







	 <p>EUROPEAN HEART RHYTHM ASSOCIATION A Registered Branch of the ESC</p>	
		
	<p>RENEWING HEALTH <i>Evaluation, outcome, costs</i></p> <p><i>Roberto Mantovan</i> <i>Claudio Saccavini</i></p>	
<p>Cannes, 22 March 2010</p>		

		
<p>Our real knowledge in telemedicine</p>		
		

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Parametro	Biotronik: Home Monitoring™	Medtronic: CareLink Network®	Boston Scientific: Latitude®	St. Jude M.: HouseCall Plus™, Merlin™.net	Sorin Group
Approvazione della FDA	2001	2005	2006	2007	N.d.
Nome dispositivo paziente	CardioMessenger 	CareLink 	Latitude Communicator 	HouseCall Plus Merlin@homeRF 	Monitor paziente di casa N.d.
Caratteristiche	Portatile, semplice	Fisso, semplice	Fisso, interattivo	Fisso, interattività vocale	Fisso

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P. Brugada

What evidence do we have to replace in-hospital implantable cardioverter defibrillator follow-up?

Pedro Brugada, Clin. Res. Cardiol., 95, Suppl 3, 2006

Primary end point: percentage of the correct decisions on the necessity of a scheduled follow-up decided upon the analyses of Cardio Reports.

Methods: The physician analyzed the Home Monitoring data before the routine follow-up (FU) visit and gave a forecast on the necessity of the pending FU, which was compared with the evaluation after the FU

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**Home Monitoring +
Physicians' background knowledge +
New patient management scheme results in:**

- **46% Reduction of Routine FU Visits**



- **Safe patient management**
- **Individualized follow-up**

P. Brugada, Clin. Res. Cardiol., 95, Suppl 3, 2006



It looks like good, but...

Which are possible resistances?



- Patient concerns:
 - *Anxiety: Is the transmission working? Are they really checking me and my device?*
 - *Trust: I'd like to see my doctor*
 - *Pride: I'm a patient not a device*



- Physician concerns:
 - *Anxiety: what about of Friday evening alerts? (legal questions)*
 - *Trust: I'd like to see my patient*
 - *Pride: I'm a doctor not a technician*
 - *Claim: who assess and pay this extra job?*



- **Administrative concerns:**
 - *Anxiety: how to organize this job?*
 - *Distrust: I don't like to pay an extra job (is it really cost effective?)*
 - *Pride: I'm a politician! Don't bother me with patients/physician concerns*



Which are the expected impacts of telemedicine?

- Reduce hospitalisation and improve disease management
- Increased links and interaction between patients and health professionals
 - Improvement of quality of life for patients suffering from chronic conditions
- Increased use of existing or commonly agreed standards and demonstration of interoperability of the new solutions in regular healthcare practice



Are these end points
demonstrated?

NO!



Systematic review of cost effectiveness studies of
telemedicine interventions

Pamela S Whitten, Frances S Mair, Alan Haycox, Carl R May, Tracy L Williams, Seth Hellmich

BMJ 2002;324:1434-7

- 55 of 612 identified articles that presented actual cost benefit data.
- Only 24/55 (44%) studies met quality criteria justifying inclusion in a quality review
 - 20/24 (83%) restricted to simple cost comparisons.
 - No study used cost utility analysis
- Only 7/24 (29%) studies attempted to explore the level of utilisation that would be needed for telemedicine services to compare favourably with traditionally organised health care.
- None addressed this question in sufficient detail to adequately answer it.



What is already known on this topic

The use of telemedicine has garnered much attention in the past decade

Hundreds of articles have been published claiming that telemedicine is cost effective

However, missing from the literature is a synthesis or meta-analysis of these publications

What this study adds

A comprehensive literature search of cost related articles on telemedicine identified more than 600 articles, but only 9% contained any cost benefit data

Only 4% of these articles met quality criteria justifying inclusion in a formalised quality review, and most of these were small scale, short term, pragmatic evaluations with few generalisable conclusions

Conclusion There is no good evidence that telemedicine is a cost effective means of delivering health care.



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Medicare payments, healthcare service use, and telemedicine implementation costs in a randomized trial comparing telemedicine case management with usual care in medically underserved participants with diabetes mellitus (IDEATel).

