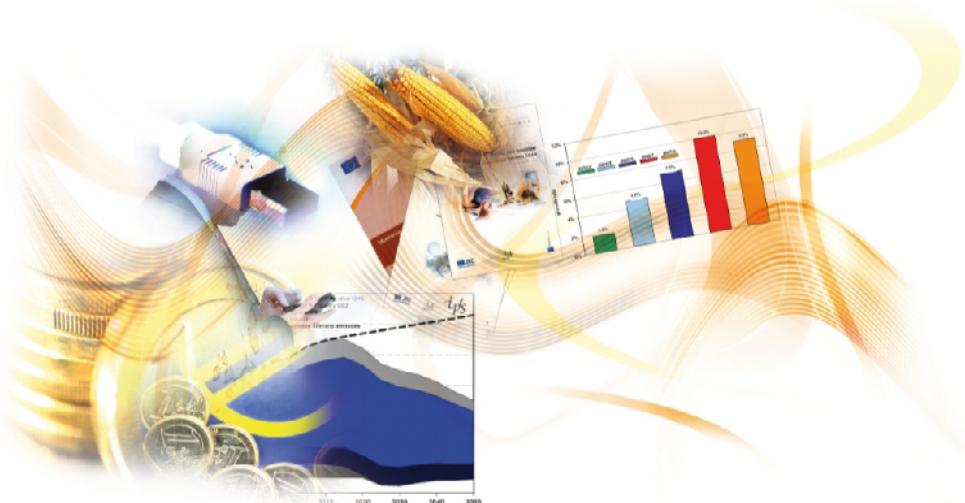


# Strategic Intelligence Monitor on Personal Health Systems (SIMPHS) Market Structure and Innovation Dynamics

Authors: Fabienne Abadie, Cristiano Codagnone, Marc van Lieshout,  
Corina Pascu, Peter Baum, Anssi Hoikkanen, Jose-Antonio Valverde,  
Ioannis Maghiros



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**Contact information**

Address: Edificio Expo. c/ Inca Garcilaso, 3. E-41092 Seville (Spain)  
E-mail: [jrc-ipts-secretariat@ec.europa.eu](mailto:jrc-ipts-secretariat@ec.europa.eu)  
Tel.: +34 954488318  
Fax: +34 954488300

<http://ipts.jrc.ec.europa.eu>  
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## List of Acronyms

<b>Acronym/ Term</b>	<b>Description</b>
<b>ACP</b>	American College of Physicians
<b>ADAC</b>	German Automobile Association
<b>B2B2C</b>	Business to Business to Customer
<b>BDOC</b>	Bed Days of Care; number of days of hospital stay; measure used to measure the average length of stay
<b>BKK</b>	Betriebskrankenkasse- German Company Health Insurance Fund
<b>CAGR</b>	Compound Annual Growth Rate
<b>CCHT</b>	Care Coordination/Home Telehealth
<b>CCM</b>	Chronic Care Management or Chronic Care Model
<b>CHA</b>	Continua Health Alliance.
<b>CHF</b>	Chronic Heart Failure
<b>CKD</b>	Chronic Kidney Disease
<b>CIS</b>	Clinical Information System
<b>CIP</b>	Competitiveness and Innovation Framework Programme
<b>CNR</b>	"Comité National Recherche", "Consiglio Nazionale di Ricerca"; French or Italian Research Committee
<b>COPD</b>	Chronic Obstructive Pulmonary Disease
<b>CORDIS</b>	The Community Research and Development Information Service
<b>CSCI</b>	Commission for Social Care Inspection
<b>CSO</b>	Clinical Systems Organisers
<b>CVD</b>	Cardiovascular Diseases
<b>CVIS</b>	Cardiology Information and Image Management Systems
<b>DALY</b>	Disability-Adjusted Life Year
<b>DM</b>	Diabetes Mellitus
<b>DRG</b>	Diagnosis Related Group: payment categories that are used to classify patients for the purpose of reimbursing hospital expenses.
<b>DHSSPS</b>	U.K. Department of Health, Social services and Public Safety
<b>ECG</b>	Electrocardiogram or Electrocardiography
<b>ECCH</b>	Northern Ireland's Connected Health and Care strategy
<b>EHR</b>	Electronic Health Record
<b>EMR</b>	Electronic Medical Records
<b>EPO</b>	European Patent Office
<b>GDP</b>	Gross Domestic Product
<b>HBT</b>	Home Based Telemanagement
<b>HHH</b>	Home or Hospital in Heart Failure Study
<b>HTA</b>	Health Technology Assessment – i.e. the systematic evaluation of properties, effects, and/or impacts of health care technology.
<b>ICI</b>	information and communication infrastructure
<b>ICP</b>	Integrated Care Pilots
<b>ID</b>	International Dollar
<b>IDF</b>	International Diabetes Federation
<b>IGT</b>	Impaired Glucose Tolerance
<b>IHC</b>	Immunohistochemistry
<b>IHD</b>	Ischemic Heart Disease
<b>IHIN</b>	Integrated regional/national Health Information networks
<b>IPC</b>	International Patent Classification

<b>IZIT</b>	Implementatie-organisatie voor innovatie van de zorg met behulp van ICT - Dutch acronym for Innovation in Healthcare IT
<b>KOALA</b>	"Kijken op afstand als logisch alternatief" = Dutch Telemedicine/ Telecare large-scale project ( <a href="http://www.koalaweb.nl/">http://www.koalaweb.nl/</a> )
<b>LFS</b>	Labour Force Survey
<b>LIS</b>	Laboratory Information Systems
<b>LMI</b>	Lead Market Initiative
<b>LTC</b>	Long-Term-Care
<b>MCU</b>	Mobile Care Unit
<b>MHC</b>	Monitoring Health Conditions
<b>MRI</b>	Magnetic Resonance Imaging
<b>MS</b>	Multiple Sclerosis
<b>MUD</b>	Medical User Devices
<b>NAHCH</b>	United States National Association for Home Care and Hospice
<b>NIC</b>	Non-Institutional Care
<b>NHS</b>	National Health Service (UK)
<b>OTN</b>	The Ontario Telemedicine Network
<b>PACS</b>	Picture Archiving and Communications System
<b>PDA</b>	Personal Digital Assistant
<b>PHS</b>	Personal Health Systems
<b>PPP</b>	Purchasing power parity
<b>PTSD</b>	Posttraumatic Stress Disorder
<b>QALY</b>	Quality Adjusted Life Years
<b>QOF</b>	Quality of Outcomes Framework
<b>R&amp;D</b>	Research and Development
<b>RCT</b>	Randomised Clinical Trial: clinical trials in which the patient group is at random divided in two, only one given the new treatment.
<b>RMT</b>	Remote Patient Monitoring and Treatment
<b>ROI</b>	Return On Investment
<b>SI</b>	System Integration
<b>SCI</b>	Spinal Cord Injury
<b>SIMPHS</b>	Strategic Intelligence Monitoring of Personal Health Systems
<b>SME</b>	Small and Medium Enterprise
<b>TA</b>	Tele Assistance
<b>TDP</b>	Scottish Telecare Development Programme
<b>UCDC</b>	Ubiquitous Chronic Disease Care
<b>USSL</b>	Italian Local Socio-Health Unit
<b>VHA</b>	The Veterans Health Administration
<b>VDE</b>	Verband der Elektrotechnik, German Association for Electrical, Electronic and Information Technologies
<b>VTT</b>	Valtion Teknillinen Tutkimuskeskus Technical Research Centre of Finland
<b>WIPO</b>	World Intellectual Property Organization
<b>WSD</b>	Whole System Demonstrator
<b>WHO</b>	World Health Organisation
<b>WoHIT08</b>	World of Health IT 2008 conference
<b>ZIF</b>	Zorg (Health) Innovatie Forum

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## Executive Summary

In an ageing Europe, where more and more citizens live with chronic diseases, telemedicine can help to make the difference in facing the global challenge posed to health systems by an increasingly heavy burden of demand for service. The European Commission realises this potential and intends to exercise leadership in fostering the deployment of telemedicine applications on a large scale. Acting in the structured framework of several policy initiatives started in 2004 with the eHealth Action Plan (COM 356), the Commission addressed in its Communication on Telemedicine (2008, COM 689) the main barriers that need to be overcome in order to facilitate greater deployment, highlighting three key issues: (1) increasing confidence and acceptance of telemedicine services; (2) gaining legal clarity; (3) overcoming unsolved technical issues and supporting market development.

This report has been prepared within the study "Strategic Intelligence Monitor on Personal Health Systems" (SIMPHS) conducted by DG JRC IPTS for DG INFSO as a one of the actions devised to address the above issues no. (1) and (3). Focusing on Personal Health Systems (PHS)<sup>1</sup> and, more specifically on Remote Patient Monitoring and Treatment (RMT),<sup>2</sup> this report explores the current status of the RMT market in Europe and addresses the question of how RMT can help face some of the challenges standing in front of the European healthcare delivery systems. By analysing the reasons of the limited deployment and identified barriers, the reports provides ample evidence on the encouraging outcomes of early RMT deployment, while analysing the impact of the outcomes and briefly modelling the potential from EU-wide deployment.

The rational of the study is based upon the following considerations:

- Fostering a functional, reliable and affordable Health Care system in general and the management of chronic disease in particular has been the key goal of European policies at national and EU level, over a number of years. Health care expenditure as a percentage of GDP has seriously risen from 4.7% in 1970 to about 9% in 2007 in 19 EU countries.<sup>3</sup> In addition, demographics have driven this trend: an aging European population which has doubled the percentage of the population over 65 between 1960 and 2008. Moreover, the ratio between economically inactive elderly and an active person is projected to fall from the current 1:4 to 1:2 in 2050 and beyond, which means that one inactive elderly will eventually be supported by 2 active people from year 2050 onwards. The resulting impact of this situation is two-fold: escalating care cost on the one hand, and shortages in health care delivery caused by the scarcity of professionals and informal carers derived from the increased demand, on the other. An increasing shortage of qualified health care personal is expected by 2020, both in physicians and nurses. This coincides with reduced potential informal carers due to increasing predominance of nuclear families, workforce feminisation, and workforce mobility.
- Chronic diseases have become widespread across all age groups causing a large part of the disease burden in Europe and posing a major challenge for health care systems financing and sustainability in Member States.<sup>4</sup> As an example, Cardio Vascular Diseases (CVD) on their own

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<sup>1</sup> PHS – See the definition given in Table 1 at page 14.

<sup>2</sup> RMT – See the definition given in Table 2 at page 14.

<sup>3</sup> OECD 2009 Health Data. This set of data did not include: Bulgaria, Cyprus, Estonia, Latvia, Lithuania, Malta, Romania, and Slovenia. These 8 countries amount to less than 9% of the total EU27 population.

<sup>4</sup> Type II diabetes affects about 6.6% of the general population and is estimated at costing €29bln per year (Jönsson and B. Jönsson (2002). "Revealing the cost of Type II diabetes in Europe." *Diabetologia* 45(7): S5-S12) while CVD incur a direct cost of €109 bln and indirect costs of approximately 83 bln in terms of direct lost productivity and that of informal care (see footnote 26)

carry a high responsibility for mortality causing more than half of all deaths across Europe,<sup>5</sup> and heart disease or stroke represent the leading cause of death across Europe. In terms of resources for instance, in Denmark, it is estimated that 70–80% of health care expenses are allocated to chronic conditions and in the United Kingdom, 8 of the top 11 causes of hospital admissions are chronic conditions such as diabetes, pulmonary conditions and cardiovascular diseases. These prominent chronic conditions are the focal point for applications for Remote Patient Monitoring and Treatment (RMT) and Personal Health Systems (PHS). RMT systems contribute to confronting these challenges in several ways: (a) they improve health care outcomes and simultaneously help control costs; (b) more importantly, they can help extend the reach of the limited –and eventually shrinking– pool of health care professionals; and (c) they are believed to ignite entrepreneurial activities and innovation, which lead to consider this combination of ICT industry and health care services as an engine for job creation and European competitiveness.

- There is increasing evidence that such services based on RMT/PHS reduce death rates, and avoid recurring hospitalisation in a cost-effective manner. However, proving beyond doubt their medical effectiveness, safety and reliability is of utmost importance for life critical systems; far more than in other realms of ICT applications. As a result of the need for further evidence, necessary investments are delayed and in general resistance against the use of the technology is reinforced. A vicious cycle is thus created leading to local champions required to provide further evidence, mainstream players not deciding to enter the market, limited market uptake and costs that remain unaffordable. The market itself is fragmented and atomised with the dominance of local initiatives and pilot projects that, with few exceptions, are not sustainable. In short, despite the positive potential for RMT and PHS a stalemate is produced.
- A number of barriers have been identified which still hamper full deployment of RMT in Europe. Market players, mainly companies providing the technology, are mentioning constraints to market scale, the lack of reimbursement, unclear Return on Investment and business model choices, fragmentation of purchasers and the difficulties in obtaining approval and certification from health care organisations. Moreover, health care professionals are confronted with an unfavourable structure of incentives for introducing RMT, due to conflicting responsibilities for RMT within health care organisations. This is mirrored by ambiguities in different reimbursement schemes, in particular the allocation between those for primary, secondary, and social care. In addition, the lack of widespread awareness on the positive outcomes which are shown by many studies and meta-reviews, is considered a major bottleneck. Furthermore, the lack of strategic leadership for structural change hampers the natural uptake and diffusion of these technologies.

