Tele-rehabilitation: Final results of the project "CLEAR"

Clinical Leading Environment for the Assessment and validation of Rehabilitation Protocols for home care (CLEAR)

CIP-ICT-PSP-2007.2.2 – ICT for ageing well
Project Number 224985

Credits

The CLEAR project (Clinical Leading Environment for the Assessment and validation of Rehabilitation protocols for home care) has been co-funded under the ICT Policy Support Program Area CIP-ICT-PSP-2007.2.2 – ICT for ageing well.

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Summary

Foreword

It is a pleasure and honour for me, as coordinator of the CLEAR project, to introduce the results achieved in the most extensive clinical experience on tele-rehabilitation ever in Europe. CLEAR has demonstrated the feasibility and applicability of such services for many diseases, and has proved to be a powerful support to extend the rehabilitation treatment and facilitate the management of chronic conditions. In the coming years Europe will certainly face a wide crisis which should bring about the re-organization of health resources to face the needs of a fascinating European achievement: **old age**. Europe is aging; years of healthy life must be considered a value to tend to. To reach the goal, the cohesive support is needed from private and public forces, where technology is to be considered a powerful support for the clinician who should always be in a position to master the clinical process. Alliances between public and private stakeholders are needed to reach the goal. I hope that CLEAR will help stimulate the birth of innovative services for the benefit of elderly people, for a fruitful maintenance of health in the fragile years of life.

Sandro Scattareggia Marchese
Managing Director Signo Motus srl
Coordinator of the CLEAR Project
July 28th 2012

As from the planning phase of the project, there was wide consensus within the CLEAR consortium on the need to properly assess the tele-rehabilitation services we were going to implement, in order to demonstrate their suitability for a wide use in different European clinical contexts, and provide stakeholders with data useful for decision making. The instrument we chose was Health Technology Assessment (HTA), never applied before to investigate all the critical aspect of a tele-rehabilitation service. Neither were the necessary HTA tools available in the relevant literature. Thus, the Rome-based partner group of the Istituto Superiore di Sanità (ISS) accepted the challenge of coordinating the efforts for developing and applying a dedicated HTA model. At the end of the CLEAR project, the official project reviewers valued this new HTA model as one of the main achievements of the project itself. My sincere gratitude goes to my ISS colleagues, for the passion and perseverance in facing the difficulties encountered, and to all the consortium partners, whose professionalism and close cooperation were essential for conducting that project's piece of work.

Velio Macellari
Director of Technologies and Health Department
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Introduction and Scope

The document intends to provide high level policy makers with a synthetic description of the main outcomes of the CLEAR project, together with a programmatic overview of the potential integration of the services within a regional healthcare system.

Executive summary

CLEAR (Clinical Leading Environment for the Assessment of Rehabilitation protocols in home care) is a project funded under the ICT Policy Support Programme – CIP-ICT-PSP-2007.2.2 – ICT for Ageing Well.
Under this project a large scale Pilot study has been conducted in four Member States of the European Union (Italy, Spain, The Netherlands, Poland) to demonstrate the feasibility of a Tele-rehabilitation service using *Habilis,* a general-purpose software platform.

But what does the term "tele-rehabilitation service" mean*?* **It is a service enabling patients to extend part of the rehabilitation treatment under the supervision of a <u>remote</u> team, <u>guaranteeing efficacy, safety, privacy and equitable access to care.</u> The tele-rehabilitation treatment can be provided at home or in kiosks (an intermediate environment between home and the clinical centre) where the equipment can be shared by several patients (for instance, kiosks may be hosted in geographical districts, pharmacies, etc.).**

With this scenario in mind, CLEAR has set up an innovative eHealth service based on the development of protocols for rehabilitation and chronic disease management.

Four pilot sites, involving more than 960 patients, have been set up in four European clinical centres of excellence: Infermi Hospital (S. Miniato, IT), Guttmann Institute (Badalona, ES), Rehabilitation Centre Het Roessingh (Enschede, NL) and the Medical University of Warsaw (Warsaw, PL).

Dedicated ICT-assisted, rehabilitation protocols have been designed for a heterogeneous group of common chronic diseases, chosen on the basis of their impact on the Health Systems, namely, osteoarthritis; paretic upper limb in stroke survivors; acquired brain injury (ABI) and mild cognitive impairments; chronic back pain (CBP) and whiplash injury (WAD); chronic obstructive pulmonary disease (COPD).

The service is deployed through Habilis, an interoperable software platform, purposely developed according to the requirements made by the physicians and IT managers of the clinical centres.

Through the Habilis platform patients receive customized rehabilitation sessions, and execute the specific session exercises at home or in the nearest kiosk. Exercise performance is recorded or diarized, according to therapists' prescriptions, and automatically sent to the therapists. The analysis software, purposely conceived to reduce the necessary time to analyse the data, allows therapists to assess the exercises, and update the treatment remotely and asynchronously.

An innovative multidimensional Health Technology Assessment approach has been set up by the Italian National Institute of Health (Istituto Superiore di Sanità – ISS). It was focused on the technical, organisational and legal maturity of all the service components. *The result is a complete, broad assessment, carried out by a pool of local independent assessors, to demonstrate service feasibility and to provide insights and guidelines for further improving the service and for facilitating the potential service uptake within other Regions or Countries*.

Beneficial to patients affected by different diseases, the service turned out to be feasible, safe and efficacious. The Habilis platform is flexible enough to be easily adopted in further contexts (e.g. other diseases and service models). Moreover the quality perceived by users is generally good, especially from the patients and caregivers point of view and from very aged patients without previous IT skills.

The sustainability analysis gave very interesting results, depending on the disease, service model (e.g. home-based, kiosk-based), local context and Health System, suggesting the need to explore business models tailored to the specificity of territorial contexts.

