FP7-ICT-611140 CARRE

Project co-funded by the European Commission
under the Information and Communication Technologies
(ICT) 7th Framework Programme

D.7.1. Evaluation methodology & plan

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December 2014

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Disclaimer

CARRE is a Specific Targeted Research Project partially funded by the European Union, under FP7-ICT-2013-10, Theme 5.1. “Personalized health, active ageing & independent living”.

Document Control Page

Project

Contract No.:	611140
Acronym:	CARRE
Title:	Personalized Patient Empowerment and Shared Decision Support for Cardiorenal Disease and Comorbidities
Type:	STREP
Start:	1 November 2013
End:	31 October 2016
Programme:	FP7-ICT-2013.5.1
Website:	http://www.carre-project.eu/

Deliverable

Deliverable No.:	D.7.1
Deliverable Title:	Evaluation methodology & plan
Responsible Partner:	DUTH - Eleni Kaldoudi
Authors:	E. Kaldoudi, N. Makris
Input from:	All partners
Peer Reviewers:	Darius Jegelevicius (KTU), Romualdas Kizlaitis (VULSK)
Task:	T.7.1. Evaluation methodology & plan
Task duration:	6 months: 1 July 2014 to 31 December 2014
Work Package:	WP7: Integration & Evaluation
Work Package Leader:	VULSK – Romualdas Kizlaitis
Due Date:	31 December 2014
Actual Delivery Date:	4 January 2015
Dissemination Level:	PU
Nature:	R
Files and format:	Deliverable report: 1 pdf file
Version:	02
Status:	☐ Draft ☒ Consortium reviewed ☒ WP leader accepted ☒ Coordinator accepted ☐ EC accepted

Document RevisionHistory

Version	Date	Modifications	Contributors
v01.0	11 July 2014	New content - layout	Eleni Kaldoudi
v01.1	30 Oct 2014	Outline to reviewers	Eleni Kaldoudi
v01.2	15 Nov 2014	Content Conformance to reviewer comments	Eleni Kaldoudi, Nikos Makris
v01.3	28 Dec 2014	Format and references	Eleni Kaldoudi
v02.0	3 Jan 2015	Including reviewers comments, final editing and formating	Eleni Kaldoudi

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Executive Summary

This deliverable presents the evaluation methodology and plan of the project. The approach is informed by the socio-technical perspective, which considers information systems as having social and technical elements, and technology's characteristics and capabilities as being revealed through use. Our approach can be classified, in Friedman and Wyatt's terms, as rooted in subjectivist assumptions, which accounts for people's views and the context of intervention (i.e. the evaluation of the system cannot be removed from its context). Following Symon's evaluation 'onion' we first present our understanding of the content to be evaluated, that is the patient empowerment concept viewed as a hierarchical cognitive process. Then we discuss the process of evaluation, presenting an adaptation of the Cornford evaluation framework. Finally, we lay out the evaluation plan, discussing ethical issues of handling personal data including privacy and informed consent.

About CARRE

CARRE is an EU FP7-ICT funded project with the goal to provide innovative means for the management of comorbidities (multiple co-occurring medical conditions), especially in the case of chronic cardiac and renal disease patients or persons with increased risk of such conditions.

Sources of medical and other knowledge will be semantically linked with sensor outputs to provide clinical information personalised to the individual patient, to be able to track the progression and interactions of comorbid conditions. Visual analytics will be employed so that patients and clinicians will be able to visualise, understand and interact with this linked knowledge and take advantage of personalised empowerment services supported by a dedicated decision support system.

The ultimate goal is to provide the means for patients with comorbidities to take an active role in care processes, including self-care and shared decision-making, and to support medical professionals in understanding and treating comorbidities via an integrative approach.

Terms and Definitions

The following are definitions of terms, abbreviations and acronyms used in this document.

Term	Definition
EC	European Commission
eHealth	Electronic health
EU	European Union
EUPATI	Research network funded by European Commission http://www.patientsacademy.eu/index.php/en/
ICT	Information and communication technologies
MedLinePlus	The National Institutes of Health's Web site for patients and their families and friends, http://medlineplus.gov.
PubMed	Free search engine accessing primarily the MEDLINE database www.ncbi.nlm.nih.gov/pubmed/
RCT	Randomized control trials
Wikipedia	The free encyclopaedia that anyone can edit http://en.wikipedia.org/

1. Introduction

This document is the outcome of the project Task “T.7.1. Evaluation methodology & plan”. The aim of this deliverable is to outline the overall approach, methodology and plan of the testing and evaluation activities to be carried out in the remaining Tasks of WP7, which deals with system integration, pilot deployment and evaluation.

CARRE aims to innovate towards a service environment for providing personalized empowerment and shared decision support services for cardiorenal disease comorbidities. The core of CARRE effort lies in semantic interlinking of three types of data (a) medical ground knowledge (b) up-to-date medical evidence and (c) personal patient data in order to create a personalized model of the disease and comorbidities progression pathways and trajectories. Visual presentations of this personalized model (against ground knowledge and against statistical views of ‘similar’ patient groups) will form the basis for patient empowerment services that will target understanding of comorbidities in the personal setting. Finally, the personalized model of comorbidities will be used for shared decision support services targeting personalized education, complex risk calculation for disease progression and comorbidity trajectories, alerts for adverse events of multiple co-existing treatments and personalized planning for monitoring.

The project work plan involves research and development of individual system components, including a number of diverse data aggregators, semantic metadata repositories and then added value services. All these components will be tested and integrated into the CARRE system. The integrated system will then be deployed during the third year of the project in two different pilot sites and evaluated.

Section 2 of this deliverable presents the overall evaluation approach of the project. This includes a brief review of evaluation approaches in eHealth systems which is used to inform our proposed evaluation approach. there is a link between what is to be evaluated (content), how it is evaluated (process) and who does it and why (context). Thus, Section 3 presents our notion of the content of evaluation, that is the patient empowerment process. In this section we describe a novel hierarchical model of the patient empowerment concept as a cognitive process. Section 4 details the evaluation process and methodology which is based on an adaptation of the Cornford evaluation framework. Section 5 gives the evaluation plan, including the context of the evaluation process. Finally, Section 5 summarizes important ethical issues of handling personal data during evaluation, including a discussion on ethical approval of the pilots, informed consent forms and data privacy.

2. Overall evaluation approach

2.1. Overview of evaluation approaches

Drawing on information systems evaluation literature we come across an interesting classification of the evaluation approaches in three zones [1]: the ‘efficiency’, the ‘effectiveness’ and the ‘understanding’ zone. The first two zones include the most widespread evaluation techniques that aim to assess whether an information system is either efficient or effective. The approaches included in the understanding zone however aim to understand the nature of the evaluation, its functions, problems and limitations. A well-known example that produces such an understanding is the content, context and process framework developed by Pettigrew [2] and adapted to information systems evaluation by Symons [3] (Figure 1). According to this framework, there is a link between what is to be evaluated (content), how it is evaluated (process) and who does it and why (context). The content is seen as determinant of the evaluation criteria and is presented in the centre ring of the evaluation ‘onion’. Based on this, one can deduce that there is not ‘one best method’ suitable for the evaluation of all information systems [1]. Following this line of thought, questions like: ‘*what is the system being evaluated*’, ‘*why carry out the evaluation*’, ‘*when are the evaluations to be undertaken*’, and ‘*where is the evaluation to be performed*’ are subjective decisions that influence not only the way the evaluation is conducted but also its outcome.