This report fully analyses the above considerations and provides a number of tentative policy options specifically aimed at fostering the take up of RMT, for the consideration of all stakeholders concerned:

- Riding the wave of policy consensus, on both sides of the Atlantic, provide governance in eHealth in general and "Telemedicine and Home Care" in particular as was expressed by the ministerial conference in Barcelona (March 2010);
- Provide increased and sustained awareness-raising and dissemination activities, especially focussing on spreading the knowledge about local champions, about the increasing positive evidence of RMT with respect to clinical and cost-effectiveness outcomes, as well as through

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<sup>5</sup> The data of the WHO comprises of more countries than the EU27, yet the tendency remains the same.

methodologically robust modelling and simulation of the potential benefits under different take-up scenarios;

- Provide further financial support for studies and research aimed at further reinforcing the evidence on outcomes and at moving towards increasingly standardised and accepted evaluation methodologies;
- Design innovative mechanisms to support networking and the emergence of hubs among RMT champions and innovators (i.e. creation of centres of excellence for chronic disease management);
- Explore the synergies between eHealth and eInclusion policies and support instruments to bring about health care and social care joined up research and innovation pilots;
- Revise the EU value chain of R&D, pilots and validation as to increase the chances of moving to the final stage of sustained service production and delivery;
- Leverage the new window of opportunity that may be opened in the post i2020 framework with the envisaged strong investment into broadband ensuring that RMT and more in general PHS are the priority type of services to be supported through these new platforms;

In sum, if the challenge for European health care systems is to increase the quantity and quality of care in response to higher demand pressures, at a time when various factors are putting public budgets at strain, then an answer to this challenge can be effectively provided with the EU-wide deployment of RMT/PHS systems.



## PART ONE: EXECUTIVE REPORT

### 1 Introduction

#### 1.1 *Background*

Health care systems in Europe are facing a number of well known challenges (rising costs, ageing population, increasing demand, shortage of health care professionals, etc.), in an economic environment of cost-control and limited public expenditure. Within this context the Lead Market Initiative (LMI) for Europe has identified eHealth as one of its six key areas of focus, for strategic (improvement in competitiveness and interoperability leading to technology advances), economic (scale economies) and social (improvements in service level and access to health services) reasons.

The development of Personal Health Systems (PHS) within the eHealth area looks particularly interesting for delivering home care and remote monitoring services to patients and contributes to the goals of the LMI. In particular PHS are expected to improve quality of care, quality of life and cost efficiency of health care processes.

Following the adoption of the eHealth Action Plan<sup>6</sup> the European Commission launched several initiatives to promote the development, use and dissemination of PHS. PHS are increasingly becoming the subject of conferences and dedicated events and reports, including:

- **The February 2007 conference on Personal Health Systems.**<sup>7</sup> Dealing with deployment opportunities and ICT research challenges. It consolidated ten-year state-of-the-art research results in PHS and provided best practices;
- **The Telehealth 2007 conference.**<sup>8</sup> The conference on "Telemedicine and innovative technologies for chronic disease management" showed the significance of on-going developments for doctors and hospitals providing case studies on extramural chronic disease management. Regulatory and legal problems were addressed and the role of doctors in solving them was discussed;
- **The Tampere PHS2008 Consultation workshop.**<sup>9</sup> Addressing R&D activities on PHS from a broad perspective, its main focus was on recent developments in artificial organs, minimally invasive systems and mental health diseases, as potential areas for future PHS applications. Brainstorming sessions on future EU research programmes and activities were included;
- **The Telehealth 2008 conference.**<sup>10</sup> The "Telemedicine and innovative technologies for chronic disease management" conference presented state-of-the-art patient-oriented services and discussed the role of the EC in promoting the roll-out of a European PHS system;
- **TheWoHIT08-EC workshop.**<sup>11</sup> The "Procuring for health benefits" workshop stressed a variety of procurement models for the adoption of telemedicine services and in particular lessons learnt from four EU country Studies-England, Northern Ireland, Spain and Denmark;

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<sup>6</sup> COM(2004)356, SEC(2004)539 available at:  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2004:0356:FIN:EN:PDF>

<sup>7</sup> European Commission: Personal Health Systems: deployment opportunities and ICT research challenges. In. Brussels: European Commission; 2007: 25.

<sup>8</sup> Whitehouse D, Virtuoso S: Telehealth 2007 - Telemedicine and innovative technologies for chronic disease management. In: Telehealth 2007 - Telemedicine and innovative technologies for chronic disease management: 11 December 2007; Brussels; 2007: 44.

<sup>9</sup> European Commission: PHS 2008 Consultation workshop. In. Tampere: European Commission; 2008: 23.

<sup>10</sup> Whitehouse D: Telemedicine and innovative technologies for chronic disease management. In: eHealth 2008: 2008; Portoroz, Slovenia: Infso; 2008: 7.

<sup>11</sup> Jones T: WHIT08 - EC Workshop Procuring for health benefits: Critical Factors for Beneficial Deployment of Innovative eHealth and Telemedicine Services. In. Copenhagen: DG Infso - ICT for Health; 2008: 28.

- **PHS2020.** This FP7 project organised several workshops and events consulting over 100 experts and stakeholders in several European regions and recently delivered its final results in terms of road mapping research activities in PHS;<sup>12</sup>
- **The 2010 PHS Consultation Workshop.** This workshop focused on state-of-the-art PHS technologies and more specifically on PHS for neurodegenerative diseases. Expert participants discussed the application of ICT in prevention, management and treatment of neurodegenerative diseases. Rising prevalence, high costs of treatment and the negative effects on employment and productivity pointed at the need for more R&D in this area.

Within this context SIMPHS (Strategic Intelligence Monitor on Personal Health Systems) was launched at the beginning of 2009 with an expert workshop held in Brussels,<sup>13</sup> and it is now delivering the findings from Phase 1 (February 2009- April 2010). SIMPHS is a three years project carried out by JRC-IPTS in cooperation with DG INFSO. It aims to develop a monitor in order to facilitate the understanding of the market and innovation dynamics of PHS in Europe. During this first year SIMPHS focused on the remote patient monitoring and treatment segment of PHS (henceforth simply RMT) in general, and on chronic diseases (i.e. chronic heart failure, diabetes, COPD) in particular. The objective of SIMPHS is to provide evidence on a number of research questions that can be applied both to PHS in general and to its different segments such as RMT:

- a) Is there among stakeholders a common understanding of PHS/RMT?
- b) Which are the main players, what is their role and goal in delivering PHS/RMT services and to what extent are they engaged in bringing about disruptive innovation in the delivery of care?
- c) Regarding market players (henceforth also referred to as “*suppliers*”): what are their expectations of the future development of PHS and the corresponding strategy and course of actions they adopt;
- d) Regarding health care professionals and their organisations (henceforth also referred to as “*providers*”): What role do they play, what kind of disruptive activities and innovations can be identified in the health care systems, what future options for a reorganisation of health care structures do they imply, and what are the related drivers and barriers?; and finally
- e) In general, what do the various players expect from government and health care policy and decision-making bodies?

## 1.2 Key concepts

Two key concepts have been developed in Phase 1 of SIMPHS: “Personal Health Systems” (PHS) and “Remote Patient Monitoring and Treatment” (RMT), which we define and put in context below. eHealth is by now an umbrella term broadly used and referring to the wide range of ICT applications in health care. In 2007, the eHealth task force<sup>14</sup> supporting the Lead Market Initiative provided a more precise definition of the components of eHealth:

1. Clinical information systems;
  - a) Specialised tools for health professionals within care institutions
  - b) Tools for primary care and/or for outside the care institutions
2. Telemedicine and homecare systems and services;

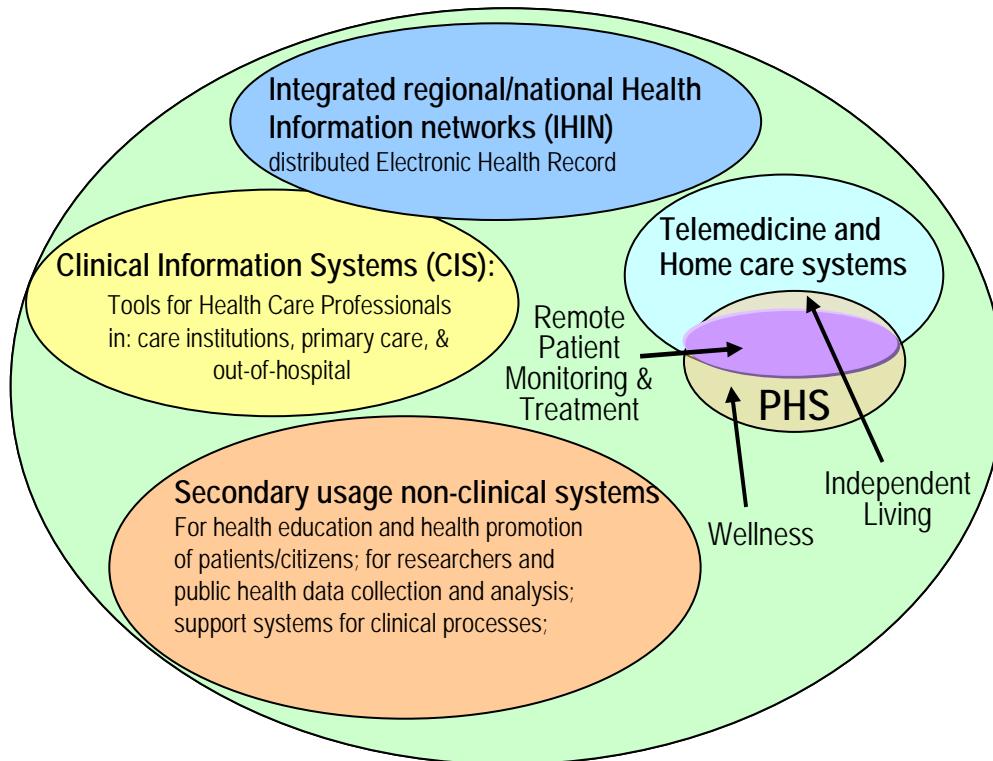
<sup>12</sup> See main results in C. Codagnone, (2010), *Reconstructing the Whole: Present and Future of Personal Health Systems* ([http://ec.europa.eu/information\\_society/activities/health/docs/projects/phs2020/phs2020-book-rev16082009.pdf](http://ec.europa.eu/information_society/activities/health/docs/projects/phs2020/phs2020-book-rev16082009.pdf)).

<sup>13</sup> See the minutes of this workshop at <http://is.jrc.es/pages/TFS/documents/090206MinutesPHSworkshopfinal.pdf>. Other workshop material can be found at <http://is.jrc.es/pages/TFS/sps.html>.

<sup>14</sup> European Commission, *Accelerating the development of the eHealth market in Europe. eHealth Taskforce report 2007: Composed in preparation for the Lead Market Initiative*, Luxembourg: Office for Official Publications of the European Communities, 2007 ([http://ec.europa.eu/information\\_society/activities/health/docs/publications/lmi-report-final-2007dec.pdf](http://ec.europa.eu/information_society/activities/health/docs/publications/lmi-report-final-2007dec.pdf)).

3. Integrated regional/national health information networks and distributed electronic health record systems and associated services;
4. Secondary usage non-clinical systems;
  - a) Systems for health education and health promotion of patients/citizens
  - b) Specialised systems for researchers and public health data collection and analysis
  - c) Support systems for clinical processes not used directly by patients or health care professionals.

**Figure 1 – Constituent elements of eHealth**



Source: Adapted from eHealth Task Force Report (see footnote 14)

As illustrated in Figure 1, although PHS are not explicitly mentioned in the LMI definition, they can be placed in the area where telemedicine and home care systems overlap with RMT. Based on this, the definition of PHS and RMT adopted in the SIMPHS project are presented in Table 1.

**Table 1 – PHS Definition**

*“Personal Health Systems (PHS) assist in the provision of continuous, quality controlled and personalised health services to empowered individuals regardless of location. They consist of:*

- a) *Ambient and/or body (wearable, portable or implantable) devices, which acquire, monitor and communicate physiological parameters and other health related context of an individual (e.g., vital body signs, biochemical markers, activity, emotional and social state, environment);*
- b) *Intelligent processing of the acquired information and coupling of it with expert biomedical knowledge to derive important new insights about individual’s health status.*
- c) *Active feedback based on such new insights, either from health professionals or directly from the devices to the individuals, assisting in diagnosis, treatment and rehabilitation as well as in disease” prevention and lifestyle management.”*

Source: PHS2020<sup>15</sup>

**Table 2 – RMT Definition**

Remote Patient Monitoring and Treatment (RMT) systems help patients with chronic diseases monitor vital signs (blood pressure, heart rate, blood glucose, weight, oxygen contents, ECG) thus improving the quality of care, the quality of life of the patient and enabling the prediction of aggravations and exacerbations of their chronic condition.

Source: Developed by SIMPHS project

By using RMT systems, patients keep control over their health conditions and are able live independently or with limited need for care. Current RMT applications are mostly used for patients suffering from Chronic Heart Failure (CHF), diabetes and/or COPD. As a general principle, PHS and RMT systems can be seen as a particular instance of doctor-to-patient services as opposed to doctor-to-doctor applications and in this respect they differ from the broad definition of telemedicine, which include also several doctor-to-doctor services (e.g. tele-radiology which is the most developed and consolidated). The possibility of automated remote treatment and interaction with the patient (though mostly confined still to R&D or pilot projects and with limited practical application) also distinguish PHS/RMT systems from telemedicine. Using an analogy from eBusiness sources, PHS and RMT systems tend to, or should be, B2C services in contrast with B2B services. In practice, however, PHS and RMT systems can take the form of B2B2C services, when an interaction between a supplier (technology provider) and the health care provider takes place before the latter actually delivers the service to the patient. Additionally, in a futuristic scenario, PHS/RMT systems can take the form of entirely patient self-managed services.

