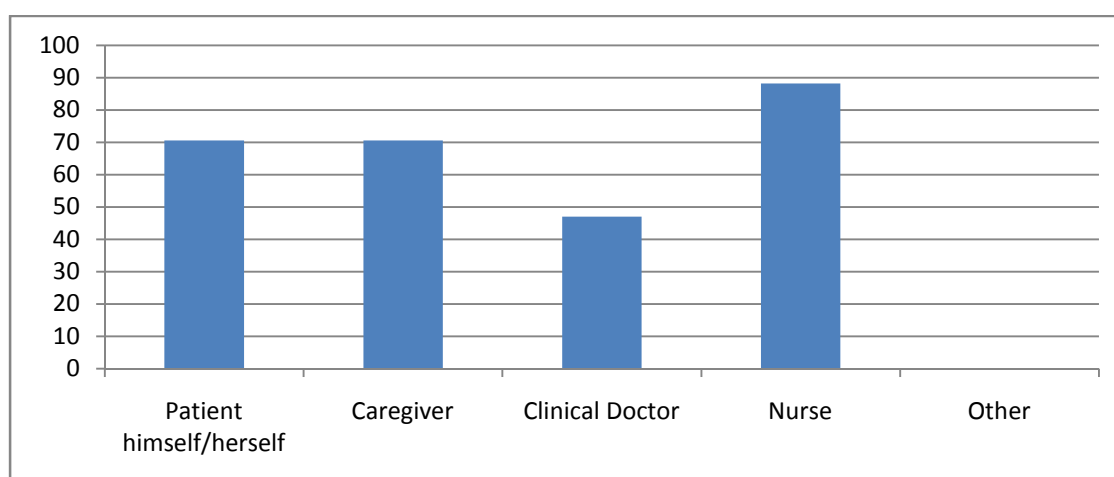


Figure 40: Person responsible for medication administration/adherence of HF patients (values in %).

We have seen that nurses and nutritionist play an important role in treatments and care of HF patients. Data shown in Table 19, reveals that nurses/nutritionist give patients more advice related to exercise training, weight loss and in dietary restriction

Table 19: Types of suggestions received in relation with patient lifestyle.

	Freq.	%
Dietary sodium restriction	12	70.6
Weight loss	16	94.1
Exercise training	17	100.0
Cardiac rehabilitation	7	41.2
Others	2	11.8

In most cases, nutritionist/nurse thinks that blood pressure, cardiac frequency and oxygen saturation should be used in order to monitor patients (Figure 41). Moreover, it seems that nurses/nutritionist required those measures in the same day in the 64.7% of cases.

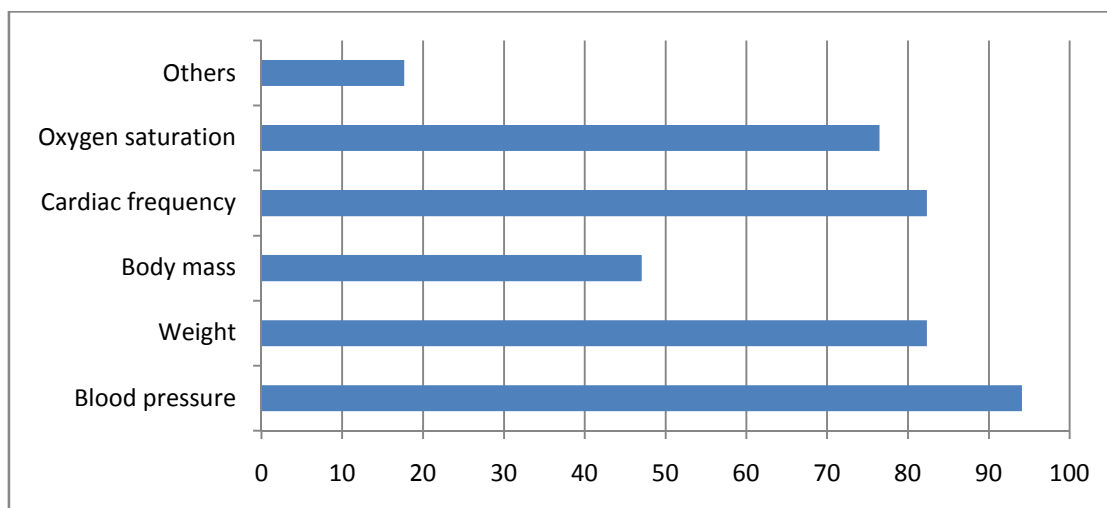


Figure 41: Physiological measurements suggested.

In spite of an increase role of nurses/nutritionist in managing patient with HF, it seems that in a hospital setting they cannot make any change in the pharmacological treatment plan of their patients. But, it is interesting notice that 29.41% of nutritionist/nurses interviewed have the possibility to make some changes according with doctors (Table 20).

Table 20: Ability of nurses/nutritionist in making changes in the pharmacological treatment plan of HF patients.

	Freq.	%
No	12	70.6
Yes, always	0	0.0
Yes, it depends on the doctor	5	29.4
Yes, it depends on the clinical condition of the patient	0	0.0

Identified Requirements

Nutritionists like healthcare professionals own high skills in managing technological devices but they prefer iPad and/or tablet to monitor HF patients. HEARTEN system should permit nurses and nutritionists to obtain information about patients' health status with emphasis on blood pressure, heart rate as well as breath/saliva biomarkers. Moreover, since those measures are important to evaluate the health status of HF patients the system must offer real time, alerts and allow direct communication with the healthcare professional in case of critical situations.

2.3.6. Conclusions

Since HF is a very common syndrome associated with high morbidity and mortality rates, the goal of the survey was to collect detailed information on patients, caregivers and healthcare professionals as a way to develop an ICT environment to help patients to improve their health conditions.

Patients recruited for the survey are in general men aged 70 to 79 years old declaring to have poor skills in handling touchscreen computer device and thinking that smartphones are the best option to monitor patients remotely. They have a slight or more severe limitation due to their HF condition and in most cases they declare to be hospitalized at least once per year.

In contrast with patients, caregivers seem to have more advanced knowledge in the use of technological device. The majority of them are women aged 40 to 49 years old. Their patients have a functional class II and III with diabetes, hypertension and obesity problems. In their opinion, direct contact is the best way to receive information from healthcare professionals. In addition, telephone calls and the hearten app are considered the best instruments to get information in case of blood pressure problems.

Considering the healthcare professionals, they are in general men aged 30 to 49 years old with advanced or high abilities in the use of electronic devices. Their patients have a slight or more severe limitation due to their heart failure condition. Unlike caregivers, they seem to prefer Ipad and/or tablet to monitor HF patients remotely. However, SMS are considered the best option to keep healthcare professionals informed in case of blood pressure problems.

Nutritionists are in prevalence women, aged 30 to 49 years old. As healthcare professionals, in general, they own high skills in managing technological devices and they prefer Ipad and/or tablet to monitor HF patients. Furthermore, their patients belong to higher functional classes and they use to contact nurses, cardiologists and internal medicine doctors to handle their medical conditions.

Overall, it seems that, the younger the patients, healthcare professionals, caregivers and nutritionist, the higher the likelihood to use ICT devices to handle heart failure condition.

2.4. Methodology overview

Navigational Development Techniques (NDT) methodology is proposed to cover the user requirement analysis [Escalona et al. 2008].

NDT is a methodology to capture and analyse information systems requirements, oriented in Model Driven Engineering paradigm. Using NDT, user requirement analysis is performed in a structured way, reducing errors, redundancies and the lack of necessary information.

NDT features:

- Requirements and analysis phases in software engineering are covered.
- Support to carry out patterns and artefacts.
- Inconsistencies and errors are reduced.
- The analysis models development is transformed into automatic systematic processes.
- Automatic generation of requirements document, analysis document, prototypes, etc.
- Support to visualise graphical models.
- Support to manage several projects simultaneously.
- Support to manage several development teams working at the same time.

NDT team offers a free development suite, called NDT-Suite, which guides the software engineer in methodology use; covering the phases of development, quality assurance, maintenance, testing and security, all of them based on V3 Metrics methodology. This fusion is based on defining a process, similar to V3 Metrics, but making use of UML models and the extensions that NDT makes of them, as well as the Model Driven Engineering processes.

Nowadays, NDT is been used in some projects and business experiences [Escalona et al. 2010] [García-García et al. 2014].

More information about NDT on: <http://www.iwt2.org/web/opencms/IWT2/ndt/?locale=en>.

2.5. User requirements analysis using NDT

We present a definition of objectives and functional requirements using NDT to make the user requirements analysis and define users' needs.

The objectives describe the needs to be met by the system. These objectives are detected via interviews with clients and users. To define the objectives, NDT define the following mandatory information:

- Code and name: Each objective must be classified with a code and a descriptive name. The code must comply with the following format: OBJ-XX, being XX to figures.
- Author: Name of the organization in charge of defining the objective.
- Notes: Description, as detailed as the author deems necessary, of the objective.
- Stability: Probability of the object suffering changes in its definition. A default value must be chosen: Closed, not closed.
- Importance: Importance for the client of the fact that the system complies with the objective. A default value must be chosen: Very high, High, Medium, Low, Very Low.

- Urgency: Urgency in the accomplishment of the objective. A default value must be chosen: Urgent, Not Urgent.

Furthermore, the following optional information defined by NDT has been included to enhance the objectives:

- Status: Situation of the objective being developed. A default value must be chosen: Proposed, Approved, Required, Validated, Implemented.
- Version: The different versions of the objective are managed within this field.
- Date: Date on which the current version of the objective was defined.
- Comments: Any other information deemed convenient.
- Priority: Priority of the objective. A default value must be chosen: High, Medium, Low.

A functional requirement defines the behaviour of a specific function of the system. Functional requirement answer the question of what can the system do. In order to capture and define the functional needs, NDT makes use of two different techniques. It proposes to apply use case diagrams [Jacobson 1995], which represent graphically the functionality of the system. Nevertheless, the exclusive use of diagrams can be very ambiguous in some cases. This is the reason why NDT proposes to add textual information to these diagrams, gathered via patterns, clarifying their meaning and what they represent. For functional requirements, NDT defines the following mandatory information:

- Name: Each functional requirement must be classified with a code and a descriptive name. The name must comply with the following format: FR-XX, being XX two figures.
- Author: Name of the organization in charge of defining the artefact.
- Notes: Description, as detailed as the author deems necessary, of the artefact.
- Constraints: It is compulsory to define constraints in a functional requirement. They can include pre-conditions and post-conditions. In case the functionality does not have any restriction, both in pre and post conditions, it must be clearly stated that it does not apply.
- Activity diagrams and scenarios: Functional requirements must be described compulsory with scenarios or an activity diagram. If the functionality to be described is complex, activity diagrams are compulsory to be used.
- Language: In this field, the language of the artefact must be specified. In this case it will be NDT Requirements.

Furthermore, the following optional information defined by NDT has been included to enhance the functional requirements:

- Version: The different versions of the artefact are managed within this field.
- Status: Situation of the artefact being developed. A default value must be chosen: Proposed, Approved, Required, Validated, Implemented.
- Comments: The different versions of the artefact are managed within this field.
- Expected Frequency: Expected frequency of the execution of the functionality which the artefact represents.
- Importance: Importance for the client of the fact that the system has the concept which models the artefact. A default value must be chosen: Very high, High, Medium, Low, Very Low.
- Priority: Priority of the artefact. A default value must be chosen: High, Medium, Low.

