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D2.1 Report on UCD strategy

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[1] L = Legal agreement, O = Other, P = Plan, PR = Prototype, R = Report, U = User scenario

[2] PU = Public, PP = Restricted to other programme participants (including the Commission Services), RE = Restricted to a group specified by the consortium (including the Commission Services), CO = Confidential, only for members of the consortium (including the Commission Services)

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Glossary

Auscultation: listening to the internal sounds of the body, usually aided by a stethoscope

BNP: Brain Natriuretic Peptide; NT-proBNP: N-terminal proBNP

CHF: Chronic Heart failure

COPD: Chronic Obstructive Pulmonary Disease

Decompensation: failure of function leading to deterioration of homeostatic mechanisms

EF: Ejection Fraction. EF is a percentage that indicates how much blood, during the contraction of the heart muscle, is pushed from the left- or right ventricle.

eHealth: relatively recent term for healthcare practice supported by electronic processes and communication. Usage of the term, however, varies. Some argue that it is interchangeable with health informatics with a broad definition covering electronic/digital processes in health while others use it in narrower sense of healthcare practice using the Internet. It can also include health applications and links on mobile phones referred to as mHealth.

Exacerbation: worsening/deterioration (of status/disease)

HF: Heart Failure

Holter: ambulatory electrocardiography device

ICD: Implantable cardioverter-defibrillator

Impedance: Extent of substance resisting the flow of electrical current of a given voltage

Oedema: fluid retention in the body

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1. Introduction

1.1. Europe is ageing

Longevity is one of the biggest achievements of modern societies; Although large differences exist among and within Member States of the European Union (EU), the average life expectancy has increased by approximately 0.25 years annually [1], resulting in a gain of 6 years on average in the last 20 years [2]. Europeans are living longer than ever before and this pattern is expected to continue due to unprecedented medical advances and improved standards of living.

The number of healthy life years (HLY), however, appears to remain unchanged [1]. Ageing is commonly characterised as a progressive, generalised impairment of function resulting in an increasing vulnerability to environmental challenge and a growing risk of disease [3]. In this way, a growing number of elderly people spend 20-25% of their lives in poor health, suffering from one or more chronic diseases [1]. Combined with low birth rates, this will bring significant changes to the structure of European societies.

Chronic diseases, which represent 82% of disease burden (expressed in disability-adjusted life years or DALYs), include cardiovascular disease (24%), mental and behavioural disorders (10%), chronic respiratory disease (4%), and diabetes (2%). Also, musculoskeletal disorders (12%) and neurological disorders (4%) were responsible for a large share of DALYs [4].

1.2. Introduction to SmartBEAT

In the light of these challenges, the SmartBEAT project – Smart system for the management of Heart Failure in older adults – is funded in Call 7 of the AAL Programme. The main goal of the SmartBEAT project is to support senior Chronic Heart Failure patients, their family, relatives and friends, cardiologists and general healthcare professionals accessing innovative ICT solutions that promote an easier, wider and sustainable access to healthcare. SmartBEAT offers an integrated solution to leverage patient self-care through autonomous condition monitoring and real-time feedback to their caregivers. Using SmartBEAT it is possible to improve disease outcomes and enhance the quality of life of senior Chronic Heart Failure patients [5].

1.3. Outline

This deliverable outlines the user-centred design (UCD) strategy developed for the SmartBEAT project. In order to frame the context, we give in Chapter 2 a description of Chronic Heart Failure and Chronic Heart Failure management. Chapter 3 explains the different stakeholder groups and the importance of involving them in the development process of innovative ICT-supported care solutions. The UCD strategy itself is elaborated on in Chapter 4, which describes all the different UCD activities for the different stakeholder groups in more detail.

2. SmartBEAT for CHF management

Chronic heart failure (CHF) accounts for a significant part of cardiovascular disease burden in Europe, and significantly increases morbidity and mortality of patients (in some cases it is higher than some of the most frequent cancers such as bowel and prostate cancer). It is estimated, by the European Heart Failure Association (HFA) that over 26 million patients suffer from CHF worldwide. This syndrome poses a huge social and economic burden on healthcare systems, as well as on patients and formal and informal caregivers [6].

In heart failure the heart is not able to pump enough blood, containing oxygen and nutrients, to meet the body's needs. This may cause symptoms such as shortness of breath (dyspnoea), intolerance to physical exercise and fatigue, as well as signs resultant of accumulation of fluid upstream from the heart (in the legs (swelling), lungs and others).

The majority of people suffering from CHF are beyond 65 years of age. Their quality of life is severely affected due to frequent hospitalizations related to acute decompensations as well as due to limitations in daily life activities because of their symptoms. Treatment to mitigate the symptoms consists of intensive medication management, regular monitoring and check-ups regarding changes in physiological status and supporting a 'CHF-friendly' lifestyle.

Today, cardiologists can monitor and coach their patients remotely. Remote monitoring devices can help to collect information. The patient uses a device at home to measure and send vital signs data to the cardiologist. In addition to remote monitoring, patients receive remote coaching for nutrition, physical exercise and other lifestyle aspects. In this way, responsibility shifts towards the patient, supported by informal caregivers and family members. Self-management can therefore be considered an important part of CHF care and, when adequately executed, helps to prevent exacerbations and hospitalisations.

SmartBEAT aims at integrating different sensors in one comprehensive remote monitoring system to be used at home, helping to prevent decompensation and hospital admissions in CHF patients. In the following sections, Chronic Heart Failure is defined, and causes, symptoms and treatment are explained. To conclude the SmartBEAT system and its aims are presented.

2.1. Chronic Heart Failure

In this section we will explain what Chronic Heart Failure is by describing definitions, epidemiology, diagnosis, classifications, symptoms and causes.

2.1.1. Definition

Chronic Heart Failure is a syndrome, not a disease itself: it has many different underlying causes, appears in different ways and levels of functional disability and severity [7]. The European Society of Cardiology (ESC) defines CHF as "a clinical syndrome in which patients have typical symptoms and signs resulting from an abnormality of cardiac structure and function [8].

As previously stated, in heart failure the heart is not able to pump enough blood, to meet the body's needs. This results from cardiac systolic and/or diastolic dysfunction. After an initial insult

(as a result, for example, of a myocardial infarction) an adaptive process starts to take place in the heart called "cardiac remodeling" (which may involve dilation of the heart chambers). This process is beneficial at first but, after a variable period of time, will eventually fail (the heart muscle walls may eventually weaken and become unable to pump as efficiently) causing worsening of cardiac function and heart failure symptoms. Cardiac dysfunction may impact the function of remote organs as, for example, the kidneys, which may respond by causing the body to retain fluid (water) and salt causing a state of congestion (accumulation of fluid in the arms, legs, ankles, feet, lungs) [9].

2.1.2. Ejection fraction

For a long time, determining the ejection fraction (EF) of the left ventricle - the proportion of blood being pumped from the heart in each cardiac cycle - has been the leading criterion to determine whether a patient suffers from heart failure.

Heart Failure with reduced ejection fraction (HFrEF) is a term used to describe those patients with heart failure symptoms that have an impairment in the contraction of the heart muscle [10]. The role of EF, however, has been recently discussed and eventually reassessed, as EF is a rough measure of the left ventricular systolic function. It became clear, alongside with the introduction of new techniques, that other measures of systolic function, beyond EF, are also important. Additionally, the role of the assessment of EF to identify those symptomatic patients that actually have heart failure (i.e. symptoms + low EF) was even more downplayed when it became clear that symptoms of Heart Failure also occurred in patient with 'normal' or preserved EF (HFpEF) [11]. Whereas both HFpEF and HFrEF present with similar symptoms, the clinical consequences may differ greatly, although both present with a dismal prognosis. [12].

2.1.3. Epidemiology

Due to a lack of timely and correct diagnosis, epidemiological data are hard to establish. Actual numbers of incidence, prevalence and mortality differ among various research studies, aetiology of CHF and countries. Most statistical data on CHF is derived from patient CHF multicentre registries (including hospitals and general practices). In most estimations, CHF seems to be a frequently occurring pathology: the estimated prevalence of CHF is 2-3 percent in the general population and between 10-20 percent among the age group 70-80. Approximately 26 million people worldwide live with chronic heart failure. In Europe, every year, 3.6 million people are newly diagnosed with CHF [13]. These numbers may be underestimated as CHF might be underdiagnosed or recorded as a secondary diagnosis. As treatment of cardiovascular diseases improves and life expectancy increases, there is a growing incidence and prevalence of CHF [14].

