ICT PSP – Accessibility, Ageing and Social Integration Programme

RENEWING HeALTH
REgioNs of Europe WorkINg toGether for HEALTH

REgioNs of Europe WorkINg toGether for HEALTH
(Grant Agreement No 250487)

Document D4.2 User Requirements - Reference Framework Version 1.0

Work Package:	WP4
Version & Date:	v1.0 / 17th May 2012
Deliverable type:	Report
Distribution Status:	Internal
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Filename:	D4.2 v1.0 Renewing Health User Requirement Ref Framework.docx

Abstract

This document serves as a reference framework for the representation of user needs and requirements by the RENEWING HeALTH User Advisory Board (UAB). This framework will serve as a focal point of the UAB activities and is hence work in progress. The starting point is a structural model (Matrix) of user requirements providing for six dimensions and three phases of telemedicine services. For these, needs and expectations of the three groups of end-users (patients/informal carers, health professionals and health care organisations) have been captured from the literature. The document will be used to structure the feed-back process from representatives of real users using the RENEWING HeALTH services.

Key Word List

Telemedicine Service Users, User Advisory Board, User-Centred Design, User Requirements, User Needs Assessment, Reference framework for user needs and requirements;

Executive Summary

This document provides for a comprehensive analysis of the requirements of the users of telemedicine services. *User requirements* are defined as the wide array of needs, preferences, expectations and constraints of users of telemedicine services which need to be taken into account at all stages, from the design to final deployment of such services, in order to ensure that the final services, including all components or constituents (applications, solutions, products etc.), effectively reflect the purpose for which they were originally conceived, while respecting users' needs and preferences to the greatest extent possible.

For the purpose of this document the term "user" refers to both direct and indirect users of telemedicine services, namely, the patients and their informal caregivers, healthcare professionals as well as healthcare authorities and payers.

The deliverable is guided by a matrix that is meant to be a starting point for an integrative consideration of user requirements on the basis of the three axes:

- Process (Design and Set up vs. Practical use vs. Evaluation/HTA).
- Dimension of analysis based on the multidimensional approach of MAST.
- Perspectives of stakeholders, i.e.
  PIC = patients/informal caregivers,
  HP = healthcare professionals and
  HCO = health care organisations/authorities/insurers/payers.

Table 1: Matrix in structure and stakeholder view

Process / Dimension (MAST)	Design / Set-up	Practical Use	Evaluation / HTA
Characteristics of the service, quality and safety	PIC, HP, HCO	PIC, HP	PIC, HP, HCO
Organisational aspects	HP, HCO	HP, HCO	HP, HCO
Health problem and clinical effectiveness	PIC, HP, HCO	PIC, HP, HCO	PIC, HP, HCO
Economic aspects	HCO	PIC, HCO	HCO
Non-health-related user outcomes	PIC, HP, HCO	PIC, HP, HCO	PIC, HP, HCO
Ethical and legal aspects	PIC, HP, HCO	PIC, HP, HCO	PIC, HP, HCO

This document is the second step in a series of four deliverables. Deliverable D4.2 elaborates on the first exploratory analysis of user requirements, which was based on a literature review as consolidated in D4.1, to include the results of two rounds of consultations with the members of the User Advisory Board.

Change History

Version History:

D4.1
0.1   11th August 2010
0.2   11th August 2010
0.3   20th August 2010
0.4   30th August 2010
0.5   1st September 2010
0.6   13th October 2010
0.7   7th January 2011
0.8   23rd January 2011
0.9   1st March 2011
1.0   11th March 2011   Version for issue

D4.2
0.1   20th January 2012
0.2   12th March 2012
0.3   19th March 2012
0.4   13th May 2012
0.5   17th May 2012
1.0   17th May 2012 Version for issue

Version Changes

D4.1
0.1   Draft Outline for discussion
0.2   Draft Outline for discussion
0.3   Draft Outline for discussion
0.4   Integrated Outline for discussion
0.5   Short Outline (PSC/WP3 discussion)
0.6   Extended outline
0.7   Revised Extended Outline
0.8   Consolidated Extended Outline
0.9   Revised "User Requirements Reference Framework"
1.0

D4.2
0.1   Integration of input of the User Advisory Board
0.2   Internal review by EHTEL and small additions
0.3   Second input from EPF and small additions
0.4   Internal review by EHTEL and cleaning
0.5   Minor changes prior to issue
1.0   Version for release

Outstanding Issues
None

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1. Introduction

1.1 Purpose of this document

The primary aim of this deliverable is to serve as a reference framework for the representation of user needs and requirements as they emerge from the RENEWING HeALTH user population and trials.

Thus the document supports the achievement of the RENEWING HeALTH key objective, to demonstrate that telemedicine services, exemplified by the implemented solutions:

- are accepted by patients and their informal caregivers, health professionals and the wider medical scientific community;
- benefit healthcare organisations both at a micro and macro level;
- provide an efficient and economic sound enhancement of the services financed by healthcare payers.

Fulfilling user needs and requirements for all user groups is a fundamental, albeit not sufficient, factor to achieve all this.

User requirements represent the wide array of needs, preferences, expectations and constraints of users of telemedicine services which need to be taken into account at all stages, from the design to final deployment of such services, in order to ensure that the final services, including all components or constituents (applications, solutions, products etc.), effectively reflect the purpose for which they were originally conceived while respecting users' needs and preferences to the greatest extent possible.

Based on the preconditions and timing of the project, the elicited user requirements will contribute to the definition and fine-tuning of future telemedicine services. Yet – based on the fact that by definition (in the project scope), RENEWING HeALTH builds on existing or at least predefined services – the User Requirements could not be implemented in the pilot services that form the constituency of this project. Still – with extra permission obtained from the Commission – the description of User Requirements will be adapted to the needs and requirements that will be reported back from the users of the trials and the trial evaluation. Thus D4.2 is the second version of the User Requirement process which was initiated with the publication of D4.1 in March 2011, which will be followed by future revisions D4.3 and D4.4.

Consequently, User Requirements in RENEWING HeALTH cannot play the role that they usually have in typical project lifecycles, i.e. guide all design and setup from the beginning.

Vice-versa, the document has taken on a more generic and universal approach to user needs and requirements. Thus it can serve as a reference framework for telemedicine services beyond the scope and lifetime of this project.

1.2 Structure of document

The first part of the document, i.e. sections 1 and 2, focus on the background and the objectives of this deliverable, its link with the overall project mission, and the link to the pilot sites and telemedicine services.

The second part, i.e. sections 3 – 5, introduces both a generic and a RENEWING HeALTH specific framework for the assessment of user requirements in relation to telemedicine services. Furthermore, following the description of the most widely used methods for eliciting user requirements, a detailed example is given for applying the "User Centred Design (UCD)" method for the design and development of telemedicine services.

Part three, i.e. section 6, is the core part of this document where the needs and requirements of the three user groups, patients / informal caregivers, health professionals, and payers, are presented and described. It is built along the lines of a user requirements matrix that has been derived from the MAST model.

Part four, or section 7, provides for the next steps of the iterative process of user requirements refinement as outlined in section 1.1 above.

1.3   Glossary

COPD	Chronic Obstructive Pulmonary Disease
CVD	Cardiovascular Diseases
HCO	HealthCare Organisations, Health Authorities, and Payers
HP	Healthcare Professional
HTA	Health Technology Assessment
ICT	Information and Communications Technologies
MAST	Method for the Assessment of Telemedicine Applications, proposed by the EU funded study MethoTelemed
PIC	Patients and Informal Caregivers
RH	RENEWING HeALTH
SCOT	Theories of Social Construction of Technology
SME	Small and Medium sized Enterprises
TAM	Technology Acceptance Model
ToR	Terms of Reference
UAB	User Advisory Board
UCD	User-Centred Design

2. Background

2.1 RENEWING HeALTH project

RENEWING HeALTH aims to improve health services in Europe for the increasing number of patients suffering from chronic conditions – in particular diabetes, cardiovascular disease and chronic lung problems.

The overall project goal is to demonstrate that telemedicine based services improve quality of life, and enable patient involvement and empowerment while optimising the use of resources in healthcare provision. The project does so by using and continuously enhancing a comprehensive, multidisciplinary and reusable evaluation methodology (MAST) to strengthen the evidence-based use of telemedicine-based services in Europe and world-wide.

More particularly, RENEWING HeALTH provides coherent clinical services through ICT that take into proper consideration patients' and professional users' needs, capabilities, risks and benefits. Thus the integration of user expectations and requirements enables the project to adjust its activities to the needs of current and future users of the piloted telemedicine services. In doing so, the fit between the services and the users' requirements and expectations will be improved.

2.2 The User Advisory Board

In support of the integration task defined above, RENEWING HeALTH has established a dedicated User Advisory Board (UAB).

The UAB has the primary mission to operate as a standing advisory committee for the Consortium to advise and provide on-going feed-back to the project team on the needs of current and future users of the piloted telemedicine services. Thus the UAB has to ensure that the interest and needs of the key actors are properly recognised and taken into account throughout the entire lifecycle of the Project. The UAB will also be in a position to observe the clinical trial process and the multi-disciplinary evaluation that the services will go through.

The role and aim of the UAB are defined in the Terms of Reference of the UAB, currently at version 14 (see Appendix A).

The UAB is currently composed of 17 pan-European organisations representing different group of telemedicine users, both direct and indirect users. The composition of the UAB reflects the complexity of user requirements involved in telemedicine (cf. section 3). The full list of UAB Members is included in this document at Appendix B.

The UAB is jointly managed by the European Health Telematics Association (EHTEL) and the European Patients' Forum (EPF) acting as Secretariat of the UAB and members of the RENEWING HeALTH Project Steering Committee.

2.3 Representing Multi-Stakeholder Perspectives

User requirements are very diverse, depending on the type of users, the type of services, and even the status of these services. Furthermore, requirements can be

analysed at different levels (clinical, technical, convenience, cost efficiency …). In the context of the UAB, the most straightforward categorisation is by the type of the users of telemedicine services, since the constituency of the UAB should be representative of those types. Thus, within this project, we assume three main categories of end-users, namely:

- (PIC) Patients and their informal caregivers.
- (HP) Healthcare professionals.
- (HCO) Healthcare organisations, health authorities, and payers.

These categories, i.e. the various perspectives and key concerns, will be considered as one structuring principle for the analysis of user requirements in this deliverable:

Patients' key concern is the improvement of their own health status and quality of life through a better approach to the management of their condition. To this end, they ask for high-quality services and expect the healthcare services to meet their needs and expectations. Only a service that mirrors these needs and expectations will lead to complete patients' satisfaction and ensure acceptance of telemedicine by the wider patient community.

Healthcare professionals' ultimate goal is to provide their patients with high quality and safe healthcare. The technology they use to deliver healthcare plays a key role in this context. Ensuring that the technology is safe and reliable is therefore their primary concern. This becomes even more important in telemedicine where a great deal of routine medical practice is delivered at a distance through ICT. Only a service that reflects the healthcare professionals' working practices and meets their high expectations in terms of patient safety will gain their acceptance.

Indirect users of telemedicine services are equally concerned about user requirements.

Health authorities and healthcare organisations are interested in user requirements because of their ultimate objective to ensure that citizens' and patients' healthcare needs are effectively recognised by the healthcare service so that they are addressed in the most effective and cost-efficient way.

2.4 Objectives

The primary aim of this deliverable is to serve as a reference framework for the representation of user needs and requirements by the RENEWING HeALTH User Advisory Board (UAB). This aim is also supported by the Terms of Reference (ToR) of the UAB.

As such, this deliverable provides a robust structure for the systematisation of user requirements throughout the project, and demonstrates how user requirements can be referenced by the project design.

In addition, this deliverable can also be used by each of the pilot sites as a project-wide reference framework and/or benchmark for the assessment and implementation of user requirements into the piloted services and their evaluation.

As a consequence, later work on user requirements may also result in an update to the Method for the Assessment of Telemedicine Applications (MAST) which targets user requirements within the various components of the assessment process.

While we describe an evolutionary process during the project lifetime, we also foresee that this process will not be closed at the endpoint of the project. By definition, the requirements of the users evolve over time. Thus, this assessment and the respective adaptations and fine-tuning of services are seen as a continuing process. As a consequence, the final deliverable D4.4 results will also have to be dynamic and supportive of a continuous learning process for the evaluation of services.

In the long run, the deliverable can also serve as a starting point for the refinement of user requirements for telemedicine based services outside the project. For this, a refinement will be done through both dialogue within the UAB, and the results of the project (overall evaluation and targeted assessment of user requirements by questionnaires).

2.5   Methodology: how D4.2 was developed

Deliverable 4.2 is the second step in a series of four deliverables. The document was built upon the first exploratory analysis of user requirements based on a literature review whose outcomes were presented in Deliverable 4.1[1].

The user requirement framework presented in Chapter 6 of Deliverable D4.1 was then subject to an on-line consultation with the members of the RENEWING HeALTH User Advisory Board; the aim was to include the results of two rounds of consultations with the members of the User Advisory Board (UAB). The consultation was meant to validate the relevance of the user requirements, to agree on a definition for each of such requirements, and identification of additional requirements as expressed by the various categories of user representatives involved in the UAB. The number of responses corresponds to the limited distribution of the online questionnaires: Six full responses were obtained from the group of healthcare professionals within the RH User Advisory Board, and seven responses (plus one response as outcome of the discussion within the UAB meeting on 30th July 2011) were obtained from the group of carers. Thus the reporting of the results focuses on the qualitative responses; the quantitative results are just given as an informal report.

The next step was to explore and review the outcomes of the online consultation in the two meetings of the UAB organised in Brussels in late August and early December 2011 respectively.

Deliverables D4.3 and D4.4 will reflect the incremental assessment process of user requirements by the RENEWING HeALTH User Advisory Board. D4.3 in particular will integrate the outcomes of a series of meetings that will be organised with local users involved in some RENEWING HeALTH pilot sites to further validate the user requirement framework through a bottom-up approach. The rationale here is to ensure that the user requirement framework, as developed by the WP4 with the input of the UAB, is perceived as relevant by the people who are actually using the telemedicine services offered by RENEWING HeALTH.

The plans for the next revisions of the RENEWING HeALTH Reference Framework for Telemedicine User Requirements are detailed in chapter 7 Next Steps.

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[1]   http://www.renewinghealth.eu/files/RH/Documents/WP/D4.1-v1.0-Renewing-Health-User-Requirements-Ref-Framework.pdf

3. Rationale of eliciting user requirements in telemedicine: a framework for user acceptance

Eliciting and integrating user requirements in the development of any telemedicine service is a rather challenging exercise. But this is an effort worth making if we are to ensure that end users acknowledge the benefit of the final service in responding to their needs, and accept it as a valuable alternative to conventional care. A number of factors present major challenges inherent in the development of any telemedicine service. These include:

- the heterogeneity of user groups, i.e. patients, relatives, informal caregivers, physicians, nurses, but also health technicians, hospital administrators as well as non medical healthcare providers such as social workers;
- the need to carefully explore ethical, legal, organisational and governance aspects involved;
- the inevitable time and financial constraints associated with studying users' needs.

User requirements can be very different even within the same user group. Factors such as user ability, age, education, income, location, motivation, cultural and social background as well as the availability of support networks are important determinants and are associated to different requirements. This diversity is increased by the fact that telemedicine relies heavily on ICT, and this poses important accessibility issues which need to be fully taken into account when designing, developing and deploying telemedicine services.

Evidence has demonstrated that telemedicine development which is driven exclusively by technological imperatives, with poor or no regard to the needs of the people who will actually use the telemedicine service and the organisational and clinical constraints, is likely to fail[2]. Integrating user requirement considerations in designing, developing and implementing telemedicine services is, therefore, a key prerequisite for their effective and successful deployment.

Developing a telemedicine service and/or application can be a very expensive and risky investment, particularly for SMEs. In the pursuit of a good return on investment, telemedicine services' manufacturers' and suppliers' primary concern is that the services they develop ultimately reach a large market. For this to be the case, they need to make sure that the added value of the new service is effectively recognised by those who are eventually going to use it. Otherwise, the chances are that the service's wider uptake will be very modest. Understanding user requirements is therefore a key prerequisite for successful investment in any telemedicine application. Interestingly, evidence shows that research in innovative healthcare technologies often fails to reach the market because of poor assessment of user needs in the design phase. User involvement often takes place only at a very late stage, when the application has already been developed and costs associated with product modification are often very expensive to bear.

Eliciting and integrating user requirements is directly associated with many advantages, such as improved service usability and safety, improved efficiency for users, reduced product recalls and modifications, and last but not least, improved user satisfaction and acceptance of the service. Remarkably, recent research has revealed that user acceptance is, after technology-related aspects, the second most

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[2]   G. C. Doolittle and R.J. Spaulding, *Defining the needs of a telemedicine service*, Journal of Telemedicine and Telecare, 2006; 12: 276-284.

important determinant of the success of a telemedicine application[3]. This suggests that user acceptance is a critical success factor for telemedicine adoption; as such, it is one of the main goals which should be sought in the design, development and implementation of telemedicine services[4]. For the very same reason, lack of acceptance is associated with the failure of many telemedicine applications despite the positive outcomes of the piloting phase.

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[3] T.H.F Broens, R.M Huis in't Veld, M.M.R. Vollenbroek-Hutten, H.J. Hermens, A.T van Halteren, and L.J. M Nieuwenhuis**,** *Determinants of successful telemedicine implementations: a literature study,* Journal of Telemedicine and Telecare, 2007; 13: 303-309.