The project context

Rehabilitation has been defined by the World Health Organization as "…the use of all means aimed at reducing the impact of disabling and handicapping conditions and at enabling people with disabilities to achieve optimal social integration". This definition incorporates clinical rehabilitation but, more importantly, it addresses the concept of social participation, highlighting the need to remove societal barriers for people with a different ability.

As a consequence the rehabilitation systems, as a whole, have to be continuously developed considering that rehabilitation -following injuries or illnesses *and even in a chronic condition*- is a basic human right[1]. *As such, equitable and easy access to all aspects of rehabilitation, including specialist rehabilitation medicine, assistive technology and social support should be assured to the entire population, regardless of economic condition or geographical location, with uniformly high standards of care*.

On the other hand, owing to aging demographics and deleterious lifestyle behaviours, the prevalence and incidence of chronic diseases and co-morbidities continue to rise. The ensuing worsening of the chronic disease scenario is not only affecting an even larger number of people, but also results in significant human and economic costs to the health system and society.

As a matter of fact, the capacity of the current health care systems to manage effectively the increase in chronic diseases is being seriously challenged, which makes it difficult to cover the increasing demand of services.

There is the need for a radical transformation of health care delivery systems through the design of innovative delivery methods, and the deployment of enabling Information and Communication Technologies (ICT) that provide remote care.

With these considerations in mind, re-organizing the rehabilitation practices - and chronic disease management procedures in general - will entail the definition of new models where the key objectives are to maintain and improve patients' social, physical and mental capabilities, and render it possible for them to receive treatment at home or "at the point of their need".

A further relevant aspect where ICT can greatly contribute to rehabilitation is the possibility to extend rehabilitation treatments over time. In fact, even though, all in all rehabilitation treatments are effective in the short term, long-term maintenance is far from being optimal.

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[1] Fifty-Eighth World Health Assembly: Resolution 58.23, "Disability, including prevention, management and rehabilitation" Geneva, World Health Organisation, 2005.

This fact is attributable to *the patients' difficulty to translate the learned skills in their everyday life* and most probably, to *the motivation drop caused by inappropriate environments and lack of supporting facilities*. As an example, the following pictures show how the recovery plateau achieved by stroke survivors is progressively lost when rehabilitation is discontinued, and how it could be maintained, even improved, if the rehabilitation treatment is extended in time. If the rehabilitation treatments -or even part of these treatments- are provided in the daily environment of the patients, supervised at a distance by a health professional, the effectiveness and efficiency of the rehabilitation can be substantially increased.
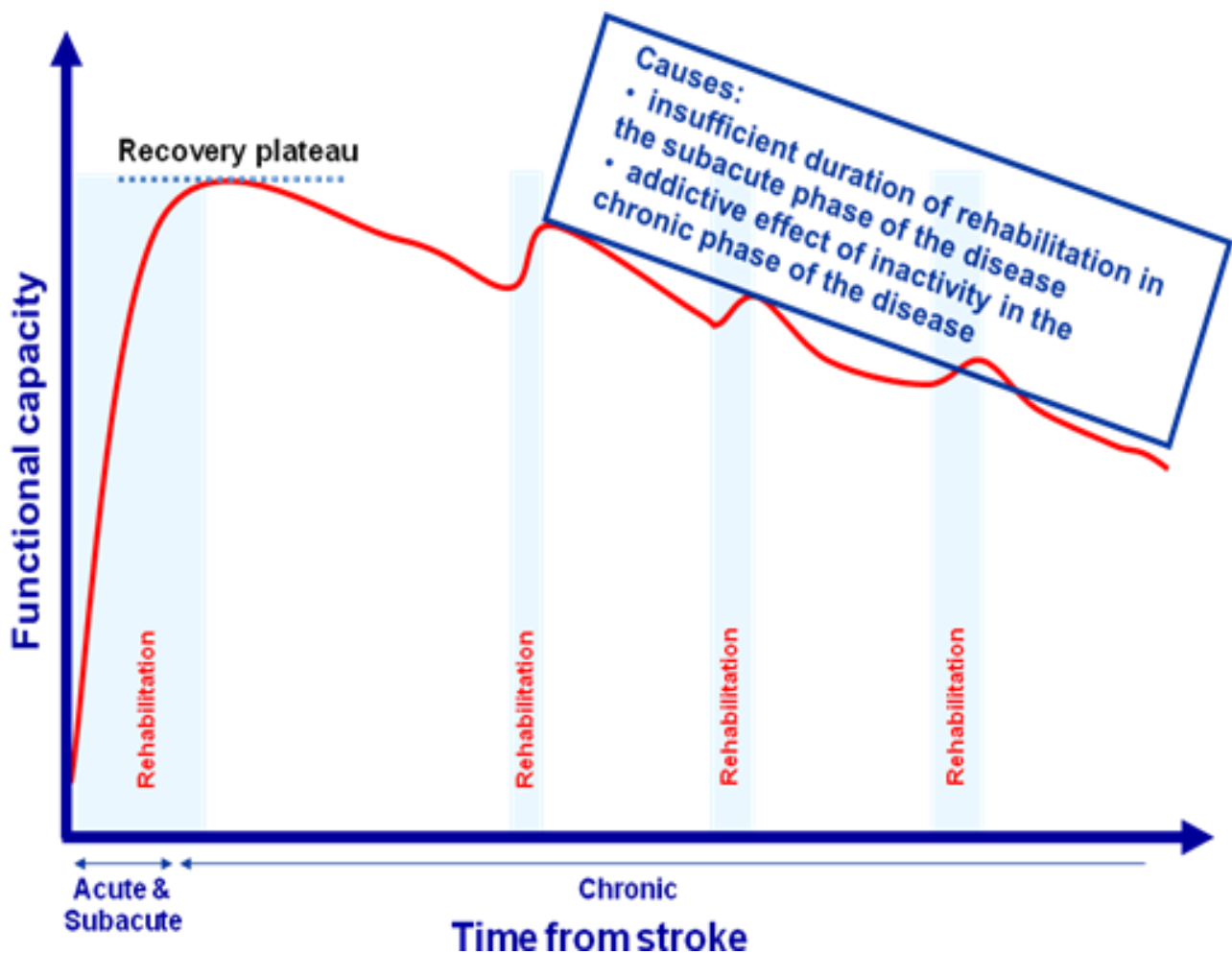
Figure 1: Loss of the recovery plateau in stroke patients