Heart Failure is, according to cohort studies and community based research and epidemiological studies, the leading cause of hospital admissions in people over 65 years-old in North-America and Europe [15]. After a first hospitalisation in which HF is diagnosed, approximately 25 percent of these patients are readmitted to the hospital within two weeks.

The costs associated with the care of HF are immense: the estimates run into billions each year. Recurrent hospitalizations, due to acute decompensations, represent the largest share in the associated costs of managing these patients and it is estimated that, in Europe and North-America, HF accounts for 1-2 percent of total health care expenditure [11].

2.1.4. Diagnosis

Heart failure is sometimes underdiagnosed due to lack of awareness of a patient's doctor and because patients do not always present with the typical symptoms of HF. The cardiovascular scientific communities like the European Society of Cardiology (ESC) and American Heart Association (AHA) have published guidelines for the diagnosis and management of HF [16]. In the SmartBEAT project, we will follow the guidelines as stated by the ESC, as they are more suitable to a European setting.

When physicians are confronted with a patient with typical CHF symptoms such as shortness of breath, fatigue and peripheral oedema, it is recommended to explore the possibility of the diagnosis Heart Failure. For this, an elaborate anamnesis, physical examination, blood testing (measuring brain natriuretic peptide - BNP) and an ECG should be conducted. According to the guidelines of the European Society of Cardiology, the diagnosis 'Heart Failure' can be made when the following criteria have been met:

Table 1 - Diagnosis of Heart Failure, adapted from [8].

Diagnosis of Heart Failure
The diagnosis of HFrEF (with reduced ejection fraction) requires three conditions to be satisfied:
1. Symptoms typical of HF
2. Signs typical of HF
3. Reduced LVEF
The diagnosis of HFpEF (with preserved ejection fraction) requires four conditions to be satisfied:
1. Symptoms typical of HF
2. Signs typical of HF
3. Normal or only mildly reduced LVEF and LV not dilated
4. Relevant structural heart disease (LV hypertrophy/LA enlargement) and/or diastolic dysfunction
LA = left atrial; LV = left ventricular; LVEF = left ventricular ejection fraction. Signs may not be present in the early stages of HF (especially in HF-PEF) and in patients treated with diuretics

Heart failure is a clinical diagnosis, i.e., it is diagnosed by obtaining a careful clinical/medical history and performing a physical examination. However, some techniques and diagnostic tools

are available to substantiate the diagnosis and cause of CHF: Electrocardiogram (ECG), Echocardiography, chest x-ray, BNP-blood test, Holter Monitor, Nuclear Heart Scan, Cardiac Catheterisation, Coronary Angiography, Stress Test, Cardiac MRI and Thyroid function tests [17].

2.1.5. Classification

The European Society of Cardiology (ESC) defines two types of heart failure based on how it develops throughout time. These are: new onset/acute and chronic. New onset/acute heart failure may be caused by a transient, and sometimes reversible, cause such as an acute coronary syndrome/myocardial infarction. Chronic HF refers to the patients who persistent symptoms, even if mild and stable, however in a considerable number of cases it's slowly progressive. These latter patients are at risk of acute decompensations/acute heart failure episodes. [8].

After diagnosing HF, patients are stratified according their functional capacity, i.e. taking into consideration the degree of physical limitation related to the underlying cardiac dysfunction. This is achieved by applying a classification designated as New York Heart Association (NYHA) functional class. [18].

Table 2 - NYHA classes of Chronic Heart Failure [19].

Class	Patient symptoms
I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).
II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).
III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
IV	Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

2.1.6. Causes

When the diagnosis Heart Failure is established, causes and concomitant disorders are identified, as they are of paramount importance for adequate treatment. There are many different, sometimes overlapping, that can be identified and underlies CHF. Indeed, morbidities such as diabetes, COPD and coronary heart disease are very common in this population. Figure 1 depicts an elaborate diagram of the risk factors, different causes and concomitant disorders related to and/or playing a role in the acute event of HF which, in almost all cases, develops in a background of CHF.

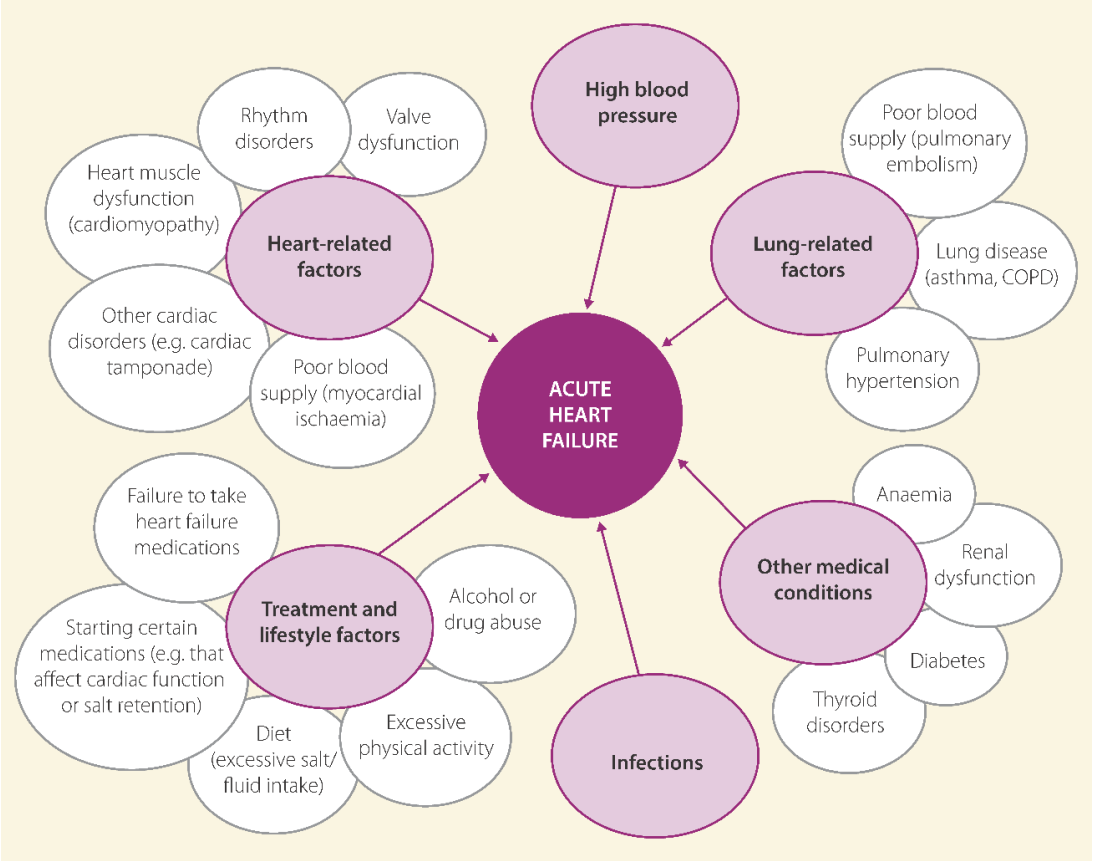

Figure 1 - Causes Acute Heart Failure [20].

2.2. CHF Management

When developing a CHF remote monitoring system, it is of great importance to not merely have an adequate understanding of Chronic Heart Failure, but also to have a good insight into treatment and management of CHF. This section will describe the organisation of CHF care in general and the importance of health monitoring for management of these patients.

2.2.1. CHF care

CHF care aims at managing the disease in order to keep patients stable and consequently avoid hospital admissions. To achieve this, various formal and informal caregivers collaborate. Besides medical treatment, a healthy lifestyle is of immense importance.

2.2.1.1. Care network

As CHF is a complex and multifaceted condition, it involves many different caregivers, service providers and systems. Additionally, patients themselves have a very important role to play in preventing deterioration of their condition. CHF care among the European Member States is relatively similar: it is mainly provided in hospitals by cardiologists and specialised CHF nurses. Besides hospital-based CHF care, there are also some specialised Heart Failure clinics, across

Europe, which are mostly relying on specialised Heart Failure nurses. These clinics are becoming more popular and common, however, are not able to cover the majority of patients yet [21].