Palmas W, Shea S, Starren J, Teresi JA, Ganz ML, Burton TM, Pashos CL, Blustein J, Field L, Morin PC, Izquierdo RE, Silver S, Eimicke JP, Lantigua RA, Weinstock RS; IDEATel Consortium.

- **Conclusion** Telemedicine case management was not associated with a reduction in Medicare claims in this medically underserved population. The cost of implementing the telemedicine intervention was high, largely representing special purpose hardware and software costs required at the time.
- Lower implementation costs will need to be achieved using lower cost technology in order for telemedicine case management to be more widely used.



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Telemedicine: An unfruitful experience of tele-expertise in nephrology.

[Alamartine E](#), [Thibaudin D](#), [Maillard N](#), [Sauron C](#), [Mehdi M](#), [Broyet C](#), [Mariat C](#).
PRES, universit  de Lyon, 69000 Lyon, France; Universit  Jean-Monnet, 42055 Saint-Etienne
cedex 02, France; CHU de Saint-Etienne, 42000 Saint-Etienne, France.

- The cost of the website was a prohibitive 75 000 euros for 3 years.
- Therefore, we had no choice that to close the experience.
- Telemedicine needs juridical rules and specific finances to work on a long run.



Economic Evaluation of Telemedicine: Review of the Literature and Research Guidelines for Benefit–Cost Analysis

Mari a E. Da valos, Ph.D. (ABD),¹
Michael T. French, Ph.D.,²
Anne E. Burdick, M.D., M.P.H.,^{3,4} and
Scott C. Simmons, M.S.³
TELEMEDICINE and e-HEALTH
DECEMBER 2009

Table 1. Research Gaps, Limitations, and Challenges with the Economic Evaluation of Telemedicine

- **Limited generalizability:** Given the heterogeneity of telemedicine programs, most of the results cannot be generalized.
 - **Disparate estimation methods:** There is no uniform methodology or guidelines to conduct standardized economic evaluation in telemedicine.
 - **Few completed BCAs:** Most economic evaluations focus on program costs, and have not deeply researched a broad range of economic benefits from a variety of perspectives
 - **Lack of RCTs:** The use of RCTs in telemedicine is scant.
 - **Lack of long-term evaluation studies:** Long-term studies in telemedicine are rare so that sustainability of these initiatives cannot be studied.
 - **Absence of quality data and appropriate measures:** Shortage of appropriate data undermines the quality and reliability of economic evaluation.
 - **Small sample sizes:** Telemedicine programs usually involve small samples, thus posing important statistical limitations.
- BCAs, benefit–cost analyses; RCTs, randomized control trials.



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TELEMEDICINE and e-HEALTH DECEMBER 2009

- Economic evaluations of telemedicine, however, remain rare
- To facilitate more advanced economic evaluations, this article presents research guidelines for conducting benefit–cost analyses of telemedicine programs



- Many small/medium size studies have been performed
- Most of them demonstrated the “usefulness” of telemedicine

Why telemedicine is not widely diffused in health systems?



Possible reasons of telemedicine poor diffusion

- Technology (?)
- Money (?)
- Organizational models
- Physician/patients concerns
- Legal aspects
- Cost/effectiveness

QUESTIONS FOR RENEWING HEALTH: RegioNs of Europe WorkINg toGether for HEALTH

How to implement
telemedicine in real “health
world”?

REgions of Europe Working toGether for HEALTH

- 1. Current use of the technology (implementation level)
- 2. Description and technical characteristics of technology
- 3. Safety
- 4. Accuracy
- 5. Effectiveness
- 6. Costs, economic evaluation
- 7. Ethical aspects
- 8. Organisational aspects
- 9. Social aspects
- 10. Legal aspects

Questions to EHRA

- Which pathologies/group of patients should be tele-monitored?
- What patient should be not monitored?
- How long should a patient be monitored?