- Stability: Probability of the artefact suffering changes in its definition. A default value must be chosen: Closed, Not Closed.
- Urgency: Urgency of the concept compliance that models the artefact. A default value must be chosen: Urgent, Not Urgent.

2.5.1. Patients' needs

A definition of objectives and functional requirements for patients' needs are given below.

DEFINITION OF OBJECTIVES

Table 21: «OBJ01» Changes in the current care model.

«OBJ01» Changes in the current care model		
Version	1.0	26/02/2015
Author	SAS	
Notes	To validate a change in the current care model, including a self-care and shared decision making model, maintaining continuity of care	
Status	Proposed	
Comments	-	
Importance	Medium	
Priority	Medium	
Stability	Not Closed	
Urgency	Not Urgent	

Table 22:«OBJ02»Selfcontrol.

«OBJ02»Selfcontrol		
Version	1.0	26/02/2015
Author	SAS	
Notes	To improve self-control of the patients' condition	
Status	Proposed	
Comments	-	
Importance	Medium	
Priority	Medium	
Stability	Not Closed	
Urgency	Not Urgent	

Table 23:«OBJ03»Selfcare.

«OBJ03»Selfcare		
Version	1.0	26/02/2015
Author	SAS	
Notes	To improve adherence to self-care program and therapeutic plan	
Status	Proposed	
Comments	-	
Importance	Medium	
Priority	Medium	
Stability	Not Closed	
Urgency	Not Urgent	

Table 24:«OBJ04»Deterioration situations management.

«OBJ04»Deterioration situations management		
Version	1.0	26/02/2015
Author	SAS	
Notes	To manage improvement or deterioration situations. For example, exacerbation, decompensations, adverse events, etc.	
Status	Proposed	
Comments	-	
Importance	Medium	
Priority	Medium	
Stability	Not Closed	
Urgency	Not Urgent	

Table 25: «OBJ05»Patient and healthcare professionals' relation.

«OBJ05»Patient and healthcare professionals relation		
Version	1.0	26/02/2015
Author	SAS	
Notes	To optimize the relation between the patient and healthcare professionals	
Status	Proposed	
Comments		
Importance	Medium	
Priority	Medium	
Stability	Not Closed	
Urgency	Not Urgent	

Table 26: «OBJ06»Content.

«OBJ06»Content		
Version	1.0	26/02/2015
Author	SAS	
Notes	To provide informative and educational content	
Status	Proposed	
Comments	-	
Importance	Medium	
Priority	Medium	
Stability	Not Closed	
Urgency	Not Urgent	

FUNCTIONAL REQUIREMENTS

Table 27:«FR01» Communication channels between users.

«FR01» Communication channels between users		
Version	1.0	26/02/2015
Author	SAS	
Notes	<p>The system must facilitate the communication between users via different channels.</p> <p>The system must propose a specific communication channel according to the symptoms, with established priority levels:</p> <ul style="list-style-type: none"> • Videoconference, on patient's demand considering decompensation symptoms like dyspnoea, oedemas, asthenia, etc. • Instant messaging like WhatsApp. • Phone call or other kinds of messages. • Asynchronous messaging. • Notification of Adverse Clinical Events. 	
Pre-condition & Post-condition	<p>Pre-condition:</p> <ul style="list-style-type: none"> • The user should have a device able to support videoconference, instant messaging, phone call, asynchronous messaging and/or event notifications. • If the patient is involved in the communication, he/she should have an adequate cognitive skill to perform the communication. <p>Post-condition:</p> <ul style="list-style-type: none"> • The communication is carried out effectively. 	
Language	NDT Requirements	
Status	Proposed	
Comments	<p>This FR cover the following cases:</p> <ul style="list-style-type: none"> • Communication between patient and healthcare professionals / nutritionists / nurses. • Communication between patient and caregivers. • Communication between caregiver and healthcare professionals / nutritionists / nurses. 	
Expected Frequency	Frequently	
Importance	Medium	
Priority	Medium	
Stability	Not Closed	
Urgency	Not Urgent	
Activity Diagram	The follow activity diagram shows the case of communication between patient and healthcare professionals, initiated by patient. The rest of cases are similar.	

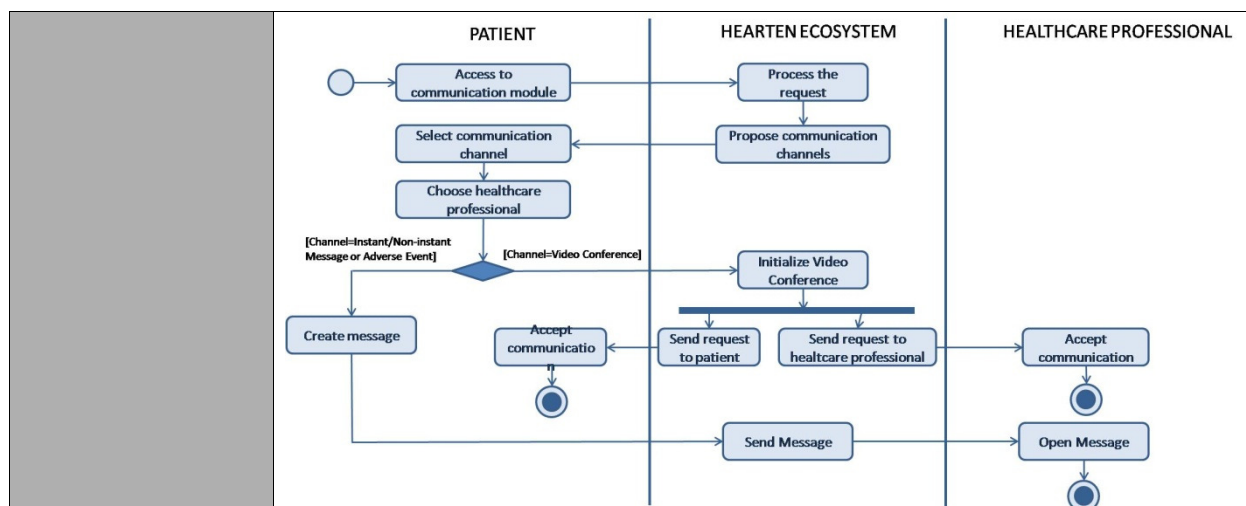


Table 28: «FR02» Documental content visualization for patients.

«FR02» Documental content visualization for patients		
Version	1.0	26/02/2015
Author	SAS	
Notes	The system must provide the ability to display documental content. Easy and comprehensive language.	
Pre-condition & Post-condition	Pre-condition: <ul style="list-style-type: none"> The patient should have an adequate cognitive skill to read and understand documental content. Post-condition: <ul style="list-style-type: none"> Documental content is displayed and understood by the patient. 	
Language	NDT Requirements	
Status	Proposed	
Comments	Educational content. <ul style="list-style-type: none"> Recommendations about: nutrition, physical exercise, obesity prevention, healthy habits, self-care, etc. Informative content. <ul style="list-style-type: none"> Standard questions resolution. Main symptoms and provoked actions. Prescribed treatment information. Average and maximum prescribed dosage, indications, possible side effects, etc. Non-pharmacological treatment information: postural recommendations, diet, etc. Self-training program for the correct use of the App. Information on monitoring devices. 	
Expected Frequency	Frequently	
Importance	Medium	
Priority	Medium	
Stability	Not Closed	
Urgency	Not Urgent	

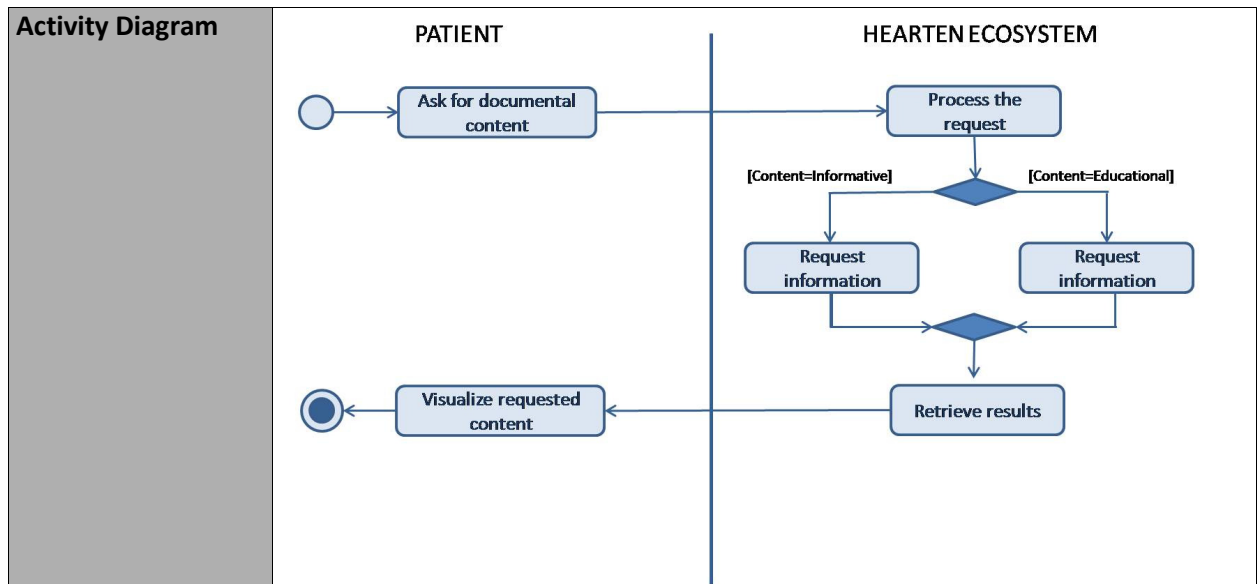


Table 29:«FR03» Self-monitoring.

«FR03» Self-monitoring		
Version	1.0	26/02/2015
Author	SAS	
Notes	The system must provide a self-monitoring module, able to register record and visualise display the following parameters about biological variables and treatment (for more detail, see «FR03.1» and «FR03.2»).	
Pre-condition & Post-condition	Pre-condition: N/A. Post-condition: <ul style="list-style-type: none"> Treatment and biological variables are monitored, recorded and/or displayed. 	
Language	NDT Requirements	
Status	Proposed	
Comments	It is necessary to provide monitoring devices of biological variables.	
Expected Frequency	Frequently	
Importance	Medium	
Priority	Medium	
Stability	Not Closed	
Urgency	Not Urgent	

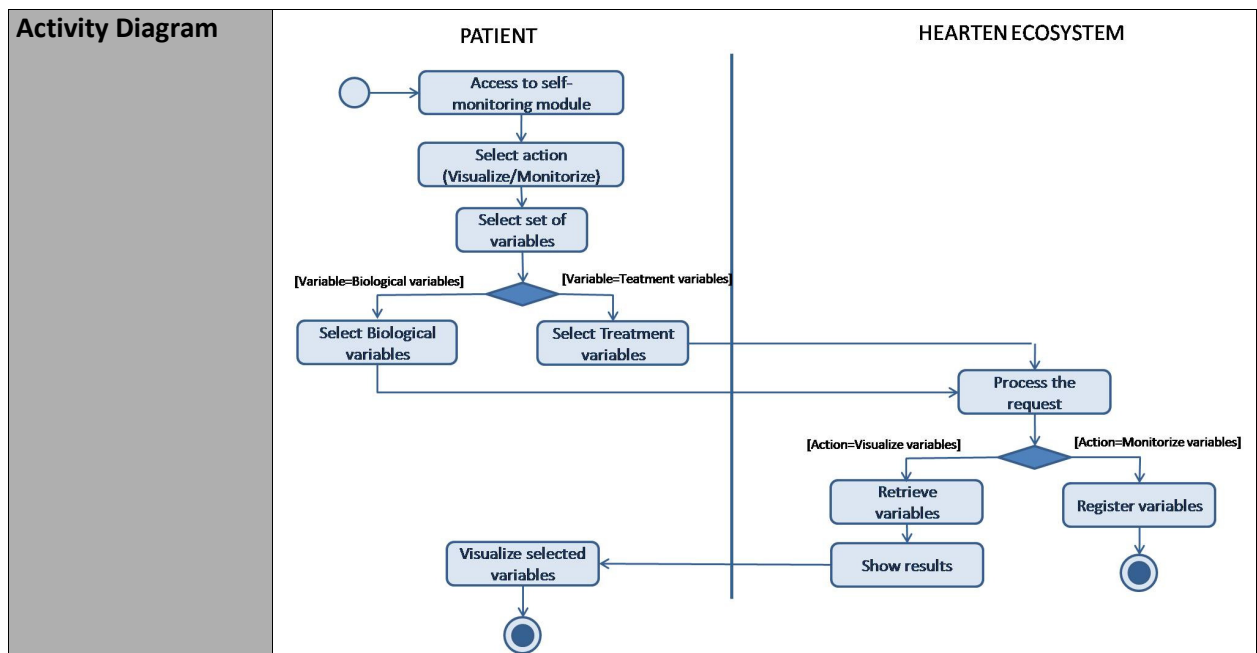


Table 30: «FR03.1» Biological variables monitoring.