The cardiologist receives extensive training in medical school after which is endorsed into specialised training of three to five years in Clinical Cardiology. The cardiologist is the expert in the field of heart conditions and cardiovascular disease.

Ideally, a multidisciplinary team of caregivers should be set up to manage Heart Failure: in addition to cardiologists and specialised CHF nurses, general practitioners, home care nurses, informal caregivers and paramedics, such as physiotherapists and dieticians, can be involved in this team. General practitioners (GP) and home care nurses have a role in the management of CHF in the patient's local environment: general practitioners are the first-port-of-call for the majority of patients and home care nurses constitute an extra link to the patient's home environment. Physiotherapists, for example, can help with adequate exercise and lifestyle changes while dieticians can support patients in adhering to a CHF-friendly diet [22].

2.2.1.2. Management

Most of times, CHF is caused by underlying diseases, infections, previous myocardial infarction, and a negative lifestyle. It cannot be cured in a strict sense, but the underlying causes of acute decompensations have to be tackled. CHF is characterised by a gradual, fast or slow, worsening only to be impeded by numerous admissions to the hospital. Eventually, patients suffering from CHF die because of an advanced disease state, with progressive caquexia. As there is no cure, treatment of CHF is concentrated, besides for improving prognosis, on early detecting and slowing down of acute decompensation, and relieving symptoms. In fact it is better to speak of management rather than treatment [8].

Medical treatment of CHF mainly focuses on medication. Standard CHF medication consists of a combination of a diuretic drug, an ACE-inhibitor (and/or angiotensin receptor blockers), selected beta-blockers and an aldosterone receptor blocker. When the symptoms persist and/or because of intolerance to medications, other drugs may be added to the treatment regimen. Whereas the efficacy of these drugs in HFrEF are well substantiated, the effect in HFpEF are quite uncertain.

Besides drugs, non-medical therapies such as improving health literacy, therapy adherence and stimulating appropriate lifestyle decisions and dietary regimens play an important role in influencing clinical outcomes [24]. Patients should be encouraged to take more responsibility in managing their condition themselves (self-management). If instructed by a well-trained CHF-specialist, at home, patients may be able to perform health monitoring by themselves and adjust their medications, diet and lifestyle in line with the given recommendations. Nevertheless, the term self-management does not imply that the patient is without support of caregivers.

A long list of strict recommendations to comply to makes CHF one of the most complex chronic conditions to manage: it is physically, intellectually, socially and emotionally demanding [25]. In addition, most of the patients are elderly and poorly educated which adds to the complexity. Therefore, the most important non-medical aspects of CHF self-management is education and psychological support for both patients and family; explaining the condition, its risks and

limitations. A water-and-salt restricted diet, daily weighting, alcohol-restrictions and daily physical exercise are also crucial to prevent CHF from acutely exacerbating. To realize such a high level of self-management, it is expected that cardiologists and CHF nurses spend time and effort in providing information and support.

Adherence to the medical and dietary regimes, doing physical exercise, and refraining from lifestyle choices facilitating exacerbations, proves to be difficult for most patients. Therefore, a comprehensive educational program provided by caregivers, as part of an overall management plan, is an essential aspect in the success of patient compliance with therapy [26].

2.2.2. Health monitoring

Since early detection of decompensation is key in avoiding CHF exacerbation and hospital admission, the health status needs to be monitored closely. Frequent monitoring of indicators of impending acute decompensations, and reacting accordingly, may prevent decompensation of CHF improving prognosis and reducing costly admissions to the hospital [23]. Monitoring these parameters is the most important tool clinicians have in managing CHF.

As CHF is influenced by so many different aspects, determining what and how to monitor is complex. In the following subsections we will present an overview of the relevant parameters, the manner in which they can be measured and the (preferred) measurement frequency.

2.2.2.1. Parameters

First of all, the underlying aetiology and possibilities for treatment influence the progression of CHF. Variables as age, gender and comorbidities determine the risk of morbidity and mortality, and similarly the biochemical status of the patient and their activity tolerance. Not all measurable/monitored parameters are indicative by themselves but should be measured and weighed in relation to each other.

Based on the guidelines from the European Society of Cardiology (ESC) and the National Institute for Care Excellence (NICE) scientific papers, the following collection of possible parameters to monitor has been assembled:

Table 3 - Parameters predicting decompensation in CHF patients [8],[27].

Parameter	Explanation
Heart rate (beat/pulse)	The number of heart beats per minute is an important and obligatory parameter in decompensation of Heart Failure.
Heart rhythm	The regularity or irregularity of the intervals between the beats. Arrhythmias can be detected by measuring heart rate and rhythm.
Respiratory rate	The respiratory rate is a very important indicator of physiological status. A higher rate is in many cases one of the early signs of exacerbations in Heart Failure.

Body Temperature	Low body temperature can indicate decompensation. For every 1°C decrease in body temperature, there is a significant risk of worsening of the health status of the patient. [28]
Blood pressure	Blood pressure (BP) is very frequently altered in CHF decompensation. It might be excessively elevated due to, for example, non-compliance with medication and/or dietary regimens, or the reverse: a BP level that is extremely low, indicating pump failure.
Pulmonary congestion	Fluid accumulation in the lungs is a hallmark of Heart Failure decompensation. Traditionally this is detected by physical examination by pulmonary auscultation, which reveals the presence of abnormal breath sounds, such as wheezes or crackles.
Weight	Accumulation of fluid beyond the lungs is also a common finding in acute HF episodes, making weight fluctuations measured through successive evaluations a good pointer towards decompensation episodes.
Physical activity	HF patients may present decreased activity and patients with acute decompensation report a reduction of exercise capability several days or weeks before hospital admission. Moreover, discouraging a sedentary lifestyle and promoting physical activity have both been shown to improve quality of life and clinical outcome in CHF. CHF patients tend to accumulate fluids in lower limbs during the day, which are mobilised to the circulatory system and then to urine during the night, making them urinate more often. Indices of physical activity give context to other parameter's measurements and a comparison of trends throughout the day and night can also indicate pending decompensation.
Sleep	Sleep is mentioned as a parameter that needs to be considered. Problems with sleep can be indicative of exacerbation of the chronic heart failure condition. Sleep apnoea is very common in relation to Heart Failure. The prognosis of Heart Failure is considerably worse when associated with sleep apnoea. Sleep apnoea can be diagnosed by asking about symptoms or by letting the patients stay overnight and monitor their sleep pattern.
Impedance (Intrathoracic)	Measuring impedance is a method to assess hemodynamics and volume status (for example in the lungs) in patients with Heart Failure. It is therefore a useful way to reveal decompensation. Impedance indicates the extent of substance resisting the flow of electrical current of a given voltage. Physiological factors such as blood volume, fluid and positioning can have an effect on the impedance signal. Intrathoracic impedance can be measured, to specify pulmonary congestion. It can be measured in the hospital [29].
Therapy Adherence (food intake, activity level, medication)	Following recommendations about medication, diet, exercise and other habits can help to alleviate symptoms, slow the progression of CHF and improve everyday life. Therapy adherence is not one single measurable parameter, but a set of different indicators such as salt and sugar intake, level of activity, medication, etc. In fact, people suffering from mild to moderate Chronic Heart Failure often can lead nearly normal lives as a result of adhering to the recommendations and restrictions.