Within the RMT domain, one could actually further distinguish between two forms. Using in this case the analogy with the world of online services, the first form represents a “pure technology delivery” and the second a “multi-channel delivery” model. The first includes RMT stand-alone services provided only through ICT and call centres, which forward the data gathered and processed to the health care provider in charge. In the second model, the ICT enabled RMT activities are one

<sup>15</sup> C. Codagnone, (2010), *Reconstructing the Whole: Present and Future of Personal Health Systems, op. cit*, pp. 8-9.

component structurally integrated into larger disease management programmes, which also entail other forms of face-to-face interactions with nurses and doctors in addition to those facilitated by the technology. In the literature this second model is also referred to as Home Based Tele-management (HBT) of chronic disease.<sup>16</sup>

### **1.3 Scope and structure of this report**

This report is a specific deliverable of the study "Strategic Intelligence Monitor on Personal Health Systems" (SIMPHS) conducted by DG JRC IPTS for DG INFSO. As stated in the Technical Annex to the Contract regulating the initiative, this report is Deliverable D3.1, "Market Structure and Innovation Dynamics", which is the main output of SIMPHS Phase I research activities. It is closely linked to the other three core deliverables presented separately to which we will be referring in the course of our exposition. These other deliverables are:

- D1.1 "Report on the Overall Structure of the Strategic Intelligent Monitor", containing:
  - Structure of the data gathered which will serve as a manual or guideline to browse the data repository at <http://is.jrc.ec.europa.eu/pages/TFS/SIMPHSdata/index.html> ;
  - A framework for evaluation and measurement including around 50 measurement indicators;
  - Data on market indicators for the 50 companies analysed in-depth (see *infra*).
- D2.3 "Report on typology/segmentation of PHS market" providing a critical review of currently used concepts and tags and proposing a segmentation with cases and exemplifications;
- D4.2 "Report on Validation Workshop" summarising the results of the Expert Validation Workshop held in Brussels in November 2009, where we presented a synthetic summary of the findings of the first year of work in the form of a Discussion Paper<sup>17</sup> that was fully validated by the experts.<sup>18</sup>

During SIMPHS Phase 1, a number of research activities have been undertaken, basically covering the following three pillars and their sub-components:

1. Desk based data gathering and analysis carried out by the IPTS team on:
  - i. Market research data;
  - ii. Identification and preliminary analysis of 200 companies involved in PHS/RMT followed by an in-depth analysis of 50 of them;
  - iii. Pilots, projects and programmes financed at EC, national, regional and local level;
2. Evidence gathered by the IPTS team field work, through interaction with experts and stakeholders.<sup>19</sup> This included:
  - i. A large stakeholder's workshop with 30 participants including representatives from the industry (suppliers), health care providers, insurers (purchasers), academia, etc.;
  - ii. Three restricted workshops with 5-7 participants each;

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<sup>16</sup> See, for instance: A. Giordano et al. Multicenter randomised trial on home-based telemanagement to prevent hospital readmission of patients with chronic heart failure. *International Journal of Cardiology* 131 (2009) 192–199.

<sup>17</sup> Available at: <http://is.jrc.ec.europa.eu/pages/TFS/documents/SIMPHSbackgroundpaperforvalidationworkshop.pdf>

<sup>18</sup> See the workshop minutes at:

<http://is.jrc.ec.europa.eu/pages/TFS/documents/MinutesSIMPHSValidationWSfinalforpublication.pdf>

<sup>19</sup> The aim of this part of the work was to unearth a wide range of elements that would help us understand the activities of the companies represented, from a description of their role on the value chain to the perception of these experts on market growth, barriers and drivers, and various other elements. The qualitative data collected enabled us to sketch a number of business models and draw some conclusions on their key characteristics.

- iii. A series of one-to-one meetings and phone interviews with experts (i.e. semi-structured interviews);
- 3. Six Self contained country case studies comprising both, desk research and field work (along the same lines as activity 1 and 2 above):
  - i. France, Germany, Sweden and the United Kingdom outsourced to VTT;
  - ii. Italy and the Netherlands carried-out by the IPTS Team;

This report is divided in two parts. **Part One** (Section 1 to Section 5) provides a very selective and synthetic Executive Report on the evidence gathered as a result of all the above mentioned activities. In **Part Two** (Section 6 through Section 10) monographic annexes reporting in-depth details of the findings are available. The structure of the two parts is outlined below.

**Part One** contains to a large extent a revised version of the Discussion Paper presented during the Expert Validation Workshop in November 2009. Given that the findings and conclusions of this paper were fully validated by the experts, **Part One** dedicates few efforts to justify our main conclusion: ***there is no consolidated RMT market and the focus should be more on what blocks the innovation dynamics rather than describing it.*** We start from this conclusion and, intend to address the following questions: (a) what are the health care needs and how can RMT contribute? (b) How much has happened so far in terms of RMT deployment? (c) Is there any evidence on whether RMT works and is it enough to develop a business case and convince stakeholders? (d) How does the above compare to the potential? And (e) what are the main barriers to achieve this potential and how can we overcome these barriers and what would be the impact if we do not act? The first question is addressed in **Section 2**, the second in **Section 3**, the third in **Section 4**, and the fifth in **Section 5**. The fourth question is dealt with using an scenario-based extrapolation and it has been addressed only in a preliminary and exemplificative fashion in this report, which would not justify treatment as a self-standing section. Accordingly, we deal with it in **§4.3 of Section 4** given that it is based on some of the parameters extracted from the evidence on RMT outcomes.

**Part Two**, as anticipated, comprises monographic annexes each addressing a specific component of the evidence gathered:

- ANNEX I: Innovative activities in RMT (included as **Section 6**), reports on the analysis of innovation activities funded at local, regional, national, and EU levels (programmes, projects, pilots);
- Annex II: RMT Company Analysis (included as **Section 7**), reports on the analysis of RMT market players (companies' analysis);
- Annex III: Summary of Country Reports (included as **Section 8**), contains a horizontal and comparative reading of the six country studies; the part of the country reports that was outsourced in its original form is available through the SIMPHS web site;
- Annex IV: Health-related data and scientific evidence (included as **Section 9**), provides first an overview of the search conducted on prevalence and costs of the chronic diseases we have focused on in this report, followed by a synoptic overview of the findings of evaluation studies (randomised control trials, meta-analysis, and other sources addressing the topic of RMT clinical and cost-effectiveness outcomes);
- Annex V: Patent analysis (included as **Section 10**), summarises the finding of the data gathered on patents.

## 2 Health care challenges and needs: how can RMT contribute?

### 2.1 The big picture

The challenges that European health care systems are facing and will face even more sharply in the future are well known and have been fully reviewed and discussed in a number of EU Public Health communications and white papers.<sup>20</sup> Below, we only briefly summarise the key points from these and from a selection of the vast body of literature available on the topic. In short, the challenges consist in preserving access, equity, quality, and financial sustainability at a time when demand-side trends increase pressure on health care systems, while public finances are increasingly under strain. Since there is a wide consensus that it is hardly possible to cut health care costs, the big challenge can be summarised as at least “*produce more and better quality output with the same level of input*”.

#### Rising expenditure

Starting in the 1970s, when the effects of a generalised increase in national income and educational levels fully manifested themselves, growth in health care expenditure has almost constantly outpaced that of GDP. On average in OECD countries between 1995 and 2005 growth rates in health care expenditure outstripped GDP growth by 1.4% (1.7% considering public spending only).<sup>21</sup> In the 19 EU countries for which OECD data<sup>22</sup> is available health care expenditure as a percentage of GDP has risen on average from 4.7% in 1970 to about 9% in 2007 (with public expenditure increasing from 3.5% to 6.6% in the same period). Hence, it is obvious that health care remains overwhelmingly a matter of public expenditure. During the same period (1970-2007), the share of public financing of total health care expenditure on average went from 74.4% to 75.8% (with only 3 countries where the share of public financing is below 70%: Greece, 60%; Netherlands, 62%; and Slovak Republic, 66.8%). Private insurance financing went down from 4.4 to 4% (except for France and the Netherlands with values above 10%). Out of pocket expenditure went down from 18.4% to 16.2% (except for Hungary, Poland, Slovak Republic, Italy, Portugal, and Spain with values above 20%)..

#### Ageing of the population

From 1960 to 2008, the percentage of population aged over 65 has doubled on average. Moreover, projection scenarios show that the ratio of old-age dependency compared to the overall population will increase from 0.25 in 2004 to at least 0.33 in 2020 and could be between 0.45 and 0.65 in 2050. This means that from the current ratio of 1 inactive old person for 4 active individuals (1:4), it can reach 1:3 in 2020 and 1:2 or even less at future stages.

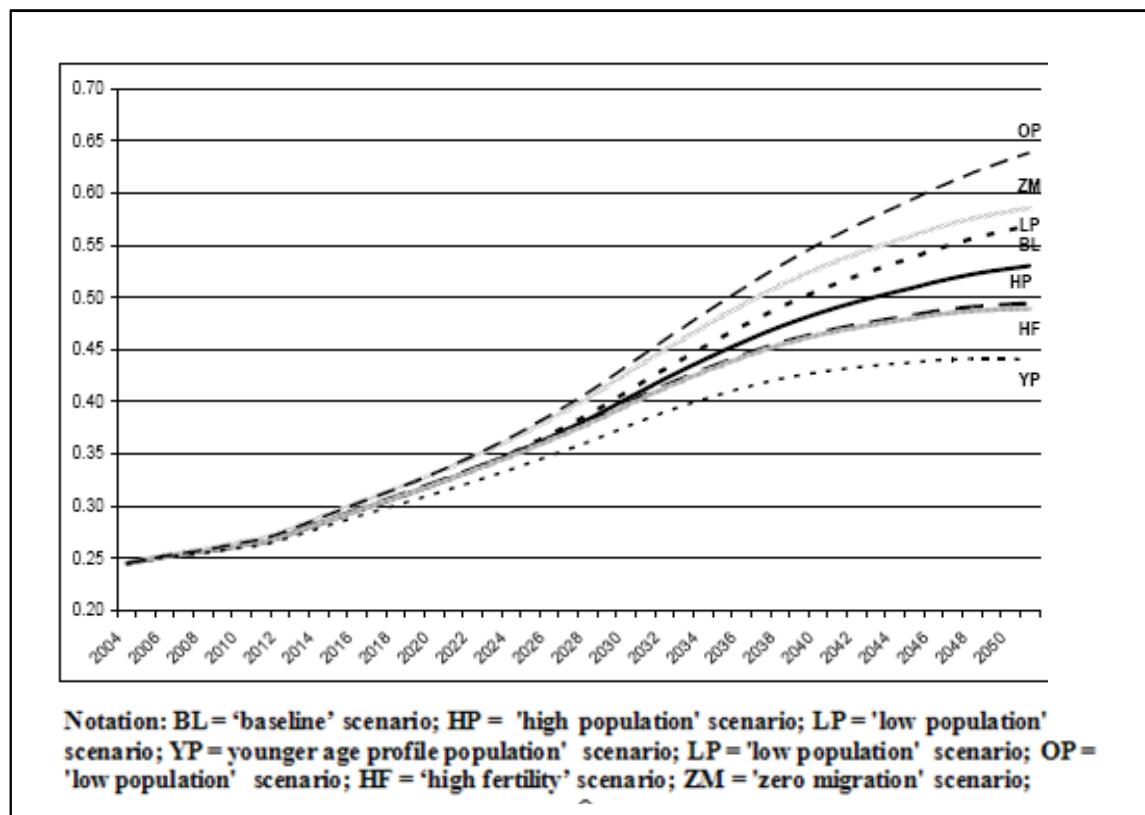
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<sup>20</sup> These includes: a) European Commission, *The future of health care and care for the elderly: guaranteeing accessibility, quality and financial viability*. Brussels. COM (2001) 723 final, 2001; b) European Commission, WHITE PAPER: *Together for Health: A Strategic Approach for the EU 2008-2013*. Brussels. COM (2007) 630 final, 2001; c) European Commission, Commission Staff Working Document, accompanying the WHITE PAPER: *Together for Health: A Strategic Approach for the EU 2008-2013*. Brussels. SEC (2007) 1376, 2007; d) European Commission, Commission Staff Working Document, Document accompanying the WHITE PAPER: *Together for Health: A Strategic Approach for the EU 2008-2013. Impact Assessment*. Brussels. SEC (2007) 1374, 2007.

<sup>21</sup> OECD 2009 Health Data. We refer here and in the reminding to the database purchased as a CD Rom and from which data can be generated in multiple fashion, but we cannot add a specific quotation or reference to pages (we do not refer to the paper version).

<sup>22</sup> They exclude of the EU27: Bulgaria, Cyprus, Estonia, Latvia, Lithuania, Malta, Romania, and Slovenia. These 8 countries amount to less than 9% of the total EU27 population.

**Figure 2 – Old age dependency, EU25, 2004-2051 (different population scenarios)**



Source: Eurostat, Statistics in Focus: Population and Social Conditions. 3/2006

While ageing has clear consequences in terms of chronic disease burden, here we want to stress the impact of ageing with respect to the sustainability of health care systems. Population scenarios reflect that we seem to be reaching a situation where the pool of active individuals working and paying taxes will shrink whilst the amount of elderly population increases which in turn results on rising costs for health care and long-term care. This scenario overcasts a potential generational tension with “fewer people at working age who may be reluctant to pay the higher taxes required in order to fulfil all of society’s needs”<sup>23</sup>. Therefore, rising public expenditures and decreasing tax base in the future are very likely to generate tremendous pressures on health care systems. We can further add that also European pension systems are at strain and reforms delaying the retirement age are needed. In this context, health care should struggle to both optimise the treatment of the elderly in chronic conditions and to prolong the active and health lives of “older workers” (aged 55-65 and slightly above, probably up to 70).

<sup>23</sup> J. Cleland et al. Telemonitoring for heart failure: the only feasible option for good universal care? European Journal of Heart Failure 2009 11(3):227.

### **Scarcity of professionals and informal carers**

According to data from the Eurostat Labour Force Survey (LFS), the expenditure caused by an increase of the number of people employed in the area of Health and Social Work in EU15 Member States has grown steadily, from 13 to 15 million in total between 1995 and 2000, rising to around €20.1 million in 2005 in the EU27.<sup>24</sup> This growth, however, is running against the hard wall of increasing scarcity of qualified personnel.