A proper usage of ICT is fundamental to address these issues. During the past years, a lot of experience has been gained with new approaches that enable treatment in the daily environment by utilizing communication and information technology, often combined with biomedical engineering. Most of these experiences, however, did not pay enough attention to service sustainability in terms of resources needed for both equipment and therapists.
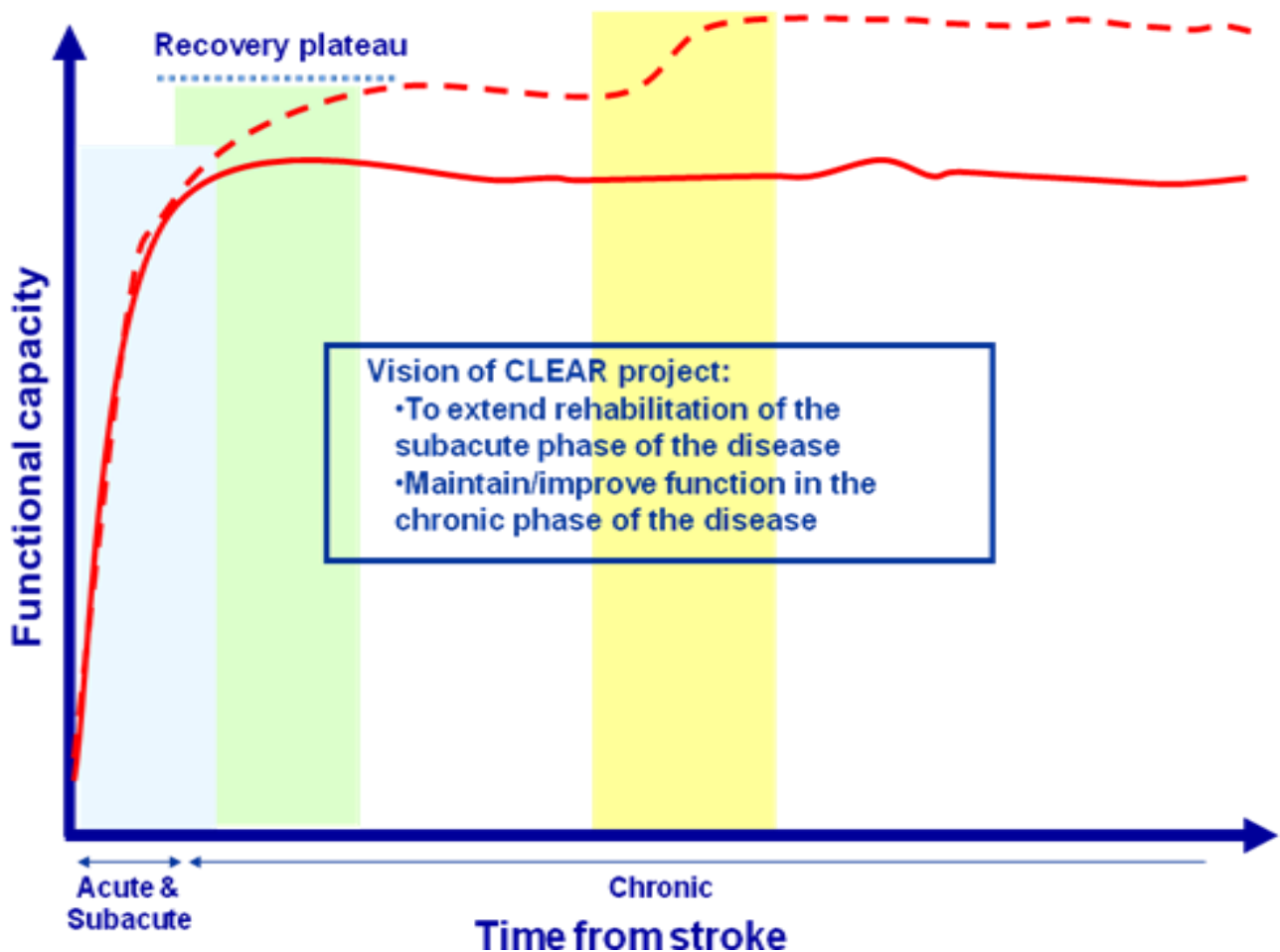
Figure 2: Vision of CLEAR

In responding to these needs and considerations, CLEAR has set up an innovative **tele-rehabilitation service** based on a general-purpose, low-cost platform, and has developed protocols for remote rehabilitation and chronic disease management, supporting patient self-training (patient empowerment) under the remote control of medical staff.

The protocols can be implemented at home or at kiosks, i.e. an intermediate environment, where equipment can be shared by several patients.

Such a service has huge potential to:
- improve patients' quality of life by reducing the need to go to healthcare centres;
- improve the effectiveness and use of resources of healthcare centres by increasing their capacity to treat more patients.

The Tele-rehabilitation Service has been deployed in four clinical centres of excellence: Infermi Hospital (S. Miniato, IT), Guttmann Institute (Badalona, SP), Rehabilitation Centre Het Roessingh (Enschede, NL) and the Medical University (Warsaw, PL), providing tele-rehabilitation treatments for three sets of most widespread chronic diseases that weigh heavily on Health Systems:

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- **Chronic Obstructive Pulmonary Disease** (COPD). One of the commonest respiratory conditions of adults in the developed world, COPD encompasses both chronic bronchitis and emphysema. It poses an enormous burden to society both in terms of direct cost to healthcare services and indirect costs to society through loss of productivity. In the Western world, COPD is probably the fourth commonest cause of death in middle aged to elderly people. The prevalence is difficult to estimate but in the USA, 13.6% of males and 11.8% of females aged 65-74 years are thought to have COPD. Tele-rehabilitation plays an important role in the management of COPD because it helps maintain the physical condition under control over time, reducing the need to travel to the Clinical Centre.