«FR03.1» Biological variables monitoring		
Version	1.0	26/02/2015
Author	SAS	
Notes	Biological variables to be taken into account: Weight, blood pressure, heart rate, breath biomarker, saliva biomarker.	
Pre-condition & Post-condition	Pre-condition: <ul style="list-style-type: none"> Monitoring devices should be connected to the system. The patient should have adequate motor and cognitive skills to connect the monitoring devices. Post-condition: N/A.	
Language	NDT Requirements	
Status	Proposed	
Comments	-	
Expected Frequency	Frequently, depending on the recommendations of the healthcare professional.	
Importance	Medium	
Priority	Medium	
Stability	Not Closed	
Urgency	Not Urgent	

Table 31: «FR03.2» Treatment management.

«FR03.2» Treatment management		
Version	1.0	26/02/2015
Author	SAS	
Notes	Treatment. Gathering of accomplished dosages (via a Dosages Collection Report).	
Pre-condition & Post-condition	Pre-condition: <ul style="list-style-type: none"> The patient should have been prescribed with at least one medication. The patient should have an adequate cognitive skill to record the dose 	

	accomplished in the system. Post-condition: N/A.
Language	NDT Requirements
Status	Proposed
Comments	This FR is related to «FR01» to manage a possible communication between the patient and healthcare professionals to solve adherence problems. Furthermore, this FR is related to «FR05» to facilitate treatments reminders.
Expected Frequency	Frequently, depending of dosage frequency.
Importance	Medium
Priority	Medium
Stability	Not Closed
Urgency	Not Urgent

Table 32: «FR04» Patient decision support.

«FR04» Patient decision support		
Version	1.0	26/02/2015
Author	SAS	
Notes	The system must provide patients with decision support, with recommended changes explained within the App.	
Pre-condition & Post-condition	<p>Pre-condition:</p> <ul style="list-style-type: none"> • Patient should have recorded any information previously to feed the system. • Patient should have an adequate cognitive skill to record information in the system. <p>Post-condition:</p> <ul style="list-style-type: none"> • Patients benefit from decision support. • Patients understand the proposed change. 	
Language	NDT Requirements	
Status	Proposed	
Comments	<ul style="list-style-type: none"> ○ About self-care decision making, considering the information collected in «FR03.1». ○ About therapeutic rules in the presence of symptoms, considering the information collected in «FR03.2». ○ About technical problems: devices disconnection, breakdown network to transfer biological variables information, breakdown server, etc. 	
Expected Frequency	Sometimes, depending on the needs.	
Importance	Medium	
Priority	Medium	
Stability	Not Closed	
Urgency	Not Urgent	

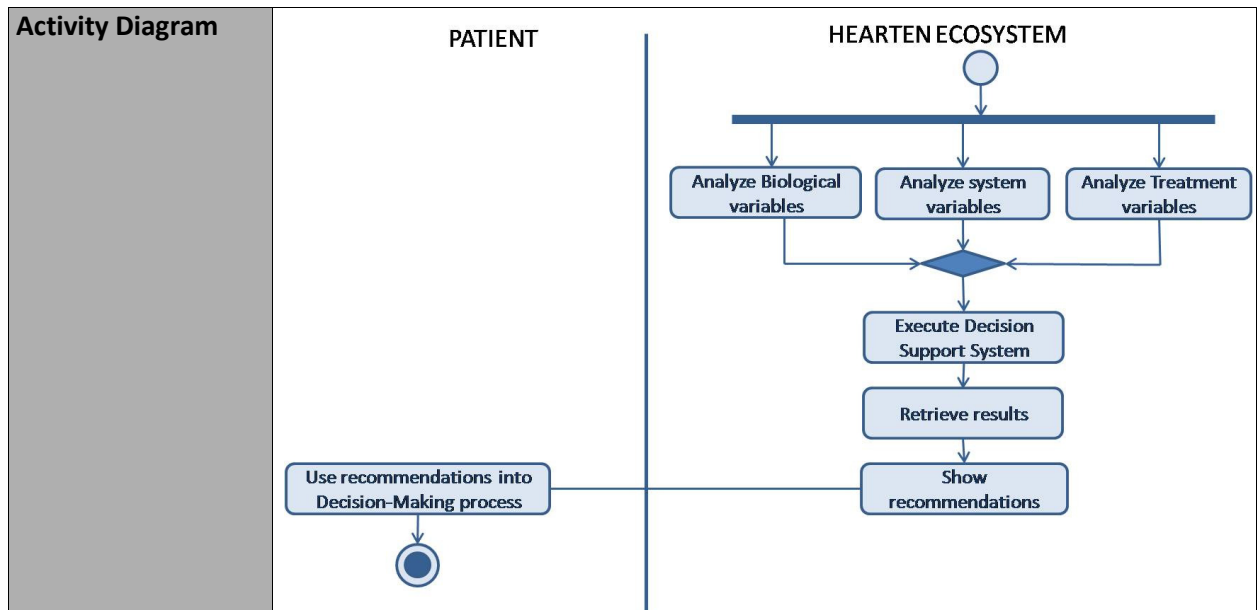
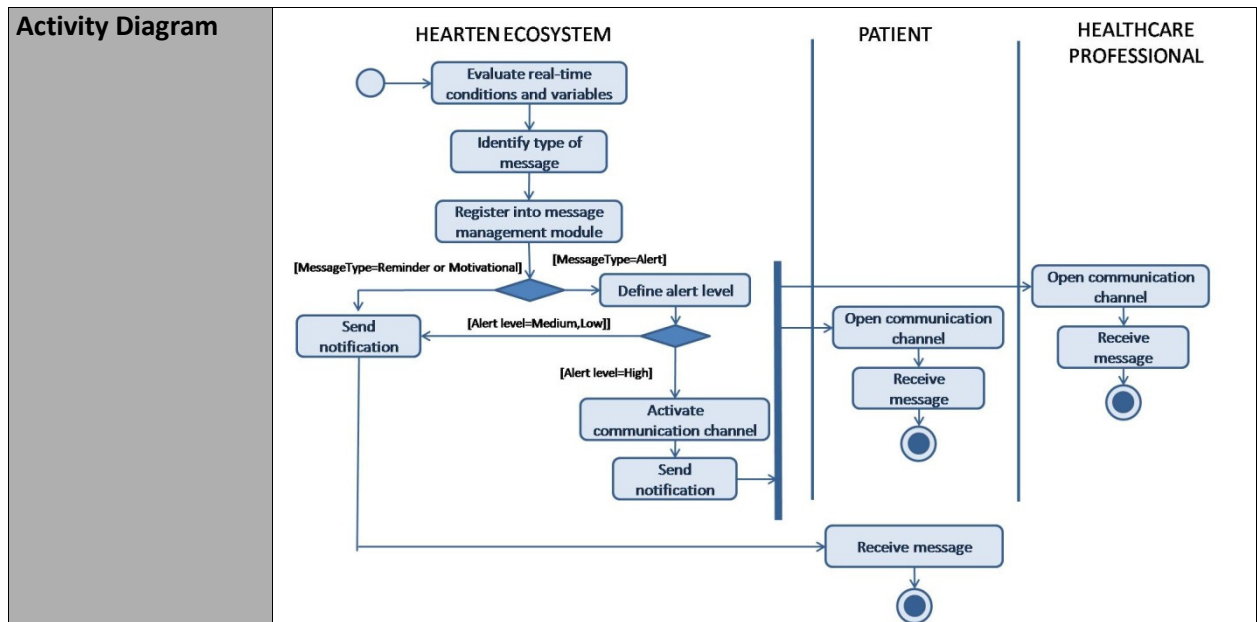


Table 33: «FR05» Alerts, reminders and motivational messages.

«FR05» Alerts, reminders and motivational messages		
Version	1.0	26/02/2015
Author	SAS	
Notes	The system must provide management of alerts, reminders and motivational messages.	
Pre-condition & Post-condition	Pre-condition: <ul style="list-style-type: none"> The patient should have been previously prescribed a (set of) alerts, reminders and motivational messages. Post-condition: <ul style="list-style-type: none"> Alerts, reminders and motivational messages are effectively delivered to patients. 	
Language	NDT Requirements	
Status	Proposed	
Comments	It is necessary to define alert levels, about: <ul style="list-style-type: none"> Dosage reminder program, considering the information collected in R03.2. Adverse events (clinical or derived from treatment), considering the information collected in «R03.1» and «R03.2». These adverse events could activate a communication channel between the patient and healthcare professionals to notify it. The system must facilitate read reminders.	
Expected Frequency	Sometimes, depending on the needs.	
Importance	Medium	
Priority	Medium	
Stability	Not Closed	
Urgency	Not Urgent	



2.5.2. Caregivers' needs

A definition of objectives and functional requirements for caregivers' needs is given below.

The objectives and functional requirements of the system are equal to the objectives and functional requirements for patients. The role of the caregiver is to cover the patient's interactions when he/she is not in a good clinical condition to manage self-monitoring or the treatment.

DEFINITION OF OBJECTIVES

The following previously defined objectives are included within the objectives of caregivers needs:

- «OBJ01».
- «OBJ02».
- «OBJ03».
- «OBJ04».
- «OBJ05».
- «OBJ06».

FUNCTIONAL REQUIREMENTS

The following previously defined functional requirements are included within the functional requirements of caregivers needs:

- «FR01».
- «FR02».
- «FR03», including «FR03.1» and «FR03.2».
- «FR04».
- «FR05».

2.5.3. Healthcare professionals' needs

A definition of objectives and functional requirements for healthcare professionals' needs is given below.

DEFINITION OF OBJECTIVES

The following previously defined objectives are included, within the objectives of healthcare professional needs:

- «OBJ01».
- «OBJ05».

Table 34:«OBJ07» Deterioration situations enhance.

«OBJ07» Deterioration situations enhance		
Version	1.0	09/04/2015
Author	SAS	
Notes	Early identification of deterioration situations (exacerbation, decompensation, adverse events, etc).	
Status	Proposed	
Comments	Related to «OBJ04»	
Importance	Medium	
Priority	Medium	
Stability	Not Closed	
Urgency	Not Urgent	

Table 35:«OBJ08» Survival.