	Regulating lifestyle choices and adjusting therapy in line with the measurements is most influential on the prognosis of the patient [30].
Functional performance	The physical examination of CHF patients is also done in the hospital. Examination of the patient's chest, jugular venous pressure (JVP), abdomen and periphery as well as measurement of arterial pressure in the supine and standing positions, have significant prognostic value and give context to other measurements.
Blood sample	Blood samples are frequently taken of CHF patients. Brain natriuretic peptide (BNP) and NT-ProBNP are, apart from being important in diagnosing Heart Failure, a strong hallmark of decompensation. Medication can be adjusted in order to reduce circulating BNP level. Electrolytes and assessment of renal function can help detect exacerbations [31].
Heartrate variability (HRV)	HRV is the variation in time intervals between heart beats and indicates the status of the autonomous nervous system in relation to the sinus node. It can therefore be a useful marker of decompensation [32].
Intra-cardiac pressures	Intra-cardiac pressure can be measured in the hospital. It is mostly measured in supine position (laying down) and to help indicate decompensation, measurements should be continuous and in different contexts, such as monitoring simultaneously with physical activity of the patient. Implantable devices are tried with measuring intra-cardiac pressure [33].
Peripheral Oxygen Saturation	Peripheral oxygen saturation can give an estimation of the cardiac output and provide information about the relationship between left-heart and right-heart pressures, indicative of decompensation in heart failure. Research into this marker is still limited and ongoing. The prognosic value is uncertain. [34]
Venous oxygen saturation	Oxygen saturation is an interesting parameter as it seems to be more sensitive to hemodynamic changes. A drop in venous oxygen saturation is a marker of decreased cardiac output and decreased hemoglobin concentration, both can indicate acute decompensation [35].

2.2.2.2. Measurement frequency

To detect decompensation in an early stage, it is important to have frequent measurements. Measurement frequency should vary according to the parameter in question. Whereas for some parameters a monthly or weekly measurement would be fine, other parameters require daily or even continuous measuring to have valuable data. The frequency of measurements required depends also strongly on the functional class (NYHA) the patient is assigned to.

Cardiologists involved in the SmartBEAT project have set up a list of their preferred measured parameters and their (ideal) frequency of monitoring, listed in Table 4.

Table 4 - Monitoring frequencies.

Parameter	Monitoring frequency	
	Minimal	**Ideal**
Heart rate	Once a day	Continuous
Heart rhythm	Once a day	Continuous
Blood pressure	Once a day	Continuous
Pulmonary congestion		Once a day
Weight		Once a day
Physical activity		Continuous
Medication application		Once a day
Questionnaire		Once a day

2.2.2.3. Remote monitoring

In regular care settings it is difficult to monitor the different parameters of CHF patients with a high frequency. An emerging strategy to cope with this challenge is the use of remote monitoring. This means that care professionals are enabled to monitor patient's health status remotely with the help of measuring equipment at home based on telecommunication technologies. With regards to Chronic Heart Failure, the added value is clear: frequent home measurements instead of some check-ups in the hospital now and then leads to earlier detection of decompensation. With the aid of remote monitoring the patient measures a selection of relevant parameters and answers some questions resulting into a personal account of experienced symptoms and physical ability. Designated care professionals have access to this multitude of measurement and self-evaluation data [36], enabling them to take immediate action, provide education and adjust medication, and in turn preventing exacerbations and hospital visits [37].

There are currently many remote monitoring systems available on the market. Concerning Heart Failure measurements, the devices and systems range from a simple weighing scale, a blood pressure cuff, to a set of sensors attached to a box brand-named 'Holter Monitor', which keeps track of heart rhythm. Some systems include ECG functionality by means of electrodes placed on the body. Most of the existing systems consist of multiple separate sensors, which makes it difficult to use, challenging the therapy adherence. Implantable devices such as an implanted cardioverter defibrillator (ICD) can tackle this challenge [38]. It is however not evident that remote monitoring based on the measurement of vital signs, weight and symptoms alone prevents hospital admissions. Experiments with other parameters, such as heart rate patterns, intrathoracic impedance seem promising in indicating decompensation in CHF, but still has to be established [39].

As self-management is a challenge for patients and particularly for patients suffering from CHF, remote coaching can provide support. It can help to increase the health literacy of patients, and more importantly, therapy adherence, as that has proven to be often the main precipitant factor of hospitalizations when prescriptions are not followed to the letter.

2.3. SmartBEAT system

The project focuses on developing useful and realistic services that reduce the need for hospital admissions and institutional care, and encourages early discharge. The SmartBEAT system will consist of the following modules:

- **Remote monitoring kit:** a combination of sensors enabling for frequent and autonomous measuring. It uses sensing devices and communication technologies to measure several clinical variables of CHF patients considered essential by expert cardiologists, such as physical activity levels, weight, blood pressure, pulmonary congestion, heart rate and heart rhythm. Thanks to autonomous measurements, therapy adherence is high so to adequately monitor the health status of the patients.
- **SmartBEAT Companion:** coaching app for the smartphone, linked to the remote monitoring kit. It is a user-friendly, integrated mobile solution to leverage health monitoring and self-care. SmartBEAT will also motivate the user through integrated condition validation, tailored interfaces and health status questionnaires.
- **Caregivers Portal:** a web application serving as the front-end for the formal and informal caregivers, each with different access permissions. The CGP will be tightly integrated with the **SmartBEAT Inference Unit** and will enable the caregivers to access the patient's medical data, such as vital signs. The portal will also provide a personalized news feed to the care givers, which will highlight important events, such as the changes in the patients' vital signs and alerts raised due to classifications. In addition the news feed will integrate the semantic search engine of the MIU to provide recommendations about the last research and scientific initiatives. The Portal will allow the caregivers to personalize the recommendation by subscribing to semantic topics of personal interest.

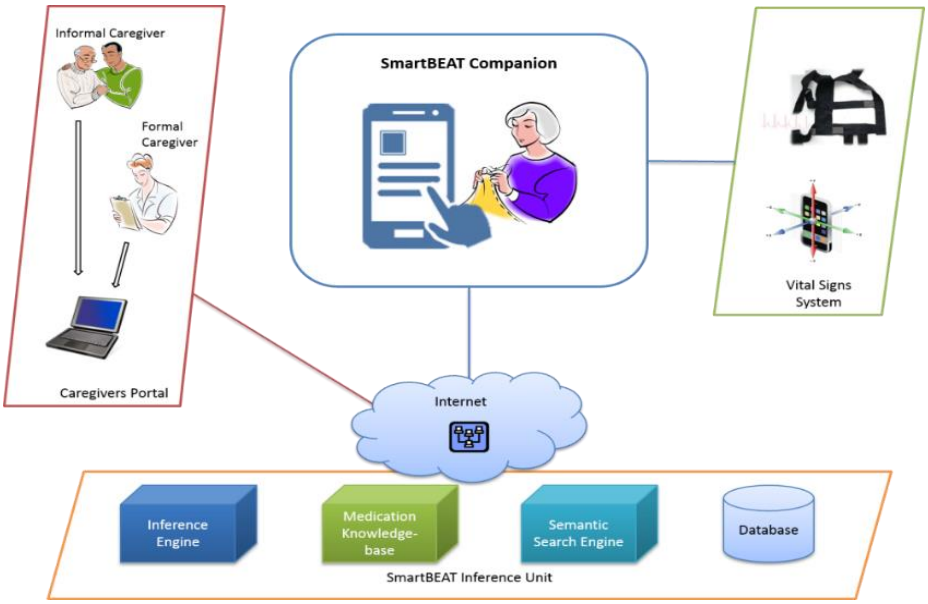

Figure 2 - SmartBEAT system.

Specialised algorithms will process the acquired measurement data and compare these data with baseline values of the patient, possibly giving rise to automatic alerts for therapeutic adjustments or notifications, according to the clinical status. SmartBEAT algorithms and features will be developed in accordance with cardiologists and partners' experience and taking into consideration the European Society of Cardiology (ESC) guidelines for CHF care. Furthermore, SmartBEAT will use data and text mining to build medication knowledge bases, empowering the solution to provide information on therapeutic regimens and to promote medication adherence.

3. User-Centred Design (UCD) in SmartBEAT

eHealth technologies can assure basic support for daily activities, detect health critical situations, and stimulate social and psychological engagement that fosters emotional wellbeing enhancing dignity and quality of life. Although technology has great potential, both patients and care professionals tend to have many reasons to be reluctant to innovative care solutions.

In order to tackle this reluctance and realize user acceptance, systems and services have to be developed in the light of the needs and wishes of different stakeholder groups. If the proposed solution indeed does grant stakeholders' requirements in a less effort or less money consuming way, they will experience a feeling of perceived usefulness. In order to realize a use intention, this usefulness perception should be combined with both enjoyment and perceived ease of use. Attractive systems with user-friendly interfaces can lower the threshold to start using new technologies for both patients and care professionals. Also, the alignment with current infrastructure and care processes will increase the chance for adoption. Therefore, it is crucial to investigate in-depth needs, requirements and contexts of the different stakeholders involved, different care systems, and legal and organisational frameworks in the different countries. These context requirements will be tackled in WP5 on Dissemination & Exploitation.