- **Musculoskeletal problems and chronic pain.** A major burden on individuals, health systems, and social care systems, with indirect costs being predominant. Osteoarthritis affects 9.6% of men and 18% of women aged >60 years. Increases in life expectancy and ageing populations are expected to make osteoarthritis the fourth leading cause of disability by the year 2020. Joint replacement surgery, where available, provides effective relief, but when waiting lists are too long, pre-surgery tele-rehabilitation can help to prevent the degradation of physical conditions due to inactivity. After surgery tele-rehabilitation could help to anticipate patient discharge, reducing costs. In addition tele-rehabilitation can be used for chronic conditions, which can be kept under control by targeted physical exercises. This is the case with back pain -the most prevalent musculoskeletal condition affecting about 4–33% of the population- and osteoporosis, a major risk factor for fractures of the hip, vertebrae, and distal forearm[2].

- **Stroke.** Although the incidence of stroke deaths is decreasing, its prevalence in the population is increasing because of enhanced survival and a growing elderly population. According to WHO estimates, the number of stroke events in European countries is likely to increase from 1.1 million per year in 2000 to more than 1.5 million per year in 2025. In any case, more than 50% of stroke survivors are alive in 5 years. Given this good survival rate and the increasing incidence of stroke, post stroke disability is becoming a high priority in health care systems. Tele-rehabilitation can be used in the post-acute phase, to help achieve the recovery plateau, and in the chronic phase to maintain it. Very often stroke patients present several disabilities at the same time (e.g. upper limb and lower limb functional disability, cognitive impairment, aphasia); a general purpose platform would be ideal to manage such complex situations.

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[2] Burden of major musculoskeletal conditions. Anthony D.Woolf & Bruce Pfleger, Bulletin of the World Health Organization 2003, 81 (9).

- **Mild cognitive impairments and Dementia** (neurological aspects). Acquired Brain Injury has a wide range of causes, it results in a huge number of potential consequences for the individual and his/her family, and many of its effects, though outwardly invisible pose a major and increasing public health challenge. For example, by 2020 traumatic brain injury –as it affects a very young segment of the population- is expected to be among the five causes of disease with higher economical repercussion when its estimation be adjusted according to life expectancy. Tele-rehabilitation can play a fundamental role to help people with Acquired Brain Injury to recover their ability at least in part by receiving part of the treatment at home. Dementia, an important public health problem, is one of the most common diseases in the elderly and a major cause of disability and mortality. In subjects over 65, crude prevalence rates for dementia vary between 5.9% and 9.4%[3]. For people with mild dementia, since there is no cure or reversal of their neurological deterioration, tele-rehabilitation can help minimize the speed of progression of the symptoms, especially those related to memory difficulties.

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[3] Prevalence of dementia in the elderly in Europe, C. Berra, J. Wancatab, K. Ritchiea, European Neuropsychopharmacology 15 (2005) 463 – 471.

Project results

The main results of the CLEAR project can be broadly divided in three main sectors:

1) The **technical achievements** obtained through the implementation and running of the platform as a "horizontal" software system used to deploy tele-rehabilitation services.
2) The **clinical achievements** of the six clinical studies on paretic Upper Limb in stroke survivors, ABI, dementia, osteoarthritis, COPD and chronic pain, carried out in the four centres of excellence.
3) **Health Technology Assessment methodological approach** tailored to tele-rehabilitation and its results.

Technical results

From a technical point of view the most remarkable results of the CLEAR project have been the successful design and implementation of an interoperable software platform (Habilis) to be used as a basis for the deployment of tele-rehabilitation services and the integration of the previously existing modules: the Online Exercise Coach, for physical rehabilitation, and PREVIRNEC, for cognitive rehabilitation. The platform is available in five languages (English, Italian, Dutch, Spanish and Polish). The main functionalities of the Habilis Platform are broadly described in Figure 3, where typical operations pertaining to a tele-rehabilitation session are given.

Clinical Centre
- Patients' data management
- Multimedia rehab. exercises libraries definition (audio/video Tutorial)
- Rehab. session definition and planning
- Assessment of the patient's compliance
- Live videoconference communication

Scheduled activities

Achieved results

Live communication

- Self management of assigned rehabilitation exercises
- Recording of results achieved
- Automatic transmission of data related to activities performed
- Live videoconference communication

Home or Kiosk

Figure 3: Habilis Platform main functionalities and deployment

Through Habilis, the clinical staff can define a series of rehabilitation exercises, customised to patients' conditions, to be remotely executed by the patients at the point of their need (home, kiosk or in a separate room within the Clinical Centres). Habilis allows the health professional to analyze the results achieved by the patients on the basis of the assigned tasks.

Clinical results

Figure 4 shows the clinical centres and related studies:

- Azienda Unità Sanitaria Locale 11 di Empoli, Regione Toscana (AUSL11), Italy.

- Rehabilitation Centre Het Roessingh (RCR), The Netherlands.

- Akademia Medyczna w Warszawie - The Medical University of Warsaw (MUW), Poland.

- Fundació Privada Institut de Neurorehabilitació Guttmann (FPING), Spain.

Figure 4: Centres of excellence where the clinical studies were conducted

The service was successfully implemented in all four centres. A total of 961 patients have been treated as of April 2012.

Table 1 reports the number of patients per group and related diseases.