[4] See also European Commission, *Telemedicine for the benefit of patients, healthcare services and society*, Commission Staff Working Paper sec (2009)943, final June 2009.

4. Rationale of user requirements in the framework of RENEWING HeALTH

4.1 Level of analysis of user requirements

User requirements can be assessed from a variety of different perspectives and at different levels of detail. The focus of this deliverable D4.2 is to provide a robust structure (framework) for the systematisation of requirements and to demonstrate how user requirements can be referenced by the project design.

This task is particularly challenging since RENEWING HeALTH is concerned will the full life cycle of telemedicine-based services, namely: 1) the establishment; 2) the practical use; and 3) the evaluation of telemedicine services. Respecting and integrating the user perspectives into the project "mechanics" thus implies the integration of user needs not only into steps 1) and 2), but also that a sufficient representation of user perspectives is properly integrated into the definition and implementation of the evaluation methodology (MAST).

In addition, the level of complexity (full healthcare service as one entity vs. small service elements) is also a variable for consideration.

4.2 RENEWING HeALTH specific matrix for the representation of user requirements

While there is no doubt that investment in user requirements benefits the developer as well as the user and the healthcare sector as a whole, identifying and effectively integrating these requirements into the development, implementation and evaluation of telemedicine services is a very challenging exercise. In an attempt to bridge the gap between the need to integrate user requirements in telemedicine services and the challenges associated to this process, this document tries to provide a comprehensive framework for user requirements. In order to effectively systematise user requirements, a matrix display was developed. The matrix is meant to be a starting point for an integrative consideration of user requirements on the basis of the three axes:

- Process (Design and Set up vs. Practical use vs. Evaluation/HTA).
- Dimension of analysis based on the multidimensional approach of MAST.
- Perspectives of stakeholders (i.e. patients / informal caregivers, healthcare professionals and health authorities / insurers / payers; see below for further explanation).

Table 2: Matrix in structure and stakeholder view

Process ⟋ Dimension (MAST)	Design / Set-up	Practical Use	Evaluation / HTA
Characteristics of the service, quality and safety	PIC, HP, HCO	PIC, HP	PIC, HP, HCO
Organisational aspects	HP-HCO	HP, HCO	HP, HCO
Health problem and clinical effectiveness	PIC, HP, HCO	PIC, HP**, HCO	PIC*, HP, HCO
Economic aspects	HCO	PIC, HCO	HCO***
Non-health-related user outcomes	PIC, HP, HCO	PIC, HP, HCO	PIC, HP, HCO
Ethical and legal aspects	PIC, HP, HCO	PIC, HP, HCO	PIC, HP, HCO

The structure of the analysis, i.e. chapter 6 of this deliverable on user requirements, follows the plan of the matrix presented above. The letter codes (PIC, HP, HCO) in the matrix represent the three different categories of users which are taken into account by this document:

- PIC: Patients and their informal caregivers.
- HP: Healthcare professionals.
- HCO: Health authorities, healthcare organisations and payers.

The asterisks (**) in the matrix denote some use case examples which explain the principles of the reasoning for the dimensions and cells:

* Health Problem & Evaluation & Patients:
Patients' preferences to be respected for defining the evaluation methods, e.g. assessing his/her subjective symptoms in addition to clinical effectiveness measures such as outcome variables.

** Clinical effectiveness & Practical Use & Health Professional:
Assessing the clinical effectiveness from the viewpoint of the health professional, e.g. that an implanted defibrillation device effectively saves patient lives in cardiac emergencies, and has at the same time a minimum of false alarms to protect patient heart function.

*** Economic aspects & Evaluation / HTA & Health authorities, Healthcare organisations and payers.
Including the cost / quality ratio from the perspective of the payer; positive economic short and/or long term effects, i.e. acquiring new clients and preserve good quality at a reasonable cost for the existing (and new) clients.

As an alternative to the structural text-based display, a dynamic view of the processes has also been developed (see Figure 1 below).
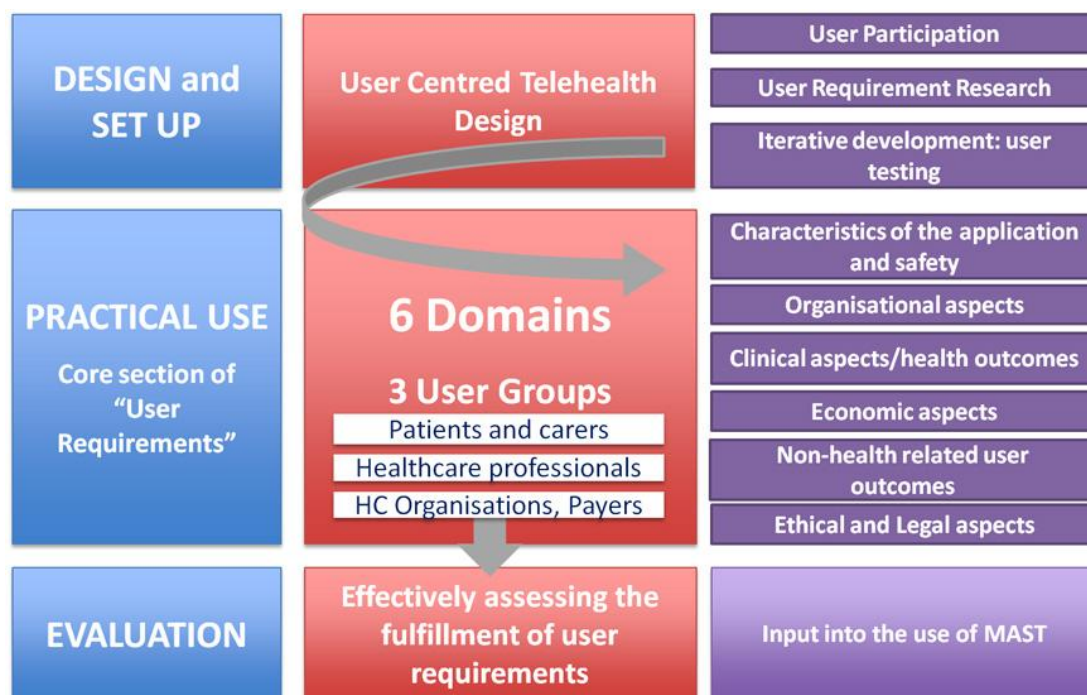
Figure 1: Matrix in a process view

RENEWING HeALTH will not develop new telemedicine services and/or devices, but rather focus on assessing and validating already existing services in nine different European Regions which have been for years at the forefront of the development and integration of telemedicine services into healthcare systems. Thus the emphasis of the RENEWING HeALTH Reference Framework for Telemedicine User Requirements is on requirements for practical use, i.e. the needs, expectations and constraints of end users of telemedicine services when they routinely use telemedicine services and/or applications. As shown in the matrix, these are structured into six domains:

- Characteristics of the application and safety.
- Organisational aspects.
- Clinical aspects and health outcomes.
- Economic aspects.
- Non-health-related user outcomes.
- Ethical and legal aspects.

Given the proximity and complementarity with the MAST assessment methodology, the dimensions guiding this document are closely related to the seven dimensions identified by MAST. For the purpose of the User Requirements Framework they have been reduced to five plus one (non-health-related user outcomes): For practical reasons, the MAST dimensions "clinical aspects" and "health outcomes" have been clustered, likewise for "characteristics of the application" and "quality and safety". Furthermore, the MAST dimension "patient perspective" is not featured in the matrix as elements of patient perspective are integrated into the five dimensions used to capture user requirements.

5. Eliciting User Requirements in the Design and Development of Telemedicine Services

5.1 Introduction

This section focuses on the methods to analyse and integrate user requirements in the design and development of telemedicine services, starting from discussions on methodologies used for eliciting user requirements. It looks specifically at user-centred approach as an alternative to technology-centred approach to telemedicine design and development.

There is an ever-increasing demand from governments and healthcare authorities as well as from agencies funding advanced healthcare technology research, including eHealth and telemedicine, to integrate user requirement assessment into service development processes. This demand is linked to the increased recognition that undertaking user requirement analysis in designing and developing telemedicine services is directly associated with many advantages such as reduced product recalls and modifications, better usability and thus higher user acceptance of and satisfaction with the final service, as well as improved patient safety and quality of care[5]. Research has in fact revealed that inappropriately specified user requirements can lead to unexpected and possibly adverse effects in the healthcare and clinical process[6][7].

The upshot of this is that all actors involved in telemedicine, regardless of whether they are direct (i.e. patients, healthcare professionals) or indirect (healthcare authorities, insurers) users, benefit from accurate user requirement analysis and, therefore, should directly engage with this process.

To better understand the context of requirements, some conclusions can be drawn from available data / statistics which are easily available; others are much more difficult to collect and require additional efforts. Let us take the example of a telemedicine application for patients with diabetes. A great deal of potential users and some of their characteristics which are likely to give rise to user requirements can be easily identified through numerous sources of data / statistics about people with diabetes that may be relevant, e.g. percentage of people with diabetes: around 5% in the UK (source: British Heart Foundation); % of people who have access to the internet at home: 70% of households have access; % of people who have specific kinds of disability; % of people who live alone, etc.

However there are many other questions that can lead to user requirements that are less easy to answer. For example: How many people with diabetes are familiar with technology? What are their attitudes, motivations and preferences regarding their care in general? What benefits / disadvantages would a telemedicine application / service bring to them? What kinds of features and functions would be useful / desirable for the proposed application / service? What information might the users

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[5] J.L. Martin, E. Murphy, J.A. Crowe and B.J. Norris, Capturing user requirements in medical device development: the role of ergonomics, Physiol. Meas. 27 (2006) R49–R62

[6] E. Ammenwerth, N.T. Shaw, Bad health informatics can kill - is evaluation the answer? Methods Inf. Med. 44 (2005) 1–3.

[7] E. Ammenwerth, J. Brender, P. Nykänen, H-U. Prokosch, M. Rigby, J. Talamon, Visions and strategies to improve evaluation of health information services – Reflections and lessons based on the HIS-EVAL Workshop in Innsbruck, International Journal of Medical Informatics, 2004, 73(6): 479-91.

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need, and in what form do they need it? How much flexibility is needed to cope with differences? Is it likely to make a difference to overall outcomes for diabetes sufferers themselves and/or the health services?

In order to be able to answer to these questions and get a thorough insight into what diabetes patients need, engaging directly with diabetes patients right from the outset when designing a telemedicine application, e.g. for daily self-monitoring of blood sugar level, is the only option.

In the following sections, the most often used approaches for the assessment of user requirements, i.e. Technology Acceptance Model (TAM) and User-Centred Design (UCD) are introduced.

Although we have identified three different processes (i.e. design / set up, practical use, evaluation) it is important to bear in mind that user requirements do not differ from one phase to the next. What changes is the approach: to be precise, the way user requirements need to be looked at.

Hence, for user requirements to be effectively reflected in the practical use phase, they need to be captured at the design and set-up phase, i.e. when the respective telemedicine service and/or application is designed, developed, tested, piloted and eventually set up.

Vice versa, if user requirements have been either poorly or not at all captured / integrated at the design stage, it is highly likely that the telemedicine service and/or application will not be aligned with the needs of the people who will eventually use it.

Given the importance of the design phase, the User-Centred Design methodologies will be discussed in particular.

5.2   Technology Acceptance Model (TAM)

The so-called Technology Acceptance Model (TAM) was developed by technology and ICT research in mid-1980s in order to explain and/or predict user acceptance of ICT services[8]. TAM is used to provide an explanation of the determinants of technology acceptance. According to Davis, the model suggests that when users are presented with a new technology, a number of factors influence their decision about how and when they will use it[9]. These factors can be categorised into two main groups:

- **Perceived usefulness** (PU): This is defined as the degree to which "a person believes that using a particular service would enhance his or her performance".
- **Perceived ease-of-use** (PEOU): Davis defined this as "the degree to which a person believes that using a particular service would be free from effort".

Over the last two decades, TAM has been used as the theoretical framework for many empirical studies of user technology acceptance / adoption in various fields,

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[8]   F.D. Davis. *A technology acceptance model for empirically testing new end-user information services: theory and result,* PhD dissertation, Sloan School of Management, Massachusetts Institute of Technology, 1986.

[9]   F.D. Davis, *Perceived usefulness, perceived ease of use, and user acceptance of information technology*, MIS Quarterly, 1989; 13: 319-340.

including healthcare, and looking at different categories of users[10]. Further studies in the 1990s have expanded the TAM approach to include subjective norms and perceived behavioural control indicators. On the basis of existing literature, Holden and Karsh have provided a definition of these two additional TAM domains applied to the clinician end user of health ICT[11]:

- **Subjective norm** (SN), or social influence, was consistently defined with respect to the opinions of important others about an individual's use of health ICT.
- **Perceived behavioural control** (PBC), or facilitating conditions, was defined variously as perceptions of existing (a) infrastructure, (b) internal and external resource constraints, or (c) skills, resources, and opportunities necessary to use the service.

Telemedicine is a particular ICT-intensive field involving different user groups and different applications, which in most cases have a strong impact on existing organisational contexts, and may interfere significantly with traditional practice routines. This means that, on the one hand, different analysis is needed for each end-user group and, on the other, that a number of additional dimensions, e.g. organisational, clinical as well as health-related factors, need to be integrated in designing a framework for user technology acceptance. Legal and ethical aspects play an equally important role in this context.

The objective of this document is not to develop a TAM framework for telemedicine. Instead, through relevant literature review, this work will try to gather concrete knowledge of the key determinants of user acceptance of telemedicine from which to derive a set of user requirements for each group of end users. The rationale of such an approach is that to be able to positively influence the determinants affecting user acceptance and thus maximise users' intention and willingness to use telemedicine as an alternative of conventional care, the whole set of user requirements needs to be fulfilled.

5.3   User-Centred Design (UCD) approaches

In this section we present the User Centred Design (UCD) as an approach which enables the elicitation and integration of user requirements in the early design of telemedicine services and applications.

For the purpose of this document, User-Centred Design (UCD) is defined as a process whereby end users' needs, preferences, expectations, and constraints are given extensive attention at each stage of the design process. In doing so, UCD should enable an effective partnership between service developers and the various groups of end users, to ensure that procedures and decisions about the service at stake are made respecting users' needs and preferences.

UCD methodologies are based upon the three core elements of: user participation, user research, and iterative development. Specific issues remain, however, to the set-up phase: how can the user be effectively empowered to participate in this phase.

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[10] For an overview of TAM in healthcare ICT see P.J. Hu, P.Y.K. Chau, O.R. Liu Sheng and K. Yan TAM, Examining the Technology Acceptance Model Using Physician Acceptance of Telemedicine Technology, Journal of Management Information Services, 1999; 16: 91-112.

[11] R.J. Holden and B.T. Karsh, *The Technology Acceptance Model: Its past and its future in health care*, Journal of Biomedical Informatics, 2010; 43: 159-172

The same applies to the evaluation stage. User requirements are the same at this stage, but the challenge from a user perspective is to make sure that the evaluation process is capable of measuring effectively the extent to which the user requirements have been taken care of. Evaluation-related issues will therefore be integrated throughout this document, with a view to ensuring that identified user requirements will actually be assessed during the evaluation process.

The process of capturing, measuring and fulfilling user requirements in the early development of a new service / application is one of the key elements of the UCD approach. UCD methodologies build upon theories of social construction of technology (SCOT) developed in the 1960s and revisited in the 1980s. Based upon the assumption that technology and society are mutually dependent, SCOT theories argue that technology does not determine human action, but that rather, human action shapes technology[12].

UCD methodologies focus on end-users through the planning, design and development of a product / service and see technology design as an iterative process whereby a product is designed, modified, and tested repeatedly in an attempt to deliver a product that matches to the largest possible extent the needs of the users – including age-related factors - and the restrictions of the context of use.

UCD is a multi-stage problem solving approach that not only requires designers to analyse and foresee how users are likely to use a service, but to test the validity of their assumptions with regards to user behaviour in real settings with actual users.

UCD ultimately means that people who are going to use what is being developed are put at the centre of the design process.

Analysis of UCD processes in service development is not provided here as it is beyond the scope of this document. What is relevant to the present analysis is that there are four UCD activities that need to start at the earliest stages of an ICT-intensive service development. These are:

1. **Specify the context of use.** Identify the people who will use the product, what they will use it for, and under what conditions they will use it.

2. **Specify requirements.** Identify any business requirements or user goals that must be met for the product to be successful.

3. **Create design solutions.** This part of the process may be done in stages, building from a rough concept to a complete design

4. **Evaluate designs.** The most important part of this process is that evaluation, ideally through usability testing with actual users, is undertaken from the product's very first inception continuously throughout its design, development as well as implementation phase.

The process ends - and the product can be released - once the requirements are fully met.

There is an international standard that is the basis for many UCD methodologies. This standard, ISO 13407 (Human-centred process, 1999), describes UCD as an iterative approach to interactive service development whereby human-centred activities are included throughout a development life-cycle in order to make the service usable and aligned to end users' needs.