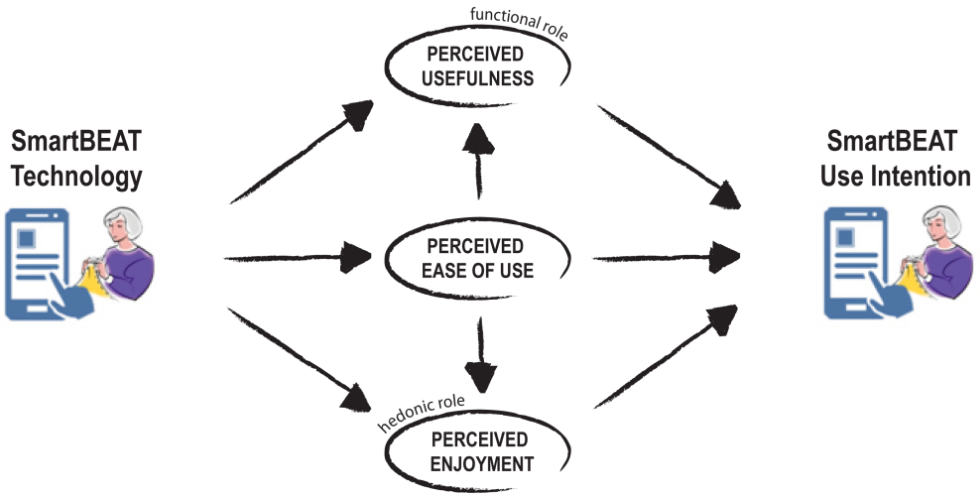

Figure 3 - SmartBEAT Use Intention.

For a successful product development process the needs and requirements of all stakeholder groups have to be investigated. Patients' and care professionals' goals should be aligned as closely as possible with business goals. This way, a good design can yield incredible improvements in user acceptance and buyer behaviour. UCD works best when it is an iterative process. With each iteration, a UCD-designer can identify new opportunities, respond to changes in user needs and business goals, and adapt to current market trends and advances in technology. Consequently, needs and requirements are defined and refined, and ideas for solutions are generated, prototyped and evaluated.

3.1. Need for user involvement in care innovation

As described in Chapter 2, Chronic Heart Failure care is complex. Many different caregivers, service providers and service systems are involved in a complex and multi-faceted CHF management. Whereas the cardiologists and CHF nurses in the hospital are responsible for diagnostics and treatment planning, also GP's and visiting nurses take a role in follow-up and early detection of decompensation in outpatient settings. Informal caregivers, in turn, play a part in coaching and observing the patient at home, and offering support in technology use. In sum, a wide variety of stakeholders with a list of requirements to take into consideration.

Until recently, patients and informal caregivers were considered to be passive recipients of care and the professional as the person who always knows what is best. We now live in a much more "consumer" oriented society and public opinion towards care professionals has changed. Patients and caregivers are increasingly referred to as "experts by experience". Also professional caregivers have a lot of experience in taking care of patients. Although technology providers are the experts in the development of innovative care solutions in a technical way, it is crucial to involve patients and caregivers as well. It is recognised that by involving those stakeholders in important decisions about the way services are delivered, those services are more likely to meet the needs of people who make use of them. Therefore, it is of high importance to have a good insight in the way care recipients live on the one hand and the way of working of caregivers on the other hand. Focus is on services enabled by technology instead of 'just' innovative technology itself.

3.2. Different user groups

In the SmartBEAT project, we see "the user" as all persons that take part in implementing, offering, using, maintaining and financing the final SmartBEAT solution. All the different user groups have different stakes in the technology. A multi-perspective view offers a high added value. Especially when aiming at organisational change, it is crucial to involve all stakeholders and to take into account their requirements for the final solution. So, when creating smart environments and implementing technology for increased quality of life and care, it is crucial to have continuous and direct interaction with all the relevant stakeholders from the early beginning to the bitter end.

AAL systems – and the incorporating functionalities and services – may address many different user groups, often referred to as AAL stakeholders. The first step is to understand who these users are [40]:

- **Primary stakeholders** - Private users of ICT for ageing solutions
- **Secondary stakeholders** – Professional users of ICT for ageing solutions
- **Tertiary stakeholders** – Suppliers of ICT for ageing solutions
- **Quaternary stakeholders** – Organisations and authorities

3.2.1. Primary stakeholders

The primary stakeholder category comprises private users of ICT for ageing products and services. Also family members and relatives who take care of people in need of assistive technologies are included in this category. Senior citizens do not constitute a homogenous group. Senior persons differ in many ways, and people's needs, expectations and limitations evolve over time [40].

Within the SmartBEAT project, the focus is on senior Chronic Heart Failure patients and their informal caregivers. The latter will directly and indirectly work with the monitoring system, will coach the CHF patient, and will support him in technology use. For the CHF patients, we will focus on NYHA classes II and III of the functional Heart Failure classification, representing the large majority of independent, ambulatory patients:

- **NYHA class II** – Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, or dyspnea (shortness of breath).
- **NYHA class III** – Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea (shortness of breath).

These classes will benefit most from remote health monitoring and coaching. As NYHA class I patients are generally very stable, they would not benefit significantly from the SmartBEAT solution. NYHA class IV patients, on the other hand, are normally severely decompensated and usually hospitalised.

Table 5 - Primary stakeholders in SmartBEAT.

Primary stakeholders	

Chronic Heart Failure patient	Characteristics:
	• Diagnosed CHF patients at home (on medication)
	  ○ NYHA class II
	  ○ NYHA class III
	• Senior patients: 65 years of age and beyond
	
	Tasks:
	• Autonomous condition monitoring
	• Medication therapy
	• Lifestyle control
	• Using SmartBEAT coaching app

Informal caregivers	Characteristics: • Private caregivers • Usually family member or relative of CHF patient Tasks: • Coaching in medication therapy and lifestyle control • Support CHF patients in technology use

3.2.2. Secondary stakeholders

The secondary group exists of stakeholders who use ICT for ageing solutions from a professional point of view. These persons or organisations work closely with private users – or in other words: the private user is the subject of their work. The spectrum of professional users covers both representatives of the health and care sector, and organisations aiming at services addressing active and inclusive ageing [38]. Besides improving care quality, secondary stakeholders aim at profits or productivity gains. Typically, the business model from the professional users is B2C (business to consumer), i.e., a technical device is used in medical services and the combination is marketed as an ICT for ageing solution. Without exception, ICT for ageing solutions will only be introduced if they function accurately in terms of the measurement, transfer and processing of patient's data.

Within the SmartBEAT project, the secondary stakeholder category is populated by health care professionals, involved in CHF care. In specialised settings, we distinguish cardiologists and CHF nurses, and in outpatient settings the most important stakeholders are the general practitioner and the visiting nurses. Depending on the country and the care system, responsibilities and task allocation in CHF management may differ.

Table 6 - Secondary stakeholders in SmartBEAT.

Secondary stakeholders	
Cardiologist	Characteristics: • Specialised care setting • Centralised Tasks: • Make diagnosis • Develop treatment plan
CHF nurse	Characteristics: • Specialised care setting • Centralised Tasks: • CHF patient follow-up • CHF routine consults • Check telemonitoring results • Coaching and education
General practitioner	Characteristics: • Local-based Tasks: • Follow-up and early detection of decompensation • General medical treatment

Homecare nurse	Characteristics: • Local-based Tasks: • Follow-up and early detection of decompensation • On-site care delivery

3.2.3. Tertiary stakeholders

The tertiary stakeholder category includes suppliers of ICT and ageing solutions – again in a very broad sense [40]. They aim at new markets for them or at market shares in an existing market in which the representatives of the secondary stakeholders are already present and active. The tertiary stakeholder organisations will invest if they are convinced that they will eventually make a profit. For the time being, however, the market for ICT for ageing solutions does not send clear signals.