«OBJ08» Survival		
Version	1.0	09/04/2015
Author	SAS	
Notes	To enhance survival.	
Status	Proposed	
Comments	-	
Importance	Medium	
Priority	Medium	
Stability	Not Closed	
Urgency	Not Urgent	

Table 36: «OBJ09» Inter-professional variability.

«OBJ09» Inter-professional variability		
Version	1.0	09/04/2015
Author	SAS	
Notes	To reduce the inter-professional variability.	
Status	Proposed	
Comments	-	
Importance	Medium	
Priority	Medium	
Stability	Not Closed	
Urgency	Not Urgent	

FUNCTIONAL REQUIREMENTS

The following previously defined functional requirements are included within the functional requirements of healthcare professional needs:

- «FR01».

Table 37: «FR06» Documental content visualization for healthcare professionals.

«FR06» Documental content visualization for healthcare professionals		
Version	1.0	09/04/2015
Author	SAS	
Notes	The system must offer informative content about the use of HEARTEN system for healthcare professionals. Self-help. This content must be defined in an easy and comprehensive language.	
Pre-condition & Post-condition	Pre-condition: <ul style="list-style-type: none"> • The professional must have an adequate technological skill to handle the device(s) (i.e. smartphone, tablet, etc). Post-condition: <ul style="list-style-type: none"> • Professionals benefit from informative content. • Professionals understand the delivered content. 	
Language	NDT Requirements	
Status	Proposed	
Comments	Related to «FR02».	
Expected Frequency	Sometimes, depending on the needs.	
Importance	Medium	
Priority	Medium	
Stability	Not Closed	
Urgency	Not Urgent	
Activity Diagram	<pre> graph LR subgraph HealthcareProfessional [HEALTHCARE PROFESSIONAL] Start(()) --> Ask[Ask for informative content] Retrieve[Retrieve information requested] --> End((())) end subgraph HEARTEN_Ecosystem [HEARTEN ECOSYSTEM] Process[Process the request] --> Request[Request information] Request --> Show[Show results] end Ask --> Process Show --> Retrieve </pre>	

Table 38: «FR07» Patient monitoring management.

«FR07» Patient monitoring management		
Version	1.0	09/04/2015
Author	SAS	

Notes	<p>The system must display the biological variables gathered via «FR03.1».</p> <p>Furthermore, the system must allow the healthcare professional to make changes in the patient monitoring protocol about prescriptions (frequency variation, modes, activate/deactivate specific constant, etc).</p>
Pre-condition & Post-condition	<p>Pre-condition:</p> <ul style="list-style-type: none"> Biological variables should have been previously gathered. <p>Post-condition:</p> <ul style="list-style-type: none"> Biological variables are displayed. Monitoring protocol about prescriptions in effectively managed.
Language	NDT Requirements
Status	Proposed
Comments	Related to «FR03.1».
Expected Frequency	Frequently, depending on the monitoring protocol.
Importance	Medium
Priority	Medium
Stability	Not Closed
Urgency	Not Urgent
Activity Diagram	<pre> graph TD subgraph HealthcareProfessional [HEALTHCARE PROFESSIONAL] Start(()) --> Access[Access to monitoring management module] Access --> Specify[Specify changes] Specify --> Retrieve[Retrieve information requested] Retrieve --> End((())) end subgraph HeartenEcosystem [HEARTEN ECOSYSTEM] Process[Process the request] --> Decision{ } Decision -- "[Action=Modify monitoring protocol]" --> RequestChanges[Request protocol changes] RequestChanges --> Modify[Modify protocol] Modify --> Save[Save changes] Save --> EndEcosystem((())) Decision -- "[Action=Visualize patient]" --> RequestInfo[Request information about monitoring] RequestInfo --> ShowInfo[Show patient monitoring information] end Access --> Process Specify --> RequestChanges RequestInfo --> Retrieve ShowInfo --> Retrieve </pre>

Table 39: «FR08» Patient treatment management.

«FR08» Patient treatment management		
Version	1.0	09/04/2015
Author	SAS	
Notes	<p>The system must allow the healthcare professional to get the therapeutic compliance gathered via «FR03.2».</p> <p>Furthermore, the system must allow the management of the prescribed treatment (average dose, maximum dose, indications, etc) via a Prescription Report.</p>	
Pre-condition & Post-condition	Pre-condition:	

	<ul style="list-style-type: none"> The professional must have an adequate technological skill to handle the device(s) (i.e. smartphone, tablet, etc). Post-condition: <ul style="list-style-type: none"> Therapeutic compliance is effectively displayed. Treatment prescription is effectively managed.
Language	NDT Requirements
Status	Proposed
Comments	Related to «FR03.2».
Expected Frequency	Frequently, depending of dosage frequency.
Importance	Medium
Priority	Medium
Stability	Not Closed
Urgency	Not Urgent
Activity Diagram	<pre> graph TD subgraph HealthcareProfessional [HEALTHCARE PROFESSIONAL] Start(()) --> Access[Access to patient treatment management module] Access --> Specify[Specify changes] Specify --> Retrieve[Retrieve information requested] Retrieve --> End1((())) end subgraph HeartenEcosystem [HEARTEN ECOSYSTEM] Process[Process the request] --> Decision{ } Decision -- "[Action=Modify patient Treatment]" --> RequestChanges[Request treatment changes] RequestChanges --> Modify[Modify treatment] Modify --> Save[Save changes] Save --> End2((())) Decision -- "[Action=Visualize treatment]" --> RequestInfo[Request treatment information] RequestInfo --> Show[Show treatment] end Access --> Process End2 --> Retrieve End1 --> End2 </pre>

Table 40: «FR09» Clinical decision support.

«FR09» Clinical decision support		
Version	1.0	09/04/2015
Author	SAS	
Notes	<p>The system must cover clinical decision support to solve problems or symptoms, including prognostic evaluation scales, and therapeutic decisions algorithms using the information registered by patients and caregivers via «FR01» (questions), «FR03.1» (biological variables), «FR03.2» (treatment).</p> <p>There are different prognostic evaluation scales, which should be used, such as PROFUND [Bernabeu-Wittel et al. 2012] or Minnesota. Programme of measure or formulae used in medical care for patients. Include an application such as MedCalc® or define a similar one.</p> <p>The clinical decision support must be delivered in an easy and comprehensive language, and must be endorsed with detailed explanations.</p>	
Pre-condition & Post-condition	Pre-condition: <ul style="list-style-type: none"> The professional must have an adequate technological skill to handle the 	

	<p>device(s) (i.e. smartphone, tablet, etc).</p> <ul style="list-style-type: none"> Information from patient should be recorded in the system and able to be accessed by the clinical decision support service. <p>Post-condition:</p> <ul style="list-style-type: none"> The professional benefits from clinical decision support. The professional understands both the motivation and the decision proposed.
Language	NDT Requirements
Status	Proposed
Comments	Related to «FR04».
Expected Frequency	Sometimes, depending on the needs.
Importance	Medium
Priority	Medium
Stability	Not Closed
Urgency	Not Urgent
Activity Diagram	<pre> graph TD subgraph HEARTEN_ECOSYSTEM [HEARTEN ECOSYSTEM] Start(()) --> ForkBar[] ForkBar --> AB[Analyze Biological variables] ForkBar --> AS[Analyze system variables] ForkBar --> AT[Analyze Treatment variables] AB --> Join{ } AS --> Join AT --> Join Join --> ECDS[Execute Clinical Decision Support System] ECDS --> RR[Retrieve results] RR --> SR[Show recommendations] end subgraph HEALTHCARE_PROFESSIONAL [HEALTHCARE PROFESSIONAL] UDR[Use recommendations into Decision-Making process] --> End((())) end SR --> UDR </pre>

Table 41: «FR10» Alerts, reminders and motivational messages management.

«FR10» Alerts, reminders and motivational messages management		
Version	1.0	09/04/2015
Author	SAS	
Notes	<p>The system must offer to the healthcare professional, in real time, alerts that the system has activated for each patient. The system must facilitate read reminders.</p> <p>Furthermore, the system must offer the healthcare professional to establish priorities between alerts, and through different alerts groups.</p>	
Pre-condition & Post-condition	<p>Pre-condition:</p> <ul style="list-style-type: none"> Real-time communications should be provided between the system and the professional device(s). The professional must have an adequate technological skill to handle the 	

	<p>device(s) (i.e. smartphone, tablet, etc).</p> <p>Post-condition:</p> <ul style="list-style-type: none"> Alerts are effectively delivered in real-time to professionals. Alerts and reminders are effectively managed and prioritised.
Language	NDT Requirements
Status	Proposed
Comments	Related to «FR05».
Expected Frequency	Sometimes, depending on the needs.
Importance	Medium
Priority	Medium
Stability	Not Closed
Urgency	Not Urgent
Activity Diagram	<pre> graph TD subgraph "HEALTHCARE PROFESSIONAL" Start(()) --> A[Access to message management module] A --> B[Specify patient] B --> C[Select action] C --> D{ } D -- "[Action=Visualize messages]" --> E[Visualize/Read messages] E --> F(()) D -- "[Action=establish priorities]" --> G[Select message/priority] end subgraph "HEARTEN ECOSYSTEM" B --> H[Process the request] H --> I[Request real-time messages] I --> C G --> J[Modify properties] J --> K[Save changes] K --> L(()) end </pre>

Table 42:«FR11» Patients follow up module.

«FR11» Patients follow up module		
Version	1.0	09/04/2015
Author	SAS	
Notes	<p>The system must offer a module to facilitate the follow up of the patients, showing in a simple screen all patients using the HEARTEN system, indicating the most important information of the patient, and providing a link to the complete patient information.</p> <p>This module must link to the Electronic Health Record (EHR) to facilitate the review of all the data related with the patient, including the different EHR environments (hospital care, primary care, social care, emergencies, etc).</p>	
Pre-condition & Post-condition	<p>Pre-condition:</p> <ul style="list-style-type: none"> At least one patient with regarded information should have been registered in the system. The EHR should be accessible on demand. The professional must have an adequate technological skill to handle the device(s) (i.e. smartphone, tablet, etc). 	

	Post-condition: <ul style="list-style-type: none"> Professionals carry out an effective follow-up of patients. Information from patients is displayed in a comprehensive way. EHR is effectively displayed.
Language	NDT Requirements
Status	Proposed
Comments	-
Expected Frequency	Frequently
Importance	Medium
Priority	Medium
Stability	Not Closed
Urgency	Not Urgent
Activity Diagram	<pre> graph TD subgraph HealthcareProfessional [HEALTHCARE PROFESSIONAL] Start(()) --> Access[Access to patient follow-up module] Access --> Specify[Specify patient] Specify --> VisualizeResults[Visualize results] VisualizeResults -- "[Action=Exit module]" --> Exit(()) VisualizeResults -- "[Action=Request detailed information]" --> VisualizeDetailed[Visualize detailed information] VisualizeDetailed --> End(()) end subgraph HartenEcosystem [HEARTEN ECOSYSTEM] ProcessRequest1[Process the request] --> RequestEHR[Request external EHR information] RequestEHR --> RetrieveEHR[Retrieve patient information EHR system] RetrieveEHR --> ShowResults1[Show results] ShowResults1 --> ProcessRequest2[Process the request] ProcessRequest2 --> RetrieveDetailed[Retrieve detailed patient information] RetrieveDetailed --> ShowResults2[Show results] end subgraph ExternalEHRSystems [EXTERNAL EHR SYSTEMS] RetrieveInfo[Retrieve patient information EHR system] --> SendInfo[Send information to Harten Ecosystem] end Specify --> ProcessRequest1 RequestEHR --> RetrieveInfo RetrieveInfo --> SendInfo SendInfo --> RetrieveEHR ShowResults1 --> VisualizeResults ShowResults2 --> VisualizeDetailed </pre>

2.5.4. Secondary actors' needs

A definition of objectives and functional requirements for secondary actors' needs is described below.