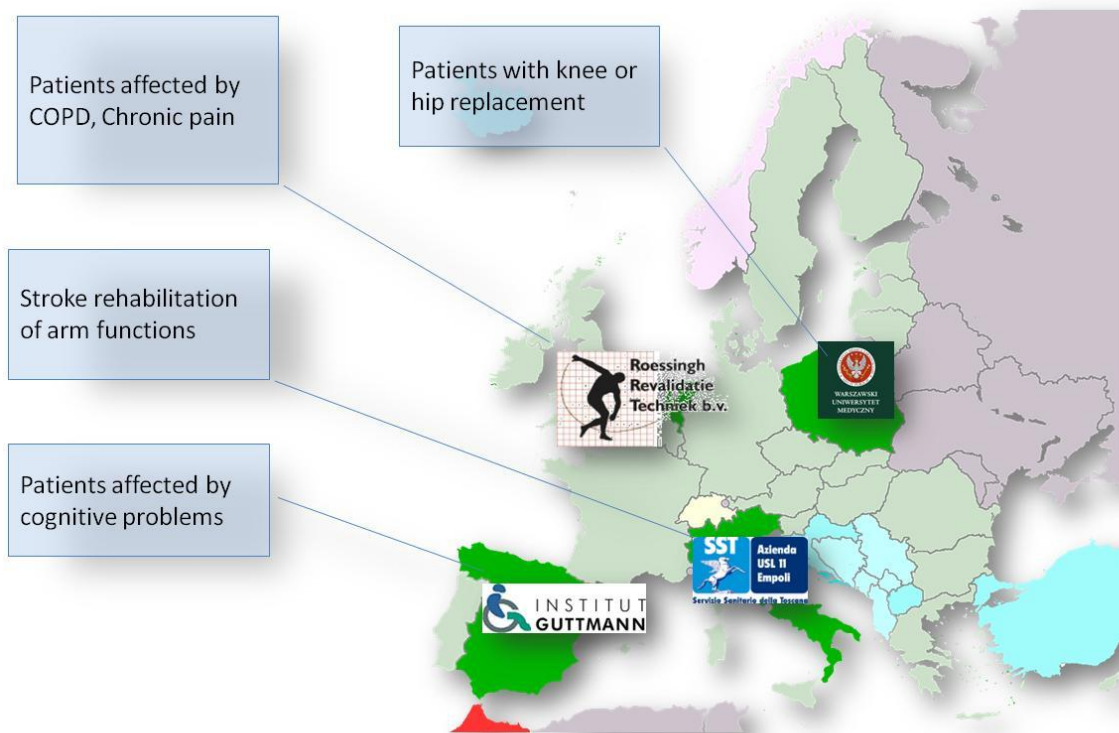| Clinical Centre	Number of patients			Disease
	Control Group	Intervention Group	Total	
RCR	35	56	91	COPD
	51	60	111	Chronic Pain
FPING	-	151	151	Acquired Brain Injury (FPING1)
	-	48	48	Mild Cognitive Impairment and mild to moderate Dementia (FPING2)
AUSL11	45	143	188	Residual hemi paresis and impaired arm residual function in Stroke survivors
MUW	155	217	372	Osteoarthritis of hip or knee before and after Total Joint Replacement (TJR)
		Total	961	

Table 1: Patients treated as of April 2012

One of the main objectives of the study was to demonstrate the feasibility of providing a tele-rehabilitation service by means of the Habilis platform as implemented in the clinical practice, and to furnish the related data for the HTA study. The following indicators were defined:

- **Satisfaction** of patients with the tele-rehabilitation application. Data related to satisfaction was collected through a satisfaction questionnaire and are reported as the percentage of patients who gave a low, average or high rating to three components: ease of use, perceived usefulness and attitude.

- **Clinical effectiveness** of the service when implemented in terms of health outcome and compliance to tele-rehabilitation. It is estimated by the percentage of subjects showing clinically relevant improvements.

- **Time investment** for providing and receiving the tele-rehabilitation service. It is estimated in euro as the average travel cost saving per week for the patients, and in minutes as the time saving during the whole treatment per patient for the healthcare professionals.

The results in terms of satisfaction, clinical effectiveness and time investment are summarized in Table 2.

		RCR		FPING		AUSL11	MUW
		Habilis as partial replacement	*Habilis as addition*	*FPING1*	*FPING2*		
Satisfaction	**Ease of use**	Low: 0.0 % Aver: 93.0 % High: 7.0 %		Low: 13.0% Aver: 73.0% High: 14.0%	Low: 2% Aver: 58.0% High:40%	Low: 3% Aver: 89% High: 8%	Low: 6% Aver: 12% High:8%
	Perceived usefulness	Low: 0.0 % Aver: 98.8 % High: 1.2 %		Low: 9.0 % Aver: 72.0 % High: 19.0 %	Low: 0% Aver:29% High:71%	Low: 11% Aver: 51% High: 38%	Low: 1% Aver: 19% High: 80%
	Attitude	Low: 13.6 % Aver: 67.9 % High: 18.5 %		Low: 7.0 % Aver: 74.0 % High: 19.0 %	Low: 0% Aver:25% High:75%	Low: 1% Aver: 96% High: 3%	Low: 2% Aver: 10% High: 88%
Clinical effectiveness	**Percentage of subjects showing clinically relevant improvement**	COPD: 62% CLPB: 59%	COPD: 77% WAD: 42%	Intramural: 78% Extramural: 28%	20% of cognitive tests; maintenance 60%.	Control group: 6% Intervention group: 49%	Lean on the results achieved like significant improvement was found[4]
Time investment	**Patient average travel cost savings (per week in €)**	COPD: 3.43 (1.65-8.10) CLBP: 3.2 (1.38-5.95)	N.A.: no time saving has been measured for clinical protocol considered as additional treatment.	262 € per week = 150€ (ambulance) *2.5 sessions (average) *0.7 (70% patients by ambulance)	No significant differences found because travelling costs are equal for both treatments	6.6 (0.07-9,8)	49.54 (2.25-135)
	Health care Professional time savings (whole treatment per patient in minutes)	COPD: 205,5 CLBP: 43.3	N.A.: no time saving has been measured for clinical protocol considered as additional treatment.	In average =60 min per session saving; a full treatment comprises 24-36 sessions (1440-2160)	In average = 60 min per session saving	79.8	In average: from 120 minutes (pre-surgery intervention) to 360 minutes (pre-surgery and post-operative interventions)[5]

Table 2: Summary of the Study Results

Efficacy has been demonstrated in all the clinical studies, which can be associated with the flexibility of the platform that can be used for different pathologies.