Within the SmartBEAT project, tertiary stakeholders will be elaborated on in WP5 on Dissemination & Exploitation, in particular in T5.2 Market Research and T5.3 Exploitation & Business Planning. In the framework of the user group identification, we have developed a preliminary list of possible tertiary stakeholders:

- SmartBEAT technology provider
- Sensor supplier
- System integrator
- Software company (EHR)
- Telecom company / Smartphone supplier
- App developer
- Vendors / Distributors

3.2.4. Quaternary stakeholders

This last category is made up of representatives of organisations and authorities who may have an impact on the dissemination and uptake of ICT for ageing solutions [40]. This similarly wide definition incorporates persons who define the socio-economic and legal context for exploiting ICT and ageing: policy-makers, insurance companies, employers, public administrations, standardisation organisations, civil society organisations, the media, etc. It is evident that a positive attitude towards the expected contribution of ICT for ageing solutions is vital for a positive market development.

Within the SmartBEAT project, quaternary stakeholders will be elaborated on in WP5 on Dissemination & Exploitation, in particular in T5.2 Market Research and T5.3 Exploitation & Business Planning. In the framework of the user group identification, we have developed a preliminary list of possible quaternary stakeholders:

- Policy makers and national, regional and local authorities
- Insurance companies
- Media

4. Definition of SmartBEAT UCD strategy

The purpose of this chapter is to provide an accurate description of the UCD strategy for the SmartBEAT project. The investigation of the users' needs are the basis for further development in technical specifications. First the overall UCD strategy is presented. Second, we will elaborate on the proposed UCD activities for each relevant user group.

The objectives of the UCD process can be summarised by the following topics:

- Identification of needs of the key user groups.
- Assessment of potential services that should be provided to help CHF patients to live longer independently and safely at home, and to support care professionals to increase quality and efficiency of care.
- Definition of the requirements for a technical solution to deliver the identified services.

4.1. Overall strategy

In this section the overall UCD strategy for the SmartBEAT project is presented. After defining the key requirements, approach, methodology and planning is described.

4.1.1. Key requirements

Before starting the actual UCD-process, it is of high importance to have clearly in mind what we exactly want to learn from it. As defined in the project proposal, SmartBEAT aims at supporting senior CHF patients and their caregivers, both formal and informal. The integrated solution needs to increase patient self-care through autonomous condition monitoring and real-time feedback to the caregivers. Using SmartBEAT, it is possible to enhance patients' quality of life and to increase quality and efficiency of care delivery.

In order to realize general user acceptance and therapy adherence (long term SmartBEAT use intention), it is crucial to seamlessly fit the needs of all stakeholders. For both CHF patients and caregivers, perceived usefulness and perceived ease of use are the key requirements. For CHF patients this means, first of all, that the technology should result in higher therapy adherence and better health outcomes. Besides, perceived usefulness is also impacted by empowering self-management, which can be realised by user-friendly and age-friendly technology. For caregivers, on the other hand perceived usefulness and perceived ease of use are mostly the results of systems with high usability levels, and the alignment with current care processes and existing infrastructure.

In sum, the technology should:

- Monitor the health status of CHF patients and measure the essential (clinical) parameters, in order to analyse and report according to the requirements for appropriate CHF care.
- Empower CHF patients in relation to self-management.
- Promote therapy adherence for CHF patients.
- Strengthen the interaction among the different caregivers.

- Be aligned with current care processes and existing infrastructure.
- Guarantee easy access for CHF patients.
- Fulfil all the above mentioned functionalities in a cost efficient way.

4.1.2. Approach

As described in Chapter 2, the management of Chronic Heart Failure is a complex issue, with a wide variety of stakeholders, activities and interdependencies. In addition, the field of technology related to CHF management is still in its infancy, so new to the majority of patients and caregivers. This in mind, the UCD strategy combines for all stakeholders information collection activities on the one hand with the presentation and discussion of different CHF technology concepts on the other hand. For the latter, several concept visualisations will be developed based on services and features from existing technologies and new ideas. In this way, feedback will be gathered about a wide variety of technological solutions, interaction styles, communication styles, data monitoring methods, data sharing rules, etc.

To prepare participants for the main UCD activities and to get the best information possible out of it, sensitizing them in advance is of great importance. Sensitizing is a process where participants are triggered, encouraged and motivated to think, reflect, wonder and explore aspects of their personal context and role in CHF management. For each stakeholder group, such a sensitizing exercise will take place, before they will participate in an interview or in a workshop session, so for them to be able to make well-informed decisions about their needs.

4.1.3. Methodology

For user-centred design (UCD), it is important to gain a good insight in people's needs. Different research techniques can reveal different levels of information (Figure 4). For example through interviews, focus groups and questionnaires, it is possible to find out what people say and think. To obtain information what people do and use, designers prefer observational research [41].

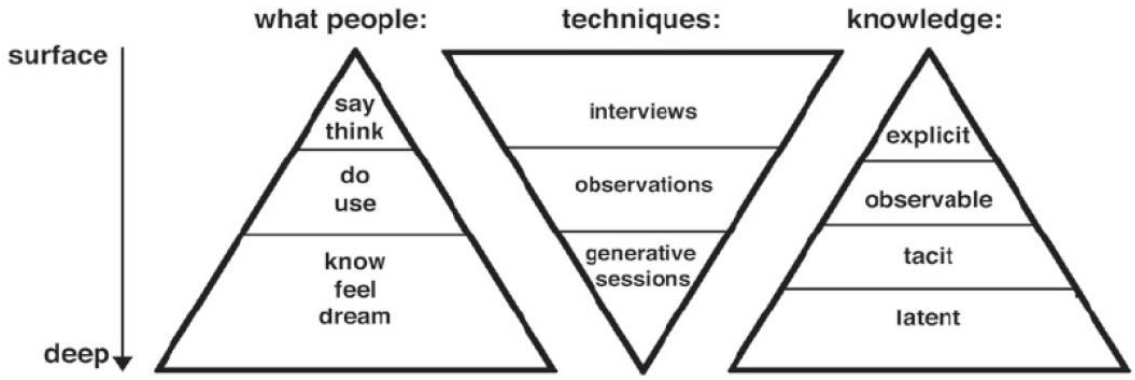

Figure 4 - Different levels of knowledge are accessed by different techniques [43].

With generative techniques tacit and even latent knowledge about what people know, feel and dream can be discovered [42]. Tacit knowledge is knowledge that people can act upon, but cannot readily express in words. Latent knowledge is knowledge that people are not aware of yet; it is not recognizable until the future [44]. By asking people to create artefacts, such as collages and models, they are able to access and express their memories of the past and express their dreams and wishes for the future.

The SmartBEAT UCD strategy is based on the combination of two design approaches: on the one hand the contextmapping method, and on the other hand the Vision in Product (ViP) design approach.

Contextmapping [43] is applied to reveal deeper level data from the CHF patients and their informal caregivers. It is a generative method of conducting contextual research with users, where tacit and latent knowledge is gained about the use context of products. It aims at informing and inspiring design teams, where users and stakeholders actively participate in the design process to ensure a good fit between the design and the use of a product. A contextmapping study typically involves a sequence of research steps including preparation, sensitizing participants, group sessions, analysis and communication (Figure 5). For data collection from cardiologists and CHF nurses more conventional methods like questionnaires, in-depth interviews and workshops will be organised.

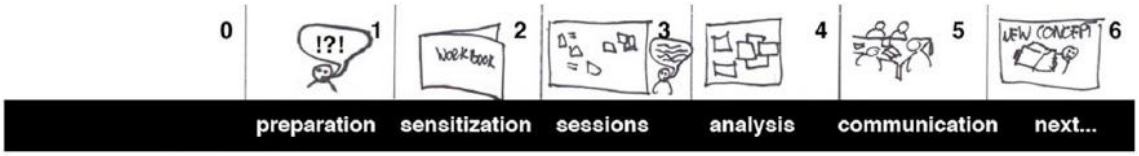

Figure 5 - Procedure of a contextmapping study [43].

The ViP approach [44] – presented in Figure 6 – adds an abstract and unconstrained way of looking at CHF management, which can lead to a richness of creative design concepts. This approach focuses on the user-product interaction, more precisely on the way a product is experienced by the user. In this way ViP frees the designer from reality and feasibility, and stimulates him to look for desirable possibilities. The ViP model consists of two phases. The deconstruction phase starts with the analysis of a product's features, followed by a user-product interaction examination, and is ended with a current context description. In the designing phase a future context, interaction and product is formulated [44].