DEFINITION OF OBJECTIVES

In the objectives of secondary actors needs, the following previously defined objectives are included:

- «OBJ01».
- «OBJ05».
- «OBJ07».
- «OBJ08».
- «OBJ09».

FUNCTIONAL REQUIREMENTS

The following previously defined functional requirements are included within the functional requirements of secondary actors' needs:

- «FR01», including only communication by phone or instant messaging.
- «FR06».
- «FR07».
- «FR08», without the possibility of make changes in the treatment.
- «FR09», without prognostic scales.
- «FR10».
- «FR11».

2.6. Use case scenarios and definition

This section defines the HEARTEN interaction case scenarios covering the following cases:

- Patient and healthcare professional interaction.
- Patient and caregiver interaction.
- Educational activity.

For each case, at least one scenario is specified, relating the functionalities explained in the scenario with the functional requirements defined in section 2.2, and including a graphical scenario to make it more understandable.

2.6.1. Patient and healthcare professional interaction case scenario

These scenarios present the regular interaction between a patient with HF and healthcare professionals in charge of her care, in a clinic status of the usual daily life, describing the situation before implement HEARTEN ecosystem, and the changes that can be produced in patient care if this ecosystem is used.

Scenario I

Manuela (M) is an 81 years old woman who lives on her own in a 3rd floor apartment in Seville, Spain. She is independent for most of her daily life activities at home without help, but she finds some difficulties when she needs to get out. She is a widow; her husband died 4 years ago. She has a son who lives in Hamburg, Germany. Her nephew, Luis (L), visits her 3 or 4 times a week to check her health state, help her with the groceries and with the drug intake. Besides, L phones her every day.

M had a myocardium heart attack 4 years ago. She was then prescribed a treatment in order to prevent new exacerbations and to keep stable her chronic heart failure. Furthermore, for the past 20 years she has suffered from type 2 diabetes with micro-vascular injury (she has a mild vision impairment because a diabetic retinopathy) and macro-vascular injury (she has a vascular ulcer in her right ankle). José Salvador (JS) is the nurse on charge of M at her primary care centre. He visits her at home every Monday and Thursday in order to assess the ulcer and provide her with medical care.

Last Sunday, M presented cold symptoms, including cough and low-grade fever, but she did not tell it to her nephew, as she did not find it important. On Monday, during his usual visit, JS noticed that M was coughing and with a runny nose, but she told him it was just a cold and that she was taking a home-made medicine.

On Tuesday, M did not answer the phone when L called her in the morning. L was really worried and went over M's house. When he came into her house (he has the keys), saw M lying on the bed, coughing, with fever, and with a low level of consciousness. He immediately phoned the Emergency

Service (ES) and an ambulance came over M's house. After assessing her, the healthcare professionals recommended to hospitalize her. L was not able to go with her aunt to the hospital at that moment, he would only go later.

During the transfer, the healthcare staff recorded in their Electronic Health Record (EHR #1) all the information that L provided about M, as well as exploration information and biological variables.

When they arrived to the Emergency Department of Virgen del Rocío University Hospital (VRUH-ED), M was assessed in the triage room, based on the information provided by the ES and then assigned with high priority to MD Ana María (AM), who started to apply M the protocol for patient stabilization and several diagnostic interventions. Dr. AM and her team gathered the information provided by the ES including printed reports and verbal information, and then recorded it into the VRUH-ED EHR (EHR #2), a different system, which does not communicate with the ES one. During the M's care delivery, Dr. AM checks in the VRUH Hospitalization Area (VRUH-HA) database (EHR #3) all the information available on the myocardium heart attack M suffered 4 years before.

After the clinical assessment in the VRUH-ED, Dr. AM and her team diagnosed a severe community-acquired pneumonia and, after stabilizing her with fluids and antibiotics, M was admitted in the VRUH-HA 48 hours later under the supervision of Dr. Francisco Javier (FJ).

On Thursday morning, JS comes over M's house to perform his usual visit. He gets really worried when he finds that M is not at home. After phoning L (his phone number is registered as the usual caregiver phone number) he is aware that M has been hospitalized again. Neither ES workforce nor VRUH staff have communicated M's situation to her primary care centre. Furthermore, the primary care EHR (EHR #4) is not able to interoperate with none of the others EHR systems. Therefore, JS gathers as much information as possible (mainly by phone) regarding M's situation and then explains it to MD Juan Eduardo (JE), who is M's usual GP at the primary care centre. With this information, Dr. JE adds a new record in the primary care EHR (EHR #4)

Two days after the admission, M feels better and wants to go back home. Dr. FJ discharges her from the hospital after transferring M's supervision to the Advanced Home Care Regional Service (AHCERS).

When M arrives home, AHCERS provides her with a portable oxygen therapy kit for the following days. They visit her at home to assess her clinical status, to carry out the measurement of electrolytes, body fluids and vital signs (with AHCERS portable devices), and they guarantee that M will know how to handle an electronic device in order to perform the follow-up by phone. The first tele-consultation is carried out during this first visit under the supervision of the AHCERS team.

M considers that tele-consultation via phone is enough for her, and the videoconference is not considered to be necessary (although it is available whenever she needs it). In this way, M could be tele-monitored and this will save her difficulty to go out to carry out a regular follow-up of her conditions. She is offered the possibility of being monitored with a distance electronic device and accepts it, as this way her quality of life is going to improve, she is going to suffer less symptoms and control better the disease, reducing hospitalization and living better and longer. She was always complaining about the fact that she was unable to make changes in her treatment and not having it reviewed frequently. She also admitted that sometimes she is not able to take the correct pharmacological dosage indicated by doctors or to meet all the treatment guidelines.

She is provided with a smartphone device (**«FR01» Communication channels between users**). Thanks to it, within the following days, the AHCRS team phones M in a daily basis (**«FR01» Communication channels between users**) and receive information regarding her vital signs and clinical variables through the tele-monitoring devices (**«FR03.1» «Monitoring patient's vital signs», «FR07» Patient monitoring management**). After assessing this information, they decide to stop antibiotics and adjust the other medication (beta-blockers and diuretics) (. Manuela also sends biological samples to Dr EP to the Hospital, both of saliva via a receptor integrated in a cup – the information is sent when she drinks from it – and of her breath via a receptacle integrated within the Smartphone - which is activated when she speaks on the phone. Thanks to these devices, Dr EP is able to know how M is doing and reduce the treatment, as she is feeling very tired and the arterial pressure figures sent by the device are very low(**«FR03» Self-monitoring, «FR07» Patient monitoring management, «FR08» Patient treatment management**). An alert is triggered (**«FR05» Alerts, reminders and motivational messages, «FR10» Alerts, reminders and motivational messages management**) within the device and is transmitted to Dr EP in order to make remote changes in M's treatment, retiring diuretic drugs via the treatment module (**«FR03.2» Medication management, «FR08» Patient treatment management**). After the changes proposed, M is feeling very well, as she is also following the instructions given by the device on what she can eat, the exercise she can make, the body weight she can keep and so on via the instructions of the app, which she periodically checks (**«FR02» Documental content visualization for patients**).She also has a better follow up of the treatment, as when M forgets to take a pill, the Smartphone reminds her need to take them according to the treatment timing scheduled in the treatment module via a sound alert or a note in the screen (**«FR05» Alerts, reminders and motivational messages**).

After 9 days under the supervision of the AHCRS, M's health status becomes better and she could continue the follow-up through her primary care centre, but given that management of her conditions at home is difficult and given that are some limitations to perform an adequate follow-up of her conditions (as happened during her lung infection), they decided to continue supervising M and they assume the healthcare delivery for M. A coordinated follow-up planning is scheduled with M, L, and M's son (via phone or videoconference) twice a week. With the help of her caregiver, M has a device that gathers information on education for patients with heart failure, helping her to understand and manage her disease via the adjustment of the dosage in accordance to her weight (**«FR02» Documental content visualization for patients**) and that has an alert system on the best moment to check with the caregivers (**«FR05» Alerts, reminders and motivational messages**).M prefers avoiding health centers and hospitals. Thus, via general recommendations, assessment of the regular situation via an alert system (**«FR05» Alerts, reminders and motivational messages**) and phone follow-up via qualified personnel (**«FR01» Communication channels between users**) (the personnel also receives via an electronic device information on constants, parameters and alerts) decompensations of her base disease can be prevented and complications avoided. For M and her caregiver it is important to know what to do regarding certain situations related with the disease, such as what to do when oedemas appear, in case of hypertension, when she is tired or when she does not urinate enough. Thanks to the self-help module and the decision-taking algorithms, which appear in HEARTEN App (**«FR04» Patient decision support**), she is able to better manage these situations, she is more self-sufficient and everyday her management of the disease is better, as she does not have to go to the doctor nor the hospital with regularity and can devote her time to other activities that improve her well-being. The specialist, Dr EP, is also happy with the evolution of M, as she can have a close contact with her with calls and videoconferences (**«FR01» Communication channels between users**), with a

frequency depending on M's evolution of constants and biological markers, which support her to take decisions on the treatment. Besides, she is timely informed on the apparition of adverse events of the medication or of the disease. In general, the adherence to the treatment improves and M has more tools for the self-management of the disease.

After 15 days Manuela is not feeling very well. She has forgotten to take her pills. After talking with a friend of her on the phone, she receives a message from her doctor reminding her to take her prescribed medication. Manuela immediately goes to her bedroom and takes the pill. After an hour, she is feeling much better!

After 25 days L visits Manuela to check how things are going. He enters to the home and finds her watching TV. He notices that she has not completed her dinner and that she continues eating unhealthy. L uses his smartphone and enters the nutritional habits of Manuela. Some hours later Manuela receives a message from her doctor saying that she should follow the recommendations regarding nutrition and make sure she perceives all the necessary vitamins through vegetables and fruits.

Appendix E shows an extended storyboard about this scenario.

Scenario II

Mrs Morrison is a 60 years old lady that has been diagnosed with HF 5 years ago. Before the disease diagnosis, Mrs Morrison was working as a lawyer but after being diagnosed she decided to quit working. She is living with her two children and her mother. Unfortunately her husband is travelling a lot and is very often away. Mrs Morrison enjoys exercising, therefore it is on her daily program to go to the stadium and exercise for half an hour. Mrs Morrison wants to be fit therefore sometimes she overacts when exercising. Mr Smallwood wants to check if Mrs Morrison is following his recommendations. He initially asks for the nutrition history of Mrs Morrison. Then he continues with asking multiple patient data such as exercising and medication history («Healthcare professional views single/multiple patient's data»). He checks the requested data and after a while he receives a message (**«FR01» Communication channels between users**) that notifies that the Mrs Morrison has tachycardia and she should stop exercising. He immediately sends Mrs Morrison an alarm (**«FR05» Alerts, reminders and motivational messages**) suggesting her to stop exercising and have a rest in order to avoid a potential heart attack. Mrs Morrison receives the alert from Mr Smallwood and stops exercising. However after 30 min she still has tachycardia. She communicates directly with her doctor by sending him a message («Direct communication from patient to healthcare professional») asking him what to do to be revealed from the tachycardia symptoms.