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[12] W.E. Bijker, T.P. Hughes, T.J. Pinch, The Social Construction of Technological Services: New Directions in the Sociology and History of Technology, MIT Press, Cambridge, 1989
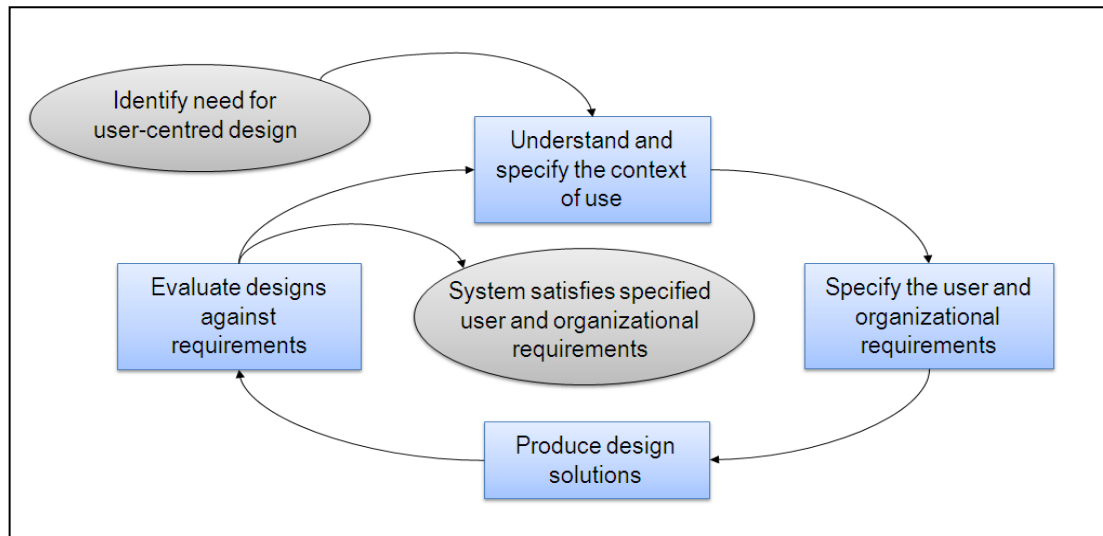
Figure 2: Iterative process of User-Centred Design

The iterative nature of these activities requires that in developing successful applications, the designer needs to have a thorough and accurate understanding of who the potential users are, how they behave, and what they actually need. This process, usually referred to as "eliciting user requirements", requires that legal, cultural, sociological, financial and other local factors also be taken into account, as they are deemed to influence and shape the needs and demands of users[13].

Given the strong implications of telemedicine for all end-users, involving them in the design and validation of new services and applications is a critical factor for ensuring their final success. User participation is a key feature of UCD. Through early focus on users, continuous testing and real user participation, telemedicine users can influence the design, and developers can gain knowledge about user needs and interests, which they may not have been thinking of / taking into account from the very early stages of the development process[14]. Through end-user participation, user satisfaction and user acceptability levels are improved, leading to a higher use and less failures in technological design[15]. As a result, a user-centred approach in telemedicine has the potential to improve the sustainability beyond the initial pilot stage[16].

While there is no widely-accepted UCD standard methodology or similar in telemedicine, our literature review identified various methodological models which have been developed to incorporate user perspectives in the design and development process of specific telemedicine services and applications. Such models cover various areas such as telehome care for patients suffering from diabetes, multiple sclerosis, COPD, heart failure[17], telemonitoring technologies for

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[13] B. Kaplan, Evaluating informatics applications—some alternative approaches: theory, social inter-actionism, and call for methodological pluralism, International Journal of Medical Informatics 64 (2001) 39–56.

[14] J. Karlsen, J. Andersen, L. Birkely, E. Oedegaard, An empirical study of critical success factors in IT projects, Int. J. Med. 3 (2006) 297–311

[15] S. De Rouck, A. Jacobs, M. Leys, A methodology for shifting the focus of e-health support design onto user needs A case in the homecare field, international journal of medical informatics, 77 (2008) 589–601

[16] P.E. Esser and R.H.M. Gossens, A framework for the design of user-centred teleconsulting ser-vices, Journal of Telemedicine and Telecare, 2009; 15: 32-39.

[17] Cfr above

elderly patients[18], tele-cardiology[19], paediatric cardiology telemedicine services[20], medical imaging applications[21], and development of internet intervention for patients with heart disease[22]. A general framework for the design of user-centred teleconsulting services was recently developed[23].

In terms of methodology, the processes and techniques for eliciting and integrating user requirements in a telemedicine setting do not differ too much from methodologies and practices used more generally for the development of any medical device.

In order to elicit user requirements, UCD relies on different methods. Among these, **exploratory methods** are often used to elicit user requirements by identifying unmet or poorly met needs. Exploratory approaches usually rely upon open-ended qualitative methods. One of the most common exploratory methods is **ethnography**. This is a method whereby researchers spend a period of time studying users within their work and/or home environment, observing their behaviour, the interactions between users, as well as between users and technology. Another method is **contextual inquiry** (CI), which consists of short, targeted observations and interviews with the end-users. It is relevant to remark that no matter which method is used, when it comes to eliciting user requirements, it is extremely important to contextualise technologies under study. This requires first and foremost testing the technology in the actual environment where it will eventually be used[24]. This also requires paying particular attention to organisational issues, an important component of healthcare professionals' requirements.

The integration of elicited user requirements is usually done by either writing **use cases**[25] or identifying **scenarios of use**[26]. Use cases are a special sequence of transactions, performed by a user and a service in dialogue, and are carried out as part of UCD to continuously evaluate a telemedicine application by testing it on the various end-users. A scenario is a concrete description of the sequence of actions that actors do, things that happens to them and changes in the circumstances of the

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[18] R.G. Curry, M.T. Tinoco, and D. Wardle, *The Use of Information and Communication (ICT) to Support Independent Living for Older and Disabled People*, October 2002, available at http://www.rehabtool.com/forum/discussions/ictuk02.pdf

[19] E.V.P Rodríguez, I. Martínez Ruiz, A. Alesanco Iglesias, J. García Moros and F. Saigí Rubió, *Organizational, Contextual and User-Centered Design in e-Health: Application in the Area of Telecardiology* , Lecture Notes in Computer Science, 2007, Volume 4799/2007, 69-82

[20] G. Weatherburn, The design of specialist paediatric cardiology telemedicine services to meet the needs of patients, Journal of Telemedicine and Telecare 2010;**16**:211-214

[21] C. Chen, J. Abdelnour-Nocera, S. Wells, N. Pan, *Usability Practice in Medical Imaging Application Development,* Proceedings of the 5th Symposium of the Workgroup Human-Computer Interaction and Usability Engineering of the Austrian Computer Society on HCI and Usability for e-Inclusion 2009, Linz, November 09 - 10, 2009

[22] **C**. Kerr, E. Murray, J. Burns, I. Turner, M. A. Westwood, C. MacAdam, I. Nazareth and D. Patterson, *Applying user-generated quality criteria to develop an Internet intervention for patients with heart disease*, Journal of Telemedicine and Telecare, 2008;**14**:124-127.

[23] P.E. Esser and R.H.M. Goossens, *A framework for the design of user-centred teleconsulting services*, Journal of Telemedicine and Telecare 2009;**15**:32-39.

[24] D. Hindus. (1999). The Importance of Homes in Technology Research. In Streitz, N., Siegel, J. Hartkopf, V., Konomi, S. (Eds.), Cooperative Buildings – Integrating Information, Organizations, and Architecture. Proc CoBuild'99, October, 1999

[25] I. Jacobson, Object-oriented Software Engineering: A Use Case Driven Approach, Adison Wesley, s.l., 1992.

[26] Carroll J. M. (2000). Making Use: Scenario-based design of human-computer interactions 45-70: Scenario-Based Design. MIT Press, Cambridge MA.

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setting[27] [28]. PACT (People, Activity, Context, Technology), is a scenario-based approach used to integrate the requirements of users using a technology in daily life. Use cases and scenarios are the source documents used as a framework for discussions with the technology developers to set priorities for functionalities.

Based on its prevalence in the existing literature on early user requirements assessment for telemedicine services and its practical usefulness, User-Centred Design (UCD) has been hereby identified as the most valuable method enabling the thorough integration of users' requirements in the development of telemedicine services and applications.

As RENEWING HeALTH is about evaluating existing telemedicine services and not about designing and setting up new services, the recommendation in favour of the use and adoption of UCD is not meant to provide guidance to the implementation of this specific project. Instead it is meant to inform future projects and, more generally, future telemedicine developments with a view to ensuring that these are aligned to the maximum extent possible to the real needs of the users.

To provide the reader with a more concrete insight into how UCD works, the following section shows how the use of UCD can ensure that telemedicine services and applications can be designed and implemented in keeping with the needs, expectations and constraints of telemedicine users. To that end, in the following section, the usability and user confidence frameworks are presented and analysed.

5.4   Exemplifying the UCD approach for telemedicine: usability and User Confidence frameworks

As described in the previous section, the concept of user research in UCD is used to refer to a process and associated activities that aim at understanding the impact of design on the targeted users in order to produce a usable product, which is functional, efficient, desirable and acceptable to its intended audience[29].

One of the key goals of adopting UCD is therefore to ensure high user acceptance of the service / application developed. One of the most important elements which need to be explored through UCD is to enhance user acceptance by ensuring that the characteristics of the service / application being developed are effectively aligned with the actual needs of users. Two major macro-factors associated with the characteristics of the application have been identified in the literature. These are **usability** and **user confidence**[30]. The first factor deals mostly with the type of service / application concerned, and the way this is adapted to fit the needs of the various user groups; whereas the second factor relates more to users' cognitive perception of the application and their (perceived) ability to use and interact with it.

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[27]   J. Bergsten, Scenarios in services design—catalysts for communication and reflection, unpublished work, Blekinge Tekniska Hogskola, 2003
http://www.cs.chalmers.se/idc/ituniv/student/2003/portfolior/it3bejo/public html/publicerat/scenarios.pdf

[28]   K. Go, J.M. Carroll, Five reasons for scenario-based design. Interacting with Computers, 2000; 13:43-60.

[29]   Kuniavsky, M. (2003) Observing the User Experience: A Practitioner's Guide to User Research. San Francisco, Morgan Kaufmann, USA, pg. 3 and 18.

[30]   Lun KC. New user interfaces International Journal of Biomedical Computing 1995;39:147-150. [PubMed]

If UCD is applied at the design and development stages, usability should be maximised; while constraints associated with user competence and confidence should be thoroughly considered and integrated in the final service / application.

User Requirements 1   Usability

According to ISO 9241, usability is the extent to which a service can be used by specific users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use. Usability measures how well, and in what way, the service assists the user in achieving his or her task in the specific context of use. Most telemedicine services/applications are used by different user groups, and not just by one group, as it is the case for other medical or surgery devices which are used exclusively by clinicians. This means that for a product to achieve optimal usability it is necessary to have a thorough understanding of the context of use, also called usability framework. According to the ISO definition, in fact, usability relates to a set of specific circumstances that are described as the elements of context of use: users, tasks, equipment, and the physical and social environments in which a product is used or is intended to be used.

Usability has multiple components and is traditionally associated with five usability attributes, namely: **effectiveness** (utility), **efficiency**, **user-friendliness**, **learnability**, and **reliability**. These are all sub-requirements of usability. All these usability attributes, which are derived from the ISO definition of usability reported above, need to be fulfilled for optimal usability to be achieved.

Ensuring that the usability framework is fully integrated in a telemedicine service / application is therefore the first key requirement for all those using and/or interacting with a telemedicine service.

User Requirements 2   Effectiveness

Effectiveness (utility), sometimes referred to as usefulness, refers to the ability of a service to perform the task(s) for which it was originally conceived. Accordingly, a telemedicine user would expect that a specific service / application allows him / her to effectively perform actions and tasks, the accomplishment of which is the reason he/she decided to use the service / application.

User Requirements 3   Efficiency

Efficiency is achieved when the service brings about improvement in terms of the time needed to perform a task. Efficiency is translated into improved productivity in performing tasks for professional users, and reduced time needed to carry out activities related to the management of the condition for patients and carers.

User Requirements 4   User-friendliness

User-friendliness is achieved when the service is easy to use by all end users. This means, for instance, that interfaces need to be intuitive and promote exploratory learning, and not provoke in the users fear of making irreversible errors, which results in user stress and anxiety[31]. Bad, non user-friendly ergonomic design of telemedicine applications is strongly correlated with higher human factor errors, and thus poorer patient safety standards. Human factors is a particular branch of engineering which, by focusing on service usability and designing service interfaces,

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[31] C.M. Johnson, T.R. Johnson, J. Zhang, *A user-centered framework for redesigning health care interfaces*, Journal of Biomedical Informatics 2005; 38: 75–87

aims at ensuring the optimisation of users' ability to accomplish their tasks error-free in a reasonable time and, therefore, to accept the service as a useful tool[32]. The addition of non-professional users to the pool of telemedicine users can potentially magnify the human errors that sometimes do occur. A key safety requirement is therefore the optimisation of the user's ability to accomplish his/her tasks error-free in a reasonable time through developing usable design and user-friendly interfaces.

User Requirements 5   Learnability

Learnability is achieved when the tasks to be performed within the service are easy to understand, memorise and remember for all end users.

User Requirements 6   Reliability

Reliability, sometimes also referred to as dependability, is commonly defined as the probability that a device, service, or process will perform its prescribed task without failure for a given time when operated correctly in a specified environment. The concept of reliability in telemedicine is often associated with the concepts of accuracy and safety. To engender users' acceptance, telemedicine services / applications must not be a less reliable method for clinical decision-making than conventional face-to-face methods.

User Requirements 7   User Confidence

For usability attributes to be effectively applied and integrated into telemedicine design, they need to be measured in terms of how they are perceived by the users. User competence and confidence are complementary attributes which are used to assess users' perceived usability of a telemedicine service.

While the requirements associated with the usability framework deal with the characteristics of the service / application and the way they have been designed to match users' needs and ensure safety, user confidence refers to users' cognitive perception of the application, his/her knowledge and ability to use and interact with it, as well as the user's ability to apply such knowledge and skills in an effective and safe way. Understanding how to assess the competence and confidence of users is critical in maximising the effectiveness of any ICT application use.

User confidence is a major determinant of user acceptability; in turn it is determined by several other requirements which are presented later in this document. For the purpose of this deliverable, the meaning of user confidence is:

- the extent to which a user of telemedicine feels confident when using and interacting with the service / application;
- the extent to which a user of telemedicine feels confident about his/her capabilities of using the service / application;
- the extent to which users of telemedicine feel confident about each other's capability of using the service / application, e.g. a physician's confidence in a nurse's of using a telemedicine application to transmit patient's vital signs properly, or a patient's confidence in his doctor's familiarity / capability with the telemedicine application being used.

An effective assessment of target user confidence level is already needed during the service development stage. Competence and confidence are key variables

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[32] Human Factors and the Future of Telemedicine, Medical Device & Diagnostic Industry Magazine, June 1999, http://www.mddionline.com/article/human-factors-and-future-telemedicine

influencing the acceptance of a telemedicine service. This requires paying attention to issues such as a user's readiness and adaptability to new technologies, as well as intellectual and cognitive capacity. Users' abilities to assimilate a new technology and becomes familiar with its operations vary considerably. Some might need intense training, while some others may not. Some users with functional or age-related limitations may not be able to achieve sufficient competence and acceptance levels. As age is one of the main factors behind the increase of chronic diseases in Europe, making a proper assessment of user competence and confidence is extremely important when designing telemedicine services / applications.

To achieve high usability standards, strengthening of user's competence and confidence is also needed. In order to strengthen users' competence and confidence, targeted user training should be performed and patient-doctor communication strengthened.

The three dimensions of user confidence are further discussed below.

User Requirement 7.1   User Confidence in the service measures the extent to which a user feels confident in the performance of a given telemedicine service / application. Confidence in telemedicine is determined by a number of factors such as effective privacy and data security protection, and maximising diagnostic accuracy, to mention a few. In order for this requirement to be fulfilled, therefore, it is necessary that a wide range of other requirements are also fulfilled.

User Requirement 7.2   User Confidence in his/her ability to use the service measures the extent to which a user of telemedicine feels confident in having the necessary skills to use and interact with the service. Some authors conceptualise user confidence in terms of self-efficacy as the judgment of one's capability to use the service[33].

There are important elements associated with user competence that need to be taken into account before establishing a telemedicine service, especially the actions which need to be taken in order to ensure that users of such services have the knowledge and skills required to enable them to make a safe and responsible use of the service.

The following steps appear to be important in this respect:
- identify the required skills and knowledge needed to use the service;
- identify the required training competencies;
- deliver a 'hands on' training programme based on the required training competencies;
- back up the training programme with an instruction booklet;
- measure the level of user competence at the end of the programme;
- follow up to ensure that users are using the service properly and skills are kept up to date through regular practice and further training if needed.

In a study aimed to evaluate user satisfaction and the effectiveness of training, it was found that high levels of satisfaction were obtained, but the level of user

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[33]   M. Rahimpour, Developing a model for patients' acceptance of home telecare, Master dissertation, Graduate School of Biomedical Engineering, University of New South Wales, Australia, 2006

competence reached 100% only when training was supported by a training manual and at least weekly practice[34].

To the best of our knowledge, there is limited literature on user competence despite the fact that this area and in particular user training is extremely important in achieving high safety standards and acceptability levels.

As this issue is also extremely important from an ethical perspective, it will be further discussed in the ethical and legal requirement section.

User requirement 7.3   Users' confidence in other users' capability to use the service*:* The third dimension of user confidence is usually far less explored, despite the fact that it is an important determinant of users' cognitive perception of a telemedicine service, and as such a key driving force behind user acceptability.