Instead of taking one specific existing product to start from, a small collection of concept visualisations with a wide variety of features and solutions is perceived more valuable as starting point for the deconstruction phase, since it starts from a broader perspective.

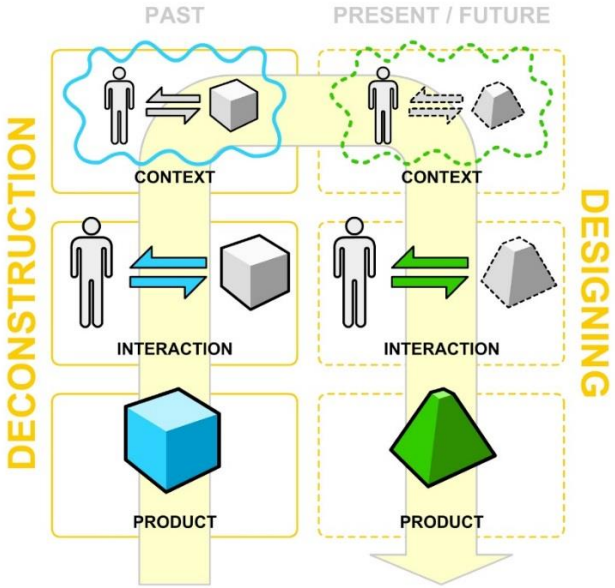

Figure 6 - Graphical representation of the Vision in Product (ViP) framework [44].

A combination of a contextmapping study and ViP approach can enrich the process, because they complement each other. While the contextmapping method gathers specific tacit and latent data about the needs, feelings and experiences of the users, ViP presents a more abstract approach. Data from the literature review are used as input for the deconstruction phase, as well as the feedback on the different concept cards. Because during the remaining UCD activities past, present and future are discussed, the findings are used in both phases: deconstruction and design.

Figure 7 - Graphical representation of the Vision in Product (ViP) framework, and how the results of our research are used as input (adapted from [44]).

4.2. UCD activities for each user group

In Chapter 3 we have described all the different stakeholders. However, the specific UCD activities described in the following sections will focus only on the key users, being CHF patients, informal caregivers, cardiologists and CHF nurses. In the UCD activities we aim for the inclusion of cardiologists and CHF nurses with a positive and open attitude towards eHealth and telemonitoring, in order to avoid thoughtless scepticism and collect well-founded answers based on practical experience. Stakeholders with a less prominent part in the SmartBEAT project, like general practitioners, visiting nurses, technology providers, and health insurance companies will be involved either in the evaluation (WP4) or the exploitation (WP5) work package.

We believe that interaction among patients on the one hand and care professionals on the other hand will lead to richer outcomes. However, we understand that there are several reasons that makes it hard to bring a group of patients or cardiologists together, due to their condition or due to busy agendas. Although we prefer and propose group sessions with CHF patients, it is also acceptable if the activities are performed on an individual basis. For the care professionals, we have set-up a strategy that could yield best of both worlds; individual in-depth interviews with cardiologist vs. workshop sessions in group with CHF nurses.

4.2.1. Patients and seniors

Self-management of CHF is physically, mentally, emotionally and socially demanding. However, living with CHF is experienced differently by each individual. First of all, CHF comes in many different appearances and levels. Second, no patient is the same. Third, CHF might evolve over time. Besides, CHF is a chronic disease often diagnosed in the 65+ population, characterised by a wide variety of age-related changes and a lack of ICT skills. In addition, a number of CHF patients is confronted with co-morbidities. So, when designing technology for CHF, we have to be aware that "the CHF patient" does not exist, and that we have to take into account interpersonal differences.

At this early stage of the design process, broad input from the patients is preferred. In this sense, the contextmapping study is the ideal method. To limit the burden on CHF patients, we will split the UCD activities in two. Whereas CHF patients will provide specific insights in living and dealing with CHF, healthy seniors will provide input related to usability for the elderly population and age-related changes. Taking into account these issues properly will have a large effect on the perceived ease of use.

To realize user acceptance and therapy adherence, it is of utmost importance to understand how the following factors have an impact on the perception of usefulness and ease of use:

- Lifestyle
- Health literacy
- ICT skills
- Age-related changes
- Healthcare network
- Social support system

4.2.1.1. Patients

Because chronic diseases change over time and dealing with it often happens in a quite unconscious way, chronic disease management can be seen as a rather abstract subject. In general, patients tend to adapt to slowly changing situations automatically without thinking or talking about it consciously. This makes Chronic Heart Failure management from a patient's point of view a rather difficult subject to explore. Because of the fact that CHF patients are not aware of their needs, feelings and experiences about this topic, a contextmapping study is conducted. This generative method is used to reveal deeper level data from the CHF patients and their informal caregivers.

The objective of the UCD activities with CHF patients is to gain insight in the needs and wishes regarding a telemonitoring system. From the CHF patients we aim at input particularly about how they manage their chronic condition, how well they are informed, how they would see the role of different caregivers, and what privacy-related concerns they have.

Inclusion criteria:

- Senior CHF patient (65+)
- NYHA class II or III
- Having an informal caregiver who is willing to participate as well

Phase 1 - Sensitizing (n=10 in Portugal and Belgium):

CHF patients will be asked to keep a diary for two weeks in which they report daily living and disease specific activities. The decision to follow them for a period of two weeks is to increase the chance on recording CHF-related events. In the sensitizing phase, participants perform a series of small assignments designed to let them think about past experiences, and make them "reflective practitioners" [45]. These diaries reveal a lot of interesting information for the researchers, but they also serve as a method to make the CHF patients themselves more conscious about the way they manage their condition. By letting them express memories, opinions, dreams, etc. around the central topic of the study, CHF management, the participants are well prepared for the generative sessions. After these two weeks, the diaries will be collected and analysed in order to use the outcomes during the generative sessions for validation and as a starting point for more in-depth analysis.

Each day the CHF patient has to report in the diary about his activities and feelings of the day, and whether he did some health measurements. During these two weeks, the CHF patient is also asked to fulfil some small assignments to explore the wider context. These assignments include:

- A short questionnaire about their personal use of ICT
- An assignment about the negative effects / limitations of CHF on their daily life
- An assignment to learn more about their health literacy
- An assignment about how they see the role/tasks/responsibilities of GP and informal caregiver
- An assignment to understand their privacy concerns

Phase 2 - Generative session (2 sessions n=5 in Portugal and Belgium):

After the individual sensitizing period, generative sessions are organised. In these sessions, the individual diaries, already analysed, are discussed. Clarification questions are asked to get a better view and understanding of the reasons for the needs, feelings, past experiences and future wishes mentioned in the diaries. By recapitulating and deepening the participants' input, they are well sensitized to start the creative exercises. The sensitizing process enhances the quality and quantity of participants' contributions in the following session assignments [46].

- Participants are asked to make designerly artefacts and tell a story about what they have made. The process of making artefacts such as drawing, collages and models, enables people to access and express their experiences. Especially in their stories, there is rich and useful information. (collage, model, time schedule, system, creature)
- Participants are asked to give feedback on the developed concept visualisations. Besides the overall impression of the solutions, specific features and components will be discussed in detail.
    - Continuous monitoring vs. specific measurement time slots
    - Continuous data transfer or only in case of deviations
    - Role of formal and informal caregivers
    - Shape of the monitoring kit (smart T-shirt, holter, stickers, etc.)

4.2.1.2. Healthy seniors

CHF is an age-related condition, median age is 75. This means that CHF patients in general are confronted with the age-related challenges. Besides a lack of ICT skills, they have to deal with physical limitations, sensory thinning and cognitive decline. To lower the burden of the UCD activities on CHF patients, we prefer to work with healthy seniors.

The objective of the UCD activities with healthy seniors is to gain a deeper understanding of age-related limitations that older people face and the way they deal with it in daily life. In this group we also investigate the use of technology, their privacy concerns, and their health literacy to check for differences with the group of CHF patients.