Figure 42: Graphical storyboard of “Patient and healthcare professional interaction scenario II”.

2.6.2. Patient and caregiver interaction case scenario

This scenario describes a typical situation where a HF patient suffering from HF uses the HEARTEN solution to his every life.

Scenario I

Actually it is the first time that Mr Hawkins is going to use his mobile in order to track his clinical status and being provided suggestions from his caregiver. The previous day, the cardiologist of Mr Hawkins’ had registered the clinical and medical data to the HEARTEN system. The same day the cardiologist that is responsible for his management provided the system with Mr Hawkins, 68 years old HF patient, woke up at 09.00 in the morning. He was feeling quite tired this day. Mr Hawkins enjoys sleeping but at 10.00 he should take his prescribed by his doctor pills.

He went to the kitchen to have breakfast and prepared his dog for his daily walk. Afterwards he went for a walk with his dog. When he came back, he was in his garden, when his smartphone rang (11.30). It was his nephew that wanted to invite him to have lunch together. When Mr Hawkins finished his conversation, he went back home and logged in the HEARTEN system through his smartphone. He checked that his personal information is appropriately entered and he also checked that his cardiologist has entered all the clinical info (**«FR03» Self-monitoring**). Then, Mr Hawkins entered the “area” of nutrition and the HEARTEN system provided him with the requested details (**«FR03» Self-monitoring**). Afterwards he wanted to see the level of exercise that he performed (**«FR03» Self-monitoring**). He entered in the area of “exercise” and the HEARTEN system displayed the requested information (**«FR02» Documental content visualization for patients**). Meanwhile all these information where also sent to his caregiver, Mrs. Muller (**«FR01» Communication channels between users**). By

the interpretation of the data, Mrs Muller noticed that the breath analysis showed that Mr Hawkins did not perceive his medication in the morning. Mrs Muller also noticed that Mrs Hawkins follows an unhealthy diet. Mrs Muller enters to the HEARTEN system the following recommendations with the indication of “urgent” (**«FR05» Alerts, reminders and motivational messages**): (i) medication area: “You forgot to take your morning medication, please double the evening dose”, (ii) nutrition area: “Try to avoid unhealthy food, eat fruits and vegetables”. The HEARTEN system sends these info to the smartphone of Mr Hawkins and also at 17.00(**«FR04» Patient decision support**) (the time that he has to take his second pill) a message was sent to his smartphone reminding her to take a double dose since he forgot to take the medication in the morning. In addition, Mrs Muller imports to the patient data the following message “Mr Hawkins forgets very often his medication”.



Figure 43: Graphical storyboard of “Patient and caregiver interaction scenario I”.

2.6.3. Educational activity scenario

The educational scenarios in the framework of HEARTEN are a technique that is used to replace and amplify real experiences with guided ones that evoke or reproduce substantial aspects of the utilization of the HEARTEN approach in the real world. It is an effective way of providing the patients and their surrounding environment with knowledge, skills, and attitudes, in order to ensure the adherence of the patients to the guidelines and their appropriate management to protect them from unnecessary risks.

The aim of the scenarios are to educate and assist the patients in: (i) understanding the cause of Heart Failure, monitor and recognize signs and symptoms (Scenario I, II), (ii) understanding indications, dosing, and effects of drugs (Scenario I), (iii) understanding the importance of following treatment recommendations and maintaining motivation to follow treatment plan (Scenario I), (iv) eat healthy

and prevent malnutrition (Scenario III), (v) understand the benefits of exercise (Scenario IV) and (vi) understanding the depressive symptoms and cognitive dysfunction that are common in HF patients (Scenario V).

The scenarios describe a situation where a HF patient uses the HEARTEN approach to identify, review and assess different cases of “educational” patients, meaning patients that have already been diagnosed with HF and are treated and managed by the doctors and the other ecosystem actors through the HEARTEN solution. Educational patients may be real patients that have been utilizing the HEARTEN solution and therefore can provide significant educational cases. In order to accomplish this, the record of these HEARTEN patients will be enriched through comments provided by the medical specialists that will in detail explain the “educational” aspects of these cases. This way the comments section will provide valuable information while highlighting and explaining specific areas of “educational” to improve the overall health status of the HF patient (physical activity, nutrition, etc).

Scenario I

Mr. Harris is HF patient that wants to be more educated through HEARTEN system regarding the cause of HF and why symptoms occur. Initially, Mr. Harris searches for a specific educational case that is the most appropriate for this specific purpose. He wants to be educated about symptoms occurring in HF (**«FR02» Documental content visualization for patients**).

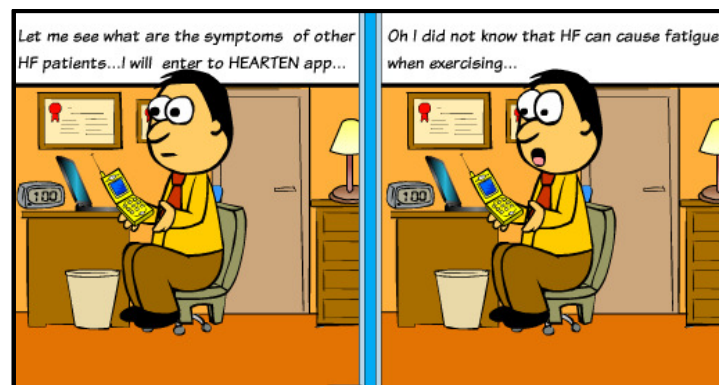


Figure 44: Graphical storyboard of “Educational scenario I”.

Scenario II

Mrs. Pelton is a HF patient that wants to see how healthy diet can play a significant role in the life of a patient suffering from HF. Mrs. Pelton wants to be educated about this specific topic(**«FR02» Documental content visualization for patients**). The system presents the dietary guidelines of the nutritionist: (i) decrease the total amount of sodium to no more than 1,500 mg (1.5 grams) per day, (ii) include high-fiber foods in your diet, (iii) reduce your fluid intake to minimize the short of breath, (iv) limit your total daily calories to 1800-2000 per day.



Figure 45: Graphical storyboard of “Educational scenario II”

Scenario III

Mr. Adison is a 65 years old HF patient that has been diagnosed with this disease one year ago. Mr. Adison is currently retired but some years ago he used to be a teacher. Despite the fact that Mr. Adison is an educated person he seems to be quite non adherent to the doctor’s recommendations for exercising. He seems not to believe that exercise can influence the progress of HF. Therefore, he is interested in being informed about the benefits of exercising through HEARTEN app (**«FR02» Documental content visualization for patients**). The system presents the benefits for exercising for a period of time: (i) reduction in body weight, (ii) reduction in blood pressure, (iii) reduction in symptoms occurrence.

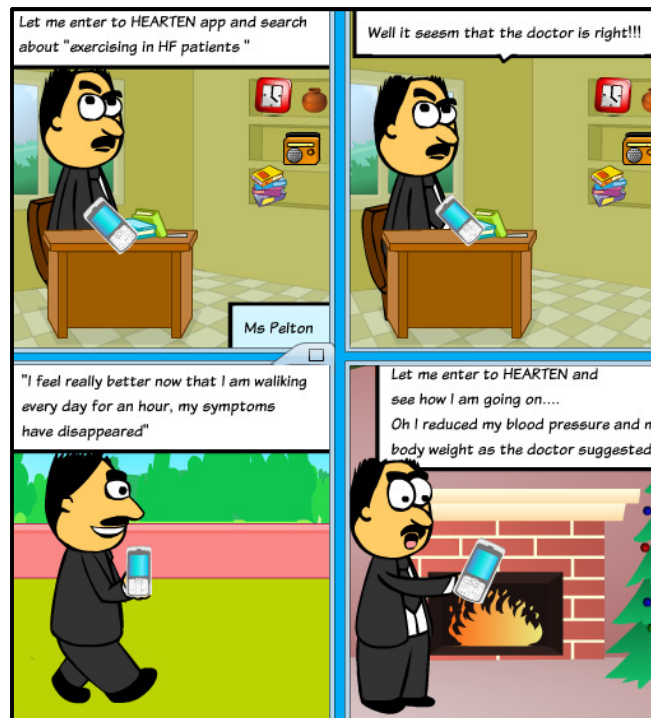


Figure 46: Graphical storyboard of “Educational scenario III”.

Scenario IV

Mrs. Williams is a patient that has been just diagnosed with HF. Mrs. Williams lives alone in her house since her husband died 10 years ago and she has no children. Mrs. Williams used to be very active before being diagnosed with HF. She participated in several social events and she was also among the most well-known chess players in Western Europe. Her doctor has suggested to adopt HEARTEN solution for efficiently disease monitoring. Mrs. Williams agreed in this suggestion. After being diagnosed, Mrs. Williams feels to be boring in participating in these social events and she also avoids being to take part in chess contents, as she used to do. Mrs. Williams enters the system and searches for depressive symptoms occurring in HF (**«FR02» Documental content visualization for patients**). The system presents the depressive symptoms of HF patients, such as (i) not taking the medication, (ii) not exercising, (iii) experiencing feelings of sadness, helplessness and hopelessness, (iv) loss of appetite, (v) not interested in doing activities that used to do. Mrs Williams realizes that she also experiences some feelings of sadness some days and that she also avoids participating in social events and chess contents. By identifying even the modest symptoms of depression Mrs. Williams could recognize her emotional status and share these feelings with her doctor in order to improve her emotional status and her overall disease management.



Figure 47: Graphical storyboard of "Educational scenario IV".

3. USES CASE SCENARIOS

3.1. Patient and healthcare professional interaction case scenario

In the following section, we present the use cases of the scenarios of section 2.6.1 through UML diagrams.

Scenario I

Use Case «Patient registration»

- Healthcare professional registers the patient into the HEARTEN system.

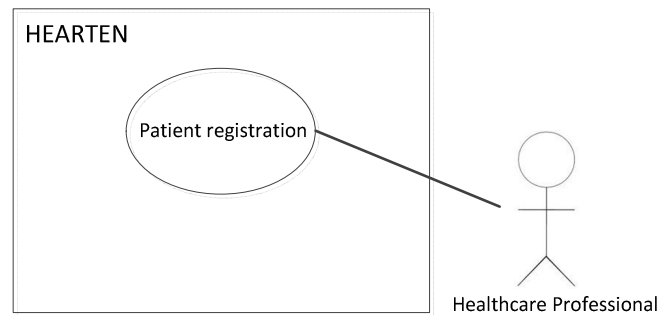


Figure 48: Use Case «Patient registration».

Use Case «Monitoring patient's vital signs»

- Healthcare professional is monitoring the vital signs of the HF patient (data breath, saliva and other sensors, nutrition data).

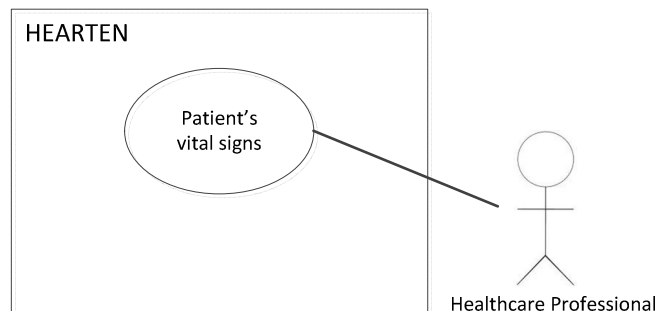


Figure 49: Use Case «Monitoring of patient's vital signs».