In order to accept a telemedicine service, a user would need to feel confident about the effective capability of other users he/she is interacting with within the same service, to use it properly and ensure the highest standards of safety and quality. It is clear that this dimension of user confidence also raises important ethical issues. A user, whether a patient or healthcare professional, should not be obliged to use telemedicine if he/she is not certain that the other users feel comfortable performing tasks within the same service, as this might not only severely hinder safety and quality of care, but also undermine mutual trust among different user groups.

As the patient-doctor relationship changes dramatically with the use of telemedicine services, with a great deal of communication taking place remotely in a depersonalised manner, it is fundamental that both patients and healthcare professionals trust each other. A key determinant for achieving trust is certainly patients' and doctors' perception of each other having the necessary competence to use the service.

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[34] Brebner EM, et al The importance of setting and evaluating standards of telemedicine training. J Telemed Telecare. 2003;9 Suppl 1:S7-9.

6. Relevant needs and requirements of the three user groups in RENEWING HeALTH

This section focuses on the operational phase of the service and provides a detailed overview of user requirements for each of the stated groups of end users, i.e. receivers (patients and their informal caregivers), providers (healthcare professionals) and payers (healthcare authorities and payers). User requirements are presented according to a set of critical domains which have relevance to any telemedicine service:

- a) characteristics of the service/application;
- b) organisational aspects;
- c) clinical and health related aspects;
- d) users' outcomes;
- e) economic aspects; and
- f) legal and ethical aspects.

Practical examples of how these requirements work in practice are provided in relation to some telemedicine services used for the managing and monitoring of patients suffering from the three disease areas covered by the RENEWING HeALTH project, i.e. Diabetes, Chronic Obstructive Pulmonary Disease (COPD) and Cardiovascular Diseases (CVD).

In line with the Matrix (see section 4.2), health related user requirements have been clustered in seven major areas, each presenting the perspective of the three groups of users.

6.1 Characteristics of the service / application

6.1.1 Patients' and informal carers' perspective

The addition of "non-professionals" to the ranks of the users amplifies significantly the role of human factors in facilitating interaction in telemedicine areas. This large audience is on average less educated and less sophisticated than practitioners and includes a wide range of capabilities and limitations. These capabilities and limitations need to be formulated in terms of requirements. When it comes to understanding the requirements of patients and informal carers, it is important to recognise that patients are not a homogenous group of users. As individuals, patients have different needs and preferences as well as different approaches to and experience with the disease. For the very same reason, particular attention needs to be paid when developing services for the elderly or for other patient groups with functional limitations, in order to counteract opposition due to the technological inexperience or constraints of these particular target groups[35].

Building upon the usability and user confidence framework outlined in the previous section, this section presents an overview of the requirements of patients and informal carers associated with the characteristics of the application.

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[35] P.C. Kuszler "Telemedicine and Integrated Health Care Delivery: Compounding Malpractice Liability", http://www.aslme.org/pub_ajlm/25.2_3b.php, American Journal of Law & Medicine, 25, nos. 2&3 (1999): 297-326

Patient Requirements 1   Usability thanks to a patient-centred approach

Definition of the requirement

Patient-centred services / applications are defined as services / applications that enable a partnership among practitioners, patients, and their informal caregivers (when appropriate) to ensure that procedures and decisions are made respecting patients' needs and preferences.

Patients and their informal caregivers would, therefore, expect that the telemedicine service / application is designed in a user-friendly manner, e.g. by paying thorough attention to ergonomic features, and taking into account important elements such as user-friendliness, comfort, aesthetics, portability and navigability.

Explanation of the requirement

A patient would expect that a telemedicine service / application is designed and developed in a way that is as patient-centred as possible. While there are many definitions of "patient-centeredness" in healthcare and telemedicine literature, for the purpose of this deliverable, patient-centred services are defined as services that enable a partnership among practitioners, patients, and their informal caregivers (when appropriate) to ensure that procedures and decisions are made respecting patients' needs and preferences[36].

Patients and their informal caregivers will be more willing to accept a telemedicine service if they know this has been developed putting the actual needs and requirements of end users at the centre of the process, possibly right from the outset. Hence, the notion of patient-centred design, i.e. the process whereby needs, preferences, expectations, and limitations of end-users of a given service are given extensive attention at each stage of the design process (as presented in section 5.3), is key to fulfilling this requirement. Although patient-centred design may entail lengthy and costly procedures, there are obviously important advantages associated with it, such as helping the designer keep the technology flexible by focusing on the tools and functions desired by the patients, and determine which tasks a patient would like to perform him/herself and those he/she would prefer the technology do for them[37].

Usability is particularly important in case of impairments (dexterity, sight, hearing, cognitive, etc.); it should be considered as something that can evolve: many chronic conditions progress over time, and it is essential to ensure that the telemedicine services / applications are sufficiently flexible to accounts for these changes, thereby ensuring they will be still usable.

Fulfilling usability requirements directly affects patient willingness to use a service / application. This can in turn also increase patients' eagerness to follow a specific treatment regime, particularly when dealing with self-administered devices.

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[36] G. Demiris, L.B. Afrin, S. Speedie, K.L. Courtney, M. Sondhi, V. Vimarlund, C. Lovis, W. Goossen, and C. Lynch, *Patient-centred Applications: Use of Information Technology to Promote Disease Management and Wellness. A White Paper by the AMIA Knowledge in Motion Working Group*, Journal of American Medical Informatics Association, 2008; 15: 8–13.

[37] R. Morales, G. Casper, P.F. Brennan, *Patient-centred Design: the Potential of User-centred Design in Personal Health Records*, Journal of AHIMA, 2007; 78: 44-46

Patient Requirements 2   User-friendliness

Definition of the requirement

This means ensuring that the telemedicine service / application is designed and implemented in a user-friendly manner by paying thorough attention to ergonomic features of the service, and taking into account important elements such as comfort, aesthetics, portability and navigability.

Explanation of the requirement

In setting up the usability framework for patients, it is important to take into considerations various factors such as care dependency, mobility, cognitive level, other disease-specific limitations, as well as language, and the patterns by which these factors may change over time. These are all critical factors to be taken into account to maximise patient safety.

According to the Unified Theory of User Acceptance of Technology (UTAUT), factors such as gender, socio-economic conditions and social influence are also variables influencing the usage of a technology[38]. Legal, cultural, sociological, financial as well as local factors can also influence the needs and demands of users[39], and therefore patients too.

Special design considerations should apply when developing telemedicine systems for elderly patients, as well as for patients with functional impairments. When interacting with the system, elderly patients do have needs different from other users, because of age-related changes in perceptual, motor and cognitive abilities, as well as lower familiarity with technology-intense applications. Empirical studies on portable applications for diabetes management showed that older users tend on average to make more errors, require more time between interactions, and are less effective in solving the tasks at hand[40].

Not taking into consideration the specific needs of these user groups could also raise important ethical issues, as there might be a risk that these people will be left out of the opportunities presented by future telemedicine developments, thereby leading to increasing health inequalities in terms of access to quality healthcare.

Fulfilling usability-related requirements can directly affect patient willingness and eagerness to follow a specific treatment regime, particularly when dealing with self-administered devices. According to the Technology Acceptance Model (TAM), there is a positive relation between usability and compliance with the telehealth intervention (adherence from a healthcare professional perspective). According to TAM, users rationally choose not to comply when the usability barriers are perceived as outweighing the expected benefits[41]. This has been confirmed by empirical

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[38]   V. Venkatesh, *User acceptance of information technology: towards a unified view*, MIS Quartely 2003; 27: 425-78.

[39]   B. Kaplan, Evaluating informatics applications—some alternative approaches: theory, social inter-actionism, and call for methodological pluralism, Int. J. Med. Inform. 64 (2001) 39–56.

[40]   A.C. Valdez, M. Ziefle, A. Horstmann, D. Herding, U. Schroeder, Task Performance in Mobile and Ambient Interfaces. Does Size Matter for Usability of Electronic Diabetes Assistants?

[41]   F.D. Davies Perceived usefulness, perceived ease of use and user acceptance of information technology, MIS Quartely, 1989; 13:210-15.

research which has also demonstrated that compliance with the telehealth intervention is in turn directly associated with higher clinical outcomes[42].

Patient Requirements 3   Reduced anxiety

Definition of the requirement

Anxiety can be defined as a negative psychological reaction that impedes a positive adaptation to and creative use of a telemedicine service / application. Patients and informal caregivers would therefore expect that the use of telemedicine services / applications is not associated with negatively psychological reactions such as anxiety.

Explanation of the requirement

A study on home telecare looked into the psychological attitudes of patients using a telecare application. The study interestingly revealed that not only do some patients felt anxious when using the system, but also when just thinking about using it. Some patients perceived the system as a computer and expressed their computer anxiety, despite being informed they did not need any computer knowledge to use it[43].

A patient would expect that the telemedicine service / application does not make him/her feel anxious either because of poor confidence in the system, or his/her ability to use it (see below, "Patient Confidence"), or because of his/her lack of readiness and/or willingness to take up additional responsibilities for the management of his/her condition.

Likewise, informal caregivers looking after the patient would expect that they will not feel anxious not only when using the system, but also when thinking of the patient using the system, because of a perceived patient's lack of confidence in or competence with using it.

Patient Requirements 4   Learnability

Definition of the requirement

Learnability refers of the ability to easily memorise and remember tasks to be performed within the telemedicine service / application. Patients and informal caregivers would, therefore, expect that telemedicine services / applications be easy to learn, and the tasks to be performed within the latter are easy to memorise.

Explanation of the requirement

This requirement is particularly relevant for older patients or patients with sensorial or mental impairments. They would expect to use a system whose functionalities are not only clearly understandable, but also developed in such a way that they are effortless to remember and hence to explain to other people when necessary, e.g. in case of emergency, acute illness, as well as the profound changes in sensory, physical, psychomotor and cognitive functioning over the life span of a patient[44].

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[42] R.M.H.A. Huis in 't Veld, S.M. Kosterink, T. Barbe, A. Lindegard, T. Marecek, and M.M.R. Vollenbroek-Hutten, *relation between patient satisfaction, compliance and the clinical benefit of teletreatment application for cronic pain, Journal of Telemedicine and Telecare,* 2010, 16:322-328.

[43] M. Rahimpoura, N. H. Lovell, B.G. Celler, J. McCormick, *Patients' perceptions of a home telecare system*, International Journal of Medical Informatics, 2008; 77: 486–498.

[44] Craik, F.I. and Salthouse, T.A., Handbook of Agingand Cognition. Hillsdale, N.J., Lawrence Erlbaum (1992)

Thus, learnability needs also to account for older patients' lowering performance when performing tasks within the systems.

Learnability is a key requirement also for people who do not use the application repeatedly, such as informal carers who may visit the patient only a few times per week, and for a limited time; sometimes they may need to assist the patient performing a particular task within the system.

Patient Requirements 5   Patient confidence

Definition of the requirement

Patients and informal caregivers need to feel fully confident when using a telemedicine service / application.

Explanation of the requirement

Patient confidence is a multidimensional concept that reflects the different factors underlying and maintaining the perception of the telemedicine service. This entails confidence in the service itself, in their ability to use and interact with the service, but also in the ability of health professionals to use and perform tasks within the service effectively.

Patient Requirements 6   Patient Sub-requirements 5.1: Patient confidence in the system

Definition of the requirement

Patients and informal caregivers need to be fully confident in the telemedicine service / application they are using. This entails being sure that the system itself is reliable, ensures data integrity, and is not subject to frequent technical failures.

Explanation of the requirement

Studies have confirmed that system reliability is a key concern from the patient viewpoint[45]. This means that the patient has to be reassured and feel confident about the reliability of measurements taken by the machine, and that data integrity is ensured when data are transmitted to the doctor so that he/she can derive accurate interpretations and make informed decisions afterwards. On the other hand, the patient needs to be assured that the system itself is reliable and is not subject to frequent technical failures. More importantly, patients need to be well aware of what to do if something goes wrong, and how to cope efficiently with unexpected technical failures. Those are all important factors affecting patient's trust in the system, which is a key determinant of patient acceptance.

Patient Requirements 7   Patient Sub-requirements 5.2: Patient confidence in using the service

Definition of the requirement

A patient should feel confident not only in the system, but also, and perhaps more importantly, in his/her capability of interacting with it and performing a variety of tasks or operations without anxiety and stress. This means that the patient needs to know exactly not only how to perform the various tasks from the easiest ones to

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[45] M. Rahimpoura, N.H. Lovell, B.G. Celler, J. McCormick, *Patients' perceptions of a home telecare system*, International Journal of Medical Informatics 2008; 77:486–498

those involving different levels of complexity, but also what to do in case of technical failures (e.g. who to contact, etc.).

Explanation of the requirement

This is a very important requirement to be taken into account at all stages, from designing to deploying a telemedicine service.

Competence and confidence are key variables influencing the acceptance of a telemedicine service. This requires paying attention to issues such as a patient's readiness and adaptability to new technologies, as well as intellectual and cognitive capacity, and how these evolve over time. Patient's ability to assimilate a new technology, and become familiar with its operations, vary considerably. Some might need intense training, while some others may not. Some users with functional or age-related limitations may not be able to achieve sufficient competence and acceptance levels. As age is one of the main factors behind the increase of chronic diseases in Europe, making a proper assessment of user competence and confidence is extremely important when designing telemedicine services / applications.

Patient Requirements 8 Patient Sub-requirement 5.3: Patient confidence in health professionals' using the service

Definition of the requirement

To accept a telemedicine service, a patient needs to be fully confident of the ability of healthcare professionals to know how to use the service, and provide high-quality care to him/her though telemedicine.

Explanation of the requirement

As mentioned in Chapter 5, one of the major factors underlying and maintaining patient confidence is the patient's perception of healthcare professionals' confidence in using the system.

A patient would certainly not accept his/her physician using a telemedicine service / application to provide healthcare to him/her for which the physician does not have the knowledge and skills required. What is at stake here is not whether or not is the healthcare professional is actually equipped with the knowledge and skills needed to use the system, but whether and to what degree the patient perceives that the healthcare professional has such skills, and an adequate level of confidence required to perform operations within the system.

Building and maintaining high confidence in both patients and informal caregivers in telemedicine therefore requires reassuring them, to the maximum possible extent, of professionals' competence of and confidence in delivering healthcare through telemedicine.

Patient Requirements 9 Ownership of the telemedicine service received

Definition of the requirement

A patient / informal caregiver using a telemedicine service / application is expected to feel ownership as a result of the consciousness that the service has been developed in order to respond in a meaningful way to his/her health, as well as his/her individual needs as a patient / informal caregiver, especially by taking into account requirements, concerns and expectations.

Explanation of the requirement

Having a strong sense of ownership in the telemedicine service received or the telemedicine application used is key in fostering patients' and informal caregivers' acceptance.

A sense of ownership comes through a genuine feeling that the service / application was developed in such a way so as to address not only clinical, but also individual needs to the widest extent possible.

Patient involvement in the design and implementation of telemedicine services is therefore positively associated with ownership. This aspect is also remarked in the Commission's 2008 Communication on Telemedicine, according to which, the fact that users are often involved too late in the development of telehealth solutions is one of leading causes of too little sense of ownership[46].

6.1.2   Healthcare professionals' perspective

Healthcare professionals work on a daily basis in a healthcare environment, thus they have the practical knowledge of which things work and which do not, how tasks are performed, which medical aspects need to be considered, and what are the organisational manners. Thus, professional end users can be regarded as experts, and as such, have to be involved in the development process. From a healthcare professional's point of view, UCD is a precondition for ensuring that telemedicine applications can be directly integrated in medical practice in an efficient, safe and reliable way.

HP Requirements 1   Usability through health professionals involvement in service design and implementation

Definition of the requirement

Health professionals would expect that the telemedicine services / applications are designed and implemented as close as possible to health professionals' clinical and personal needs, and respecting their requirements and preferences.

Explanation of the requirement

Just like patients and informal caregivers, healthcare professionals are equally concerned by potential usability barriers associated with a specific telehealth application[47]. Looking at the various components of usability outlined in the usability framework described in Chapter 5, healthcare professionals are primarily interested in the actual utility of the application (effectiveness). Empirical research has shown that the way a healthcare professional perceives the usefulness of a telehealth application has a significant influence on their intention to eventually use the technology. This may suggest that healthcare professionals, especially physicians, tend to have a propensity to adopt a relatively pragmatic approach, and tend to focus on the usefulness of the technology itself[48]. Therefore, for a telemedicine service to be accepted by healthcare professionals, it is necessary to design

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[46] European Commission, *Telemedicine for the benefit of patients, healthcare systems and society*, Commission Staff Working Paper sec (2009)943, final June 2009.

[47] Q. Tara, L. Corley, S. Key, *Nursing Staff Requirements for Telemedicine in the Neonatal Intensive Care Unit*.(Technology Information), Journal of End User Computing , July 1, 2001

[48] P.J. Hu, P.Y.K. Chau, O.R. Liu Sheng and K. Yan TAM, *Examining the Technology Acceptance Model Using Physician Acceptance of Telemedicine Technology, Journal of Management Information Systems*, 1999; 16: 91-112.

applications which are able to meet specific needs of individual physicians, bearing in mind that healthcare professionals tend to regard technologies mainly as tools which become acceptable only when desired utilities in their practices have been proven.