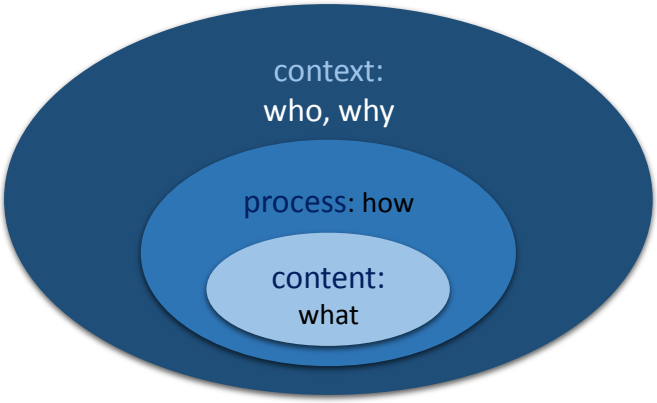

Figure 1. Symons' evaluation onion (Symons 1991 & Pettigrew 1985)

The link between the type of the system and the evaluation approach used is seen also in the work of Farbey, Land and Target [4]. They argue that different information system applications require different approaches to be used for evaluating their impact. They present the 'benefits evaluation ladder', taxonomy of information system's application with eight rungs. The first rung represents mandatory changes and moving up the ladder we come across automation, direct value added systems, management information and decision support systems, infrastructure, inter-organizational systems, strategic systems and finally at the top business transformation. Each rung has a different degree of risk, uncertainty, and returns on investment estimation, and therefore evaluation complexity. Evaluating simply the cost of alternative solutions and the technical characteristics is enough for a system an organisation is forced to introduce but not for a strategic system that will alter the way of managing and organising business.

Supporters of this link are also Smithson and Tsiavos [5]. In their work they demonstrate the complexity of evaluation by using the 'W-word' framework. Questions of what is the system being evaluated, why carry out the evaluation, when are the evaluations to be undertaken, and where is the evaluation to be performed are considered as subjective decisions that influence not only the way the evaluation is conducted but also the outcome of it. Whether the 'object' of the evaluation is seen as software and hardware, as network, as data or as a system that includes both technology and people operating in a given context gives an insight in the evaluation method followed. The boundary that is drawn on the artefact of evaluation depends not only on the evaluators' intentions but also on intentions of different groups of stakeholders. Actor network theory [6] is used in this approach to argue that evaluation is an action of representation (substitution) of the complex reality of an information system to a more manageable form (series of numbers and tables) that can be easily handled by decision makers.

The selection of the 'what is to be evaluated' is dominated by the meaning that is attached to the information system and it varies among different groups of stakeholders. In the case of assistive environments and eHealth this notion can explain the reasons underlying the debate between the various evaluation approaches used. We can group eHealth evaluation approaches in three different categories on the basis of the meaning that evaluators and stakeholders attach to such applications: (1) drug or therapeutic agent; (2) technical managerial innovation (techno-economic logic); and (3) information system embedded in a clinical and social context.

Cornford and Klecun [7] presents a similar classification of evaluation approaches based on ethical perspectives. They argue that eHealth (a more encompassing term) draws on three different disciplines: medicine, information systems and information society. The ethics of each discipline vary and impose different evaluation frameworks to be followed. Medicine with its strong moral rule about patient's right and doctor's duty is translated into evaluation schemas based on a gold standard of proof testified by randomized control trials. The information systems discipline although presenting less explicit ethical concerns produces evaluation frameworks that examine technical, organizational, professional and societal aspects of eHealth and assistive environments as well as user satisfaction. Finally, ethics of information society impose evaluation approaches that emphasize on utilitarian principles like social inclusion, deskilling, loss of jobs etc.

2.1.1. Different perceptions of eHealth

Reviewing the literature on eHealth evaluation approaches we came across three different perceptions. Each one leads to the adoption of a different view on the meaning and the aim of the evaluation activity and therefore of a different evaluation technique.

2.1.1.1. eHealth as a 'drug'

The most dominant perception of eHealth is that of a 'drug' that can be prescribed to patients. Patients are thought to obey to this prescription and use technology in their homes according to the instructions given and in the end an immediate effect in their health condition is expected to be observed. Randomized control trials (RCT) are therefore presented as the most legitimate and credible evaluation technique. Indeed, most of the reviews exclude from their sample studies that do not use RCT [8]. There is big debate on the appropriateness of such a technique to evaluate eHealth applications. Here we present another deficit of the notion that eHealth and new medicines are equivalent interventions in patients' lives. In the case of drugs, patients have two options: to obey to the prescription or ignore it. However, in the case of information and communication technologies (ICT) while patients interact with it they '*enact structures which shape their emerged and situated use of it*' as Orlikowski argues in the structuration theory [9]. Information and communication technology is not a black box that closes after development An interpretation of this view in our context would suggest that each patient will draw on their skills, power, knowledge, assumptions, and expectations about the technology when using it at home and therefore enact a distinctive 'technology-in-practice' [9]. RCT focuses only on certain predefined outcomes ignoring this aspect of patients' interaction with ICT, which could answer the why of RCT's outcomes.

2.1.1.2. eHealth as a technical innovation

A slightly more expanded view of eHealth is that of a technical/managerial innovation that will reduce cost of healthcare delivery, will raise physicians' productivity and patients' (seen as 'customers') satisfaction. Following this view, evaluators draw on economic theory to check cost effectiveness and productivity issues of each innovation. On this category we can place another slightly different view of eHealth that still fits to the notion of eHealth as an innovation. Most eHealth applications today are funded by governmental bodies in order to establish a new modern way of healthcare delivery and bring ICT benefits in the health care sector. This means that eHealth applications are seen as short-term projects that have a predetermined end and should be evaluated till the end of the funding. Evaluation is done quickly and by using methods that allow comparison and often serve publication purposes. Whetton points out that although evaluation is conducted on pilot short-term telemedicine projects there is a widespread expectation that it assesses the long-term value of telemedicine [10].

2.1.1.3. eHealth as an information system embedded in a clinical and social context

Literature reveals that recently several researchers abandon partial views on eHealth and perceive eHealth as an information system that is embedded in a clinical/social context. All three components of eHealth – technology, people and context– are included in the evaluation and the interplay between them is examined in depth. Pragmatic approaches that consider the organizational context have been proposed and qualitative evaluation using semi-structured interviews have been carried out [11], [12], [13]. However, most of this work does not usually employ any theoretical framework to guide research and draw conclusions [14]. They do not present detailed descriptions of their method of gathering data and therefore their researches are strongly criticised as not credible.

Indeed, interpretive research requires adopting a theoretical model in order to present which aspects the evaluator wishes to study. This framework serves not only to structure the report of stakeholders' experiences but also to interpret them in a way that general patterns of interaction can be derived [9]. Thus, research would lead to a conclusion that may be meaningful beyond the limits of the specific study and bring a scientific contribution to eHealth evaluation area.

To overcome such shortcomings, researchers should familiarize themselves with information systems theories and make use of them while conducting telemedicine research [14]. Such attempts have already led researchers to construct their own evaluation frameworks of telemedicine and eHealth, For example, Taylor suggests that evaluation should consider whether telemedicine is first safe, second practical and last worthwhile [15]. Skiadas and Argoyiannis also present a three stages evaluation framework that includes: assessment that provides the specification of the evaluation criteria of the different stakeholders, then formative evaluation that focuses on the description of system's short term effects on the process and its

influence upon stakeholders, and third summative evaluation that determines the impact of the system on health outcomes [16].