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[4] A precise percentage could not be calculated because of the big amount of multi-factorial variables.
[5] Such evaluation does not take into account that with the Habilis platform the patient can greatly increase the time spent in the rehabilitation activity at home.

Health Technology Assessment results

The HTA study was coordinated by the Italian National Institute of Health (Istituto Superiore di Sanità, ISS).

At the beginning of the project a thorough analysis of the literature showed that traditional HTA models were not adequate for investigating all the main aspects related to a tele-rehabilitation service. Therefore, an HTA model tailored to the operative context related to the project was developed and validated, including a set of tools aimed at retrieving information about service performance. The key aspect of the model is the HTA matrix of nine dimensions.

HTA activities were aimed at providing evidence falling into the following three main macro-areas:

- **Systematic Review**. Aimed at retrieving information about the performance of the tele-rehabilitation services coming from the technical and scientific literature. This activity was associated to the HTA dimension Evidence Based Information.

- **Clinical Trial**. Aimed at furnishing evidence of the implemented tele-rehabilitation service using the information obtained on-site from the service itself. Such information regarded the following dimensions of the HTA matrix: Clinical Impact, Risk Management, Economic Evaluation & Organizational impact, Ethical and Social issues, Quality perception, Security, Privacy and Liability.

- **Economic Evaluation**. Aimed at investigating service performance from the economic point of view. A critical passage is the Cost Analysis of service implementation.

Conclusions

The HTA study conducted within the context of the CLEAR project did represent a "validation-on the-field" for the proposed HTA methodology, model and instruments. In brief:

- The implemented HTA methodology can be considered a project result in itself.

- The implemented HTA model and set of tools were adequate to investigate all the main aspects of the implemented service in different operative contexts (answered questions > 80%).

- The implemented methodology, even though effective, was complex and time consuming (maybe not affordable within a research project). Further refinements are needed.

- HTA results can be generalized to all those local contexts which are "similar" to, or comparable with, the investigated ones in terms of personnel costs, organizational issues and clinical approach to the treatment, and only with respect to same pathologies and disease level.

- The growth of a proper cultural background is still needed for an effective HTA.

- Strong cooperation is needed among all partners involved in HTA activities.

- The HTA study conducted within the CLEAR project does represent the **first complete HTA experience in tele-rehabilitation relying on data from clinical trials**.

All the HTA studies conducted within the CLEAR Project were fully satisfactory from a HTA point of view for all the investigated dimensions. **The experiences conducted at all the involved Clinical Centres are likely to be reliably replicable in most countries - at least in Western Europe -** where Internet distribution, technology level, patient literacy and computer skills are comparable.

In so far as the same treatment protocols are applied (like it was during the CLEAR project) the HTA results may remain applicable at a more general level. In any case, CLEAR HTA results may be considered valid only with respect to the specific investigated pathology they refer to.

All HTA studies can be considered reliable, with >80% of answered questions (range 80-94%), showing that the service was feasible, at least with respect to the investigated pathologies and the involved Clinical Centres.

Other relevant observations:

- *The service was safe*. No severe adverse events occurred, which shows that Risk Management was effective within the CLEAR project.

- The Habilis tele-rehabilitation service was compliant with MD SAFETY issues, which means that the *Habilis technology could be considered ready to be used as a medical device*.

- Habilis technology showed a satisfactory level of maturity: some residual software bugs were identified and solved during the project.

- The service was compliant with ethical and privacy issues but for some potential privacy violation with respect to the Dutch Standard NEN 7510. The problem was investigated and solved, thus the next release of Habilis platform will be fully compliant with all related European standards.

- Quality, as perceived by users, is all in all good, especially from the patients and caregivers point of view. Health care professionals were generally satisfied regarding individual treatment, while in some cases they asked for a quality improvement of the overall service. Thus some aspects related to software interfaces, service continuity and local organizational issues are to be further investigated and solved. Worthy of note is the fact that high satisfaction was reported when the service was applied to cognitive patients, in particular old patients affected by dementia.

- Human resources were a fundamental component in delivering rehabilitation by remote control. *Optimization strategies and procedures may be implemented to reach or enhance the cost-effectiveness of the service*.

- *As for service sustainability, a lot of work is still to be done to change the attitude of most Healthcare systems regarding their policy of reimbursement for rehabilitation, of chronic patients in particular. No specific regulations or official guidelines are currently on the ground at a European level to support the adoption of tele-rehabilitation services. No strong evidence has yet been furnished about the effectiveness and cost-effectiveness of such services. The results of the Economic Evaluations cannot be generalized to other operative contexts where salaries, the costs of technologies and care delivery processes are likely to be different from the investigated ones.*

Programmatic synthesis for potential integration within Regional Healthcare Systems