In OECD countries on average:

- a) The number of medical graduates per 1000 practicing physicians has steadily declined, from 40.9 in 1990 to 33.1 in 2005. As a result the density of practicing physicians per 1,000 population has more than doubled between 1970 and 2000 (from 1.3 to 2.8) but this growth has started to hover in this decade (in 2005 was only 3.1) and the density is expected to decline in the future;
- b) The number of nurse graduates per 1,000 practicing nurses has steadily declined and decreased from 59.9 to 44.8 between 1990 and 2005. As a result, the density of practicing nurses per 1,000 population has more than doubled between 1970 and 2000 (from 3.3 to 7.6) but this growth has also started to hover in this decade (in 2005 was only 8.0) and the density is expected to decline in the future.

This increasing scarcity of professional carers is compounded by the increasing predominance of nuclear families, workforce feminisation, and workforce mobility, which reduces the pool of informal carers and makes the care of the chronically ill and of the elderly in general even more difficult, thus adding to the demand for health care and social services professionals.

## **2.2 The rising chronic diseases burden**

Chronic disease management is one of the main challenges of health care; while it is easy to assess the overall burden and cost for supporting the patients for each disease as relatively high, especially among the older patients, measuring it is rather difficult. To start, the literature on chronic disease burden and costs is vast, and comparisons are almost impossible. We have thus decided to present for some chronic disease a rule-of-thumb extrapolation, which although has limited scientific validity, will provide an estimate of the order and magnitude of costs incurred. This will be preceded by comments and assumptions related to the availability and accuracy of the data used to estimate costs.

### **Premise on the data available.**

Naturally, the most important trend from the health care demand side is the ageing of the population with the associated increase in chronic disease prevalence and cost pressures. We briefly focus below on diabetes, Chronic Obstructive Pulmonary Disease (COPD) and cardiovascular diseases (CVD, with a particular focus on Chronic Heart Failure – CHF), as they represent those most often targeted by RMT.<sup>25</sup> Data on prevalence and costs to society of chronic diseases presented in detail in Annex IV (Section 9); a general premise is justified here since it explains the limit of the extrapolations presented in section 4.3. It may also be used to explain why further research is needed to build a robust forecast model from which reliable scenario-based extrapolations could be extracted. Internationally, comparable prevalence rates are much more difficult to gather than mortality rates

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<sup>24</sup> European Commission, Staff Working Document, accompanying the WHITE PAPER, op. cit (point c) in footnote 20), p. 8 SEC(2007) 1376, 2007.

<sup>25</sup>. General reference texts on the topic of chronic disease rising burden include reports and books published by WHO or The World Bank such as for instance: E. Nolte, M. McKee, (eds.), *Caring for people with chronic conditions: a health system perspective*. Maidenhead, UK: Open University Press / McGraw Hill (<http://www.euro.who.int/document/E91878.pdf>), 2008; and O. Adeyi, O. Smith, S. Robles, S. *Policy and the Challenge of Chronic Noncommunicable Diseases*. Washington DC: World Bank. (<http://siteresources.worldbank.org/INTPH/Resources/PublicPolicyandNCDsWorldBank2007FullReport.pdf> ), 2007.

for most of the diseases. For instance, for CVD, EU-wide data on prevalence<sup>26</sup> is not routinely collected or updated. The reason for this difficulty is two-fold. First, national level data are not directly comparable due to differences in the diagnosis process and this is reflected in the statistics. Second, data generated from official statistics bodies and reports and in the scientific literature use different measures (prevalence, incidence, morbidity, DALY, etc) which makes comparison very difficult.

Standardised and comparable EU-wide ready to use data are available only for Diabetes (Diabetes Atlas, see footnote 29). For CVD, CHF and COPD, findings resulted in a mix of data coming from different sources (WHO reports, scientific literature, etc) that are not comparable and even contradictory<sup>27</sup> at times. Costs for each chronic disease were considered from two different angles: first, the calculation of aggregate costs and burden to health care and to society as a whole and second, the more micro level measures derived from clinical metrics of costs per patient per year, average costs of one hospital day and of diagnostic tests. These differences in costs add complexity to the situation. The literature review provided measures of aggregate costs for general CDV and for Diabetes (expressed in various units such as actual Euro costs, DALY burden, costs in International Dollars). Regarding costs per patient, very disparate and contrasting figures for the same type of disease in the same country were found. In addition, using different articles reporting the findings of Randomised Control Trials (RCT) very inconsistent (across time and space) measures of standard clinical costs (hospitalisation/diagnostic) were extracted. For the purpose of robust extrapolation, such micro level measures of costs and clinical metrics need to be collected for all countries.<sup>28</sup> For CHF only, and using benchmarks derived from results of different RCT and applying them to prevalence data (of questionable comparability), we managed to produce a view of the order and magnitude of costs.

## **Diabetes**

The Diabetes Atlas of the International Diabetes Federation (IDF) in 2010 (available in table 1) reported almost 33 million individuals affected by diabetes in Europe, a figure expected to reach 40 million in 2025 (20% average growth).<sup>29</sup>

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<sup>26</sup> S. Allender, *European Cardiovascular Disease Statistics*, 2008 edition. London: British Heart Foundation (<http://www.heartstats.org/uploads/documents%5Cproof30NOV2007.pdf>) 2008, p. 36.

<sup>27</sup> So as to facilitate the development of EU27 extrapolations of potential outcomes and impacts, much more time and resources would be needed to build and validate comparable prevalence data from disparate sources and national specific statistics. (SIMPHS Phase 2).

<sup>28</sup> For instance the *eHealth for a Healthier Europe! Opportunities for a better use of health care resources*, Swedish Presidency of the EU ([http://www.se2009.eu/polopoly\\_fs/1.8227!menu/standard/file/eHealth%20for%20a%20Healthier%20Europe.pdf](http://www.se2009.eu/polopoly_fs/1.8227!menu/standard/file/eHealth%20for%20a%20Healthier%20Europe.pdf) ), required six months of work devoted entirely to gather clinical metrics for six EU Member States, from which the several extrapolations were produced (but the report provides only the findings and not the clinical metrics and statistics upon which they were based).

<sup>29</sup> <http://www.eatlas.idf.org/index-2.html>

**Table 3 – Diabetes prevalence in the EU27**

	20-79 Population 2010 (000s)	Diabetes patients 2010 (000s)	Crude prevalence
Austria	6.301,6	708,4	11,2%
Belgium	7.643,9	610,0	8,0%
Bulgaria	5.790,2	519,5	9,0%
Cyprus	634,1	65,9	10,4%
Czech Republic	7.824,3	677,3	8,7%
Denmark	3.907,0	301,5	7,7%
Estonia	994,0	97,9	9,8%
Finland	3.863,4	319,8	8,3%
France	44.091,3	4.164,2	9,4%
Germany	62.654,4	7.494,3	12,0%
Greece	8.560,7	754,0	8,8%
Hungary	7.514,8	658,9	8,8%
Ireland	3.171,2	180,3	5,7%
Italy	44.509,9	3.926,2	8,8%
Latvia	1.719,4	169,7	9,9%
Lithuania	2.484,3	239,8	9,7%
Luxembourg	348,9	24,3	7,0%
Malta	306,8	29,9	9,7%
Netherlands	11.943,4	922,4	7,7%
Poland	28.618,0	2.674,6	9,3%
Portugal	8.033,8	997,6	12,4%
Romania	16.129,0	1.351,4	8,4%
Slovakia	4.074,6	314,0	7,7%
Slovenia	1.546,2	152,9	9,9%
Spain	33.943,8	2.939,3	8,7%
Sweden	6.618,6	484,4	7,3%
United Kingdom	44.056,1	2.139,6	4,9%
EU27	367.283,7	32.918,1	9,0%

Source: <http://www.diabetesatlas.org/book/export/html/250>

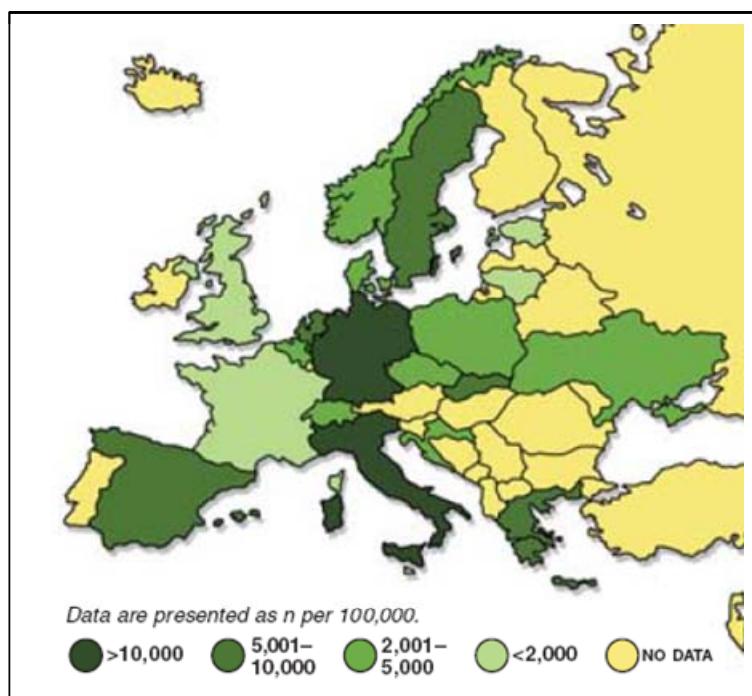
Prevalence for all forms of diabetes among the 20-79 population ranged from 3.4% in Ireland to 12% in Germany and Portugal. Still the Diabetes Atlas reports that the cost of Diabetes in Europe amounted to 82.3 billion in International Dollar (ID)<sup>30</sup> in 2007 and is expected to grow to 98 billion ID in 2025. According to the IDF, increase in prevalence may be even sharper due to rising obesity in the population, which is strongly associated with type II diabetes. A meta-analysis of some countries studies has found that the cost of diabetes ranges from 2.5% to 15% of total national health

<sup>30</sup> Quoting Wikipedia, the international dollar (ID), also known as the Geary-Khamis dollar, is a hypothetical unit of currency that has the same purchasing power that the U.S. dollar had at a given point in time. It is based on the concepts of purchasing power parities (PPP) of currencies and the international average prices of commodities. Figures expressed in ID cannot be converted to another country's currency using current market exchange rates; instead they must be converted using the country's PPP exchange rate.

care expenditure depending on diabetes prevalence and the level of treatment available.<sup>31</sup> Applying these percentages to total health care expenditure of 2007 in EU19 (1177 billion of Euros using OECD Health Data 2009<sup>32</sup>), these costs can range from 29 up to 176 billion Euros. There are various other measures of costs per patients that vary widely depending on the country or the sources, which are reported in detail in Annex IV (section 9).

**Chronic Obstructive Pulmonary Diseases (COPD).** Data on COPD prevalence in Europe is scarce (due to different diagnosis practices and classification systems) and suffers from under-estimation.<sup>33</sup> Figure 3 below provides a graphic snapshot provided by the *European Lung White Book* dated 2003<sup>34</sup> and shows lack of data availability in many countries. The most recent data available on COPD prevalence (relating to different years, different country level sources, and based on different reference population) was compiled by WHO<sup>35</sup> in 2007

**Figure 3 – Map of COPD prevalence in Europe**



Source: European lung white book (see footnote 34)

The picture is equally fragmented but rich with different studies and estimations about the costs associated with COPD, which vary wildly (examples of which are reported in Table 4). The 2007 WHO study reports direct costs only for a few European countries and with discordant figures. From

<sup>31</sup> M. Suhrcke, et al, *The Contribution of Health to the Economy in the European Union*. Brussels: European Commission, 2005 [http://ec.europa.eu/health/ph\\_overview/Documents/health\\_economy\\_en.pdf](http://ec.europa.eu/health/ph_overview/Documents/health_economy_en.pdf)

<sup>32</sup> The data reported for 2007 is 1530 billion of US dollars (to which we applied a standard average exchange rate for that year)

<sup>33</sup> It is often under diagnosed as many accept breathlessness and limited exercise tolerance as features of ageing and regard smoker's cough as normal. On this aspect see for instance R. Pauwels, and K. Rabe, Burden and clinical features of chronic obstructive pulmonary disease (COPD), *Lancet*, 364 (2004): 613–20.

<sup>34</sup> R. Loddenkemper R, et al. *European lung white book - the first comprehensive survey on respiratory health in Europe*. Huddersfield, UK European Respiratory Society, 2003.

<sup>35</sup> Denmark (3.7% among individuals aged 20–90 years), England (9.9% among individuals 60–75 years), Finland (11% among individuals 30 years and older), Italy (11% individuals of 25 years and older), Norway (4.1% among individuals of 16–70 years) and Spain (9.1% among individuals of 40–69 years) WHO, *Global surveillance, prevention and control of Chronic Respiratory Diseases – A comprehensive approach*, Geneva WHO (<http://www.who.int/gard/publications/GARD%20Book%202007.pdf>), 2007, p. 24.

a different perspective the burden of COPD in Europe is estimated to be 393 DALYs per 100,000 population (disability adjusted life-years), with particularly high rates in individuals aged 70 and above.<sup>36</sup> At European level, the predicted number of deaths attributable to COPD is expected to increase from almost 270,000 in 2005 to over 338,000 by 2030, while the absolute burden of COPD is projected to fall from approximately 3,440,000 to 2,950,000 DALYs.<sup>37</sup>

**Table 4 – Examples of Cost calculations of COPD**

<p><b>2003 International Study.</b> Mean average direct cost of COPD per patient: \$4,119 in USA, \$3196 in Spain, \$606 in The Netherlands, \$ 522 in France. From 52% to 84% of costs are due to hospitalisation. (Wouters, E. The burden of COPD in the Netherlands: results from the confronting COPD survey, <i>Respiratory Medicine</i> 97(Supplement 3): S51-S59)</p>	<p><b>French scenario.</b> Altogether 3 million French over 45 i.e. 5-10% of the population suffer from COPD and 16,000 people die of COPD every year. COPD is responsible for 800,000 hospital stays per year costing €3.5 billion, out of which more than half is due to unexpected hospital stays in relation to complications (translated and adapted from <a href="http://bpco.ffaair.org/plan2.php?id=7&amp;title=&lt;p&gt;BPCO">http://bpco.ffaair.org/plan2.php?id=7&amp;title=&lt;p&gt;BPCO</a>)</p>
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Source: See reference inside the box

### **Cardiovascular diseases (CVD)**

Cardiovascular disease is the collective term for all diseases affecting the circulatory system (heart, arteries, blood vessels), which include coronary heart disease, stroke, CHF, and various others (many taking different forms and sub-classifications). One of the most authoritative sources on CVD statistics and costs is the *European Cardiovascular Diseases Statistics* published annually by the British Heart Foundation.<sup>38</sup> As anticipated, this source concludes that there are no EU-wide comparable sources on CVD prevalence. As a general indirect indication in developed European countries CVD account for 17% of DALYs lost (the largest cause after neuropsychiatric disorders): every year over 12 million DALYs are lost due to CVD.<sup>39</sup>

The same source provides, instead, more standardised and comparable data on the costs of CVD.<sup>40</sup> CVD costs in 2006 to EU health care systems reached €109 billion, or about 10% of total health care expenditure. Wide variations across countries can be observed in Table 5.