2.2. Overall evaluation approach

CARRE addresses the specific medical domain of cardiorenal disease comorbidities and will provide proof-of-concept via deployment and validation in two different healthcare settings. CARRE research aims to address this need following a "*first understand, then conquer, and then decide*" approach that:

- first fosters understanding of the complex interdependent nature of the comorbid condition in general and as specialized for the specific patient,
- then calculates informed estimations for disease progression and comorbidity trajectories, and
- compiles a variety of personalized alerting, planning and educational services so that patients (and professionals) are empowered, and can, eventually,
- makes shared informed decisions.

The ultimate goal is to provide the means for patients with comorbidities to take an active role in care processes, including self-care and shared decision making, and also to support medical professionals in understanding and treating comorbidities via an integrative approach.

Pilot evaluation will thus focus on the aspect of patient empowerment. There is an agreement between researchers that the evaluation process of eHealth addressed to the patient (e.g. home eHealth or patient empowerment eHealth) is more complicated than that of the rest telemedicine applications [11]. The most common reason mentioned is the diverse group of stakeholders. Stakeholders come from different parts of the healthcare system with different value systems, different perceptions of risk and different expectations for a personal eHealth application. Costs and benefits may fall unequally between the various groups of stakeholders. The second reason often seen in the literature is the diffused context that eHealth addressed to the patient is applied to. The surrounding context (each patients' home and condition) varies. Also, patient empowerment applications are few and short (in terms of pilot applications duration). Both these facts make it difficult to generate data of sufficient scope and scale for conducting a thorough analysis. These obstacles require careful consideration of the evaluation approach to be used. Another difficulty that should be pointed out is that patient empowerment applications are usually designed without the participation of the most important group of stakeholders, the patients themselves. Whole systems are developed without patients to be asked about their needs and preferences. Just like the production of new pharmaceuticals and therapeutic procedures, patients are most likely exposed to the application after development has been completed, while during development process their position is expressed mainly indirectly, via their doctors and nurses. This tactic may preserve physicians' status and power over patients but may cause the development of patient empowerment systems that ignore patients' abilities or needs.

Based on the above, we choose to address CARRE intervention as an information system embedded in a clinical and social context. This requires an interpretive approach guided by a formal framework that involves evaluation of system functions, human perspectives and the organizational context. For each one of these dimensions, the evaluation will address structure, process and outcome (as detailed in Section 4). The overall evaluation is designed in three phases.

The first phase involves testing of individual system components in the lab mainly against predefined use cases (as in D.2.1). This phase involves mainly system evaluation and will be performed as part of "Task 7.2. Aggregator Testing and Integration". Testing will address benchmark testing of the individual components including reliability (fault tolerant analysis and debugging), and functionality (as described in use cases and functional requirements, D.2.1 and D.2.2), efficiency (component performance and scalability) and maintainability (inspection of documentation).

The second phase involves test piloting working prototypes of individual system components in a controlled environment, for example the lab or the outpatient clinic. The goal of this evaluation is to provide a basic service assessment using a prototype, so that to drive the finalization of the functionality and user interface of the server components and the patient (and medical expert) applications. This evaluation is in fact part of the system development. Once a first prototype reaches maturity, it will be used in a controlled environment for a first evaluation by a number of medical personnel and representative patients. This will help especially the patients to get introduced and easily grasp the idea of the patient empowerment services, a task rather difficult

to achieve in the abstract phase of system functional requirements investigation and design. The techniques employed here will include observation of the different stakeholders groups, unstructured and semi-structured interviews, documentation review and researchers' interaction with the technology used. In this preliminary evaluation, a small group of volunteers (patients and medical professionals) will be involved. Quotations from stakeholders will be presented in their own words letting readers to interpret them. Evaluation here mainly aims to assess system and service usability and exploit the results to guide the development of mature versions of the system.

The third phase involves evaluation of the CARRE system in real deployment in two pilot settings with patients recruited in DUTH and VULSK University Hospitals. The focus here is to evaluate the impact on patient and doctor satisfaction and empowerment and assess the potential for better health outcomes and quality of life.

The following sections present in more detail the content of the evaluation and the methodology and plan.

3. The 'what': patient empowerment as a cognitive process

The question of '*what is to be evaluated*' is a central issue to all approaches, and this in turn is dominated by the meaning that is attached to the information system and it varies among different groups of stakeholders. Therefore, in this section we attempt a discussion on what is patient empowerment and how this is perceived in current literature. Also, we present our view of the concept via a novel all-inclusive model of patient empowerment as a cognitive process.

Patient empowerment has emerged as a new paradigm that can help improve medical outcomes while lowering costs of treatment by facilitating self-directed behaviour change. Conceptually, 'empowerment' relates to (a) the goal of the individual to have control over his/her own quality of life, and (b) the process of creating a professional relation where the person or community takes control over the change process determining both the goals and the means to achieve them. The concept seems particularly promising in the management of chronic diseases [17], [18] and it is directly connected with personalized patient services, education and preventive measures. Currently, the research community appreciates that improving a person's ability to understand and manage his or her own health and disease, negotiate with different teams of health professionals, and navigate the complexities of health systems is crucial to achieving better health outcomes [19].

The concept of empowerment appears in many different contexts, as the process of enhancing the capacity of individuals or groups to make choices and to transform those choices into desired actions and outcomes. Especially, the field of human resource management formally addresses empowerment as a cognitive process. Thus many studies investigate interventions that are designed, developed and assessed following a cognitive model of the empowerment process [20], [21], [22].

In this section we argue that patient empowerment also should be treated as a cognitive process. We also propose a cognitive model that can be used as a basis to design effective patient empowerment eHealth interventions and then devise the appropriate and efficient methodology and tools for a systematic evaluation of the intervention and its outcomes. The model proposed here has been published as a CARRE funded intermediate result [23].

3.1. Patient empowerment

Julian Rappaport (1987) defined empowerment as *"a process, a mechanism by which people, organizations, and communities gain mastery over their affairs"* [24]. Empowerment, in its most general sense, refers to the ability of humans to gain understanding and control over personal, social, economic and political forces in order to take action to improve their life [25].

In health science, patient empowerment is understood as an enabling process or outcome [26], [27] by which patients are encouraged to construct self-regulation, self-management and self-efficacy in order to achieve maximum health and wellness [28]. Empowerment can therefore be described as a process where the purpose of an educational intervention is to increase patients' ability to think critically and act autonomously; while it can also be viewed as an outcome when an enhanced sense of self-efficacy occurs as a result of the process [18]. According to the European Network for Patient Empowerment [29] an empowered activated patient:

- understands her/his health condition and its effect on her/his body;
- feels able to participate in decision-making with her/his healthcare professionals;
- feels able to make informed choices about treatment;
- understands the need to make necessary changes to her/his lifestyle in order to stay healthy and/or effectively manage disease;
- is able to ask questions and challenge her/his healthcare professionals; and
- takes responsibility for her/his health and actively seeks care when necessary.

The concept of patient empowerment has emerged in 1970s in USA and UK as part of the rise of New Right politics [30]. The concept eventually evolved as a new paradigm that can help improve medical outcomes while lowering costs of treatment by facilitating self-directed behaviour change. The concept seems particularly promising in the management of chronic diseases [17], [18] and it is directly connected with personalized patient services, education and preventive measures. Patient empowerment has gained even more popularity since the 1990's, due to the emergent of eHealth and its focus on putting the patient in the centre of the interest.