CLEAR has contributed to lay the groundwork for tele-rehabilitation services diffusion and adoption in Europe, since it demonstrated on a large scale pilot that, notwithstanding criticalities, tele-rehabilitation is feasible, and that **the tele-rehabilitation services can be efficacious, safe, "easy to use" and accepted both by clinicians and patients, and could be effectively deployed to extend part of the rehabilitation treatment at home or at the point of patient needs for different diseases at reasonable costs**. More in detail, the results obtained from the clinical studies and the related Health Technology Assessment are summarized in Figure 5, where a comparison with the *ex ante* treatment is given.
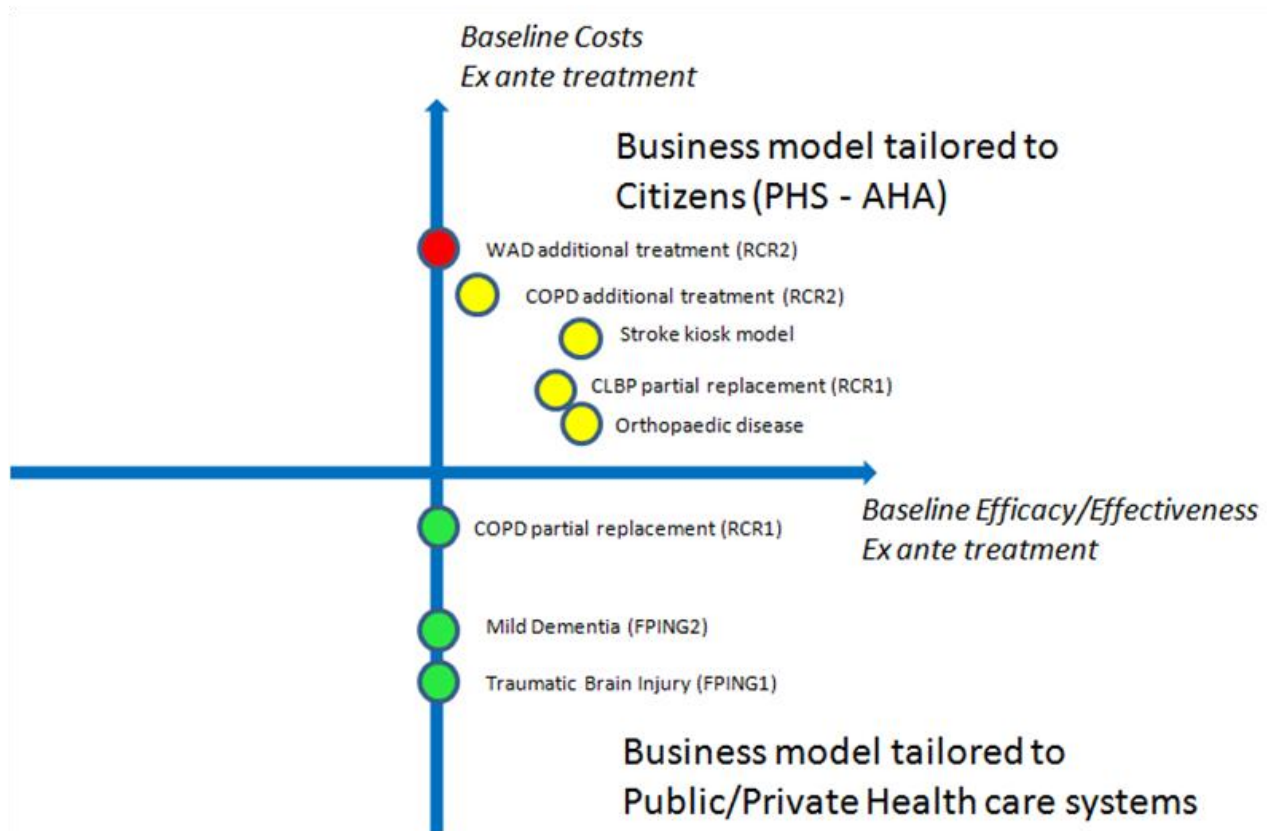

Figure 5: Study comparison

Figure 5 shows that efficacy has been demonstrated in all the clinical centres, showing that the tele-rehabilitation treatment is at least as efficacious as the traditional one.

As for effectiveness, in order to obtain sustainable models of delivery, **an efficient organizational environment must be implemented to carry out the necessary activities for the optimal empowerment and treatment of patients**.

From the results obtained two main conclusions can be drawn:

1) Habilis exercise treatment is beneficial to patients affected by different diseases, and can be proposed in personalised health systems to stimulate patient's activity at home, **extending rehabilitation time**. The model is to be designed within Personalised Health Systems (PHS) to support an Active Healthy Aging (AHA). Patient motivation is a key to reach the expected rehabilitation goals (e.g. through serious games, patient feedback, etc.).

2) The treatment of chronic conditions through exercise *has to be managed within an integrated care framework (primary, secondary, tertiary care) to reach full sustainability*.

A model that can certainly be taken as an example for the integration of such kind of services is the Chronic Care Model, defined by Wagner (1996). He suggested that, in order to be effective in the management of chronic conditions, a framework of continuity of care should be obtained through the exploitation of territorial resources. Such a model, already adopted in different countries, is tailored to prevent chronic diseases (Wagner 1999, and Glasgow et al. 2001). When integrated with strategies and concepts aimed at prevention, health promotion and empowerment, it results in what Barr et al. (2003) have called *the Expanded Chronic Care Model* (ECCM). As stated by Ham (2010), for *high performance chronic care health systems,* ICT integration has a central role in covering the big fracture between primary and secondary care.