<sup>36</sup> E. Nolte, M. McKee, (eds.), *Caring for people with chronic conditions: a health system perspective*, op cit., p. 25.

<sup>37</sup> *Ibid.*

<sup>38</sup> S. Allender, *European Cardiovascular Disease Statistics*, 2008 edition. London: British Heart Foundation (<http://www.heartstats.org/uploads/documents%5Cproof30NOV2007.pdf>) 2008.

<sup>39</sup> *Ibid.*, p. 37.

<sup>40</sup> *Ibid.*, pp. 103-104 for the data reported year, and entire chapter 12 for a more detailed analysis.

**Table 5 – Health care costs of cardiovascular diseases**

Countries	Total Health care costs (000 €)	Costs per capita	% of Total Health care costs
Austria	1,632,865	198	6%
Belgium	2,030,028	193	6%
Bulgaria	273,275	35	14%
Cyprus	45,397	59	5%
Czech Republic	1,097,573	107	13%
Denmark	989,983	182	5%
Estonia	103,753	77	15%
Finland	1,246,204	237	10%
France	13,003,422	207	7%
Germany	34,029,860	413	14%
Greece	1,921,710	173	10%
Hungary	751,847	75	10%
Ireland	768,777	183	6%
Italy	13,790,198	235	10%
Latvia	108,378	47	9%
Lithuania	201,243	59	13%
Luxembourg	115,605	252	5%
Malta	29,098	72	6%
Netherlands	4,424,508	271	9%
Poland	2,830,204	74	17%
Portugal	1,599,351	151	10%
Romania	725,833	34	15%
Slovakia	397,836	74	13%
Slovenia	181,966	91	7%
Spain	5,694,611	130	7%
Sweden	2,784,356	308	10%
United Kingdom	18,911,391	313	12%
EU27	109,689,271	223	10%

Source: European Cardiovascular Disease Statistics, op. cit, p. 104

Inpatient hospital costs account for 54% of total CVD costs (which is about €59 billion), while drugs represent 28% (about €30 billion). About one fifth (€24 billion) of CVD expenditure is consumed by Coronary Heart Diseases (CHD) and 17% (about €18 billion) by strokes. Indirect non-health care costs of CVD include €41 billion in lost productivity, and €42 billion for the cost of informal care. So the total burden may add up to €192 billion per year.

**Chronic Heart Failure (CHF).** This disease is of particular interest for it is one of the chronic diseases most commonly targeted by RMT. CHF is a syndrome, often associated with diabetes mellitus and hypertension, which has shown little decline in incidence since the 1980s.<sup>41</sup> Due to population ageing and improved survival resulting from improved treatments, the projected burden of CHF is set to increase further.<sup>42</sup> While there is consensus about this general trend, precise and comparable quantifications of prevalence are non-existent. Indeed, epidemiological data regarding

<sup>41</sup> A. Mosterd, and A. Hoes, Clinical epidemiology of heart failure, *Heart*, 93(2007): 1137–46. Moreover, it is possible to estimate that one third of death attributed to coronary heart disease may also be related to CHF.

<sup>42</sup> S. Stewart, et al, Heart failure and the aging population: an increasing burden in the 21st century? *Heart*, 89 (2003): 49–53.

CHF incidence, prevalence and prognosis in the population in general are scarce for a number of reasons.<sup>43</sup>

It is worth reporting some illustrative examples of such variability.<sup>44</sup> According to an article on the epidemiology of CHF published in the late 1990s the disease affects between 0.1% and 2% of the general population, whereas it goes up to 10% among those aged 75 and above.<sup>45</sup> It is easy to note that the range from 0.1% and 2% is a challenging large interval if we were to apply it to the current 500 million EU27 population: anywhere between 500,000 and 10 million! The prevalence rate for the elderly is difficult to apply since the data publicly available from Eurostat are broken down into age groups “65-79” and “80 and above”, but not “75 and above”. If we apply it to the group 80 and above we get a total of 2.1 million, whereas when applied to the aggregate group 65 and above it would give us a total of 8.5 million. Another source from 2002 reported that prevalence in Europe ranges from 1% to 3% of general population and may reach 10% among the very elderly<sup>46</sup>. The same source claims that, at the time of writing (likely to be year 2000 considering the lengthy publication process), there were 6.5 millions Europeans suffering from CHF (prevalence of 1.3% of EU27 population in 2000).

A survey-based estimation of prevalence in Portugal produced a figure of 4.36% prevalence of the population aged 25 and above (prevalence was 1.36% in age group 25-49; 2.93% in age group 50-59; 7.63% in the age group 60-69; 12.67% in the age group 70-79; 16.14% in age group 80 and older).<sup>47</sup> Considering the UK patient data reported in Table 6, the prevalence value of the total population is 1.6%.

**Table 6 – Chronic Heart Failure: UK Evidence on prevalence and costs**

**Prevalence.** It has been estimated that there are about 393,000 men aged 45 and over living in the UK with definite heart failure, and 314,000 women, giving a total of around 707,000 (<http://www.heartstats.org/datapage.asp?id=1125>)

**Costs.** Hospital inpatient costs take 60% of NHS expenditure for CHF against only 8% against outpatient home care (Source [www.heartstats.org](http://www.heartstats.org)). Yearly 86,000 CHF patients are hospitalised for a total costs of GBP 378 million (Department of Health, Hospital Episode Statistics, <http://www.doh.gov.uk/hes/>)

*Source:* See reference inside the box

CHF is estimated to absorb between 1% and 2% of health care costs in industrialised countries,<sup>48</sup> which applied to the OECD Health Data 2009 figure for total health care expenditure in EU19 would amount to between 11.7 and 23.5 billion Euros. CHF patients amount to 5% of all hospital

<sup>43</sup> Information is derived from different sources (hospital statistics, small surveys, clinical trials, national statistics, etc) and their comparability suffers from the broad definition of CHF used with an undefined level of diagnostic accuracy (see for instance F. Ceia et al, Prevalence of Chronic heart failure in South-western Europe: The EPICA Study, *The European Journal of Heart Failure* 4 (2002): 531.

<sup>44</sup> These are instrumental to the disclaimer we present later when providing our extrapolation scenario for CHF.

<sup>45</sup> N. Sharpe, and R Doughty, Epidemiology of heart failure and ventricular dysfunction. *Lancet* 353 (Suppl. 1, 1998): 37.

<sup>46</sup> J. Mc Murray and S. Steward, The Burden of Heart Failure, *European Heart Journal Supplements*, 4 (2002, Supplement D): D50.

<sup>47</sup> F. Ceia et al, Prevalence of Chronic heart failure in South-Western Europe: The EPICA Study, *op. cit.*, p. 531.

<sup>48</sup> A. Bundkirchen, and R. Swinger, Epidemiology and economic burden of chronic heart failure, *European Heart Journal Supplement* (2004), 6(D): 57–60. Mc Murray and Steward in the article cite previously (The Burden of Heart Failure, *op. cit.*, p. D50) report CHF to absorb 2% of total health care expenditure.

admissions and consume a lot of resources mostly for hospitalisation.<sup>49</sup> This is because CHF patients are often re-hospitalised: re-hospitalisation after two weeks (from 10% to 19%),<sup>50</sup> is as high as 50% after 3 months,<sup>51</sup> and 45% after six months.<sup>52</sup> Already more than a decade ago it has been noticed that many of these readmissions could be prevented<sup>53</sup> by various means including better monitoring and compliance (see below).

**Non-Compliance problems.** The term compliance is most often used in the clinical literature to refer to the degree to which patients' behaviours coincide with clinical prescriptions (whether these are related to taking medication or following lifestyles guidance). The term non-compliance has a negative connotation related to the one-way direction and is sometimes substituted with "adherence" or "therapeutic concordance". Non-compliance is the cause of additional and avoidable costs of chronic diseases, especially among the elderly who follow exactly and steadily clinical prescriptions. It has been estimated, for instance, that patients over 70 take an average of seven prescription medicines and three over-the-counter drugs per day.<sup>54</sup> From a study carrying out in depth interviews with CHF patients, it turned out that 50% of the interviewed did not know the exact dose of prescribed medication and 60% could not remember the exact time for taking it.<sup>55</sup> As a result non-compliance is a source of cost inflation and of avoidable hospitalisation in all industrialised countries<sup>56</sup>. Indeed, particularly salient is the non-compliance problem among CHF patients and a recent meta-analysis study found that 9 out of 11 studies indicated that non-compliance was the main cause of worsening conditions often leading to re-hospitalisation.<sup>57</sup> Treatment effectiveness for CHF has increased but so have the prescriptions and without support to patients non-compliance will increase and the potential improvements of more effective treatment will be lost for many patients who will continue to give rise to avoidable hospitalisation costs.

In essence the burden of chronic disease on the health care systems is huge and it will only get bigger as prevalence of chronic disease increases with the ageing population. One may reach that conclusion, despite the fact that data available is not directly comparable, even within the national confines of one Member State, mainly due to the diversity in the definitions used, the difference in the diagnostic procedures as well as the different measurement characteristics.

### **2.3 RMT can clearly help**

The various trends and elements illustrated in the previous two sections quite clearly provide compelling evidence calling for the introduction of RMT and other PHS applications. We elaborate

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<sup>49</sup> See J. McMurray and S. Stewart, Epidemiology, aetiology and prognosis of heart failure. *Heart* (2000): 596–602 and .Mc Murray and S. Steward, The Burden of Heart Failure, *op. cit.*

<sup>50</sup> C. Ashton et al., The association between quality of inpatient care and early readmission. *Annals of Internal Medicine*, 122(1995): 415–21.

<sup>51</sup> J. Vinson et al., Early readmission of elderly participants with congestive heart failure. *Journal of American Geriatric Society*, 38 (1990): 1290–5; K. Harraj et al. Simple clinical variables are markers of the propensity for early readmission in heart failure patients. *Journal of Cardiac Failure* 5 Supplement (1999): 80.

<sup>52</sup> A. Di Lenarda et al. Current presentation and management of heart failure in cardiology and internal medicine hospital units: a tale of two worlds—the Temistocle study. *American Heart Journal*, 146(2003):E12.

<sup>53</sup> L. Erhardt and C. Cline. Heart failure clinics: a possible means of improving care. *Heart*, 80 (1998):428–9.

<sup>54</sup> B. Fleming, *et al* Medication use by home health patients. *Journal of Geriatric Drug Therapy*, 7 (1993): 33-45.

<sup>55</sup> C. Cline et al, Non-compliance and knowledge of prescribed medication in elderly patients with heart failure. *European Journal of Heart Failure* 1(1999): 145 – 9.

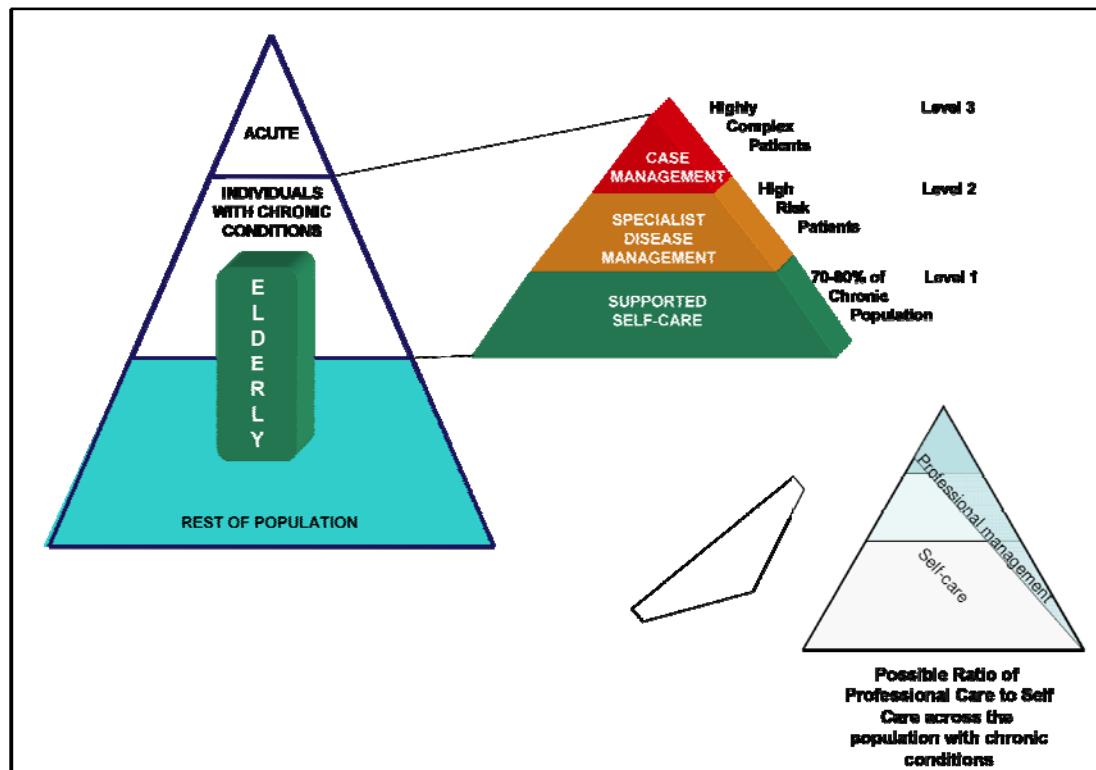
<sup>56</sup> P. Kausnik, *et al*, User-adaptive Reminders for Home-based Medical Tasks: A Case Study. *Methods of Information. Medicine*, 47(2008): 203–207.