A recent review [31] shows that patient empowerment services mainly aim at educational programs seeking patient reinforcement. Indeed, patient education interventions seem to have taken the lead in the early attempts to strengthen patients. To illustrate this we have searched PubMed database for the term 'patient education'. Figure 2 shows the results (red line), as a plot of number of papers per year for the last five decades. According to this graph, published works on "patient education" first started to appear during the 1960s, following an increasing curve from the mid-70s until 2006, when their yearly numbers started to decline. At the same time, research interest begun to focus on the related concepts of 'patient engagement' and 'patient empowerment'. PubMed searches with these terms (also plotted in Figure 2, with green and blue lines respectively) indicate an increasing research interest, especially during the last decade.

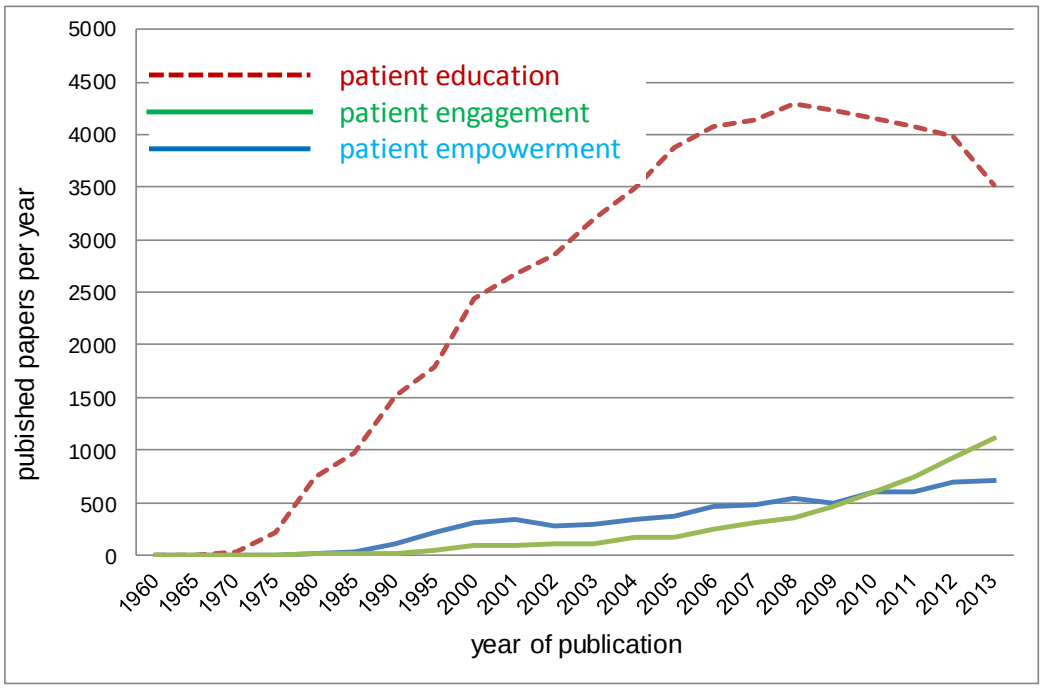

Figure 2. Plot of the PubMed search results for the terms "patient education" (red dashed line), "patient engagement" (green dotted line), and "patient empowerment" (blue compact line). The results of the three searches are plotted as number of published papers per year for the year range 1960 to 2013.

Reviews of the field reveal three basic dimensions of patient empowerment: *education*, *engagement*, and *control* [32], [33]. Patient *education* is perceived as a set of planned educational activities designed to improve patient health behaviour and health status. Its main purpose is to maintain or to improve patient health as well as to train the patient to participate actively in his or her own healthcare treatment by increasing self-efficacy [34]. Patient *engagement* involves two different concepts: cooperation with health providers and an active

engagement in managing one's own health status and disease. The *control* dimension refers to the patient's ability to participate actively in strategic decisions about his or her health and disease management.

Although there is a clear distinction between these three dimensions, often empowerment interventions include all three dimensions in their goal and, eventually, in their design. This has obvious implications for the methodology and tools that will be used to evaluate the specific intervention. For example, evaluation of patient education interventions should examine expected outcomes such as: understanding health information; ability to recognize new or warming signs or symptoms of disease progression and transition; and self-satisfaction of being well-informed on the treatment options of his or her condition or disease.

The evaluation of interventions targeting patient participation should exam different outcomes such as: the degree of patients' involvement in treatment plans; lifestyle and behaviour changes; and the ability and willingness to share information and feelings. Finally, evaluation of interventions that attempt to increase patient control should take into account outcomes such as confidence in the ability to make decisions about treatment plans, maintaining a personal health record, and other major choices related to health management.

Research so far has revealed interdependencies between these dimensions. For instance, a study extensively researched the communication between doctors and patients and have noticed that patient education helped patients gain more control and management of their health, which in turn encourage patients to ask more questions and be more active regarding their health treatment [35]. Moreover, researches revealed that the maintenance of control by obtaining information about health statuses, lead to an increased participation ratio in decision-making regarding treatment [36]. Furthermore, DiMatteo et al [37] conclude that patient education or structural changes to the medical interaction (i.e. doctor and patient co-authoring medical records) have led patients to play more active roles and develop a greater sense of control of their health and lives. Despite such findings, current literature lacks of a tiered, hierarchical approach towards patient empowerment.

3.2. A cognitive approach to patient empowerment

In its core meaning, empowerment is strongly related to the control on one's own action. In this respect, empowerment could be considered as a complex construct that involves various cognitive processes and skills [38]. Specifically, some of its basic elements include: knowledge acquisition through perception, thinking and learning, awareness of one's own current conditions and /or needs, active participation in the management of the current or future condition and in the relevant decision making [39].

Following the overall approach of cognitive psychology, we propose to treat patient empowerment in terms of three levels of increasing complexity and importance: awareness, participation and control (Figure 3).

3.2.1. Awareness

The first and most basic level refers to the complex task of health awareness. The patient (or the healthy citizen in general) should be aware of:

- his or her own health status;
- health related risks and lifestyle or environment induced hazards;
- potential disease progression to more severe stages;
- potential disease transition to other comorbidities; and
- measurements needed to stay healthy and/or prevent disease occurrence, progression or transition.

This level corresponds to the educational dimension described above. However, we believe that it is more appropriate to treat it as a personal awareness of one's own health rather than the process of formal education. This underscores the fact that the patient should clearly understand the implications of the information provided and is able to act upon it.

In any case, this level on its own can be viewed as an educational process with three sub-levels of increasing complexity [40]: information gathering (i.e. simple facts), knowledge (i.e. information with a purpose), and understanding (i.e. conscious knowledge, achievement of explanation and grasp of reasonableness).

Supporting access to information is the easiest and most straightforward task for patient empowerment interventions, be it via conventional channels of printed material, or via the nowadays more popular channels

based on the internet and even mobile personal devices. Indeed, today there are many authoritative on-line databases that provide education material designed specifically for the patient. One notable example is the effort of the National Library of Medicine USA, who along the PubMed research abstracts database provides also the MedLinePlus (www.nlm.nih.gov/medlineplus/) service for patient information. Another important example is the EUPATI network funded by EU, which is a comprehensive collaborative effort towards educating the patients so that can take active part in their treatment and in the research towards new treatments.