HP Requirements 2   Maximising clinical effectiveness

<u>Definition of the requirement</u>

Clinical effectiveness refers to the performance of a technology in regular clinical practice, in terms of the ability of the technology to generate specific pre-determined clinical outcomes. Health professionals would expect that telemedicine services/ applications be at least as clinically effective as services / applications used in conventional clinical practice.

<u>Explanation of the requirement</u>

This requirement elaborates a bit more on the previous one. From a healthcare professional perspective, effectiveness is in fact primarily understood in terms of clinical effectiveness. Clinical effectiveness refers to the performance of a technology in regular clinical practice in terms of the ability of the technology to generate specific pre-determined clinical outcomes. As such, clinical effectiveness is a general requirement embracing a number of specific requirements, which will be further explored in D4.3 following with a series of meetings with healthcare professionals participating in the RENEWING HeALTH trials.

HP Requirements 3   Maximising efficiency of telemedicine services

<u>Definition of the requirement</u>

Efficiency is achieved when the telemedicine service brings about improvement in terms of time or resources needed to perform a specific task without compromising the efficiency of other tasks or of the full healthcare delivery process. Health professionals would expect that telemedicine services / and applications enable them to accomplish tasks more efficiently.

<u>Explanation of the requirement</u>

Efficiency is achieved when the telemedicine service system brings about improvements in terms of the time needed to perform a specific task - of course, without compromising the efficiency of other tasks or of the full healthcare delivery process. As such, efficiency turns out to be a key requirement for the professional users looking for the right balance between ensuring safety and quality of care for the patients while enhancing his/her productivity in performing tasks, also through reduced time needed to carry out specific tasks.

HP Requirements 4   Maximise user-friendliness

<u>Definition of the requirement</u>

User-friendliness is achieved when the service / application is easy to use by health professionals. In order to ensure that a telemedicine service / application is perceived as user-friendly as possible by health professionals, it is crucial to maximise navigability, intuitive understanding of how to perform tasks, as well as effective error-handling.

Explanation of the requirement

Ensuring that a telemedicine service / application is as user-friendly as possible is a key requirement not only for the patients, but for health professionals as well. Health professionals' primary objective is to provide the best possible care for their patients. Providing them with user-friendly systems and applications in the clinical setting is key to maximise quality of care and patient safety.

HP Requirements 5   Maximise learnability

Definition of the requirement

Learnability implies that the tasks to be performed using a telemedicine service are easy to understand, memorise and remember for all end users. Health professionals would therefore expect that telemedicine services / applications be easy to learn, and the tasks to be performed within the latter easy to memorise.

Explanation of the requirement

Learnability was identified as a key requirement for patient acceptability, and associated with various benefits such as effortless use and interaction with the system, reduced anxiety and higher confidence. Learnability turns out to be equally important for healthcare professionals as well, particularly for those who may be using at the same time a variety of different applications with different functionalities and interfaces. The risk of errors may increase substantially if every single application is not easy to remember, particularly in situations characterised by high workload, urgency, stress or lack of sufficient medical staff.

HP Requirements 6   Maximising Reliability

Definition of the requirement

Reliability is the probability that a system will perform its prescribed duty without failure. A professional user would expect that a telemedicine service / application is not a less reliable method for clinical decision-making than conventional face-to-face methods.

Explanation of the requirement

As described in the usability framework presented in Chapter 5, reliability, sometimes also referred to as dependability, is commonly defined as the probability that a device, service, or process will perform its prescribed task without failure for a given time when operated correctly in a specified environment. The concept of reliability in telemedicine is often associated with the concepts of accuracy and safety. To engender users' acceptance, telemedicine services / applications must not be a less reliable method for clinical decision-making than conventional face-to-face methods.

HP Requirements 7   Healthcare professional confidence

Definition of the requirement

Healthcare professionals need to feel fully confident when using a telemedicine service / application.

HP Requirements 8   Healthcare professional confidence in his ability to use telemedicine

Definition of the requirement

A health professional should feel confident not only in the system, but also, and perhaps more importantly, in his/her capability of interacting with it and performing a variety of tasks or operations without anxiety and stress. This means that the health professional needs to know exactly not only how to perform the various tasks from the easiest ones to those involving different levels of complexity, but also what to do in case of technical failures (e.g. who to contact, etc.) as well as in case of emergencies.

HP Requirements 9   Health professional confidence in patients' using the telemedicine service

Definition of the requirement

To accept a telemedicine service, a health professional needs to be fully confident of the ability of patients to know how to use the service / applications, especially when the service entails some degree responsibility shift for the management of the health condition to the patient, e.g. self-monitoring.

Explanation of the requirement

Just as a patient is concerned about his perception of his/her doctor's ability to use the telemedicine service, a healthcare professional, as the person who is ultimately responsible for delivering high quality healthcare to his/her patient, would definitely not accept his/her patient using and interacting with a telemedicine application for which he/she lacks the necessary competence and/or which he/she is not familiar with because of fear, unwillingness or lack support to use it.

Building and maintaining high healthcare professionals' confidence in telemedicine, therefore requires reassuring them to the maximum possible extent of patients' competence of and confidence in receiving healthcare services through telemedicine.

It is clear that this dimension of user confidence also raises important ethical issues. A user, whether a patient or healthcare professional, should not be obliged to use telemedicine if he/she is not certain that the other users feel comfortable performing tasks within the same service, as this might not only severely hinder safety and quality of care, but also undermine mutual trust among different user groups.

HP Requirements 10   Ownership of the telemedicine service provided

Definition of the requirement

A health professional using a telemedicine service / application is expected to feel ownership as a result of the consciousness that the service has been developed in order to respond in a meaningful way to his/her clinical, professional and individual needs.

Explanation of the requirement

Having a strong sense of ownership of the telemedicine service provided is a key driver of health professionals' acceptance of telemedicine.

A sense of ownership comes through a genuine feeling that the service / application was developed in such a way as to address not only the clinical, but also professional and individual needs, to the widest extent possible.

Healthcare professionals' involvement in the design and implementation of telemedicine services is therefore positively associated with ownership.

6.1.3 Healthcare authorities' / payers' perspective

If they use such services within their organisations, healthcare authorities are also concerned by the characteristics of telemedicine services, particularly with a view to ensuring the highest standard of patient safety.

Providing the best quality care for patients and ensuring the safety of a telemedicine service is a key concern for healthcare authorities. Efficacy and safety have been identified as major public policy concerns in this respect[49].

HCO Requirement 1   Maximising safety of telemedicine applications

Definition of the requirement

HCO will not accept telemedicine services unless they ensure at least the same level of safety as conventional healthcare services.

Explanation of the requirement

Safety issues associated with telemedicine are far more complex than in conventional care, and include not only apprehension about malfunctioning equipment which could occur in relation to any medical device, but also concerns regarding potential adverse effects on patient management decisions through delayed or missing information, misunderstood advice, or inaccurate findings due to patient or healthcare professional error[50].

6.2 Organisational aspects

Technology and ICT research suggests that it is not just making the technology work that matters[51]. Organisational issues are critical in the implementation of telemedicine. The consequences of new technology on the way healthcare is organised and delivered need to be appropriately assessed when developing telemedicine. Organisational issues have been identified as representing one of the most significant obstacles for telemedicine deployment[52]. Telemedicine relies as a matter of fact on technology of the most intrusive sort[53].

Organisational aspects need to be looked at on three different levels:

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[49] G. Demiris, L.B. Afrin, S. Speedie, K.L. Courtney, RN, M. Sondhi, V. Vimarlund, C. Lovis, W. Goossen, and Lynch, *Patient-centred Applications: Use of Information Technology to Promote Disease Management and Wellness*. A White Paper by the AMIA Knowledge in Motion Working Group, J Am Med Inform Assoc. 2008 Jan–Feb; 15(1): 8–13.

[50] Demiris G. Disease management and the Internet. J Med Internet Res. 2004;6(3):e33. [PubMed]

[51] The organisational challenge for healthcare from Telemedicine and eHealth I.H. Monrad Aas, Work Research Institute, Oslo, October 2006.

[52] J. Gladwin, T.D. Wilson, Validation of theoretical model linking organisational fit and diffusion of innovation in information service development, Health Informatics Journal, 2000; 6:219-227.

[53] M. Rigby, The management and policy challenges of the globalisation effects of informatics and telemedicine, Health Policy 1999; 46: 27-103.

- at the level of the healthcare service (macro-level);
- at the level of the organisation providing healthcare services (meso-level);
- at the level of the individual healthcare professional and patient (micro-level).

Level c) is addressed in sections 6.2.1 and 6.2.2. Levels a) and b) are dealt with jointly in section 6.2.3 under healthcare authorities' and payers' perspective.

6.2.1 Patients' and informal carers' perspective

This part focuses on the requirements relating to the how telemedicine impacts on a patient's / informal caregiver's life, especially with regard to their right to privacy.

Patient Requirements 10   Minimising intrusiveness of telemedicine

Definition of the requirement

Patients and informal caregivers would prefer that the intrusiveness of a telemedicine service / application is minimised, and effectively counter-balanced by other benefits, i.e. improved quality of life, health status etc.

Explanation of the requirement

The potential of intrusiveness is one of the downsides of telemedicine, e.g. preventing the patient conducting his "normal" life because of tele-homecare related duties, such as frequent or untimely measurements and consultations, or unwanted disclosure from private life.

For example, if it is true that most patients would prefer to stay home and avoid regular lengthy and expensive routine visits to the doctors, it is also true that they would not like to be obliged to stay home all the time because of the need to comply with tele-homecare-related duties, such as frequent measurements and consultations, which could lead to stress as well as negative psychological repercussions.

A patient would be willing to accept telehealth in as far as the benefits in term of health as well as economic and quality of life-related outcomes are not negatively counter-balanced by the excessive intrusiveness of telemedicine, e.g. preventing the patient conducting a normal life with negative implications in terms of quality of life[54]. This is why it is extremely important to test telemedicine services in real life situation, as opposed to laboratories, in order to understand how the system will impact on and will be integrated into patients', family's and informal caregivers' daily lives.

6.2.2 Healthcare professionals' perspective

A study dating back to 2001 interestingly revealed that "whether an information service is "successful" or not is decided on the shop floor".[55] This means that at the end of the day, the success of telemedicine will depend to a great extent on healthcare professionals' perception of benefits brought to them by telemedicine;

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[54] Eric J. Thomas, Joseph F. Lucke, Laura Wueste, Lisa Weavind, Bela Patel, Association of Health Information Technology and Teleintensivist Coverage With Decreased Mortality and Ventilator Use in Critically Ill Patients *Arch Intern Med.* 2010;170(7):648-653.

[55] Berg M. Implementing information services in health care organizations: myths and challenges. Int J Med Inform 2001;64:143–56

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also in terms of integration of telemedicine services into their daily practice, and the extent to which telemedicine enables them to improve their daily practice.

HP Requirements 11   Integrating telemedicine in healthcare professional's routine

Definition of the requirement

Healthcare professionals would expect that the change in routine resulting from the implementation of telemedicine services eventually enables them to perform their tasks more quickly, more accurately and that their overall work productivity is increased.

Explanation of the requirement

Shifting from conventional to telemedical healthcare provision entails dramatic changes in professional users' daily practice. This change in routine can be initially perceived by providers as something that is unnecessary, especially because healthcare workers may feel they are already providing the best care to their patients[56]. Healthcare professionals would, therefore, expect that the change in routine resulting from the implementation of telemedicine services enable them to perform their tasks more quickly, more accurately and that their overall work productivity is increased[57][58].

HP Requirements 12   Matching telemedicine with healthcare professionals' working environment

Definition of the requirement

A professional end-user of telemedicine would expect that the telemedicine service and equipment is adapted to the normal workplace, rather than trying to remodel the workplace around the service and equipment.

Explanation of the requirement

Professional end-users are generally busy people who will regularly use a service, or an instrument, only if it is easy accessible and can be easily integrated into their daily practice.

Although empirical studies have suggested that just as healthcare professionals are largely concerned by the easy-of-use of telemedicine applications, things may be different if we shift the attention from the single application to the system as a whole. In other words, although the single telemedicine equipment is easy to use, it can become more threatening if incorporated into a 'telemedicine centre' or specialist 'telemedicine room', which is located far away from physician's office and sometimes considered too far to go[59]. A simple step such as locating the

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[56] Malone P. Clinical care and education for trauma using telemedicine: Overcoming barriers to implementation and use. Telemed J E Health 2003; 9:41.

[57] P.J.H. Hu, P.Y.K. Chau, O.R.L. Sheng and K.Y. Tam, Examining the technology acceptance model using physician acceptance of telemedicine technology, *J Manag Inform Syst* 16 (1999), pp. 91–112

[58] D.J. Barker, P. van Schaik, D.S. Simpson and W.A. Corbett, Evaluating a spoken dialogue service for recording clinical observations during an endoscopic examination, *Med Inform Internet Med* 28 (2003), pp. 85–97

[59] P. Yellowlees, Successful development of telemedicine systems—seven core principles, Department of Psychiatry, royal Brisbane Hospital, Brisbane, Australia, p.5.

telemedicine equipment in close proximity to the physician may have a significant effect on the eventual adoption of the system[60].

From a professional end user perspective, the key to organisational user-friendliness is adapting the telehealth system and equipment to the normal workplace, rather than trying to remodel the workplace around the system and equipment. Real user-friendliness means for instance that a clinician providing tele-consulting services to patients is provided with tele- and video- consulting facilities in the normal workplace in order for him/her to efficiently integrate telemedicine-related work with mainstream activities.

Taking into account these requirements is particularly important to manage the "so-called" transition from conventional to telemedicine care, where the healthcare professionals will need to provide some sort of telemedicine care to some patients while continuing to provide healthcare in a more conventional manner to others; this requires healthcare professionals' ability to coordinate the two services ensuring that at the same safety and quality standards apply to both groups.

HP Requirements 13   Facilitate exchange of information related to patients' health between different levels of healthcare providers

Definition of the requirement

Health professionals would expect that telemedicine facilitates the communication and exchange of information between different healthcare providers, both within and beyond the healthcare setting in which they practice.

Explanation of the requirement

Telemedicine services, as well eHealth services in a broader sense, offer a huge potential for facilitating cross-institutional and cross-sectorial information exchange. Maximising this potential is particularly important to health professionals. In order for this to be possible, interoperability aspects needs to be properly addressed when introducing telemedicine services in a healthcare setting.

6.2.3   Healthcare authorities' / payers' perspective

The introduction of health IT has for many years been dominated by technological concerns – sometimes resulting in services that produced additional organisational overhead for the administration, and more particularly for healthcare workers, e.g. in hospitals. In turn, the evaluation of the efficiency of eHealth and telemedicine services remained often incomplete, since the organisational overhead was not taken into account. Likewise, the evidence provided that a particular telemedicine service has been proven to save resources (personal, financial, lost labour days) was also often incomplete. That type of evidence does not necessarily imply that the eHealth or telemedicine service is more efficient than traditional practice when all the direct and indirect effort needed to establish the service are fully taken into account (such as when e.g. applying the MAST model for assessment).

Today, while a managerial approach has become a ubiquitous asset of modern healthcare, healthcare institutions and healthcare payers (health insurances etc.) manage the care processes with a constant view on cost efficiency and best

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[60] G.C. Doolittle and R.J. Spaulding, Defining the needs of telemedicine service, Journal of Telemedicine and Telecare; 2006: 12: 276-284.

resource use. This perspective results in related user requirements specific tp healthcare organisations (HCOs) as highlighted below.

HCO Requirement 2   Efficiency by matching the needs of the healthcare service

Definition of the requirement

HCOs would expect that strategies be developed for the introduction of telemedicine applications which take into account the idiosyncrasies of the health service sector, and the particular structures and cultures of specific local and regional healthcare services.

Explanation of the requirement

Strategies and deployment plans for telemedicine services are required to ease HCOs' tasks of responding to the needs of their clients within the financial, organisational etc. boundaries as defined by policy, culture and regional idiosyncrasies. In most cases, that implies the need to respond to the health needs of the "clients" of the health care service, i.e. of the patients in the serviced area or domain in the case of a health service provider, the insured persons / patients for an health insurance organisation, and the citizens / patients in the case of a (tax-financed) regional or national healthcare system, by means that comply with the overall mission of the HCO, their organisational setup and financial boundaries.

HCO requirement 2 and 3 are closely related, yet are assessed at different levels or aggregation: HCO 2 means assessing the healthcare service at the macro level, i.e. National or Regional, HCO 3 at the local level and the level of individual provider organisations. Given a particular service, the generic requirement has to be broken down for the use case of the service in question (e.g. telemonitoring for cardiovascular disease) and the particular healthcare setting.

HCO Requirement 3   Efficiency by matching the needs of the healthcare organisation

Definition of the requirement

Telemedicine services need to fit into the normal organisational working environment. Healthcare authorities, especially hospitals and clinics, would expect that issues such as working procedures, team work, communication, safety culture, and management attitudes be properly taken into account.

Explanation of the requirement

cf. HCO 2. HCO 3 implies assessment at the local level, and the level of individual provider organisations. Given a particular service, the generic requirement has to be broken down for the use case of the service in question (e.g. telemonitoring for cardiovascular disease) and the particular health care setting.

HCO Requirement 4   Increased employees' productivity

Definition of the requirement

A healthcare authority would expect that health professionals' overall productivity is increased as a result of introducing telemedicine.