Use Case « Alerts, reminders and motivational messages by the healthcare professional»

- Healthcare professional sends an alert to the HF patient

There will be three types of alerts provided by the doctor.

- i. Alert regarding the patient's vital signs
- ii. Alert regarding patient's medication non-adherence
- iii. Alert regarding lifestyle changes suggestions
- iv. Alert regarding patient empowerment

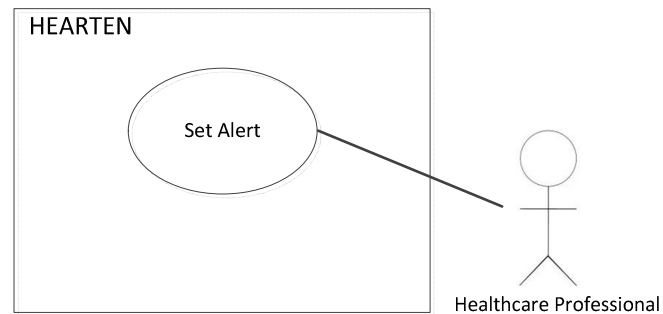


Figure 50: Use Case «Alert sent by the healthcare professional».

Use Case « Medication management»

- The healthcare professional provides the HF patient with medication adjustment to improve his/her health condition.

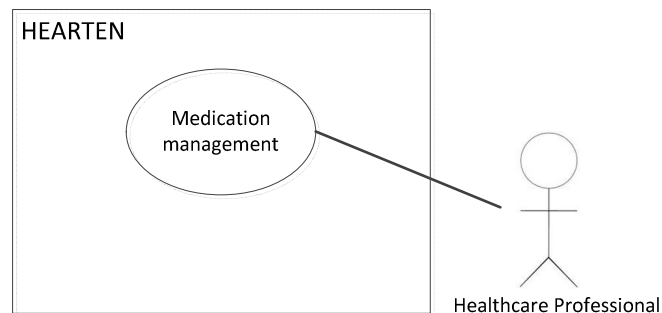


Figure 51: Use Case «Healthcare professional provide medication adjustment».

Use Case «Healthcare professional views single/multiple patient's data»

- Healthcare professional asks to view single/multiple patient's data.

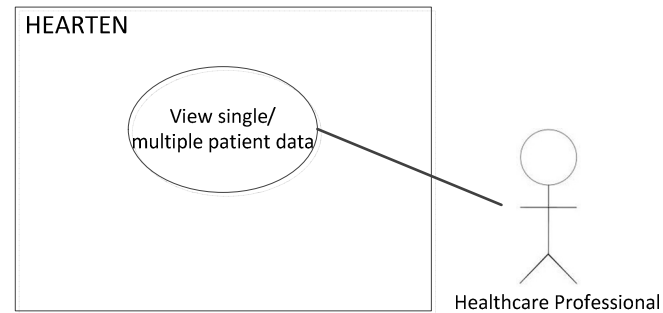


Figure 52: Use Case «Patient registration».

Use Case «Direct communication from patient to healthcare professional»

- The patient communicates directly with the healthcare professional asking for advice/assistance

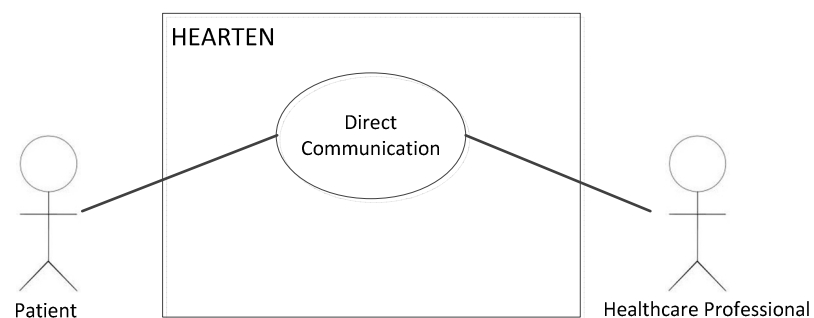


Figure 53: Use Case «Direct communication from patient to healthcare professional».

In the following figures we present the use cases as identified in scenario I, II of patient and healthcare professional interaction.

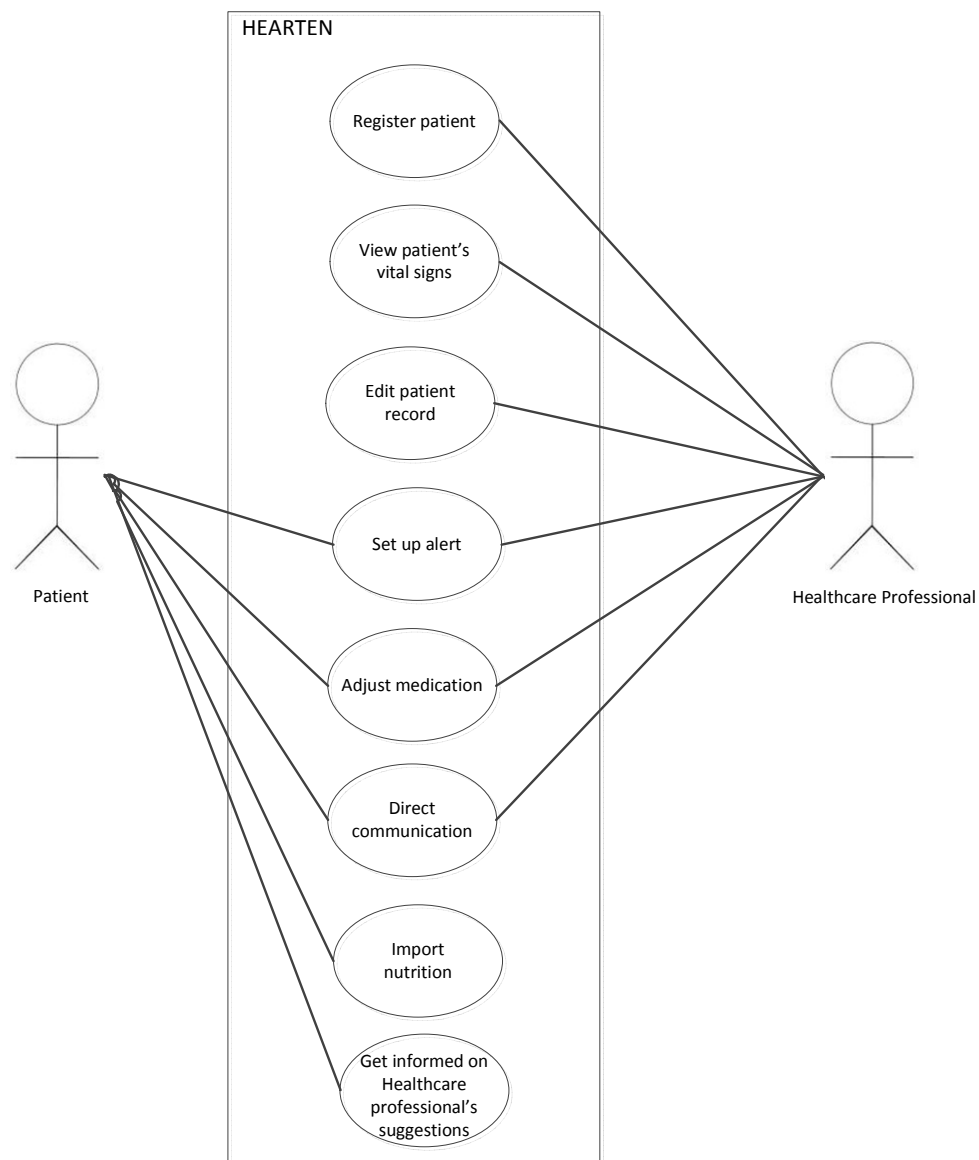


Figure 54: Patient and healthcare professional use cases.

3.2. Patient and caregiver interaction case scenario

Scenario I

Use Case «Communication channel through patient and caregiver »

- The caregiver communicates with the patient providing the following recommendations (Exercising, nutritional and medication non-adherence issues).

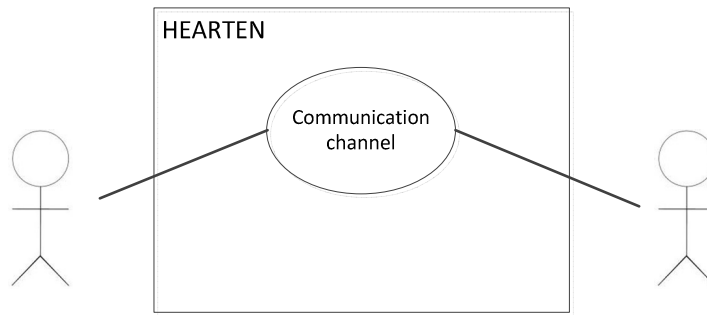


Figure 55: Use Case «Communication channel through patient and caregiver».

Use Case «Import additional patient information »

- The caregiver imports to the HEARTEN system additional info based on the overall health status of the patient or/and info that could be used as a complementary source of information for the healthcare professionals.

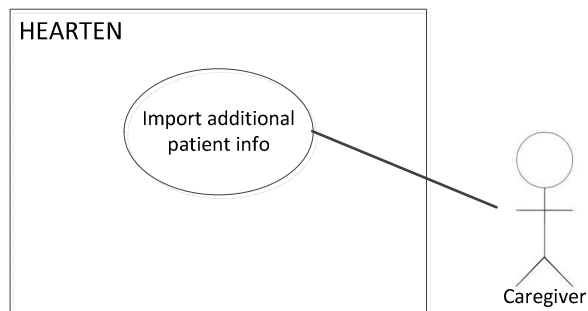


Figure 56: Use Case «Import additional patient information».

In the following figures we present the use cases as identified in scenario I of patient and caregiver interaction.

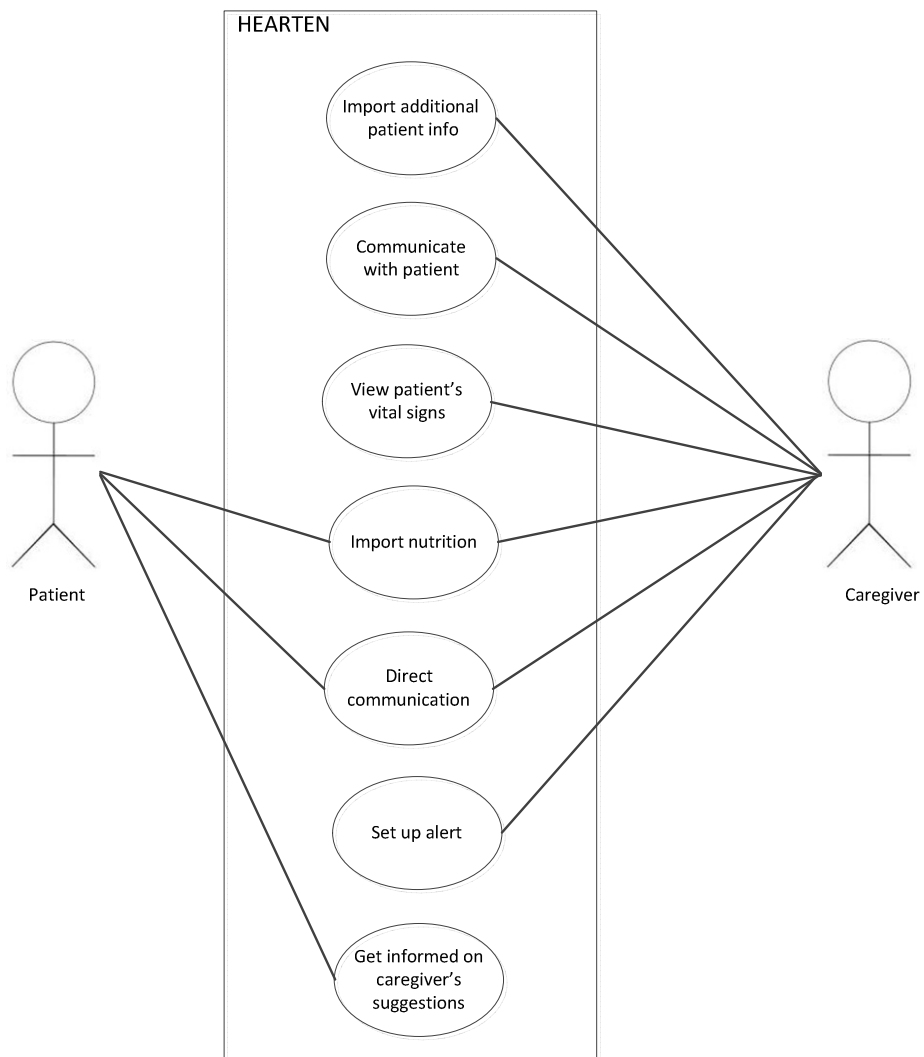


Figure 57: Patient and caregiver use cases.