RENEWING HEALTH: REgioNs of Europe Working toGether for HEALTH

- Programme: Competitiveness and Innovation Framework Programme CIP runs for the years 2007-2013
- Funding Scheme: Information and Communication Technologies Policy Support Programme ICT PSP, Funding Instruments: Pilot Type A
 - Principle Actor Involved: Regional Healthcare Authorities
 - Content of the 3rd Call of Proposals in 2009
 - Theme: ICT for Health, ageing and inclusion
 - Objective: ICT for patient-centered health services
 - **Budget: € 14 M** - European Co-financing: € 7 M
 - Duration: 32 months
- Starting: 1st February 2010 – Kick Off Meeting: 8th February 2010, Venice



The Consortium Arsenal.IT: Veneto's Research Center of eHealth Innovation



- Founded in 2005 as "*Telemedicine Consortium*", currently groups together all the 23 *Local Health Authorities* of Veneto Region.
- Director: dr Claudio Saccavini





- Has acted as an *Observatory* by performing *systematic surveys* on *Telemedicine applications* developed over time by the member Health Authorities.
- Has succeeded in highlighting the critical issues of *interoperability, standardization and organizational impact* as factors for driving the diffusion of Telemedicine applications in the care delivery process.



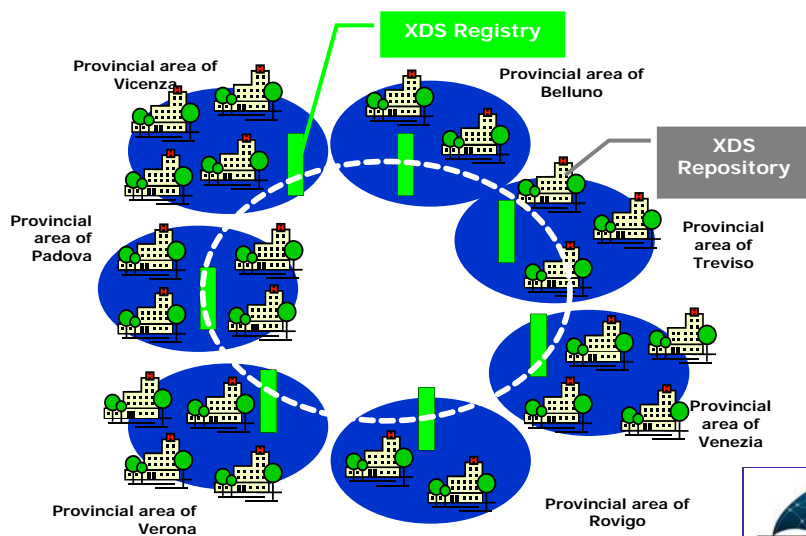
HEALTH OPTIMUM - HEALTHcare Delivery OPTIMisation throUgh teleMedicine - is a Telemedicine Project aimed to support different specialties thanks to Application of Telemedicine.

- **Phase 1: Market Validation** (18 months May 2004 – January 2006)
 - ✓ **Purpose:** market validation of organizational models based on telemedicine services
 - ✓ **11 healthcare** Providers in Veneto Region
 - ✓ **3 European** Member States: Italy, Spain, Denmark
- **Services involved:**
 - ✓ **Historical Services:** Telecounselling Service for Neurosurgery and Telelaboratory



- **Phase 2: Initial Deployment** (24 months June 2007 – May 2009)
 - ✓ **Purpose:** deploy organizational models based on telemedicine services
 - ✓ all the **23 healthcare Authorities**
 - ✓ **5 European Member States:** Italy, Spain, Denmark, Sweden, Romania