Explanation of the requirement

Healthcare services in the industrialised nations face steeply rising demands due to the ageing society and the ongoing increase of citizens with chronic conditions, while at the same time the healthcare workforce is shrinking. On the healthcare service level, telemedicine has been identified as one of the solutions that can help to cope with the resulting demand / resources imbalance. Telemedicine is expected to contribute to overcoming the shortage of health professionals by improving overall productivity of the individual healthcare worker, and healthcare system, by allowing health professionals to look after more patients while maintaining if not improving the quality of services provided, as well as patient safety.

To show how telemedicine can contribute to improving healthcare professionals' efficiency and productivity - and thus alleviate the challenges posed by the shortage of health professionals - let us take the example of in-home nursing care. Without the support of telemedicine, nurses are able to perform a certain number of face-to-face home visits during a given day (e.g. four-five visits a day), while with the support of telemedicine they can combine physical visits with virtual visits using videophones and other means. This way, physical encounters can be limited to those patients and situations requiring special attention and for which physical presence of a health professional is needed, while remote consultations can be used in all other cases. By reducing unnecessary physical visits, not only could nurses follow up more patients during that same period of time with savings of travel time and thus costs, but they could also stay in touch more regularly with individual patients through a balanced combination of physical and virtual visits. While such virtual visits cannot and should not completely replace in-patient visits, they provide a valuable supplement that can improve the quality of healthcare service provided by nurses[61].

HCO Requirement 5   Increased employees' satisfaction and motivation

Definition of the requirement

Healthcare authorities would expect that employees are more satisfied and motivated as a result of introducing telemedicine.

Explanation of the requirement

Telemedicine is expected to contribute to health professionals' satisfaction in many ways. For instance, by helping to minimise unnecessary travelling and healthcare worker dislocations for the need of information exchange and routine monitoring and check-ups, telemedicine could make patient treatment processes more efficient, thus leading to better health professional satisfaction. Moreover, better long term management of patients with chronic conditions will overall confirm the utility of the healthcare organisation for "keeping their patients healthy", and lead in turn to an endorsement of public recognition, and thus improve positive identification of those working in the healthcare organisation. Also, the ability to better and more efficiently balance work load and organisational issues may lead to better employee satisfaction. Improving satisfaction among healthcare workers is a key concern for healthcare organisations, as more satisfied employees tend to be more motivated, and committed.

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[61] Telehealth and health care provider shortages, Position Statement and Recommendations from the America Telemedicine Association, March 2007, http://www.americantelemed.org/files/public/policy/Telehealth_and_the_Provider_Shortage.pdf

HCO Requirement 6   Improved organisational performance

Definition of the requirement

Healthcare authorities would expect that also the organisation as a whole may become more productive as a result of introducing telemedicine.

Explanation of the requirement

HCO 6 mirrors the employees' productivity requirement [HCO 4] at the organisational level.

6.3   Clinical and health-related aspects

This section presents user requirements associated with clinical and health related aspects. A clear assessment of clinical aspects is a critical issue in any telemedicine service. This assessment should also help understand whether a specific service can actually be delivered through telemedicine or whether conventional or other services should be favoured instead. There are some clinical areas and services which adapt well to telemedical delivery, whereas others may not.

The assessment of clinical requirements in telemedicine requires a clear description of the clinical goals and outcomes of the intervention. The identification of clinical goals should help address the clinical relevance of the application to the specific healthcare service to be provided. The clinical outcomes, instead, refer to the health benefits for patients and healthcare professionals as a result of the use of the telemedicine service.

6.3.1   Patients' and informal carers' perspective

As mentioned above, patients' key concern when deciding on whether to accept to receive telemedicine is the improvement of their own health status as well as quality of life through a better approach to the management of their condition. Clinical and health related considerations therefore play a paramount role in shaping patients' attitudes towards telemedicine and their decision to eventually use it.

Clinical related aspects which should be looked at from a patient / carer perspective are presented below.

Patient Requirements 11   Maximising health outcomes

Definition of the requirement

A patient would reasonably expect that the use of telemedicine leads to better or at least not inferior clinical / health outcomes vis-à-vis those realistically attainable through conventional care. Health outcomes are e.g. reduced morbidity, reduced hospitalisation and early readmission, infection rate, as well as reduced mortality risk.

Explanation of the requirement

The impact of telemedicine on the health condition is a key concern for a patient and his/her informal caregivers. Such impact is usually referred to as health outcomes. By health outcomes we mean the positive / negative impact of a health service / treatment / medication on aspects directly linked to the health status of a patient,

such as mortality risk, infection rate, morbidity, adverse events, and emergency room visits. By enabling the early detection of the worsening of the condition enabled by regular remote monitoring of vital parameters, emergency visits could be significantly reduced. This should in turn reduce morbidity and mortality risks with significant impact on patients' and informal care givers' (especially family members) overall quality of life.

One could say that the impact of telemedicine on health outcomes can be regarded as good if this compare at least favourably with health outcomes in conventional care. Patients would therefore not accept telemedicine as a valuable complement to conventional healthcare services, if this does not ensure at least the same health outcomes that are achievable through conventional care only.

Patient Requirements 12   Maximising quality and reliability of care

Definition of the requirement

A patient would expect that quality of care is not undermined because of the introduction of telemedicine as a complement or replacement of conventional care.

Explanation of the requirement

The patient needs to be reassured that the development and adoption of telemedicine services and solutions is not exclusively driven by the need to replace existing services with more cost-effective solutions, but that these new systems enable at least the same quality of care that would be ensured through conventional care.

Consequently, a patient would reasonably expect that the introduction of telemedicine services leads to better or at least not inferior quality of care *vis-à-vis* quality standards realistically attainable through conventional care.

Patient Requirements 13   Maximising patient's perception of healthcare professional's ability to draw the same conclusions using telemedicine

Definition of the requirement

A patient being treated through telemedicine rightly expects that a professional end user can draw the same, correct conclusions using the telemedicine service / application as he/she can from a face-to-face consultation and using standard medical devices and IT support. To put it differently, a patient would expect that wrong decisions on the management of the disease are not made because of the consultation using telemedicine. This is especially important in management and monitoring of patient with chronic conditions, involving various typology of tele-consultation.

Explanation of the requirement

This requirement complements both the previous one "Maximising quality and reliability of care" but also "Patient's confidence in healthcare professionals' using telemedicine"; as such, it contributes to shaping patient's confidence in telemedicine and thus patient's cognitive perception of its usefulness, safety and reliability.

6.3.2 Healthcare professionals' perspective

As discussed in section 6.1.1, healthcare professionals are particularly interested in the overall effectiveness of a telemedicine service, especially its clinical effectiveness.

According to the NHS Quality Improvement Scotland (NHS QIS 2005), clinical effectiveness is the extent to which specific clinical interventions do what they are intended to do, i.e. maintain and improve the health of patients, securing the greatest possible health gain from the available resources.

As highlighted by MethoTelemed in the preparation of MAST, the description of clinical effectiveness of telemedicine applications is very detailed; there exist hundreds of instruments and outcome measures relating to the specific conditions of the patients in the studies[62].

HP Requirements 14   Possibility to make decisions based on good evidence

Definition of the requirement

A healthcare professional will not accept telemedicine as a means for delivering care to his/her patients if he/she is not fully assured that with telemedicine he can draw conclusions with at least the same level of accuracy as he/she would draw from conventional methods.

Explanation of the requirement

Regardless of how data was originated, processed and transmitted, providers have the moral obligation to ensure the highest quality of medical conclusions, recommendations and policies for appropriate patient care management. Being responsible for the health of their patients, it is therefore critical to health professionals to ensure the highest level of accuracy when using telemedicine in order to draw conclusions, such as diagnosis, etc.

HP Requirements 15   Maximise patient care and management

Definition of the requirement

Health professionals would expect that telemedicine enables better patient management, especially in terms of timely and faster diagnosis and treatment, and lead to overall better efficacy of healthcare.

Explanation of the requirement

Health professionals perception of the impact of telemedicine services has to be anchored in a comprehensive assessment of the service provision. For some clinicians, it may be biased by the traditional focus on acute patient care. This is particularly important when it comes to managing critical situations. A study revealed that doctors were particularly concerned about their ability to manage patients in a critical situation through telemedicine[63]. Patient care and management improvements have to be assessed with a holistic perspective - telemedicine services lead particularly to improvements in a long term time-scale. Improvements

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[62] The MAST Manual (MAST - Model for Assessment of Telemedicine)
[63] S. Gullen, User Satisfaction with home telecare based on broadband communication, Journal of Telemedicine and Telecare 2002: 8 81-90.

imply fewer critical emergencies which could change the perception of physicians that "save patients' lives". Maximising patient care thus relies on a long term perspective; epidemiological data may be needed to assess these improvements.

HP Requirements 16   Maintain efficient communication with patients

Definition of the requirement

A healthcare professional would not accept that the "de-personalisation" inherent in telemedicine will adversely affect care because of risk of losing control of patients and undermine trust.

Explanation of the requirement

As for patients, healthcare professionals are equally concerned about the implications of telehealth for patient - doctor relation and communication. In particular, a health professional would not accept that the "de-personalisation" inherent in telehealth will adversely affect care because of the risk of losing control of patients and weakened trust.

HP Requirements 17   Strengthening patient adherence

Definition of the requirement

A professional user of telemedicine would expect an increase of patients' adherence to treatments, medications, recommendations and nutritional regimes as a result of using a telemedicine service. Better patient adherence should result from higher involvement of the patient in the management of his/her own health; this in turn should lead to better disease management and enhanced patient – professional trust.

Explanation of the requirement

The term "adherence" as opposed to "compliance" reflects the changing role of patients from passive to active recipients of healthcare services who are increasingly involved in the management of their own health, the latter being one of the key pre-conditions for telemedicine deployment. The word "compliance" implies that the patient does what the doctor tells him/her, and patient acceptance is based on the doctors' status. "Adherence", a more acceptable term, implies that the patient in collaboration with the physician seeks to optimise the disease management process; the relationship is here based on trust.

As adherence is a key component of good quality care, it is in healthcare professionals' own interest to expect that telemedicine leads to better patient adherence.

Achieving adherence implies, however, empowering patients, including through health literacy.

Adherence to treatment / medication is not only extremely important in terms of health outcomes. Studies have demonstrated that there are other potential benefits associated to higher medication adherence, such as reduced transfers or referrals, fewer physician office visits, reduced hospitalisation rates, or fewer emergency room visits[64]. Adherence to treatment can therefore also lead to economic benefits

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[64] Sokol MC, McGuigan KA, Verbrugge RR, Epstein RS. Impact of medication adherence on hospitalization risk and healthcare cost. Med Care 2005;43:521–530.

through the reduction of healthcare utilisation (see paragraph 6.4), thus the better the adherence, the better the financial effect.

6.3.3 Healthcare authorities' / payers' perspective

The expectations of the healthcare organisations, particularly in their roles as payers for healthcare, focus on the reduction of the frequency and length of hospital stays.

HCO Requirement 7   Reduced hospitalisation

Definition of the requirement

Healthcare organisations expect a reduction in the overall hospitalisation rates for patients in telemedicine regimes.

Overall reduction in hospital admission rates, avoidance of (early) readmissions, and linked to this, fewer emergency room visits are key outcomes monitored in many telemedicine studies and trials. Reductions have been shown for all three categories. Hence it is straightforward that healthcare organisations expect to observe this also with their particular telemedicine service.

Explanation of the requirement

HCO Requirement 8   Reduced length of stay

Definition of the requirement

Healthcare organisations expect that telemedicine services enable earlier discharge of patients from hospital care due to the intensified homecare and monitoring offered by telemedicine regimes.

Explanation of the requirement

While hospital admission rates, early readmissions and emergency room visits are overall reduced by many telemedicine services, hospitals may expect also a reduction in the mean length of stay of their inpatients. Yet, some evidence exists that those patients admitted to hospitals being under telemedicine service regimes may experience even longer hospitals stays when they have finally been admitted to hospital. If this is so, the explanation would be that only more severely ill patients are admitted under telemedicine regimes while less severe conditions can be managed at home with the help of the telemedicine service, as long as the same level of quality and patient safety standards are maintained.

6.4   Economic aspects

One of the key areas which policy makers look at when deciding whether or not to invest in telemedicine is the economic implication of such investment in terms of optimisation of the delivery of healthcare to citizens.

RENEWING HeALTH, in line with its ultimate objective of demonstrating that telemedicine is not only safe, but also a more sustainable way to deliver healthcare for the benefit of patients, healthcare professionals and regional and local communities as a whole, is looking particularly closely at the economic dimension. The User Advisory Board intends to contribute to the understanding of the economic benefits of telemedicine from an end-user perspective.

In our literature review, we have found that economic evaluations of telemedicine remain rare, and only a few studies have accounted for the wide range of economic costs and benefits from the perspective of all user groups.

Integrating the whole range of economic-related aspects for all user groups concerned when conducting an evaluation of telemedicine services allows for more credible and comparative evidence of their economic viability. In this section we provide a list of user requirements which need to be taken care of when assessing the economic viability of establishing a telemedicine service.

6.4.1 Patients' and informal carers' perspective

Despite the fact that economic considerations are important determinants of patient acceptability of telemedicine services, cost/benefit analyses of telemedicine do not usually take into account the economic impact of using telemedicine on patients and their families.

A research study evaluated patients' cost savings in a telemedicine project at the University of Arkansas for Medical Sciences' (UAMS) during 1998-2002. Differences in patients' cost savings from telemedicine were assessed by gender, age, ethnicity, education, occupation, annual household income, health insurance status, and household and community size. The research also investigated the impact of telemedicine on travel distance for medical care, missed days at work, and family expenses. Results suggest that without telemedicine, 94% of patients would travel more than 70 miles for medical care; 84% would miss one day of work; and 74% would spend $75-$150 for additional family expenses. With telemedicine, 92% of patients saved $32 in fuel costs; 84% saved $100 in wages; and 74% saved $75-$150 in family expenses. Patients living alone and in smaller rural communities were significantly more likely to miss one day of work without telemedicine than patients with larger households and those residing in larger rural communities. Females were more likely to have family expenses over $150 without telemedicine than males. With this initial evidence, we can say that patients' costs savings are likely with telemedicine, however there is a need for more research into this[65].

Patient Requirements 14   Reduced healthcare expenditure

Definition of the requirement

Patients with chronic conditions would expect reduced direct costs of healthcare by entering into a telemedicine service.

Explanation of the requirement

As telemedicine should reduce unnecessary in-patient visits as well as hospitalisations, which, in turn, should result in less use of human and financial resources in healthcare, patients would expect to pay less for healthcare if they decide to use telemedicine.

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[65] Ann B. Bynum, Cathy A. Irwin, Charles O. Cranford, George S. Denny. The Impact of Telemedicine on Patients' Cost Savings: Some Preliminary Findings; Telemedicine Journal and eHealth. December 2003, 9(4): 361-367. doi:10.1089/153056203772744680.

Patient Requirements 15   Minimising time off work

Definition of the requirement

Patients and their informal caregivers would expect to minimise the time off work caused by the healthcare for their illness, particularly by reducing hospital stays and ambulatory visits.

Explanation of the requirement

Economic benefits of telemedicine for the patients should not be limited to money they actually spend for the healthcare services they need, but should take into account elements that, albeit indirectly, affect patients' income and expenses. These include minimising the time off work, or school, due to hospital stays and ambulatory visits, and hence lead to increased earning and new career opportunities, as well as decreased risk of job loss. Very few studies have looked at these elements in conducting economic evaluation of telemedicine. One of the possible reasons for that is that assigning financial value to non-financial outcomes can prove difficult to do in practice, especially if one considers that such outcomes can be measured in the medium-long term only. A paper published in 2009 on the economic value of telemedicine provides a comprehensive framework for conducting economic evaluation of telemedicine, and offers a way to assign financial value to non-financial patient-related outcomes of telemedicine[66].

Patient Requirements 16   Less travel expenses

Patients with chronic conditions would expect less travel expenses for ambulatory visits, as well as less travel expenses for relatives caused by hospital stays.

Explanation of the requirement

As telemedicine should significantly reduce unnecessary physical encounters, a considerable number of travels needed to reach healthcare facilities could be avoided. As a consequence, patients should expect to save money they regularly spend on transportation, accommodation and other expenses associated with outpatient visits and hospital admissions. This holds particularly true for low-income patients, as well as patients living far from healthcare facilities.

6.4.2   Healthcare professionals' perspective

As long as telemedicine services do not become an integral part of the reimbursement schemes of public or statutory health insurance based services, as well as of the reimbursement schemes of private health insurers, health professionals have either a risk of not being allowed to practice telemedicine by their employer, or of losing their own money in a self-employed setting.

HP Requirements 18   Reimbursement of telemedicine

Definition of the requirement

To accept telemedicine, health professionals would expect that telemedicine services that they have already included in their daily practice, or that they intend to include for good reasons, will be reimbursed.

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[66]   M.E. Davalos, M. T. French, A. E. Burdick, S. C. Simmons, Economic Evaluation of Telemedicine: Review of the Literature and Research Guidelines for Benefit–Cost Analysis, Telemedicine and eHealth, December 2009. http://www.liebertonline.com/doi/pdf/10.1089/tmj.2009.0067

Explanation of the requirement

A key condition for wider deployment of telemedicine is the recognition of telemedicine as a properly evaluated and legally valid medical act in order to ensure universal acceptance and allow for reimbursement.