As illustrated in Figure 6, there is indeed the need for a better integration between the above-mentioned care sectors that have to be aligned through sustainable disease management programmes.
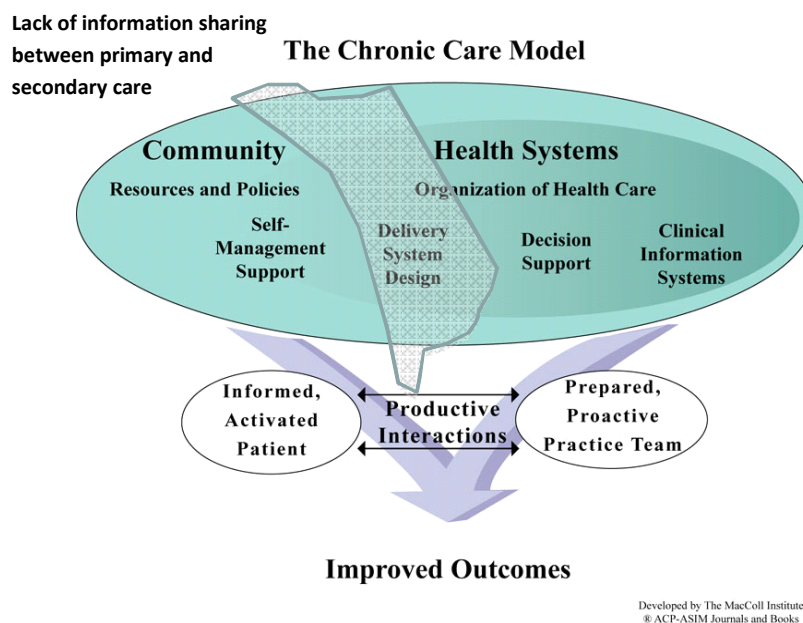

Figure 6: Area of intervention where ICT can play a significant role

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An ideal enabling environment is depicted in Figure 7, which illustrates an example of an ICT-assisted Integrated Care Management approach.
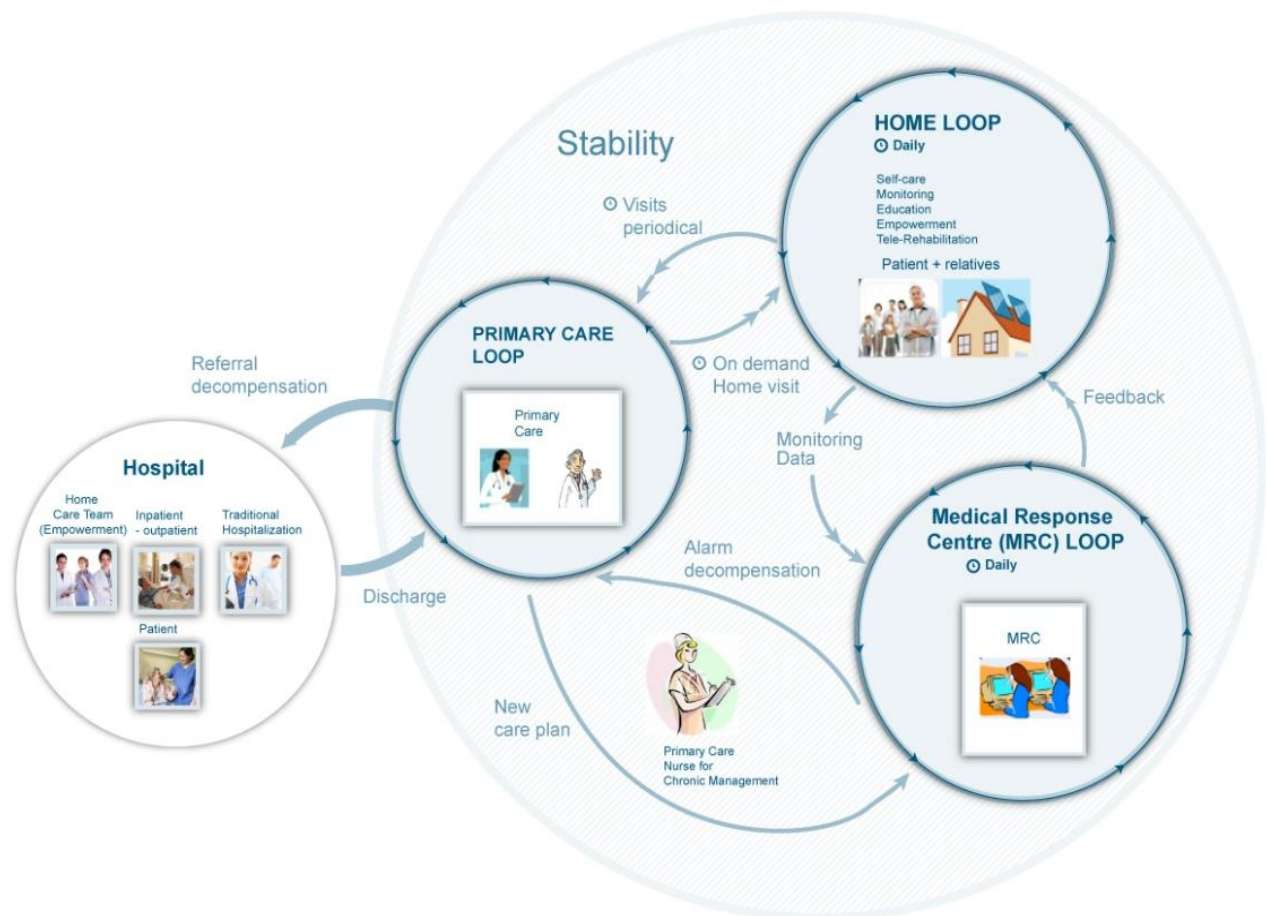

Figure 7: Example of an Integrated Care Management approach for Chronic Care

The figure shows on the left the hospital and the primary care spheres that stand for the health system as a whole (primary-secondary-tertiary care). While on the right, *an ICT assisted framework is shown, led by a Medical Response Centre (MRC) orchestrating the patient's care needs at home*. The MRC will function as a first intervention level by monitoring patients' activities and status at home. The MRC will take care of patients' needs during their stable status as well. This constitutes, at any time, an alert ring capable to liaise between patients and the health system as necessary when patients' conditions and needs change.

ICT-assisted clinical pathways are to be re-designed in alignment with such a vision and will need to be adapted to the characteristics (including the availability of financial resources) of the receiving contexts (geographical districts). The CLEAR Project has demonstrated that such needs are sometimes different even within the same geographical district.