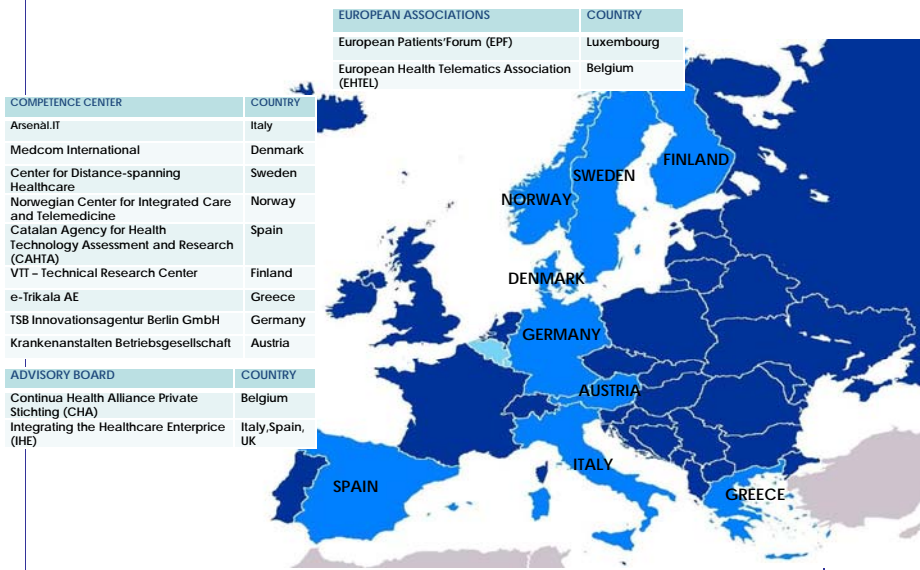
- **Services involved:**
 - ✓ **Historical Services:** Telecounselling Service for Neurosurgery and Telelaboratory
 - ✓ **New Services:** Telecounselling Service for Stroke Management, Oral Anticoagulation Therapy (OAT)



- **Programme:** Competitiveness and Innovation Framework Programme CIP runs for the years 2007-2013
- **Funding Scheme:** Information and Communication Technologies Policy Support Programme ICT PSP, **Funding Instruments:** Pilot Type A
- **Principle Actor Involved:** Regional Healthcare Authorities
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Background: the overall background of the project is a number of EU conferences and reports describing telemedicine and the potential benefits of a wider use of telemedicine applications in Europe.

Objective: to validate, in real life settings and **with a common rigorous assessment methodology**, the use of existing Personal Health Systems for innovative types of Telemedicine services used to monitor chronic patients with **Cardiovascular Disease (CVD), Chronic Obstructive Pulmonary Disease (COPD) and Diabetes** and to prepare for their wider deployment.





- **Reduce hospitalisation** and improve disease management
- Increased links and interaction between **patients and health professionals**, facilitating more active **participation of patients** in the care processes
- **Improvement of quality** of life for patients suffering from chronic conditions
- Increased use of **existing or commonly agreed standards** and demonstration of interoperability of the new solutions in regular healthcare practice
- Provide **a convincing business case** to be presented to National, Regional and Local Health Authorities and to stimulate them to speed up the deployment of patient-centered eHealth service solutions



		RENEWING HEALTH: Work Packages
WORK PACKAGE	Leader	
WP 1 Project Co-ordination, Management and Quality Assurance	VENETO REGION	
WP 2 Dissemination	VENETO REGION	
WP 3 Evaluation Methodology and Pilot Evaluation	REGION SYDDANMARK	
WP 4 User Advisory Board Management	EHTEL	
WP 5 Industrial Advisory Board Management	CHA	
WP 6 Standard and interoperability framework definition	REGION CENTRAL GREECE	
WP 7 Security, privacy and ethical issues	VENETO REGION	
WP 8 Real life pilot in Veneto	VENETO REGION	
WP 9 Real life pilot in Syddanmark	REGION SYDDANMARK	
WP 10 Real life pilot in Norrbotten	COUNTY OF NORBOTTEN	
WP 11 Real life pilot in Northern Norway	REGION NORTHERN NORWAY	
WP 12 Real life pilot in Catalonia	CATALONIA	
WP 13 Real life pilot in Finland	SOUTH KARELIA	
WP 14 Real life pilot in Central Greece	REGION CENTRAL GREECE	
WP 15 Real life pilot in Austria	CARINTHIA	
WP 16 Real life pilot in Germany	BERLIN	
WP 17 Liaison with other EU initiatives	COUNTY OF NORBOTTEN	
WP 18 Scalability of the RENEWING HEALTH initiative	REGION SYDDANMARK	
WP 19 Further Deployment	SOUTH KARELIA	

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		RENEWING HEALTH: Work Package 3
<h3>WP 3 Evaluation Methodology and Pilot Evaluation</h3> <p>The main objectives are ensuring that:</p> <ul style="list-style-type: none"> ▪ the evaluation of each pilot is based on the FAST assessment model to produce a systematic and multi-disciplinary assessment of the impact of telemedicine services; ▪ each pilot is evaluated in accordance with the agreed trial protocol and therefore produces valid and reliable data about <ul style="list-style-type: none"> ✓ the clinical outcomes, ✓ the quality of life of patients, ✓ the satisfaction of the different categories of users, ✓ the organisational and economic impact of the service, <p>by using common primary indicators for each cluster of pilots to obtain comparable results</p>		
		

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A **multi-disciplinary process** that summarizes and evaluates information about the medical, social, economic and ethical issues related to the use of telemedicine in a **systematic, unbiased and robust manner**.