As recognised by the Commission in its 2008 Communication on Telemedicine for the Benefit of Citizens, Healthcare Systems and Society, legal clarity is needed as regards the reimbursement of telemedicine services. According to the principle of subsidiarity, the classification of telemedicine as a valid medical act should be carried out at national level by Member States in cooperation with professional bodies. It should be based on general principles relating to standard (i.e. "non-telemedicine") medical acts applicable according to the national legislation of the Member State. This principle ensures that adequately regulated health services are not replaced by less regulated telemedicine services, and it avoids discrimination between suppliers of the same service which would be incompatible with the *e-Commerce Directive* (Article 4).

In various Member States, for a medical act to be recognised as such, the presence of the patient and the physician in the same place at the same moment is a condition sine qua non. This condition is obviously not fulfilled in telemedicine. This is a concrete case where European guidance would be highly needed.

6.4.3 Health authorities' / payers' perspective

When discussing clinical and health related user requirements, medication compliance, timely and accurate diagnosis and treatment and patient management were identified as key requirements of professional users of telemedicine.

Medication compliance, accurate diagnosis and treatment and patient management are not only means for health improvement, but can also have benefits through the reduction of healthcare resource usage[67]. For instance, reduced transfers or referrals, fewer physician office visits[68], reduced hospitalisation rates, or fewer emergency room visits[69] can be relevant outcomes indirectly derived from medication adherence, timely diagnosis and treatment.

Sokol and colleagues studied the impact of medication adherence on healthcare utilisation and costs, and found that hospitalisation rates were significantly lower for patients who complied with their medication regimen[70].

HCO Requirement 9   Reducing unnecessary use of health services

Definition of the requirement

Telemedicine can result in reduced use of healthcare resources through early detection of a condition, timely treatment, and the avoided need for further tests[71].

[67] M.E. Davalos, M. T. French, A. E. Burdick, S. C. Simmons, Economic Evaluation of Telemedicine: Review of the Literature and Research Guidelines for Benefit–Cost Analysis, Telemedicine and eHealth, December 2009. http://www.liebertonline.com/doi/pdf/10.1089/tmj.2009.0067

[68] Lehmann CA, Mintz N, Giacini JM. Impact of telemedicine and healthcare utilisation by congestive heart failure patients. Dis Manage Health Outcomes 2006;14:163–169

[69] Malasanos TH, Burlingame JB, Youngblade L, Patel BD, Muir AB. Improved access to subspecial-ist diabetes care by telemedicine: Cost savings and care measures in the first two years of the FITE diabetes project. J Telemed Telecare 2005;11(suppl 1):74–76

[70] Sokol MC, McGuigan KA, Verbrugge RR, Epstein RS. Impact of medication adherence on hospitalisation risk and healthcare cost. Med Care 2005;43:521–530.

Explanation of the requirement

Telemedicine services are conceived as an integral means of prevention and disease management programmes that jointly aim at avoiding health risks, detecting elevated risk factors before the onset of manifest disease, and manage chronic conditions in a way that minimises complications and secondary disease manifestations (such as renal failure as a late complication of diabetes).

Better management of a healthy state and the planned use of healthcare resources instead of unplanned emergencies, emergency rooms visits and hospital admission can overall save healthcare and societal resources. Of course living longer implies also a longer period of healthcare usage - yet it is particularly the avoidance of unplanned care that helps to achieve cost savings.

HCO Requirement 10   Supporting local economy

Definition of the requirement

Telemedicine can help to provide more services locally so people do not have to travel out of the community for care. This may lead to more local spending instead of outside spending.

Explanation of the requirement

For sparsely populated areas, remote regions or smaller municipal units, telemedicine can also help to keep healthcare related spending within the community. These economic effects may particularly be established by setting up healthcare centres or hospitals in collaboration with a larger partner organisation that provides expertise remotely to local health professionals.

HCO Requirement 11   Better quality / cost ratio for healthcare

Definition of the requirement

If telemedicine leads to improved health outcomes and hence enhanced patients' well-being while using similar or fewer resources, there will also be a better quality / cost ratio for healthcare.

Explanation of the requirement

Telemedicine supports a better planning of healthcare provision and thus results not only in improved health outcomes (better management of a healthy state) but also in less use of healthcare resources eaten up by unplanned emergencies, emergency room visits and emergency hospital admissions. Thus the resources can be more efficiently used, leading to a better quality / cost ratio for healthcare and societal resources. Furthermore, increase in healthcare workforce productivity and healthcare service efficiency should enable healthcare organisations / authorities to free up resources, which can be reallocated to providing health services that would be otherwise unavailable.

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[71] Mulholland HC, Casey F, Brown D, Corrigan N, Quinn M, McCord B, Rogers J, Craig BG. Application of a low cost telemedicine link to the diagnosis of neonatal congenital heart defects by remote consultation. Heart 1999;82:217–221

HCO Requirement 12   Business model

Definition of the requirement

For a serious planning of telemedicine services – particularly those needing major advance investments – sound business plans are needed by healthcare organisations.

Explanation of the requirement

Given the need for the strategic redesign of healthcare services and the investment in equipment, and in organisational measures such as call centres, education, evaluation etc., systematic planning should underpin the decision for and the establishment of telemedicine services. Use cases and the calculation of business plans are key elements for this.

6.5   User (non-health related) outcomes

User requirements can also be formulated in terms of positive outcomes that the various user groups would expect as result of the use of telemedicine. A patient and his/her informal caregivers would expect for instance that not only does the telemedicine application ensure high usability and safety requirements, but it also enable him/her to play a more empowered role in managing the disease. Similarly, a healthcare professional would expect for instance higher professional satisfaction as a result of delivering healthcare to his/her patients.

6.5.1   Patients and informal carers perspective

Patient Requirements 17   Better quality of life

Definition of the requirement

Patients and informal caregivers would expect improvement in Quality of Life (QoL) as a result of receiving telemedicine services, as opposed to or complemented by conventional healthcare services

Explanation of this requirement

Telemedicine services carry the potential to enhance the quality of life of patients and informal care givers. Telemedicine can affect quality of life in many different ways, directly by, for instance, leading to better health status (see Patient Requirements 11), or indirectly through, for instance, reducing the number of / time spent on travelling for outpatient visits.

This is proved by different studies which show that tele-consultations managed by physicians or nurses can have, for example, a positive impact on the Quality of Life of rural patients requiring on-going medical attention that can be ensured remotely through telemedicine, provided no risks are involved[72]. The fact that patients and informal caregivers are less worried about their health status, and have a better acceptance of their condition because of a more continuous way of receiving care, can also result in quality of life improvements[73].

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[72] Ferrer-Roca O, Garcia-Nogales A, Pelaez C. The impact of telemedicine on quality of life in rural areas: the Extremadura model of specialized care delivery. Telemed J E Health. 2010 Mar; 16(2):233-43.

[73] Dalfrà MG, Nicolucci A, Lapolla A, The effect of telemedicine on outcome and quality of life in

Telemedicine could and should therefore benefit all patients, both in terms of clinical outcomes and improved quality of life, and not just those living in rural or outreach areas.

Patient Requirements 18   Maintaining efficient communication with healthcare professionals

Definition of the requirement

A patient would expect that patient-doctor communication will not be undermined ("de-personalisation") because of using telemedicine as a means for receiving counselling and advice.

Explanation of the requirement

Since telemedicine always requires a thorough reassessment of how patients and doctors best relate and communicate to one another, it is fundamental that both patients and doctors (see below) do not perceive the "de-personalisation" inherent in telemedicine-based communication as undermining the patient-doctor relationship and mutual trust between them.

Patient Requirements 19   Favouring concordance

Definition of the requirement

A patient would expect that decisions regarding his/her health are based on concordance while using telemedicine as a means for receiving healthcare services.

Explanation of the requirement

This requirement complements Patient Requirements 18 pertaining to patient - healthcare professional communication. The term "concordance" refers in fact to the interaction between patient and health professionals whereby both actors are considered equal partners in a "therapeutic alliance", and the beliefs of both parties carry equal value. Concordance has several implications for patient adherence as concordant prescribing processes are likely to result in higher adherence by patients. Accordingly, concordance should also be a desirable outcome for healthcare professionals as well.

By enhancing continuity of care and actively involving the patients in the management of their health, telemedicine carries a great potential for favouring concordance in patient - health professionals interaction. Achieving concordance also implies empowering patients, including through health literacy.

Patient Requirements 20   Patient Empowerment

Definition of the requirement

Patients and their informal caregivers would expect that telemedicine leads to their empowerment, especially because of improved health literacy, increased ability for self-care, and increased knowledge of the condition.

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pregnant women with diabetes, J Telemed Telecare, July 2009 vol. 15 no. 5 238-242.

Explanation of the requirement

One of the key outcomes of telemedicine is the empowerment of patients. Empowerment is in turn determined by improved health literacy, and increased ability for self-care. All together, these factors can empower the patient enabling him/her to play a more active role in healthcare. As such, patient empowerment is not only a key patient-related outcome of telehealth, but also a fundamental pre-condition for patient acceptance and safety of telemedicine. The two main components of the empowerment requirement are presented below as sub-requirements.

Patient empowerment can at the same time be also regarded as a pre-condition for using telemedicine, as it is part of the skill-set a patient / informal caregiver needs to have in order for him/her to be able to use telemedicine confidently. For this reason, this requirement has also been listed in the ethical requirements.

Patient Requirements 21   Patient Sub-requirement 20.1 Improved patient health literacy

Definition of the requirement

Patients and their informal caregivers would expect that their health literacy skills are improved as a result of using telemedicine.

Explanation of the requirement

Health literacy can be defined as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate decisions. Health literacy is more than the ability to read and comprehend written medical information and instructions, as it encompasses all the following skills: basic health knowledge, reading, comprehending and evaluating health information, application of health preventing, promoting and self-care behaviours, verbal communication with health professionals, and health decision-making[74].

As telemedicine often involves the active engagement of patients and informal caregivers in the management of the condition, they would reasonably expect to strengthen their health literacy skills.

Health literacy can at the same time also be regarded as a pre-condition for using telemedicine, as it is part of the skill-set a patient / informal caregiver needs to have in order for him/her to be able to use telemedicine confidently. For this reason this requirement has also been listed in the ethical requirements.

Patient Requirements 22   Patient Sub-requirement 20.2 Increased ability for self-care

Definition of the requirement

Patients and informal caregivers would expect to acquire additional knowledge of and ability for self-care as a result of using telemedicine.

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[74] See Report of the European Patients' Forum Conference on Health Literacy: http://www.eu-patient.eu/Documents/Policy/HealthLiteracy/EPF_HealthLiteracyConference_2008_Report.pdf

Explanation of the requirement

For the person with a chronic condition, there is no way not to self-manage the disease / illness. The need for self-management is magnified by the use of telemedicine systems. In telemedicine, patients are expected to provide concrete support to practitioners going far beyond mere adherence to treatments and medications.

Since most telehealth applications entail a higher degree of self-care management (SCM), looking exclusively at patient's confidence in handling the technology / application is not enough. Patients using telemedicine need to gain additional knowledge about the condition as well as about the day-to-day management of the condition. Most telemedicine services / applications involve a transfer of responsibilities from healthcare professionals to the patient, his/her family, and informal caregivers, with varying levels of health professional oversight. For some conditions, such as diabetes, COPD, and coagulopathies, telemedicine enables the patients to get involved pro-actively in the management of the disease by, for instance, adjusting medication dosages, while for other conditions (e.g. hypertension, chronic heart failure) such adjustment by patients is not yet usual but could become so.

Patients would therefore expect to acquire additional knowledge of and ability for self-care, including the following elements:

- knowing how to recognise and respond to changes in a chronic disease, dealing with problems and emergencies;
- using medicines and treatments effectively;
- finding and using community resources;
- coping with fatigue, pain and sleep problems;
- maintaining good nutrition;
- making decisions about when to seek medical help;
- working with your doctor(s) at a distance as well as other care providers;
- managing work, family and social activities.

Ability for self-care can at the same time also be regarded as a pre-condition for using telemedicine. Having a sufficient degree of self-care ability as required by the telemedicine service received is in fact part of the skill-set a patient / informal carer needs to have in order for him/her to be able to use telemedicine confidently. For this reason, this requirement has also been listed in the ethical requirements.

6.5.2 Healthcare professionals' perspective

HP Requirements 19   Increased professional satisfaction and motivation

Definition of the requirement

Healthcare professionals would expect that their overall professional satisfaction and motivation is improved because of providing care to patients through telemedicine.

Explanation of the requirement

Increasing health professionals' satisfaction is a crucial element behind the acceptance of telemedicine among this user group.

One interesting review of scientific studies, which explored user satisfaction with telehealth, pointed out that when assessing user satisfaction of telemedicine one should bear in mind that the construct of satisfaction is undefined, and its understanding depends upon rather subjective considerations of what can be labelled as being actually "satisfactory"[75]. Accordingly, for some the concept of satisfaction simply means "adequate", others use the term to mean "less than adequate", i.e. that some aspects could be improved, while for others, it refers to something that is "less than optimal".

This having being said, one could say that a health professional is "satisfied" with telemedicine if his/her satisfaction with telemedicine compares favourably or at least not less favourably with the satisfaction he/she gets from more traditional ways of delivering healthcare. The same of course holds true for patients.

Telemedicine could improve health professionals' satisfaction in many ways: Telemedicine can for instance minimise travelling and healthcare worker dislocations for the need of information exchange and routine monitoring and check-ups. Long term management of patients with chronic conditions will overall improve and endorse the role of the health professionals for "keeping their patients healthy", leading to an overall improvement of professional identity and public recognition of the healthcare organisation. Also, more efficiently balancing work load, IT-enabled management of many clinical and all non-clinical tasks, may lead to better satisfaction.

HP Requirements 20   Increased patient satisfaction

Definition of the requirement

Healthcare professionals would expect that their patients are more satisfied with the healthcare service they receive thanks to the addition of telemedicine to traditional ways of providing healthcare.

Explanation of the requirement

Healthcare professionals would also expect that their patients are more satisfied because of using telemedicine as a replacement or complement to conventional care. Increased patient satisfaction tends to be associated to better adherence to treatments, medications and nutritional regimes, and improved patient-doctor relation and mutual trust, which in turn contribute towards increased healthcare professional satisfaction and hence willingness to accept and use telemedicine.

6.5.3   Health authorities' / payers' perspective

This section will be explored in the next iteration of this deliverable D4.3.

6.6   Ethical and legal aspects

The requirements analysis also needs to address issues that go well beyond the medical or clinical context to embrace a wide range of ethical issues. Some major legal and ethical issues associated with the use of telemedicine, such as telemedicine intrusion into patient life and patient-doctor communication, have already been discussed under other domains. As telemedicine activity grows, there

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[75] Whitten P, Love B. Patient and Provider Satisfaction with the Use of Telemedicine: Overview and Rationale for Cautious Enthusiasm. *J. Postgrad. Med.* 2005;51(4):294-300

are, however, a number of other issues that needs to be discussed including: whether or not telemedicine is the best solution for the patient, what is the real impact of telemedicine on patients', informal carers' and healthcare professionals' well-being; how will it affect the doctor-patient relationship and the "art of medicine"; will telemedicine increase equity and equality of access to services or exaggerate differences between the better off and the poor, the educated and the less educated; will it contribute toward social cohesion or amplify social isolation and exclusion; will telemedicine be used for empowerment of patients or will its main aims be cost cutting and control (e.g. standardisation of medical practices)?.

Furthermore, issues such as accreditation and malpractice liability need to be taken into account as well. These are all general ethical considerations that policy makers and healthcare authorities should take into account when considering setting-up the telemedicine system model of care in their territory.

The following paragraphs present a more detailed overview of major ethical and legal implications of telehealth from the perspective of the three user groups identified for this document. The overview starts with presenting security related issues involved in telemedicine. As security concerns are equally relevant to all user groups they are presented jointly as "user requirements".

Requirements in this domain are subject to particular emphasis within RENEWING HeALTH, i.e. work package WP7 Security, Privacy and Ethical Issues. A synthesis of D7.2 Security and privacy recommendations were not included in D4.1.

6.6.1 Patients perspective

Patient Requirements 23   Respecting patients' right to privacy

<u>Definition of the requirement</u>

Patients and informal caregivers would expect that their right to privacy is properly respected.

<u>Explanation of the requirement</u>

Intrusiveness (see Patient Requirements 10) could also negatively affect patient's privacy as a result of patient's feeling that there might always be somebody watching him. The continuous monitoring inherent in many telemedicine services may prove to be an infringement of patients' rights to privacy.

Although some studies have reported that many patients seemed to welcome the additional monitoring, and families also seemed to be very accepting of the technology because they felt that someone was always looking in on the patient, many patients may not feel confident with such an intrusion into their private life, despite the benefits that this might bring to them, such as for instance early detection of injuries, illness or worsening of the condition, and the possibility to offer immediate care to patients.

Patients may also be sceptical about the use of video images, and the idea of "unseen persons" during exams or consultations.

Patient Requirements 24   Protecting confidentiality of patient data

Definition of the requirement

To accept telemedicine, patients need to be reassured that all concerns with the technology have been properly addressed through a combination of legal, technical and administrative security measures, to ensure maximum level of confidentiality of personal and health data exchanged.