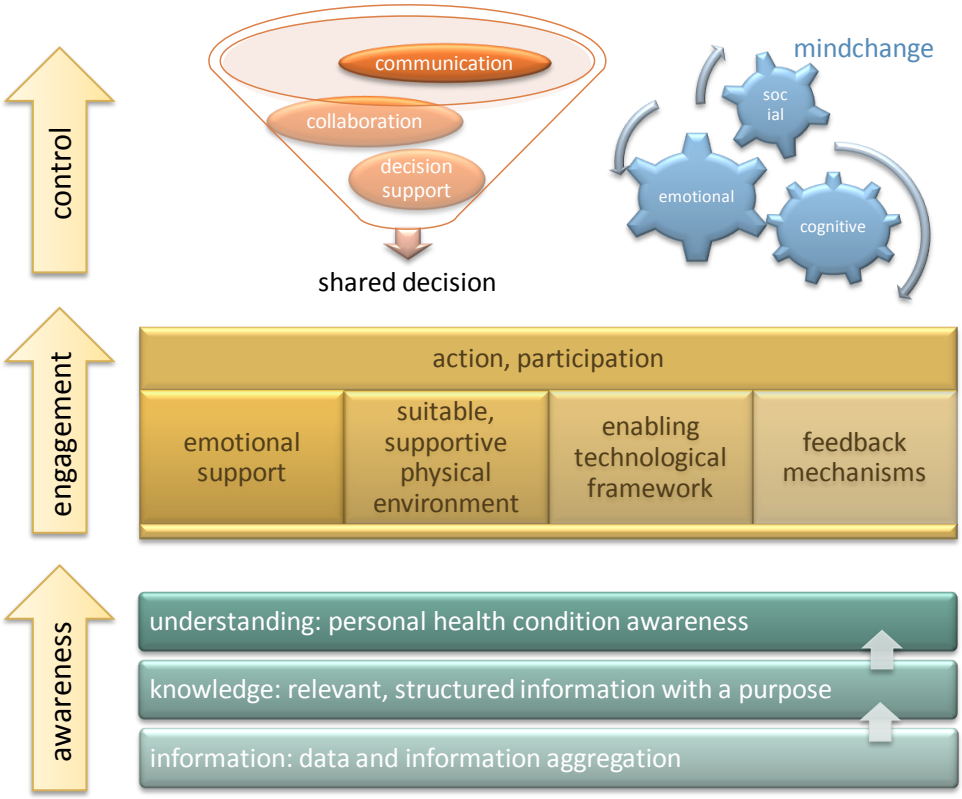

Figure 3. Patient empowerment modelled as a cognitive process. There are three distinct levels of increasing complexity and importance: awareness, engagement and control. Each level presents its own contributing factors.

Structuring and organizing information with a particular educational purpose refers to knowledge. Managing and supporting this second level of the educational process is a rather complex issue. Semantic eHealth interventions can certainly help by providing relevant material and semantic medical concept maps that will allow the wealth of the available medical evidence and core knowledge to be digested and presented to the patient within context. Also, advanced visual analytics may offer alternative ways for patients to grasp difficult medical concepts.

The final step of self-understanding relates to the patient's ability to realize his or her personal condition in relation to the medical evidence. This actually means achievement of health awareness. In order to support this, interventions should follow a combined approach of coupling medical evidence and core knowledge to the personal characteristics of the patient. This personalization most often will require integration of personal health data, including personal health records, real-time biomedical sensor measurements, as well as data related lifestyle and behaviour, beliefs and intentions – nowadays harvested via semantic analysis of unstructured personal data available in web based social networks or via web search histories.

3.2.2. Engagement

This second level of patient empowerment strives to achieve patient's engagement in the health care process. Here we should emphasize active and proactive participation in managing the disease and its treatment and

in preventing disease progression and transition. Successful patient's participation can be achieved only when the patient is health aware. However, this is not the only prerequisite. The patient additionally needs emotional strength, a suitable, supportive physical environment, an enabling framework and last but not least an accurate feedback about the progress of his/her disease and disease management in order to be able to re-adjust participation.

Emotional strength can generally be reinforced by easing the communication with healthcare providers and most importantly within social groups. Both can be easily supported by common eHealth interventions that allow an easy and seamless communication with healthcare providers or provide the environment for on-line social support groups.

Creating a supportive physical environment may prove more intriguing. As we cannot easily alter physical environments to help patients, we could instead try to alter something equally important: the *perceived* environment. Here, future eHealth interventions should provide the means to identify resources and opportunities the environment already provides, which the patient (or its digital assistant) can exploit to increase the level and quality of participation in disease management. A simplistic example would involve an application that highlights a route within a city suitable for wheelchairs or places that offer salt free foods.

For the patient to be able to participate effectively in personal health management a number of other tools and services often need to be available – these comprise what we call the enabling framework. These may include specialized equipment and/or digital interventions that provide the necessary prerequisites for the patient to be able to act. Fortunately, nowadays a wealth of such underline technologies are available, ranging from personal wearable health sensors to cloud based personal health applications and dedicated personal assistants.

Finally, active participation requires improvement of the self-efficacy [34]. That is, it is necessary for the individual to know her/his own abilities and skills or to estimate accurately her/his needs for being able to be engaged in action. One of the most crucial tools for the formation of the self-efficacy is the accurate feedback, positive or negative, for individual's action that is received from the external environment. Only active engagement can be meaningful and effective in fulfilling its aims.

3.2.3. Control

Control in this context can include two different aspects: decision making and mind changing.

Decision making refers to a collaborative process where patient and healthcare professionals discuss and interact to reach a shared decision. A prerequisite for this is the patient to be health aware and actively involved in her/his health management. Only then, the patients' participation in decision making should be effective. However, this aspect of control of action involves extensive interaction and collaboration. Both are widely supported by current eHealth applications in a variety of ways, including also advanced collaboration environments and shared digital spaces. Some interesting examples include the emergent technology of personal health records, owned by the patients themselves, who however can give targeted access to their health providers when needed.

Also considerable research work is available in the field of medical decision support systems, which can be generally viewed as either (a) the so-called 'strong' artificial intelligence systems whose behaviour is at some level indistinguishable from humans; or (b) an alternative approach that looks at human cognition and decides how it can be supported in complex or difficult situations, something like a form of 'cognitive prosthesis' that will support the human in a task [41]. In any case, shared decision support interventions need to take into account both patients and healthcare professionals and integrate data and events from various sources of personal health data and medical evidence.

On the other hand, control of action involves internal cognitive processes – what we refer to as mind changing; that is the capacity to modify one's own mental states like beliefs or intentions. This entails the representation of causal determinants of lasting behaviour change from the perspective of the individual, including perceptions, cognitions, and emotions. Together, they describe the personal-level motivational signature of direct goal-seeking behaviour [42]. This level of empowerment is probably the most demanding, since it is based on highly interdisciplinary research, which involves behavioural scientists, psychologists, behaviour simulation and experiments and finally information scientists. Attempts to support mind changing need to take into account individuals' motivations, their previous relevant knowledge, attitudes and habits, and then design an intervention which is aimed at changing representations first, and in turn their behaviours. Mind changing

is at the basis of human social interactions because it means that we can identify our own and others' mental states and act upon them [43], [44]. This can be obtained by several means: communicative actions, like requests, commands, evaluations, assertions, etc. and non-communicative actions, which aim to modify the emotions, feelings, and beliefs of others without directly stating one's intentions.