Patient & clinical outcomes <ul style="list-style-type: none"> • Quality of Life • Health condition • Compliance • Medication • Self-management • Pilot related indicators 	Organisation <ul style="list-style-type: none"> • Task distribution • Personnel satisfaction • Co-operation relations within the organisation or with external part • Workflow • Education and knowledge sharing • Pilot related indicators
Technology <ul style="list-style-type: none"> • User-friendliness • Stability • Security • Inclusiveness • Integration • Pilot related indicators 	Economy <ul style="list-style-type: none"> • Hospitalisation and readmissions (numbers and length) • Consultations with GP etc. • Medication costs • Personal resources • Technology and maintenance costs • Pilot related indicators

The methodology used follows the principles of the **Health Technology Assessment** in its general structure with reference to the **Core Model Project EUnetHTA**



WP 4 User Advisory Board Management - EPF, EHTEL

Bringing together representatives of the **different categories of users** of the services foreseen in the context of RENEWING HEALTH to advise the Project Team about **the real need of the users** and to give feedback services actually piloted in order to improve the fit between the latter and the user needs.

WP 5 Industrial Advisory Board Management – CHA and IHE

An Industrial Advisory Board will be created to provide advice to the Consortium from companies and people with profound market knowledge. The Board will bring together experts with competence in management of **clinical data, standards, open sources, business trends in the Personal Health System sector, semantic integration** etc



WP 6 Standard and inter-operability framework definition

This work package aims at creating a group **of clinicians** from the various pilot sites, bringing together key technical experts using the membership of **CHA** and the external support of **IHE** and performing a profiling exercise as described in the **M403 Phase 1*** report liaising with the appropriate standardisation bodies and industrial associations

WP 7 Security, privacy and ethical issues

The main objective of this work package is analysing the **regulations, laws and practices** concerned with security, privacy and ethical issues relating to the handling of clinical data in force in the participating countries/regions and **formulating recommendations to the entire Project Team** about how to deal with these aspects.

* joint project – European Commission and European Standards Organisations



WP 8 Real life pilot in Veneto

For the Veneto Region, the following are involved:

- 6 Local Health Authorities and 2 Hospital Trusts
- 4000 patients with CVD and 500 patients with COPD

This work package aims **at testing, with FAST, in real life conditions** the set of telemedicine services which have been selected for the pilot site and collecting the values of the indicators specified by the assessment methodology before and after the trials.

The main tasks are:

- Integration of existing services
- Patients and professionals recruitment and training
- Field trials



WP 18 Scalability of the RENEWING HEALTH Initiative

The objective is to initiate an extension of RENEWING HEALTH by creating an **open environment for the exchange of knowledge** and information with other regions that are interested in following or cooperating with RENEWING HEALTH.

WP 19 Further Deployment

This WP prepares the ground for the **deployment** in regions not yet mature enough to join the RENEWING HEALTH Initiative during the lifespan of the Project. The WP will also produce both **guidelines and a Deployment Plan**.



- ★ Provide a structures framework for assessing the **effectiveness and contribution to quality of care** of telemedicine and PHS
- ★ Provide a **tool for self-evaluation** that allows to identifies the **areas needing improvement** to re-shape the existing services in to a new Model of Telemonitoring Service that:
 - ★ Allows the monitoring of patients anywhere and anytime
 - ★ Provides patients with the means to manage their health conditions outside traditional care setting
 - ★ Enables, on a large scale, continuity of care enhanced interaction among patients and Primary Care Settings as well as Secondary Care Settings
 - ★ Provides health professionals with more comprehensive monitoring and diagnostic data for decision making





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