Explanation of the requirement

Protecting confidentiality and security of patient data is a particularly sensitive issue in telemedicine. Lack of security standards do play an important role in the legal challenges facing telehealth (e.g. malpractice), and have profound implications for the acceptance of telemedicine services. Telemedicine brings with it concerns about privacy, security and confidentiality that go beyond those associated with protecting medical records, because of the unique combination of patient data, video imaging, and electronic clinical information that is generated between two distant sites during a telemedicine encounter. The privacy concerns that normally pertain to patient medical records may be magnified within the telehealth arena.

Additionally, fears about the reliability of the technology and the potential devastation that loss of information would cause, leave some wary of telemedicine.

Patient Requirements 25   Informed consent

Definition of the requirement:

In order to make a decision as to whether to use telemedicine, patients have the right to be provided with all necessary information about the telemedicine service before giving their consent.

Explanation of the requirement

As in conventional healthcare, patients using telemedicine have the right to autonomous, informed participation in healthcare decisions. Informed consent is required for all clinical treatments and procedures, including those delivered via telemedicine.

Practitioners should provide information about the telemedicine programme / service that patients reasonably have to know, including:

a) differences between care delivered using telemedicine and conventional face-to-face care;

b) benefits and risks of using telemedicine in the patient's specific situation;

c) consideration of whether use of telemedicine is the right solution for the patient (see following requirement);

d) informing the patient of rights and responsibilities when receiving telemedicine treatment;

e) ensuring that the patient has the knowledge required as well as promptness and readiness to use telemedicine;

f) assuring the patient that all security and safety requirements have been fulfilled.

Before accepting to opt for telemedicine, a patient would, therefore, expect that all these pieces of information have been provided to him/her, and that all additional

questions and concerns a patients may want to raise are properly and thoroughly addressed.

Patient Requirements 26   Telemedicine as the best solution for the patient

Definition of the requirement

To accept telemedicine, a patient would need to be assured that telemedicine represents the best solution for him/her, and that a thorough consideration of all medical, clinical, organisational, as well as ethical aspects have been thoroughly assessed before inviting him/her to join a telemedicine programme and/or use a telemedicine service.

Explanation of the requirement

To foster patient acceptance, it is crucial to make sure that decisions concerning whether or not a patient should be receiving healthcare through telemedicine are based on a thorough assessment of the clinical, as well as the personal, situation of the patient and informal care givers looking after him/her.

Patients and informal caregivers should be involved on an equal footing in decisions concerning the use of a telemedicine service, and the alignment of this service to their needs, preferences and limitations.

Patient Requirements 27   Affordability of the telemedicine solution

Definition of the requirement

A patient would reasonably expect that the telemedicine services are affordable. A patient would accept telemedicine if his perception of (additional) costs involved is reasonably justified by the additional benefits in terms of better health outcomes and quality of life.

Explanation of the requirement

One could ask oneself the following question: since patients get additional benefits in return – provided that such benefits actually materialise (i.e. an improved quality of life, reduced hospitalisations, better health outcomes etc.) - should these patients have to pay for this? This, however, may also raise ethical issues as regards patient access to better quality healthcare. If telehealth services are more expensive than conventional healthcare services, access to telemedicine will only be granted to those patients who can actually afford the costs. This may not be the ultimate goal of a policy maker aiming to pursue a reduction in health inequalities.

Patient Requirements 28   Maintaining trust between patients and health professionals

Description of the requirement

Patients would expect that telemedicine services do not compromise the personal relationship between them and healthcare professionals. This is a necessary prerequisite for using telemedicine.

Explanation of the requirement

Ensuring that telemedicine does not undermine trust between patients and health professionals is a key pre-condition for end-users to accept these services as a valuable supplement to traditional healthcare services. To this end, it is important to

involve both patients and health professionals in defining the best treatment option for the patient, with a view to making sure that the depersonalisation arising from virtual consultation, if any, does not compromise the relationship between end-users.

Patient Requirements 29   Providing appropriate training to the patients

Description of the requirement

Patients will not use telemedicine services unless they are provided thorough training to ensure they are fully confident with the service, as well as with their ability to use and interact with it.

Explanation of the requirement

Availability of appropriate preparation so that patients, families and informal carers are sufficiently competent at and confident in using the system is a key requirement to avoid harm, and ensure higher safety for the patient in using telemedicine.

Before starting using telemedicine services, patients shall therefore be provided appropriate training and support to ensure they are fully confident with using and interacting with the service. Training should also include the adaptation of patients' communication skills in order for them to be able interact remotely with health professionals, especially in terms of understanding advice and instructions received, and implementing / following up on them accordingly.

Patients' instructions and manual should be adapted to the level of competence and experience of the patients taking into account constraints and limitations of older patients, and patients with physical, sensory, cognitive or mental impairments.

6.6.2   Healthcare professionals' perspective

HP Requirements 21   Clear legislation on medical liability in telemedicine place

Description of the requirement

Healthcare professionals will not accept telemedicine unless clear legislation on medical liability is in place, taking into account the multiplication of intermediaries in the field of health services arising from the introduction of telemedicine. At the same time, Health Professionals must be reassured that their professional liability insurance schemes will cover their contribution to telemedicine services.

Explanation of the requirement

Traditionally, medical liability is restricted to the relationship between the patient and the healthcare professional. This means that if a patient is a victim of medical negligence or of a medical error, he/she will usually seek to introduce a civil or criminal lawsuit against the doctor. With the ever increasing use of eHealth and telemedicine tools, as well as the multiplication of intermediaries in the field of health services, and the legal relationships between the various actors involved in providing healthcare services to the patient, it is much more difficult for the patient to know where liability lies if something goes wrong[76].

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[76] See Celine Van Doosselaere, Petra Wilson, Jean Herveg and Denise Silber, eHealth…… but is it legal? Eurohealth, Health, Technological Development and the Law, Volume 13, Number 2, 2007.

There exist general legal rules at EU level providing consumers and thus patients with a legal guarantee of high quality products and services, whether by traditional or electronic means. These rules, however, do not explicitly mention nor do they address health or eHealth specifically.

The EU Product Liability Directive (Council Directive 85/374/EEC) imposes a duty of strict liability on producers. In order to establish liability, two elements must be present, namely a defect in the product, and harm to the consumer. Although this Directive does not specifically regulate medical liability issues, it is extremely relevant to situations (both doctor-patient and doctor-doctor) where patient harm has resulted after use of a defective product. Thus a patient who is injured due to a defective telemedicine product would have cause for action against the producer (if identifiable) or the medical practitioner. The medical practitioner in turn, who is also a consumer, could also have an action against the supplier or producer from whom he or she acquired the product if an injury arose through the use of a defective product used in a reasonable and responsible way. In general in the eHealth arena, the purchaser of an eHealth product will also need to make reference to the relevant national legislation based on Directive 1999/44/EC on the Sale of Consumer Goods. Beyond the sale of the product, Directive 2001/95/EC on General Product Safety applies, requiring that any product put on the market for consumers, or likely to be used by them, is safe.

HP Requirements 22   Licence

Description of the requirement

Health professionals, especially physicians, would expect that they can be practising (tele)medicine in a remote state in which they do not have a practising license.

Explanation of the requirement.

The idea if licence corresponds to two elements:

1) Health professionals can be confident that they do not violate their professional obligations when practising telemedicine in their home country. Background: many professional codes of conduct still foresee that healthcare encounters have to be face to face

2) Health professionals can be confident that they practise in accordance with the regulations on the mutual recognition of health professional qualifications, and do not violate their professional obligations when practising telemedicine in another state than their home country.

HP Requirements 23   Maintaining Trust between patients and healthcare professionals

Description of the requirement

Healthcare professionals would expect that telemedicine services do not compromise the personal relationship between them and patients. This is a necessary prerequisite for accepting telemedicine.

Explanation of the requirement

Ensuring that telemedicine does not undermine trust between patients and health professionals is a key pre-condition for end-users to accept these services as a valuable supplement to traditional healthcare services. To this end, it is important to involve both patients and health professionals in defining the best treatment option

for patients, with a view to making sure that the depersonalisation arising from virtual consultation, if any, does not compromise the relationship between end-users.

HP Requirements 24   Providing   appropriate   training   to   healthcare professionals

Description of the requirement

Healthcare professionals will not accept telemedicine as a means to provide healthcare to the patients unless equipped with the knowledge and skills required for using these services.

Explanation of the requirement

Training of healthcare professionals is a fundamental pre-condition for healthcare professionals' acceptance of telemedicine. Healthcare professionals will not provide healthcare through telemedicine unless they are provided comprehensive training to ensure they are fully confident with the service, as well as with their ability to use and interact with it. Training should also include the adaptation of health professionals' communication skills in order for them to be able to manage and interact remotely with patients, thereby ensuring that de-personalisation is minimised and trust is maintained.

6.6.3   Healthcare authorities' perspective

This section will be explored in D4.3.

7. Next Steps

As explained at the beginning of this document, Deliverable D4.2 complements the results of the exploratory analysis of user requirements undertaken in the framework of D4.1 with the outcomes of the consultations undertaken with the members of the User Advisory Board aimed at a first validation of such framework. As mentioned in D4.1, the exploratory analysis was based on the results of a literature review and the cross-validation of these results against the outcomes of the EU funded project MethoTelemed, which has also studied the assessment of user requirements as one element of a comprehensive evaluation and health technology assessment.

At this stage, a systematic framework for presenting and discussing requirements of the three categories of users of telemedicine services, i.e. patients and carers, healthcare professionals, healthcare authorities and payers, has been presented. Yet the method to achieve a suitable reference for user requirements must be iterative and process-oriented. Thus these requirements will be further tested through evidence collected from the implementation of the telemedicine services at the RENEWING HeALTH pilot sites, through a series of meetings with real users participating in some of the pilot sites. This evidence will be integrated in future, incremental versions of this deliverable. Deliverables D4.3 and D4.4 will reflect the iterative assessment process of user requirements. The final outcome of this process, at the end of the project, will be set out in deliverable D4.4.

The results of step 2 are contained in this User Requirements Reference Framework. Plans for the next steps include refining the current results specifically to:

- Complete the blank spaces in the analyses above, particularly in sections 6.5 and 6.6, i.e. non-health related outcomes, and ethical and legal aspects.
- Implement feedback and new evidence from the UAB and the pilots.

Furthermore, in order to fulfil the UAB tasks vis-à-vis the clinical trial process and the multi-disciplinary evaluation that the services will go through, a stronger collaboration with WP3 Evaluation Methodology and Pilot Evaluation has been established. Future releases of the deliverable will also provide an assessment of whether the RENEWING HeALTH evaluation methodology effectively takes into account user requirements as identified by the UAB.

In particular, the project plan foresees the measurement of the satisfaction of patients, relatives, informal caregivers and healthcare professionals through questionnaires that will be defined in the early stages of the project; these will be validated with a small subset of users in the various pilot sites prior to the start of the large scale pilots. As part of the process of user requirements development, the UAB will engage closely with these activities.

Appendix A: RENEWING HeALTH User Advisory Board Terms of Reference

User Advisory Board
Terms of Reference

Version v014

0 Aims of the RENEWING HeALTH project

RENEWING HeALTH (REgioNs of Europe WorkING together for HEALTH) aims to improve health services in Europe for the increasing number of patients suffering from chronic conditions, in particular diabetes, cardiovascular disease and chronic lung problems. The Project goal is to demonstrate that telehealth based services improve quality of life, enable patient involvement and empowerment while optimising the use of resources in health provision.

1 Mission of the User Advisory Board

The User Advisory Board (UAB) of RENEWING HeALTH has the primary mission to operate as a standing advisory committee for the Consortium to advise and provide on-going feedback to the Project Team on the needs of current and future users of the piloted telemedicine services. In so doing, the UAB should improve the fit between the services and the users' requirements and expectations.

The UAB will also be in a position to observe the clinical trial process and the multi-disciplinary evaluation the services will go through.

The UAB has to ensure that the interest and needs of the key actors are properly recognised and taken into account throughout the entire lifecycle of the Project.

2 Composition of the Users Advisory Board

The UAB represents the three main categories of end-users of the telemedicine services piloted in the context of RENEWING HeALTH, i.e.

1. Patients and their informal caregivers.
2. Healthcare professionals.
3. Health authorities, healthcare organisations and payers.

To achieve a meaningful representation of the three main categories of end-users, the UAB Management (cf. 5) invites respected organisations to become members of the UAB. The selection also seeks to balance the users groups involved, e.g. for the diseases represented.

The UAB may invite as guests other organisations representing additional stakeholder perspectives such as e.g. telemedicine service providers as needed.

Also, mutual invitations to and from the Industry Advisory Board are considered as useful. However, the UAB shall not include as members stakeholders who may have a commercial interest in the Project.

In total, the UAB targets a membership of no more than 20 organisations and foresees meetings attended – on average – by 8 to 15 UAB members. In addition, representatives of the RENEWING HeALTH pilot sites, cluster representatives and/or users' representatives at the regional level may be invited to contribute to the meetings on a case by case basis.

The UAB may also invite external individuals to provide extra expertise were found suitable. Invitations will be issued by the UAB Management on behalf of the UAB Chair; nominations for invitations can be suggested by all members of the UAB and the Consortium.

3   Tasks of the User Advisory Board

The UAB will take care of

1) Assessing and voicing user needs, capabilities, risks and benefits.

2) Assuring that the implemented solutions support the empowerment and satisfaction of the patients.

3) Assuring that the implemented solutions improve the satisfaction of healthcare professionals, benefit the wider medical scientific community and reflect the interests of Health authorities, healthcare organisations and payers.

4) Advising the Project on the robustness of the evaluation methodology.

For 4) the User Advisory Board will in particular provide feedback on the evaluation process and results of value and impact of these services at different levels, including the clinical outcome, user satisfaction, and the economic and organisational impacts.

Thus the main elements of the work programme will include at least the following elements:

- Feedback on the organisation of the telemedicine services and their results
- Feedback on the organisation of the clinical trials
- Feedback on the different aspects of MAST and its implementation
- Feedback on the Project findings, conclusions and recommendations
- Participation in horizontal project activities to be performed during the Project's life-cycle by providing recommendations to other work packages in the delivery of their tasks.

4   Interaction of the User Advisory Board and the full Consortium

The UAB expresses user views e.g. by reporting on user needs, instantiate those needs in concrete feedback and providing recommendations at any time during the lifecycle of the Project and at Project Steering Committee meetings. Recommendations from the UAB shall be thoroughly considered by the Project Coordinator and the Work Package Leaders.

Through the Chair and the Management, the UAB establishes formal links with the Project Management Team, notably the Project Coordinator, Leaders of other work packages and Cluster Managers, to ensure continuous and timely access to relevant Project internal and external documentation to make recommendations accordingly.

The UAB shall consider, if and when appropriate, liaising with the Industrial Advisory Board (IAB) in order to better coordinate the advisory activities throughout the

Project implementation. In this context, one or more joint UAB-IAB meetings may also be held.

5   UAB Organisation

The UAB appoints a Chair, who has to be approved by the Coordinator of the Project. The Chair is supported by a Secretariat, here referenced as "UAB Management" (cf. RH DoW).

The UAB Management is the responsibility of the European Health Telematics Association (EHTEL) and is supported by the European Patients' Forum (EPF). The UAB Management is responsible for the overall coordination of the development of specific recommendations from the UAB, i.e. passing the relevant documentation and information to the other members of the UAB, and invites them to provide recommendations within a reasonable timeframe. The UAB Management observes the deadlines for delivery and organises all meetings of the UAB.

The members of the UAB will hold face-to-face meetings two to three times a year. The UAB meetings will take place in different venues both in central European locations and in the participating regions taking into consideration the schedules of the Project partners and whenever possible in conjunction with other Project meetings. Also virtual meetings in the form of audio or videoconferences may be held.

Where necessary, travel and accommodation expenses of UAB members are covered.

6   Rights and responsibilities of the members of the Users Advisory Board

The UAB shall be involved in all relevant Project activities and shall receive, in a timely manner, all the documentation which is needed for its members to grasp the various aspects of the Project which are relevant for the constituencies that they represent.

In turn each member of the UAB will be responsive to the requests by the UAB Chair and UAB Management and deliver their comments by the specified deadlines.

Members of the UAB shall ensure their availability to attend the meetings (face-to-face or virtual meetings) and to suggest reasonable alternative dates when needed. In order to ensure the smooth and timely running of the UAB the members shall consider the possibility to send delegates or submit written contributions to the Chair before the scheduled meetings.

Appendix B: RH User Advisory Board Membership

Table 3: Members of the User Advisory Board

AER	Assembly of European Regions	www.aer.eu
AGE	AGE Platform Europe	www.age-platform.eu
AIM	Association Internationale de la Mutualité	www.aim-mutual.org
CPME	Standing Committee of European Doctors	www.cpme.be
EFA	European Federation of Allergy and Airway Diseases Patients Association	www.efanet.org
EHMA	European Health Management Association	www.ehma.org
EHRA	European Heart Rhythm Association	www.escardio.org
EHN	European Heart Network	www.ehnheart.org
EHTEL	European Health Telematics Association	www.ehtel.eu
EPF	European Patients Forum	www.eu-patient.eu
ESIP	European Social Insurance Platform	www.esip.org
EUREGHA	European Regional and Local Health Authorities	www.euregha.net
EUROCARERS	European Association Working for Carers	www.eurocarers.org
HOPE	European Hospital and Healthcare Federation	www.hope.be
IDF	International Diabetes Foundation	www.idf.org
UEMS	European Union of Medical Specialists	www.uems.net
YOUTH	European Youth Forum	www.youthforum.org