<sup>57</sup> H. Martje et al, Non-compliance in patients with heart failure: how can we manage it? *European Journal of Heart Failure* 7 (2005): 5-17.

this need further in this section. Chronic patients can be divided into three categories, following the approach of the UK Department of Health, illustrated in Figure 4, as follows:<sup>58</sup>

- **Level 3:** include top "hospital returners" who are heavy users of unplanned secondary care.
- **Level 2:** represent patients suffering from a complex single need or multiple conditions
- **Level 1:** represent individuals at an early stage of a disease or having it in less complex forms

**Figure 4 – The Health Pyramid and different categories of chronic patients**



Source: Authors' elaboration (Deliverable 2.3) and adaptation from sources quoted in footnote 58

Although the mix changes, for all three groups the management of patients requires both professionals' intervention and self-care. It is probably pleonastic to stress that RMT can be at the same time a support to the professionals and an opportunity for enabling better self-care, as it can provide patients and their informal carers with knowledge, information, skills and confidence to care for themselves and their condition effectively. The application of RMT can avoid acute worsening of conditions in Level 2 patients by providing timely information to professionals and can help prevent avoidable hospitalisation in Level 3 patients helping them, for instance, increase their adherence to the clinical prescriptions.

However, it may be unrealistic to assume that RMT and PHS or eHealth applications in general, could reduce health care costs; these may not necessarily decrease but can be contained. Moreover, the policy objectives of most actions aimed at changing the conditions of health care delivery are primarily aimed at improving the outcomes for citizens and patients. Cost-effectiveness can usually

<sup>58</sup> UK Department of Health, Supporting People with Long Term Conditions, 2007, ([http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH\\_4100317](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH_4100317)); D. Singh and C. Ham, Improving Care For People With Long-Term Conditions: A Review of UK and International Frameworks, Birmingham, University of Birmingham Health Centre Management Services (HCMS) and NHS Institute for Innovation and Improvement, 2006 ([http://www.improvingchroniccare.org/downloads/review\\_of\\_international\\_frameworks\\_chris\\_hamm.pdf](http://www.improvingchroniccare.org/downloads/review_of_international_frameworks_chris_hamm.pdf)).

be the result of improvement in quality, and cost-effectiveness metrics are also a measure of improvement in quality. In summary, efficiency and effectiveness are sought in order to increase patient safety and health status, while ensuring financial sustainability. In this respect, it is worth noting that the *eHealth for Healthier Europe* study recently published by the EU Swedish Presidency looks primarily at goals from the perspective of the user/patient such as safety, quality, availability, empowerment and continuity of care and does not contain one single figure on cost reduction.<sup>59</sup> In a recent editorial Cleland et al observed how “*many patients do not get the basic investigations and treatment that they should. The point of Telehealth is that it will enable many more patients to enjoy the standard of care offered to only a selected few at the moment*<sup>60</sup>”.

Indeed, if RMT services can provide the same quality and safety of the traditional approach with fewer staff, then it is difficult to see why it should not become a preferred option. Fewer staff does not mean firing professionals but rather releasing resources from some routine activities and redeploying them for more acute matters or for clinical research and innovation, bearing in mind the anticipated lack of health care professionals compared to care needs in the future. Assuming all else remains the same, if RMT reduces avoidable hospitalisation, there will be more resources available to treat the foreseeable increase in the number of patients more urgently needing inpatient care.

In brief, RMT can certainly help pursue the objective of “producing more, better, and more effective output with the same input”. If RMT together with other measures could, for instance, delay by five years the two most costly last 2 years of life and prolong the capability to work for those aged 55-65, it would produce exceptional benefits from all perspectives. For instance, for the patients who live more years in relatively less difficult conditions or can prolong their active work life. Also for the health care sector there are benefits, since it is well known that intensive care costs during these last years of life of a chronically ill person are lower if the person is already fairly old.<sup>61</sup> In addition, this postponement of costs (for either care or pensions) and/or the prolongation of tax contributions represent important “cash flow” outcome (delayed disbursement, prolonged revenues) from the perspective of deeply concerned Member State Finance Ministers. RMT has a role to play in this context as the drivers for the seismic revolution Cleland *et al* envisage are all there.

**Table 7 – Telecare a seismic revolution**

*“Telecare will become the preferred method for managing most long term medical conditions and this revolution may well be as seismic for health care as the industrial revolution was to Western economies 200 years ago. When and how this revolution will occur is not yet clear... ”*

*The secret weapon of telemonitoring, as yet not deployed, is that it can actively engage the largest health-care workforce in the world; that is the patients and their carers.*

Source: See footnote 60

<sup>59</sup> *eHealth for a Healthier Europe! Opportunities for a better use of health care resources*, Swedish Presidency of the EU ([http://www.se2009.eu/polopoly\\_fs/1.8227!menu/standard/file/eHealth%20for%20a%20Healthier%20Europe.pdf](http://www.se2009.eu/polopoly_fs/1.8227!menu/standard/file/eHealth%20for%20a%20Healthier%20Europe.pdf) ).

<sup>60</sup> J. Cleland et al. Telemonitoring for heart failure: the only feasible option for good universal care? European Journal of Heart Failure 2009 11(3): 227-228.

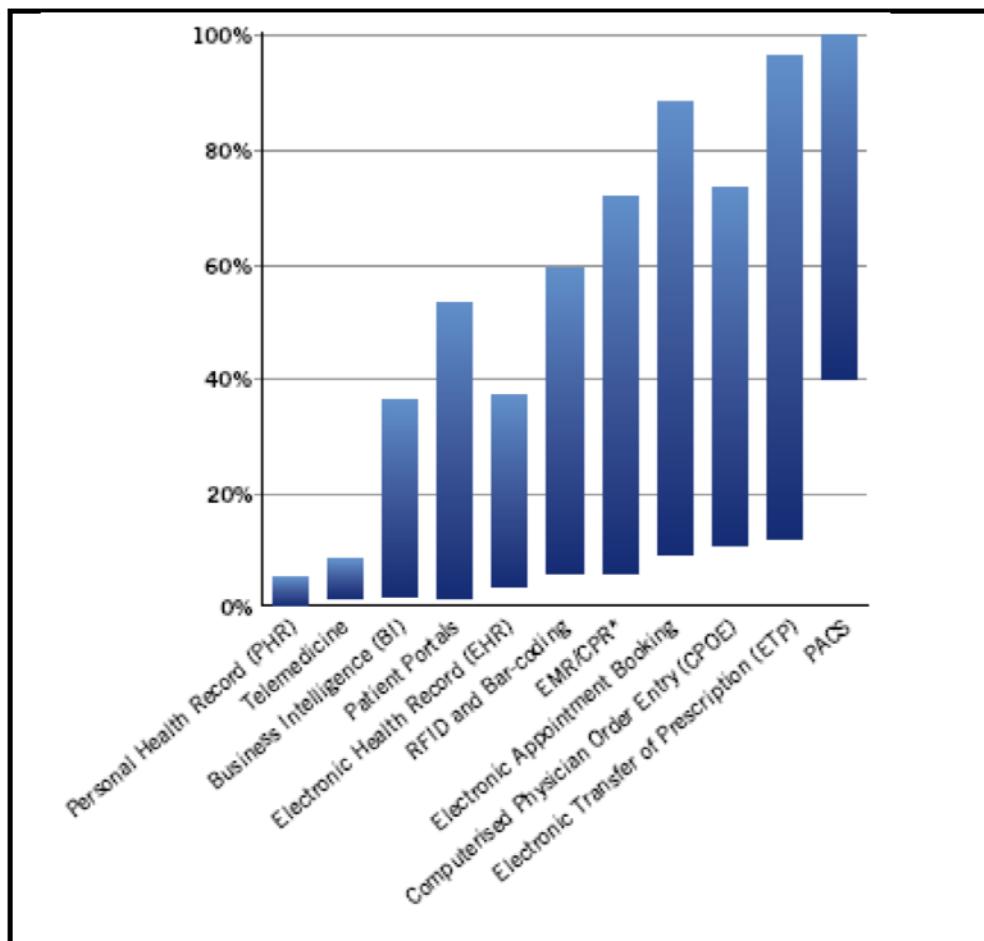
<sup>61</sup> See European Commission, *The future of health care*, op. cit. p. 4.

### 3 RMT deployment: the obvious is not yet happening

Given the compelling needs and opportunities for RMT one could have expected to find at least some sizeable and consolidated level of deployment. On the contrary the evidence shows that the “obvious is not yet happening”.<sup>62</sup>

While we present below our own evidence about the limited development of RMT, its relative slow pace of adoption can be appraised indirectly looking (Figure 5) at Telemedicine adoption,<sup>63</sup> a part of which is RMT, in comparison to other eHealth applications, even for countries that seem to introduce eHealth as a priority and despite the fact that over the last 10 years the continuing R&D efforts in this area have been successful.

**Figure 5 – eHealth adoption in six Member States**



Source: eHealth for a Healthier Europe, op. cit, p. 26

<sup>62</sup> This expression is taken and adapted from the analysis in E. Shortliffe, E. Strategic Action in Health Information Technology: Why The Obvious Has Taken So Long. *Health Affairs*. 24 (2005): 1222- 1233.

<sup>63</sup> The figure, taken from the earlier mentioned eHealth for Healthier Europe study, is based self-reported levels of adoption of different eHealth technologies in the six EU Member States on which the study focuses (Czech Republic, France, Netherlands, Spain, Sweden, and United Kingdom).

### **3.1 What do market data reveal?**

Many estimates exist in relation to the size of the RMT market, which is defined in very different ways (telecare, telehomecare, telemonitoring, etc). We selected the two that were more comparable and specifically focussed on an entity closest to the definition of RMT used in this report.

**Frost&Sullivan (F&S) 2008 report.**<sup>64</sup> According to F&S the RMT market in Europe was worth €127.9 million in 2007 and is expected to reach €292.3 million in 2014. This market is allegedly split as follows: 40% (€ 52.2 million) to equipment vendors and 60% (€ 76.4 million) to services providers. While what is meant by service providers was not entirely clear in the report, we were able to clarify with F&S that their definition of revenues for services include: "... wide range of data communication hubs for remote monitoring and home care applications with various connectivity options (wired/wireless), various remote transmission options (phone line, net and cellular) and call centre management coupled with rough interpretation of clinical data (summary reports). It does not include patient feedback or physicians/nurses work as they do not contribute to RMT market revenue generation".<sup>65</sup> According to F&S data, United Kingdom is the leading country in Europe in terms of RMT revenues with a 25% share. Germany follows with a 20% contribution to RMT revenues. Italy comes third with a share of 17%, while France is fourth with 15% of total revenues. Spain represents 5% and ranks 7th. Benelux and the Nordic countries represent 12% and 6% of RMT revenues in Europe respectively.

**Global Market Data (GMD) 2009 report.**<sup>66</sup> GMD data only deals with the RMT devices market, which in Europe is valued at €28.1 million in 2008 and forecast to grow by 2.9% annually for the next seven years to reach €34.5 million by 2015. It is worth noting that for 2008 the figure provided by GMD for the device market is only a bit more than half of the similar figure provided by F&S (€ 28.1 million versus €52.2 million). According to GMD the increasing number of patients with cardiovascular diseases and the expanding use of remote patient monitoring in homecare settings for the older population will primarily drive the growth. From GMD data the leading European market appears to be France (which is only ranked as fourth in F&S).

**Market data in context.** While market reports stress good RMT CAGR and prospects for growth, the small almost insignificant value of the RMT market, even when the bigger number estimated by F&S is considered, can be appreciated in Figure 6 below, which brings this value into perspective. The estimated market value is about 0.9% of the total eHealth market value.

From a different perspective the order of magnitude of the RMT market can be appreciated looking at the specific field of diabetes through the data provided by GMD in a separate report on global Self Monitoring Blood Glucose market segment:<sup>67</sup> in 2008 globally blood glucose strips and meters captured 99.3% of the market, while RMT used for diabetes type I patients only 0.7%.