3.3. Other educational activity scenario

Scenario I-IV

Use Case «Documental content visualization for patients»

- The patient enters to HEARTEN and asks to be educated about specific topics related to HF.

This could concern:

- Definition and aetiology of HF
- Symptoms occurring
- Self-care
- Pharmacological treatment
- Adherence

- Diet and alcohol
- Exercise
- Psychosocial aspects

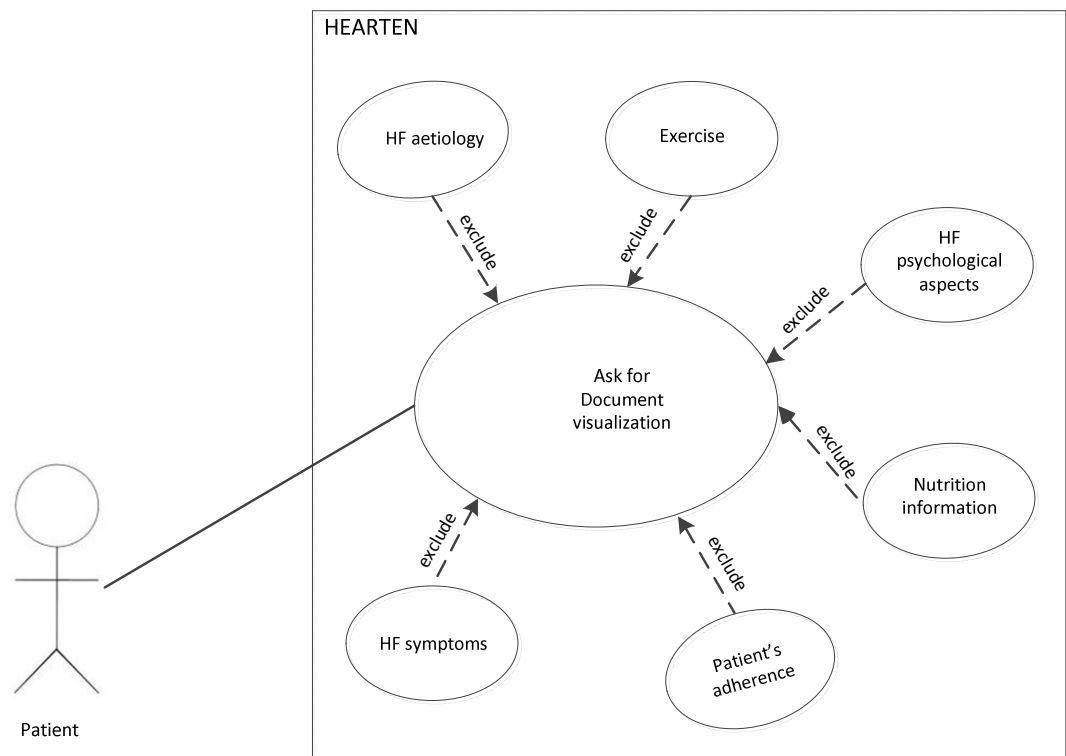


Figure 58: Use Case «Documental content visualization for patients».

4. LEGAL AND ETHICAL ISSUES

Improving the quality of life of HF patients – as the Hearten project intends to do – is already a positive ethical objective, in line with article 35 of the Charter of Fundamental Rights of the European Union (2000).⁶ However, as any research activity involving human subjects and focused on developing medical devices, it is necessary that the desire for improving the HF management should never compromise on the one hand the patients safety and rights and, on the other, that the devices be designed in compliance with the appropriate legislation.

In order to address the ethical and legal issues emerging from the research activities carried out within the Hearten project, three main “solutions” have been identified in Annex 1:

1. T1.4 Legal and Ethical Framework.
2. The Ethical and Privacy Manager.
3. The Ethical Advisory Board.

The ‘**Legal and Ethical Framework**’ task in WP1, which starts at Month 1 and finishes at Month 36, is the task devoted to the ethical and legal issues. Its aim is to set up an Advisory Board and to ensure that all Hearten research activities and the data and resources utilized during the pilot study preparation, operation and execution are compliant with EU legislation. Task 1.4 is led by UNIPi, in the person of MD. Maria Giovanna Trivella; other participating partners are: UMR, SAS, EVE.

The **Ethical and Privacy Manager**. The person responsible for managing ethical and legal issues is MD Maria Giovanna Trivella. As reported in Part B of Annex 1, the role of the E&P Manager is to ensure that all measures have been taken in order for the project to timely identify, analyse and address potential ethical and privacy issues arising from accessing patient health information. Moreover, the Dr Trivella, will closely co-operate with the PC and the TM and inform all partners about the necessary measures that have to be taken at all project phases, including project requirements analysis and architecture design, components implementation, platform integration and system evaluation.

Finally, the **Ethical and Legal Advisory Board (ELAB)**. Since the Hearten project start, a dedicated board (i.e. ELAB) has been set up in order to have all the expertise and the professional competences useful for revision and monitoring of the complex project activities. In fact, due to the different scenarios involving human beings from clinical arena to patient home, a peculiar attention to the ethical issues and the privacy needs must be paid. The multiple actors have to be well informed and prepared in order to obtain and define the different user requirements for the best design of protocols and system architecture at the different project steps. Within the appendix the bio sketches of the

⁶ ‘Everyone has the right of access to preventive healthcare and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities’ Article 35 - Healthcare, Official Journal of the European Communities, C 364, 18/12/2000 .

ELAB are reported (see Appendix A). The competences cover medicine and ethics fields, ICT database and data exchange, legal area and psychology.

A dedicated section on ethical and legal issues has been published also on the project web-site (see website <http://www.hearten.eu/ethical-and-legal-issues/>).

4.1. Ethical and Legal Issues

The ethical and legal issues concerning the Hearten project are mainly related to the participation of patients in research activities and to data protection (e.g. careful in patient's information as well as respectful of her/his consent and/or dropout willingness, guarantee their confidentiality and anonymity). They have been identified in the ethical screening enclosed in Part B of Annex 1.

The way in which these issues will be addressed within the project, the normative framework of reference as well as the experimental protocols designed for the activities to be conducted in WP4 and in WP4, will be the objective of the series of deliverable entitled 'Legal and ethical considerations', D1.8, D1.9 and D1.10 which are due at month 6, 12 and 24 respectively. Therefore, we refer the reader to D1.8 for more details on regulatory framework and the experimental protocol for WP4.

In this report, it suffice to say that all the local, national and European regulations will be taken into account for carrying out the project activities. The different protocols (research step, WP4; pilot study WP9) will be defined and submitted to the Local Authorities, as required in the different countries involved. For WP4 protocols, University of Pisa (UNIP) in Tuscany region and University of Rostock in Germany will be submitted together with the informed consent forms. For WP9, due on the last year of the project, after the system architecture definition and implementation, UNIP and SAS will submit for approval the final protocols for pilot studies. The specific protocols and the required additional documentation will be described within the deliverable D1.8 and its subsequent versions.

As to the legal implications, issues referring to privacy code, the European researcher conduct code and to all the European Directives for data safety and security will be taken into considerations. Also this matter will be carefully described within the deliverable D1.8 and its subsequent versions.

5. CONCLUSIONS

This deliverable underpins the functional basis that will enable the start of the HEARTEN ecosystem development, including all ecosystem actors needs as well as the use cases of the environment.

This report belongs to the WP3: “Ecosystem needs analysis and design of the architecture of the mHealth environment” framework. Through this document, the following objectives have been fully achieved:

- Definition of user requirements
- Definition of the patients’ needs and expectations

And the following objective has been partly achieved:

- Definition of system architecture and functional specifications

The introduction addresses the comparison between the different typologies of healthcare systems currently existing in EU28. Northern European countries (Sweden, Denmark, Finland, Ireland, Netherlands and United Kingdom) present both universal non means-tested and mean tested, with predominance of in kind formal services or of tied and regulated cash allowances. Continental countries (Germany and France), show an overall universal non means-tested and a mix of in kind formal services and untied cash allowance. In Mediterranean countries (Italy and Spain) the healthcare system is based on the principle of social assistance with a recently introduced of universal non means-tested and untied cash allowance. Finally, in Central-Eastern European countries (Poland and Bulgaria) are the families who are legally or implicitly bound to care services.

In order to define users’ needs, the NDT methodology has been applied aiming to capture and analyse information systems requirements. Within this framework, the needs of all different user’s roles (patients, caregivers, healthcare professionals and nutritionists/nurses) involved in the HEARTEN ecosystem have been duly defined. This analysis has yielded a total number of 9 system objectives and 11 functional requirements.

In order to address the functional requirements definition, questionnaires and interviews have been performed and carried out aiming to broaden the scope beyond the own experience from healthcare professionals involved in this project (from SAS, UMR and UNIPi). In this sense, a total number of 65 questionnaires and 60 personal interviews have been carried out. Given the level of functional and cognitive decline of the patients included in this project, interviews have been more focused on carers and health professionals. Analysis carried out from questionnaires and interviews includes demographics information for all actors and, depending on the end user role, the following specific domains have been considered:

- For patients: lifestyle habits, technological skills and health status.
- For caregivers, healthcare professionals and nutritionists/nurses: technological skills and preferences, and patient's needs and interactions.

Appendix B shows the final version of the questionnaires released, and Appendix C includes a spreadsheet accounting the gathered responses for each questionnaire. The section 4.5 of this document addresses the analysis of the survey outcomes, including the regarded conclusions.

Furthermore, the definition of clinical scenarios in order to identify interactions between: (I) Patient and healthcare professional; (II) Patient and caregiver; and (III) Educational activity, has been carried out. This definition has been performed in both textual and illustrative formats. Section 3 deals with use case scenarios definition and analysis according to the aforementioned clinical scenarios.

Some aspects regarding ethical and legal issues related to the functional requirements definition have also been addressed in this deliverable. In this sense, the HEARTEN Ethical Advisory Board (EAB) has been set up and identified legal and ethical issues have been reported to them. The EAB has not found any reason to modify proposed functionalities so far. Appendix A show a descriptive bio-sketch of the researchers involved in the EAB.

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