3.3. Patient empowerment in CARRE

The project aims to create a set of empowerment interventions that address all level of the proposed empowerment model. In particular:

- provide visual and quantitative model of disease progression pathways and comorbidities trajectories, based on current medical evidence (awareness: information aggregation and knowledge);
- personalize the risk model to each individual based on his personal medical data and real-time sensor measurement to support disease status awareness (awareness: understanding);
- use the personalized model in conjunction with real time monitoring to create a set of alarms to enable patient engagement (engagement: enabling framework);
- provide advanced decision support services and mind change interventions based on the real-time coupling of medical evidence, personal health status and intentions and beliefs, as deduced from social web data mining (control).

This mapping of CARRE services to the proposed patient empowerment model is presented collectively in Table 1.

Table 1. Mapping of CARRE services to the empowerment model.

model level	CARRE service
awareness: information aggregation and knowledge	provide visual and quantitative model of disease progression pathways and comorbidities trajectories, based on current medical evidence
awareness: understanding	personalize the risk model to each individual based on his personal medical data and real-time sensor measurement to support disease status awareness
engagement: enabling framework	use the personalized model in conjunction with real time monitoring to create a set of alarms to enable patient engagement
control	provide advanced decision support services and mindchange interventions based on the real-time coupling of medical evidence, personal health status and intentions and beliefs, as deduced from social web data mining

In more detail, patient awareness support in CARRE spans all the three sub-levels of providing information, supporting knowledge and advancing understanding. Specific patient awareness services are presented in Figure 4 and include the following:

- Information: links to relevant educational content as provided by on-line repositories with educational material for the patient (e.g. MedLinePlus and Wikipedia). This CARRE service has the added-value of professional and patient rating of the educational material.
- Knowledge: semantic description of educational content, semantic enrichment and interlinking with relevant data on the semantic web gives the chance for creating relevant concept maps and thus enhancing processing of information towards knowledge.

- Understanding: this is achieved mainly by combining generic educational material and medical knowledge with personal data on health status and its forecasted progression (based on medical evidence).

Thus the above CARRE services should be evaluated for their ability and efficiency in enhancing patient awareness, and in particular providing relevant information to the patient, advancing knowledge via semantic mappings and enabling understanding of personal health status by combining generic information with personal health information.

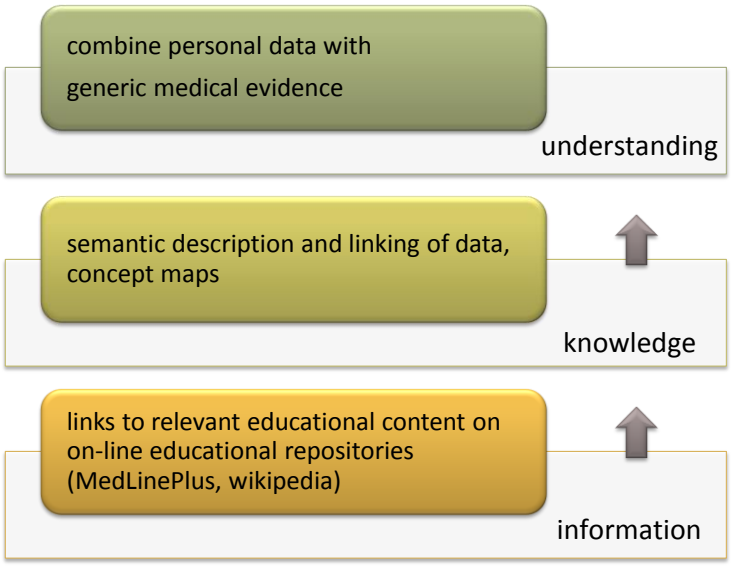

Figure 4. Supporting patient awareness in CARRE

Patient engagement in CARRE (Figure 5) is mainly supported by the rich technological framework of personal and wearable sensors and other aggregators of personal data (medical history and intention). These personal data are then used to create personalized trajectories and progression pathways for disease status and corresponding health alerts that form the basis of patient engagement in health and diseased management. Also, the generated personal health progression maps as they evolve in time and possibly altered due to patient behaviour and behaviour change can prove effective feedback mechanisms for the patient. Evaluation of this dimension in CARRE should aim to assess the degree of user satisfaction related to the novel technological framework. Also, evaluation can also measure the impact the feedback to the patient has on his/her health status and disease progression.

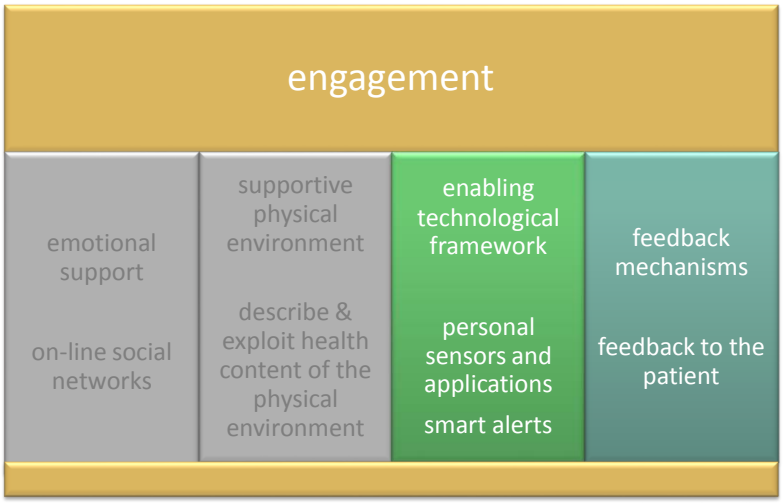

Figure 5. Supporting patient engagement in CARRE

Finally, patient control in CARRE is addressed via the decision support services and mind change interventions based on the real-time coupling of medical evidence, personal health status and intentions, as deduced from social web data mining. Thus, evaluation of these services should aim to measure the degree of patient control in managing their own disease via automatic alerts and assisted planning.

4. The 'how': evaluation methodology

4.1. eHealth evaluation framework

Literature review reveals the need to base evaluation on a theoretical model that will guide our research and serve to the interpretation of the data in a way that general patterns of interaction can be derived. In order to construct such a model for patient empowerment application evaluation, we selected the context, process and content framework created by Cornford and Doukidis [45], which derives from information systems literature and precisely from interpretative thinking, but also encompasses medical evaluation literature. The reason for the selection of this evaluation framework is that it serves our view of the evaluation as an attempt to understand the context, and the interplay between technology-people-context and as a *'continuous learning process rather than a search for judgment'* [46].

Cornford, Doukidis and Forster [45] have proposed an evaluation framework for telemedicine and eHealth interventions that views eHealth effects from three different angles: the structure, the process and the outcome (Figure 6). These three angles are applied at three levels: the level of the systems functions, the human perspectives and the organizational context.

	System functions	Human perspectives	Organizational context
Structure	technical detail	changed work conditions and implied requirements	sustainability, opportunity costs, management needs, skill requirements
Process	information processing correct and valid	human participation in tasks; social interaction	altered delivery and practice
Outcome	relevant, applicable, reliable	quality of service and outcomes	effect in the world

Figure 6. The evaluation framework by Cornford T, Doukidis GI, Forster D (1994)

In the level of systems functions, the evaluation of structure involves the assessment of the technical details of the telemedicine application, the examination of the process focuses on the information processing and that of the outcome on whether the system as a technological innovation has relevant, applicable and reliable results. In the human perspective level, all stakeholders and participants in the telemedicine application are included and their acceptability searched. Actors may vary from owners, providers, and consumers of the system. In each case, the changes in their work conditions, or their behaviour should be assessed in the structure layer, their view on the changes in the mode of operation and health care experience is to be addressed in the process layer while systems effectiveness through the eyes of the different actors is judged in the outcome layer. The aim is to view the system applying different lenses according to actors' role in it. Finally, at the organizational context which in the case of telemedicine is the health care system in the layer of structure the attention is drawn on systems sustainability assessment, while impact on the delivered quality of health provision and on the health status of the patients is examined in the process and outcome layer respectively.