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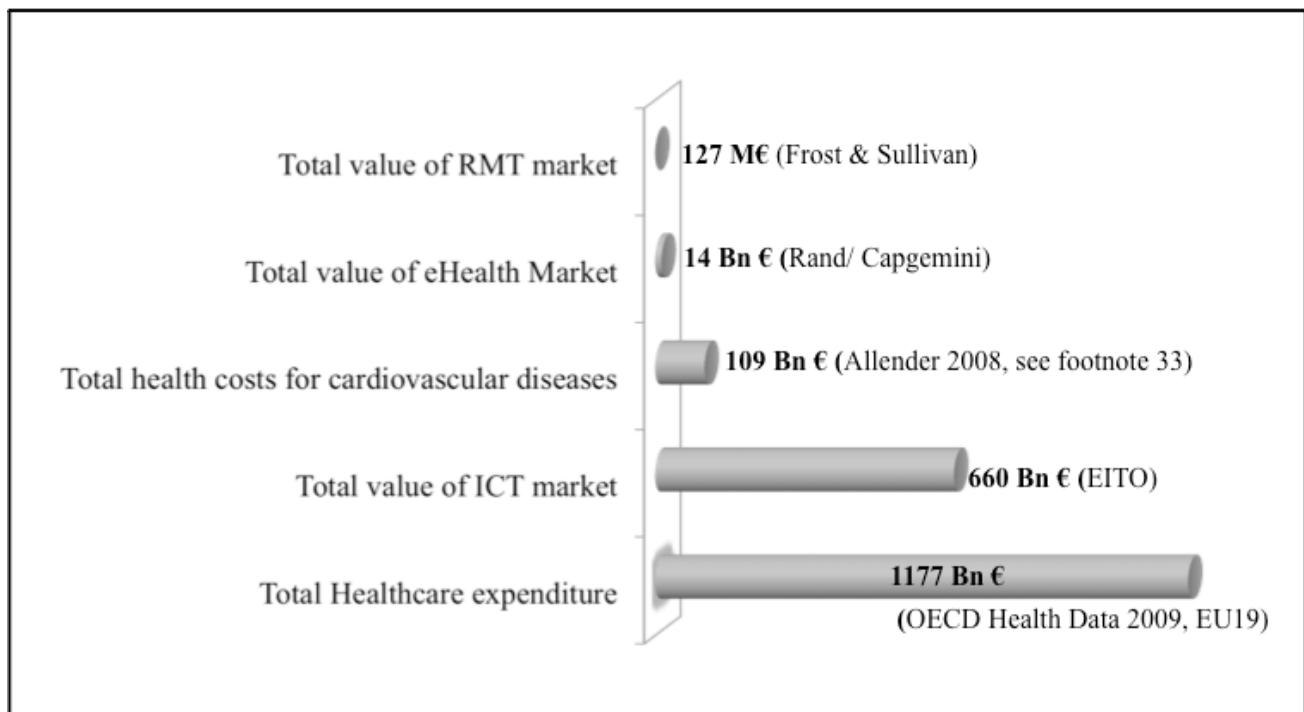
<sup>64</sup> European Remote Patient Monitoring Market M22C-56, 2008.

<sup>65</sup> From e-mail sent by F&S to IPTS on October 29 2009.

<sup>66</sup> European Remote Patient Monitoring Market: Strategic Analysis and Opportunity Assessment, August 2009.

<sup>67</sup> Global Self Monitoring Blood Glucose Market: increasing Adoption to Drive Growth, March 2009.

**Figure 6 – Orders of magnitude: the “invisible” European RMT market**



Source: in parenthesis inside the figure

**Critical assessment of the estimated figures.** There are doubts as to whether market research companies can actually capture all the relevant sources of data to produce reliable estimates. Even defining the companies that are active in the RMT/PHS market is extremely difficult due to the fuzziness of the market’s overall structure. Companies position themselves in different ways with some offering technological devices only, others monitoring and analyzing services, and only a few offering end-to-end services including medical services. Clear definitions of which stakeholders should actually be included into the RMT/PHS market are lacking.<sup>68</sup> Also determining the active attitude of companies positioned in the market from “interested in the market and piloting” to “active in the market and doing business” is equally difficult.

As a consequence, one is left to wonder to what extent market research data over- or under-estimate the overall size of the market.<sup>69</sup> Our research has revealed that RMT is characterised by many small scale and very local initiatives that, we are quite confident, market research does not identify. For instance, during the field mission to Italy with the help of interviewed experts we produced a rule of thumb estimate showing that the size of the Italian market as quantified by F&S (€1 million) should be increased by one third in order to account for small and localised initiatives (€45-50 million). Second, while the F&S quantification of RMT services excludes the medical part, we are aware of companies also providing this component (and in any case the medical part is always provided by health care institutions/professionals). This is an important element that is apparently not counted when estimating the figures above. In conclusion, the size of the RMT market is very small, both as a proportion among other eHealth activities and as an alternative to chronic disease management solutions. Moreover, even if the estimates are increased by 30%, taking into account small scale local

<sup>68</sup> Although this data is not clearly available from market data, we have provided a detailed discussion of all major stakeholders in Deliverable D1.1 in the section on measurement and indicators. We are not repeating it here as it would disrupt the flow of narrative.

<sup>69</sup> Market research reports analysed were not fully transparent on how their data are estimated.

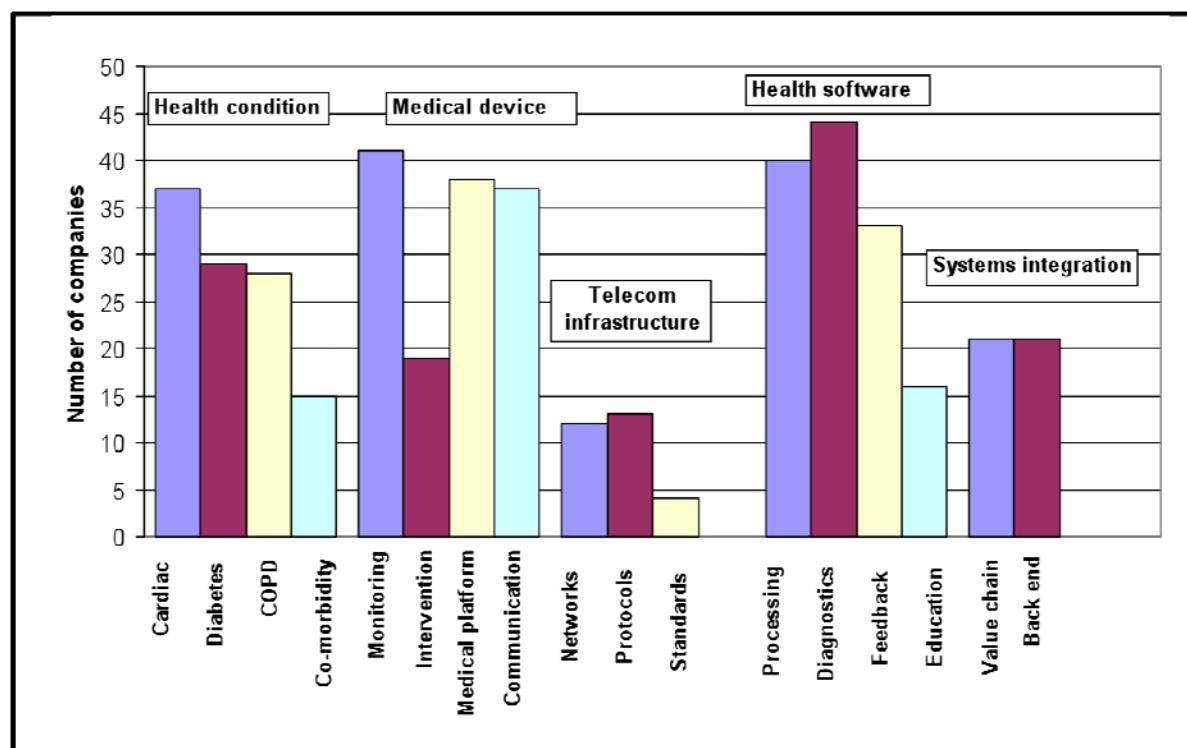
initiatives overall Europe and despite the very positive CAGR estimated, the market will remain small for the next few years.

### 3.2 RMT market players

As the previous section showed, the quantification of the market is a perilous exercise. In order to complement the findings of market research we carried out a review of PHS/RMT market. A review was conducted of more than 200 companies active in eHealth likely to provide PHS/RMT services, out of which 50 were studied in more detail. The picture that emerges is that of an under-developed market, characterised by fragmentation, small-scale operations and lack of integration into health and social care. Each of the companies was checked for location, size, number of years in business, geographical focus areas, market segments targeted, type of products/services offered, and role on the PHS/RMT value chain. The boundaries between a company's PHS/RMT activities and other Health IT activities are often difficult to distinguish but the analysis helped get an overview of how the PHS/RMT market is developing and which actors provide what type of products and services. Some of the main findings will be reported below, while all findings are in Annex II, Chapter 7.

**Main characterisation in general (200+ companies).** There are only few cases of pure PHS/RMT players of a certain dimension and success, and most players operate also in other eHealth or Health IT related areas. Even when such pure players could be identified, they seem to provide system integration, devices, and remote monitoring, but seldom in an integrated manner. The PHS/RMT market, thus, appears to be rather fragmented, albeit with a high level of activity at product level. While devices and remote monitoring are provided by a large number of companies fewer companies appear in the higher-end service provision, which includes the medical component of the service.

**Figure 7 – Companies' offering (200+ companies)**



Source: Authors' elaboration on collected information on companies offering RMT services

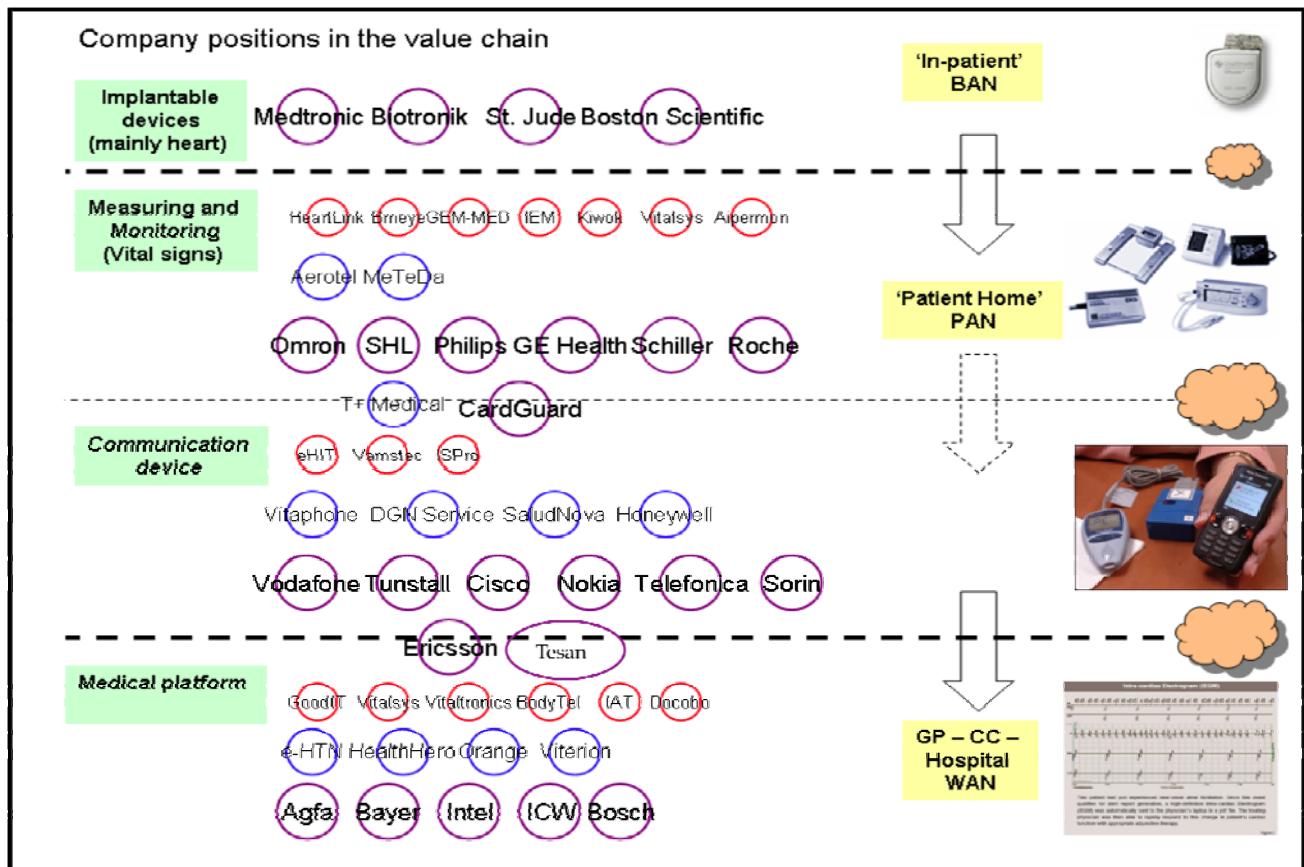
Most of the companies offer a mix of products and services often characterised by a high degree of flexibility. In other words depending on the specific needs of the health care provider for whom they

implement the RMT solution, their offer is usually tailored to each case delivering as much or as little of the solution as required. For most players, the service provision ends at the point of care when the data gathered on the patient is handed over to a hospital or public emergency services. Many of the companies consulted do not provide call centre facilities, but subcontract that function if needed. This shows that fully integrated services are not widespread and RMT businesses are more often a technology-driven undertaking.

Products for pulmonary conditions, diabetes, and heart conditions are the most common, while a number of players offer other devices/tools for disease management, patient databases, sensors, hospital information systems, teleconsultation and teleradiology, wellness devices as well as scales, spirometers and other monitoring/measurement devices. Large players in the health care industry seem to be interested into the RMT market but remain in a “wait and see” situation, possibly because of the high fragmentation which makes it difficult to gain significant revenues and leverage economies of scale. On the other hand, there is quite a large playing field for SMEs that contribute to PHS development with novel products, services and business models, thus helping to drive the market. Generalist ICT companies and Telco have entered the RMT market by expanding their portfolio, some offering personal health services (e.g. Ericsson, Orange), others offering hospital information management and system integration services (e.g. Intel, Cisco, Nokia).

**50 companies analysed in the value chain.** Out of the 200+ companies identified as offering related services, some 50 considered to be offering Telemedicine services were selected for further analysis. Figure 8 below is an attempt to map this selection of 50 companies analysed in detail, situating them on the PHS/RMT value chain according to their main activity focus. Except for companies specialised in implants, many of the players mapped operate across several areas, which makes it difficult to draw a clear player profile.

**Figure 8 – RMT Companies’ value chain (50 selected companies)**



Source: Authors' elaboration on gathered companies' information

In Figure 8, the 50 selected companies are assigned a colour depending on relative size (red to small companies, blue to medium size and purple to big companies). Some companies have an integrating role and others provide services over two parts of the value chain or even over the whole value chain but this is not discernable on the graph (e.g. VITAPHONE or SALUDNOVA). More analysis on the characteristics of the companies can be found in Annex II (section 7) of this report.