Inclusion criteria:

- Seniors (65+)
- Healthy and independent, free of severe (chronic) diseases

Phase 1 - Sensitizing (n=10 in Norway and the Netherlands):

Similar to CHF patients coping with their chronic conditions, also (relatively) healthy seniors have to deal with age-related changes in their daily life. Since decline in physical, sensorial and cognitive capabilities is a slowly process, elderly tend to adapt automatically and unconsciously. Only when drastic changes take place, or one is confronted with new activities or technologies, age-related changes stand out more explicitly.

With the help of a two week diary study, in which the healthy seniors have to report moments in which they are confronted with their limitations due to a higher age, they will become more conscious about their changing abilities. These diaries reveal also a lot of valuable information for the researchers. After these two weeks, the diaries will be collected and analysed in order to use the outcomes during the generative sessions for validation and as a starting point for more in-depth analysis.

Each day the CHF patient has to report in the diary the moments in which they are confronted with physical limitations, sensory thinning and cognitive decline. During these two weeks, the healthy seniors are also asked to fulfil some small assignments to explore the wider context. These assignments include:

- A short questionnaire about their personal use of ICT
- An assignment about the impact of ageing on their daily social life
- An assignment to understand their privacy concerns
- A short questionnaire to learn more about their health literacy

Phase 2 - Generative session (n=10 in Norway and the Netherlands):

After the individual sensitizing period, generative sessions are organised. In these sessions, the individual diaries, already analysed, are discussed. Clarification questions are asked to get a better view and understanding of the reasons for the needs, feelings, past experiences and future wishes mentioned in the diaries. By recapitulating and deepening the participants' input, they are well sensitized to start the creative exercises. The sensitizing process enhances the quality and quantity of participants' contributions in the following session assignments [46].

- Participants are asked to make designerly artefacts and tell a story about what they have made. The process of making artefacts such as drawing, collages and models, enables people to access and express their experiences. Especially in their stories, there is rich and useful information. (collage, model, time schedule, system, creature)
- Participants are asked to give feedback on the developed concept visualisations. Besides the overall impression of the solutions, specific features and components will be discussed in detail.
    - Continuous monitoring vs. specific measurement time slots
    - Continuous data transfer or only in case of deviations
    - Role of formal and informal caregivers
    - Shape of the monitoring kit (smart T-shirt, holter, stickers, etc.)
    - …

4.2.2. Informal caregivers

Within the SmartBEAT project, informal caregivers will directly and indirectly work with the monitoring system, will coach the CHF patient, and will support him in the use of the technology. We expect that there is a large variation among informal caregivers and the role they play in the management of CHF.

The objective of the UCD activities with informal caregivers is to have a good insight in the role of informal caregivers, with regards to the use of ICT in general and to chronic disease management in particular.

Inclusion criteria:

- Private caregiver (usually family member or relative) of senior CHF patient
- Living near to the senior CHF patient
- Computer access

Phase 1 - Sensitizing (n=10 in Portugal and Belgium):

Informal caregivers are asked to support the CHF patient in completing the diary. In this way they are closely involved in the sensitizing process, and they think about the different aspects of CHF management themselves as well. In this way, the informal caregivers are also more conscious about how the patient and the informal caregiver experience life with CHF.

Phase 2 - Online questionnaire (n=10 in Portugal and Belgium):

After two weeks of sensitizing together with the CHF patient, the informal caregiver is asked to fill out an online questionnaire. This questionnaire includes the following topics:

- The impact of ageing on the life of the CHF patient
- Their role in the care management of CHF
- The challenges they face concerning caring for and communicating with the CHF patient

4.2.3. Cardiologists

The cardiologist is the expert on CHF care. He is mainly involved in examining the patient and when deemed necessary doing additional tests in order to determine the cause of symptoms, make a diagnosis and develop a treatment plan.

The objective of the UCD activities with cardiologists is gaining insight in what kind of data concerning CHF monitoring is important, the way they want the data to be presented and how they make decisions regarding the data derived from tests and monitoring. In addition we would like to learn from them what the best target population to benefit from a CHF telemonitoring system is, and how they see collaboration and task division with GP's.

Inclusion criteria:

- Cardiologist
- Familiarity with telemonitoring (preferred)

Phase 1 - Online questionnaire (n=2 in all 4 countries):

For both cardiologists and CHF nurses an identical online questionnaire will be developed. The questionnaire will include the following topics:

- The most suitable group for a CHF telemonitoring system
- The required parameters and measurement frequency
- Data interpretation and decision making

Phase 2 - In-depth interview (n=2 in Belgium and Portugal):

We understand that cardiologists have a very busy schedule in taking care of patients. Therefore, organizing workshops with groups of cardiologists is unrealistic. Consequently, we will organize individual in-depth interviews, approximately two weeks after filling out the online questionnaire. By recapitulating the answers, we try to deepen their input. In these interviews, we will also investigate in more detail the following:

- Attitude towards eHealth in general, and telemonitoring technology in particular
- Preferred method of data visualisation
- Opportunities and threats of telemonitoring
- Role of the GP

4.2.4. CHF nurses

In the hospital, cardiologists work closely together with specialised CHF nurses, who take over most routine consults. CHF nurses are responsible for educating and coaching of patients and supporting them in self-management. They are allowed to do health examinations and make medical decisions within given limits (i.e. based on the treatment plan developed by the cardiologist).

The objective of the UCD activities with CHF nurses is gaining insight in what kind of data concerning CHF monitoring is important, the way they want the data to be presented and how they make decisions regarding the data derived from tests and monitoring. In addition we would like to learn from them what is the best target population to benefit from a CHF telemonitoring system, and how they see collaboration and task division with GP's.

Inclusion criteria:

- CHF nurse
- Familiarity with telemonitoring (preferred)

Phase 1 - Online questionnaire (n=6 in all 4 countries):

For both cardiologists and CHF nurses an identical online questionnaire will be developed. The questionnaire will include the following topics:

- The most suitable group for a CHF telemonitoring system
- The required parameters and measurement frequency
- Decision making

Phase 2 - Focus group session (n=6 in Belgium and Portugal):

For in-depth investigation with CHF nurses we propose to organize two workshop sessions with three CHF nurses, because we believe that interaction and discussion among CHF nurses can result in more valuable output. In the first part of this sessions, we will clarify and discuss about the outcomes from the online questionnaire. The topics that will be discussed are the same as for the cardiologists:

- Attitude towards eHealth in general, and telemonitoring technology in particular
- Preferred method of data visualisation
- Opportunities and threats of telemonitoring
- Role of the GP

In the second part of the session, CHF nurses are asked to give feedback and to discuss on the developed concept visualisations. Besides the overall impression of the solutions, specific features and components will be discussed in detail, from a care professional viewpoint.

- Continuous monitoring vs. specific measurement time slots
- Continuous data transfer or only in case of deviations
- Role of formal and informal caregivers
- Shape of the monitoring kit (smart T-shirt, holter, stickers, etc.)
- …

4.3. Research documents developed

For the SmartBEAT UCD activities, different research documents are developed. Besides diaries, questionnaires and interview questions, also informed consent forms and data collection sheets are produced.

All research documents – listed below – are developed in English. Local partners responsible for the execution of the UCD activities in respectively Portugal, Norway, Belgium and the Netherlands take care of the translation to local languages.

CHF PATIENT:

- PAT_Informed consent form
- PAT_Diary
- PAT_Data collection sheet_Quantitative
- PAT_Data collection sheet_Qualitative
- PAT_Creative session outline

HEALTHY SENIOR:

- SEN_Informed consent form
- SEN_Diary
- SEN_Data collection sheet_Quantitative
- SEN_Data collection sheet_Qualitative
- SEN_Creative session outline

INFORMAL CAREGIVER:

- IC_Informed consent form
- IC_Questionnaire
- IC_Data collection sheet

CARDIOLOGIST:

- CAR_Questionnaire
- CAR_Data collection sheet
- CAR_Informed consent form
- CAR_Interview outline

CHF NURSE:

- CAR_Questionnaire (same questionnaire for cardiologists and CHF nurses)
- CAR_Data collection sheet
- NUR_Informed consent form
- NUR_Interactive workshop outline

Overarching, 5 concept visualisations are developed in order to be used in the UCD phase 2 activities for the different user groups.

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