In CARRE, we adopt an earlier adaptation of this model proposed by authors of this deliverable [47], which further analyzes the framework in order to account for the special requirements of the patient empowerment environment and its actors (see Figure 7). The emphasis is given to the human perspective, as in patient empowerment applications we encounter the unique setting with the patient/citizen at home (or at their own environment), secluded from direct contact with the healthcare personnel and/or technical support. The chart in Figure 7 gives the basic questions that have to be tackled for every evaluation angle and every different level. It should be noted that depending on the goal of an evaluation study or phase, some or all of the cells in the proposed framework may be tackled.

	CARRE system functions	Human perspectives			Context and Environment
		Experts	Patients	Admins	
Structure	Are requirements met; does the system work; does it present technical problems? Testing of input and output aggregators and interfaces.	What are the changes to experts working conditions and practices; do they need to obtain new skills, and abilities?	Are patients required to obtain new skills, and abilities?	Is the system cost-effective?	Could this system be sustained and supported within the cardiorenal healthcare services? Could it be accepted within the home context?
Process	Is CARRE service operation correct & valid ? (testing of all individual component services)	How was the experts' mode of operation changed? Are these changes seen as desirable to them? Test input and output services	How is the patients' behaviour altered; which are the changes in their self-management?	Does it imply changes to administrator's working practices?	Could such a system be routinely used in healthcare process?
Outcome	Are the functions of the CARRE system usable and reliable? (testing of input and output services as an integrated environment)	Was their effectiveness within the health care system affected?	Does the use of the system result in changes in the perceived quality of care/life?	Does the system improve specific clinical parameters?	Could such a system improve the health status and quality of life for renal patients?

Figure 7. The proposed evaluation framework, as a detailed adaptation of the Cornford, Doukidis and Forster framework for the specific case of home eHealth.

4.2. Evaluation of System Functions

4.2.1. Structure

This part of evaluation refers to the system component testing. Major system components include all aggregators, the RDF repositories, the visualization service and the decision support system. Evaluation in this axis is mainly benchmark testing that will assess whether the individual system components meet initial technical requirements, with emphasis on input and output. Testing will involve main component functionality as well as input and output and will include:

- Reliability: fault tolerant analysis and debugging. This will assess whether each component functions and this is error free.

- Efficiency: component performance and scalability. Tests will measure the performance characteristics of each component and assess its scalability, calculating existing software scalability limitations and suggesting necessary and possible improvements.
- Maintainability: inspection of documentation. This will assess the degree of the software portability and other issues related to maintenance, including the degree to which the software is ready to install and/or port to other platforms and its dependence and on supporting software and network technologies.

4.2.2. Process

This part of evaluation refers to component and service benchmarking that will assess whether the individual system components and the integrated services meet initial functional requirements (as set in use cases and functional requirements, D.2.1 and D.2.2). Testing will involve pilot data transfer, processing and display to assess whether this is correct and satisfactory.

4.2.3. Outcome

Evaluation here will involve users (patients and healthcare professionals) who will use early prototypes of CARRE components and services in the controlled environment of the lab or the clinic to assess whether project outcomes are perceived as relevant and reliable. Evaluation here will be part of the development process and will be conducted mainly via semi-structured interviews. The results (mostly as direct quotations) will be directly used to guide further improvements and finalize component and service development.

4.3. Human perspective: healthcare professionals

4.3.1. Structure

Evaluation here will involve healthcare professionals who will use early prototypes of CARRE components and services in the controlled environment of the lab or the clinic to assess whether project outcomes bring changes to their working conditions and practices and to which extent new skills and abilities are required. This evaluation will be part of the development process and the results will be directly used to guide further improvements and finalize component and service development.

4.3.2. Process

This part of the evaluation will be carried out in the real setting of CARRE pilot deployment. Healthcare professionals will be asked to report and evaluate the induced changes in health care delivery and the evaluation will focus on user satisfaction.

4.3.3. Outcome

This part of the evaluation will be carried out in the real setting of CARRE pilot deployment. The evaluation will attempt to assess if and how CARRE enhances the effectiveness of the health care professional to manage and empower the cardiorenal patient.

4.4. Human perspective: patients

4.4.1. Structure

Evaluation here will involve patients who will use early prototypes of CARRE components and services in the controlled environment of the lab or the clinic to assess whether project outcomes bring changes to their everyday lives and habits and to which extent new skills and abilities are required. This evaluation will be part

of the development process and the results will be directly used to guide further improvements and finalize component and service development.

4.4.2. Process

This part of the evaluation will be carried out in the real setting of CARRE pilot deployment. Patients will be asked to report and evaluate the induced changes in personal life and disease self-management and the evaluation will focus on user satisfaction.

4.4.3. Outcome

This part of the evaluation will be carried out in the real setting of CARRE pilot deployment. The evaluation will attempt to assess if and how CARRE enhances the perceived quality of care and quality of life. Also, the evaluation will measure achieved patient empowerment.

4.5. Human perspective: healthcare administrators

4.5.1. Structure

This part of the evaluation addresses the cost-effectiveness of the system. It requires a market analysis and large-scale deployment plan (part of which will be dealt with in Task “T.8.3: Exploitation and sustainability plan”). However, deep cost-effective analysis is beyond the scope of this project.

4.5.2. Process

This part of the evaluation addresses induced changes in the working practices of health care administrators and their satisfaction. As it requires large scale, long-term deployment to induce such changes, this evaluation is beyond the scope of this project.

4.5.3. Outcome

This part of the evaluation addresses improvements in specific clinical parameters and the management of the disease, i.e. statistically significant changes in disease management (as opposed to individual patient management). Health outcomes of an intervention that aims to alter risk factors related to lifestyle are normally measured in studies that involve long observation times of the order of several years. However, a first indication of health outcomes can be observed within the one-year pilot trial scheduled for the third year of the project.

4.6. Organizational Context

4.6.1. Structure

This part of the evaluation tries to ascertain whether CARRE intervention could be sustained and supported within the healthcare system and whether it could be accepted in the social context. Although part of this will be dealt with in Tasks “T.8.3: Exploitation and sustainability plan” and “T.7.5: Implications for care pathways, organizational and business models”, deep analysis is beyond the scope of this project.

4.6.2. Process

This part of the evaluation tries to which extent CARRE intervention alters the delivery and practice of care. Although part of this will be dealt with in Task “T.7.5: Implications for care pathways, organizational and business models”, deep analysis is beyond the scope of this project.

4.6.3. Outcome

This part of the evaluation will be carried out in the real setting of CARRE pilot deployment. The evaluation will attempt to assess if and how CARRE improves the health status and quality of life for cardiorenal patients. It should be noted that this will only be a first indicative analysis, as a deeper evaluation of project impact to health status would require long term, large scale deployment which is beyond the scope of this project.

4.7. The "who" and "why": evaluation plan

The evaluation as described above will be carried out in consecutive phases. Initial evaluation is benchmark testing. The second phase involves evaluation during development in a controlled environment (lab or clinic). The third phase is the evaluation by volunteers in the real setting of two different pilot sites. The concluding part of evaluation would involve long term, large scale deployment and is outside the scope and work plan of this project. The evaluation plan is shown in Figure 8, and is presented in detail in the following paragraphs.

	CARRE system functions	Human perspectives			Context and Environment
		Experts	Patients	Admins	
Structure	aggregators and interfaces functioning	changes to working conditions and practices; new skills, and abilities	new skills, and abilities		
Process	service operation correct & valid	induced changes in function and satisfaction	Induced changes in self-management and satisfaction		
Outcome	service usable and reliable	effectiveness	perceived quality of care and life	improving specific clinical parameters	potential to improve the health status and quality of life

Figure 8. Overview of the project evaluation phases. Blue indicates phase 1, yellow indicates phase 2, green indicates phase 3. Grey indicates phase 4 of the adopted model, which however requires large scale, long term deployment and is outside the scope of the project's work plan.

4.7.1. Phase 1: component testing

Why: Test reliability, efficiency, functionality and maintainability of system components.

When: During development and testing of individual system components, i.e. during year 1 and 2 of the project.

Where: In the lab.

Who: System developers. Healthy volunteers, mainly members of the development team.

4.7.2. Phase 2: component and service prototype testing and understanding

Why: Understand system functionality & include patient and healthcare professional in the design and development. Assess user satisfaction and include this in the design. Understand system interaction with stakeholders.

When: During design, development and prototype pilot implementation. That is, during year 1 and 2 of the

project.

Where: In the controlled environment of the lab and (potentially) the clinic or outpatient unit.

Who: Selected patient and healthcare professional volunteers. Selection will be based on availability and will try to represent all user groups (as described in D.2.1).

4.7.3. Phase 3: service evaluation

Why: Assess user satisfaction and interaction in a real environment. Understand service interaction in the organizational context. Measure perceived enhancements in professional effectiveness, as well as in self-management and perceived quality of care and life. Assess empowerment, clinical outcome in health status and quality of life.

When: Deployment as experimental patient support protocol during the 3rd year of the project.

Where: Real environment in two different clinical deployments with volunteers in DUTH and VULSK University Hospitals.

Who: Health care professionals and patients. Patient cohorts will be on a volunteer basis and selection will be based on internet availability and basic ability to use CARRE technology – apart from this will be randomized. The following patient cohorts will be considered:

1) almost healthy volunteers at risk of cardiorenal disease, including overweight/obese and hypertensive patients – in both pilots DUTH and VULSK;
2) patients regularly treated for a comorbidity that enhances risk for cardiorenal disease (e.g. diabetes, metabolic syndrome, etc.) – in both pilots, DUTH and VULSK;
3) chronic renal patients and cardiorenal type 4 patients – in DUTH pilot; and
4) chronic cardiac patients and cardiorenal type 2 patients – in VULSK pilot.

4.7.4. Phase 4: long-term outcomes assessment (beyond the project's lifetime)

Why: Assess the long term health and organizational impact of the project outcomes in large cohorts and involving diverse populations. This part of the evaluation is outside the scope and work plan of the project.

When: After the end of the project and for a time duration of at least 3 years.

Where: In large cohorts in several different European countries.

Who: Patients cohorts exhibiting any comorbidity related to cardiorenal syndrome, truly randomized.

5. Ethical handling of data

Ethical issues raised by the project research and the evaluation process fall within the spectrum of ethical principles of eHealth research, as for example analysed in recent work of the EC funded ETHICAL project [48]:

- Trust: Openness and transparency about security risks. Researchers have an ethical responsibility to ensure that research subjects have fully understood the security and privacy implications of taking part in the research. Include a requirement to inform research subjects immediately if a breach occurs.
- Privacy: Not to be confused with confidentiality, privacy refers to: "*The right of individuals to be left alone and to be protected against physical or psychological invasion or the misuse of their property. It includes freedom from intrusion or observation into one's private affairs, the right to maintain control over certain personal information, and the freedom to act without outside interference"* [49].
- Ownership: Patients have a right to know where their data are transferred and how it is used and exchanged.

- Dignity: Emphasis on human sensitivities: place cost, efficiency and, to some degree, experimentation ahead of them.
- Equity: This is often challenged by social and financial impacts of biometric and medical applications.
- Proportionality. Limit actions to what is necessary to achieve the objectives of the project and the evaluation. For example, data should not be retained longer than necessary, should not be transferred over unsecured connections.

Project evaluation takes into account all these principles. Furthermore, evaluation poses requirements for institutional ethical approval, including informed consent and data protection aspects. Approval by the ethical committees of the partners hosting the clinical pilots, but also of any other partner who is to be involved in the first phases of evaluation via (non-patient) volunteers.

Informed consent will be sought by any one participating in the testing and evaluation in any phase and in any way. Copies of all ethics submissions and relevant approvals will be retained by the respective partner and/or the coordinator.

Testing and evaluation will include the collection, use and storage of personal data, and therefore, the project must adhere to all aspects of the EU Data Protection Directive (and its planned replacement, the General Data Protection Regulation). The main ethical issues associated with the project will be handled as follows:

5.1. Informed consent & privacy

Informed consent will be required for deployment of the pilots, as the project will involve the use of human subjects for testing the technologies we are developing. For the same reason, prior to the pilot, the CARRE evaluation protocol will have to be approved by the appropriate ethical committees for the respective partners running the testing and/or pilot implementations.

In all cases informed consent will be sought from each individual participating in the research, on an entirely voluntary basis, with the possibility of withdrawal at any time. Volunteers who are not able to give consent will not be included in the research, nor will we be working with specific vulnerable populations. It should be noted that the research will pose very few risks to participants – indeed, the only potential risk concerns data privacy. In this regard, the stringent protections of European data protection legislation for ‘sensitive’ ‘personal data’ will apply, as will the specific safeguards indicated below. In particular, privacy issues have been incorporated in the applications and data security is being built into our systems from the ground up, as described in the relevant individual tasks.

5.2. Data protection & system security issues

The project will only use private data during pilot demonstration deployment. This data will be treated as strictly confidential, with personal identifying information being stored separately from other individual-level data, such as monitoring information and other user inputs. Personal identifying information in the evaluation protocol will be stored under lock and key at each participating centre. The storage and processing of this data will remain subject to strict obligations of confidentiality and be used solely for analytical and research purposes that correspond to the aims of the present project.

All personnel involved in the study will have to sign a confidentiality declaration and may not disclose any data that they deal with in the course of the study nor make any other use of it than that required for project aims. Laboratory personnel and persons involved in data analyses will have no access to personal data – this will be stored separately under lock and key.

Personal data gathered within the present project will be used solely for the current project and any follow-up project by this consortium with similar health-related aims. It will not be made available for any other purpose, nor will it be sold or used for any commercial purposes.

Data will never be released outside the consortium, nor will consortium members be allowed to use the data for any other purpose than the development of the health-related technologies in CARRE. Should the involvement of further partners or bodies be deemed necessary – for instance, in order to access further expertise or different technology platforms – those partners will only be allowed access to pseudonymised

data and then under the same strict conditions and legal requirements as existing consortium members. A legally binding contract will be drawn up in any such case, in order to uphold these obligations of confidentiality and data security. Such an arrangement will only be entered into upon the agreement by the project General Assembly, following reasonable notification to all project partners and allowing reasonable opportunity for them to object and/or require further information.

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