While, we are fully aware that the mapping presented above, does not reflect the actual position of many of the companies, we intentionally included it here as a picture that is indicative of market fragmentation and which may be used as a starting point for further analysis. At a first glance, one can safely conclude that there are plenty of devices on the RMT market, confirming that at least this most basic technology block is not an issue. However, when considering maturity of the technology on offer, the lack of widely accepted standards and infrastructure interoperability are still challenges and alliances like CONTINUA<sup>70</sup> or associations like COCIR<sup>71</sup> bringing together a sizable number of companies are attempting to reach consensus on technical issues affecting the market.

**Revenue streams, pricing, and business model.** We must stress that very limited information was obtained (even during interviews), on how RMT products and services are priced and how revenues are generated. In general market players were reluctant to provide figures on pricing and the share of their revenues coming from RMT, probably because of the sensitivity of such data (cost of service provision) considering also the likely small size of the revenues generated. The only information on

<sup>70</sup> <http://www.continuaalliance.org/>

<sup>71</sup> <http://www.cocir.org/index.php?mode=0>

the pricing of RMT services is what could be found in public procurement official documentation and/or in reimbursement guidelines for three Italian regions (see *infra*).

Most activities seem to be confined to national if not regional boundaries, and the main driver for targeting new markets is the responsiveness of health care systems to RMT reimbursement (i.e. Pais Vasco, ES and Lombardy, IT). As it takes many years for RMT companies to reach a positive ROI, funding is a major issue for sustaining the business. For large companies, including Telco and mobile operators, investment decisions to participate in PHS and RMT markets are driven by socio-economic trends and growth perspectives in the medium to long term, not by actual revenues. The same goes for relatively small affiliates of large multinationals which enjoy financial backing from long established businesses enabling them to be present on a market segment with a promising future. For SMEs the outlook is very different; while, sometimes surprisingly, initial funding is not a problem, some have to struggle to maintain operations, due to the short-term nature of health care providers' budgets which contrasts to the rather long time needed for RMT business profitability or even because reimbursement simply does not compensate the costs of providing an RMT service.

Generally revenues may be derived from providing and installing devices, developing software, processing and storing data as well as carrying out technical and clinical triage for the provision of care services, and providing call centre services. Some companies charge a one-off fee, sometimes subsidised, for the device and monthly subscription fees paid by the patient privately, or reimbursed by an insurance company. Others negotiate contracts for a number of patients with a health care provider directly (at local, regional level in coordination with a local secondary care unit). Some mobile players propose care distribution models where the benefits of early discharge are shared among several of the value chain stakeholders but the sustainable implementation of such models is still being trialled. Even for RMT schemes led by public health care authorities the costs structure is not always clear, and does not reflect the actual value of the service provided.

All companies interviewed in the field research deal with RMT for chronic disease management. While few deliver services over the full value chain of products and services, most companies offer solutions adaptable to each of the three most common chronic conditions and their co-morbidity. Some players indicated further interest in the wellness part of the market, offering products for lifestyle, home and elderly social care. Cardiac implant companies started developing RMT with new generation implants, a niche market within RMT.

Business models seem to develop in an iterative, pragmatic way. Even when a company develops a sound business plan based on solid market forecasts and realistic reimbursement perspectives, reality often turns out to be different and forces changes on their initial plans (e.g. need to diversify into other branches of eHealth to secure stable revenues). Although more empirical data is needed to draw sound conclusions, the business strategy of the companies interviewed seems to be linked to the following elements:

- The health care system of the country of origin of a company influences its business model offer, focusing on the needs of a specific stakeholder (e.g. health care rather than social care or private insurance);
- A company that covers the full RMT value chain, which by including specialised call centre services seems to limit the focus of the activities to one chronic disease condition for example only cardiac disease management (i.e. HTN, Vitaphone). This may be explained by the complexity and costs of running an in-house medical centre with several medical specialties;
- A further element is the orientation of a company in terms of its medical or technological expertise. In other words, when a company is created around a technology, its offer is likely

to be wider as technology can in principle be applied to various diseases while a company from the medical sector will concentrate on its specialty (e.g. diabetes for Roche).

### **3.3 R&D, pilots and programmes**

**Why look at pilots, projects, and programmes.** The review of companies, both by means of desk research and expert interviews reveals an RMT market fraught with difficulties, characterised by fragmentation, small scale operations, and the availability of discrete specialised technological solutions, much less of integrated service provision that could contribute to the much awaited new models of care. Though, to integrate RMT technology into care pathways and bridge the gap between the promises of technology and the reality of health care and social care is the target today. To do so advances are needed at organisational and institutional innovation. As this is unlikely to happen through market forces alone, we considered that the review of market players had to be complemented by an analysis of what has been and is being done in R&D activities, in pilots and in experimental programmes at EU, national and regional level, so as to provide a more comprehensive picture and assess to what extent the move from R&D, through pilots and programmes, eventually to sustained and stable services is likely to drive the health care transformation.

**EU funded R&D and Pilots.** Since 1989 EU research funding for eHealth has exceeded the € billion mark spanning more than 500 eHealth projects. Within the FP5, FP6, FP7, eTen and CIP European Commission funded programmes,<sup>72</sup> 23 projects (see projects names in Table 11) clearly focus on RMT. In addition some Living Labs also tackle RMT as part of their eHealth or Active Ageing activities. Integrating health-monitoring tools into textiles e.g. through wearable electronics and body sensors, has been the focus of a number of FP5 and FP6 projects while research on new bio-sensors has gained importance under FP7 (e.g. for continuous monitoring of blood pressure, blood oxygen levels and heart function). Innovative closed-loop approaches for chronic disease management is another feature of FP7 projects like HeartCycle (coronary heart disease and heart failure), Metabo (diabetes) and Chronious (COPD and CKD – chronic kidney disease). In some cases the platform used even connects to electronic patient health records (Heartfaid/FP6 or Linkcare/eTEN). The systems developed are intended to report automatically to clinicians, who may adapt therapies and make lifestyle recommendations (medical loop), as well as involve the patients in the management of their disease (patient loop). Remote communication of data is ensured by wireless, mobile communications, using PDAs, mobile phones, Internet technologies, home-interactive TV or agent technologies. The latter are promising technologies for chronic disease management, in the form of continuous support personal assistants in daily life allowing compliance support, interface with monitoring devices, real-time medical advice (e.g. PIPS, and Saphire FP6 projects). Mobile trans-European services for chronic disease management have been researched into by projects like FOR-ALL and HealthService24 (eTEN). Finally, robotics is considered as having great potential for home patient monitoring although this may be the case in a more distant future.

"Integrated care" services (i.e. the combination of social and health care) for effective management of chronic disease can be found in a large number of projects. A series of "integrated care" projects led by Hospital Clinic of Barcelona since 2000 shows the high potential of this approach. Further examples include Health-Life, Linkcare, Better Breathing FOR-ALL (eTEN) and CommonWell or NEXES (CIP). The CIP promotes the deployment of ICT solutions supporting integrated care management and home care. Most of the projects we considered have foreseen clinical trials with 'real' patients but outcomes are often still to be assessed. In some cases results are available as for

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<sup>72</sup> European Commission R&D funding instruments through Framework Programme 6, 7 as well as the European Community eTEN programme and its successor, as of 2007) the Competitive and Innovation Framework programme (CIP).

Heartfaid (FP6), Better Breathing (eTEN), Health-eLife (eTEN), HealthService24 (eTEN) or the HHH (FP5, Home or Hospital in Heart Failure) study. Observations strongly emphasise the need for further confirmation of findings by means of large-scale randomised intervention trials, at European scale, such as the one recently launched with funds from the CIP programme.<sup>73</sup> The analysis of projects shows that the innovation focus is shifting from a technological to organisational innovation, with the increasing prominence of "integrated care" projects. At the same time, projects increasingly include a pilot component aimed at testing the RMT/PHS solution in real settings, with real patients so as to generate the much-needed evidence of RMT/PHS efficiency and effectiveness as well as to share the benefits produced with as many patients as possible.

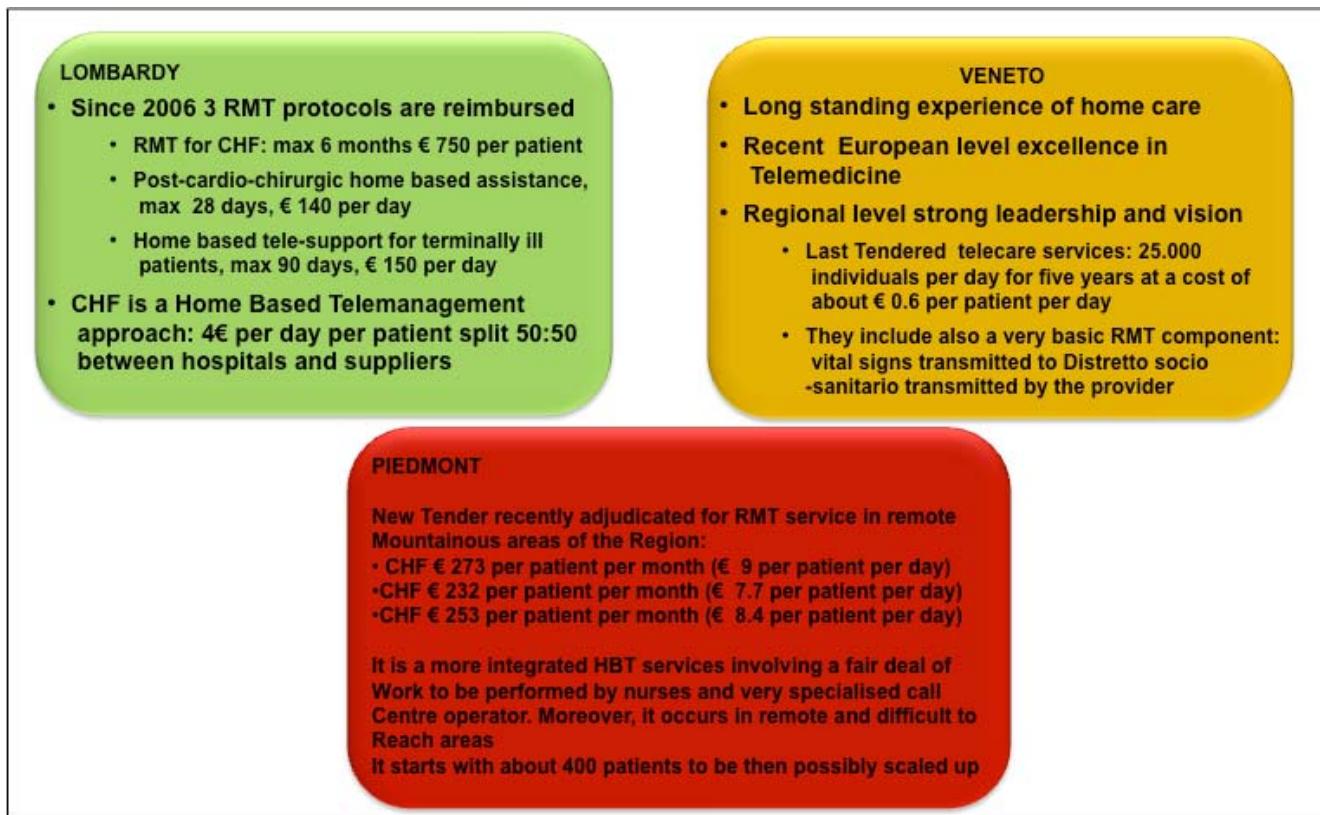
**National and regional levels pilots and programmes.** Like for projects, the pilot and programme landscape is very varied, with small, medium and large-scale initiatives at local, regional and national level. EU Member States further support regional and national RMT projects and pilots via public funding and public-private partnerships (e.g. in the UK, Italy, Germany and Spain) in addition to private or industry-led initiatives (e.g. in Austria, and Hungary). Projects span from monitoring to early prevention and home care. Chronic Heart Failure (CHF), diabetes and pulmonary conditions like COPD (and co-morbidity) are most addressed, followed by Chronic Kidney Disease (CKD) and neurodegenerative diseases. Local, regional or national pilots and projects often start from a very small scale (ten to fifty patients) and get scaled-up to a few hundred patients in a later stage (or not mainly depending on whether financing is sustained over a number of years). Very few large-scale RMT projects with thousands of patients (e.g. ECCH, Northern Ireland and WSD, England), have been launched so as to strengthen the evidence about RMT benefits and enable the transformation of health care delivery through RMT. A number of examples are presented below; they are only illustrative and do not aim to fully capture all of the activities occurring in the field.

In Italy after some years of experimentation sustained services are being provided in three regions (Lombardy, Piedmont and Veneto), although under different arrangements (see Figure 9).

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<sup>73</sup> Regions for Europe Working together in Health; RENEWING HEALTH <<http://www.renewinghealth.eu>>

**Figure 9 – RMT and telecare activities in three Italian regions**



Source: Data gathered by IPTS during field mission to Italy (interviews and official documents)

In Lombardy a number of reimbursed protocols for RMT have been formally defined and regulated by the regional administration and the services are currently being provided. Piedmont and Veneto, on the contrary, have launched procurement tenders that have been adjudicated to external suppliers with a fixed number of patients to be targeted by the services on offer (to be selected by local health authorities in collaboration with hospitals and GPs) and also a fixed price. Considering the price for RMT of Chronic Heart Failure patients we could establish that it ranges from 4 €per day per patient to up to 9 €per day per patient depending on the complexity of the services and on the amount of required intervention by professionals. It must be stressed that these fees are for services including the intervention of professionals, whereas the lower price of the Veneto case is for traditional telecare services for the elderly to which a very basic and limited monitoring of vital parameters has been added.

The ECCH programme (Northern Ireland), the regional Telecare Development Programme (TDP, Scotland), Telescot (NHS Lothian) and the Whole System Demonstrator (WSD) in England are all large-scale RMT initiatives aimed at scaling-up deployment from a couple of hundred patients (Telescot) to five or six thousand patients (ECCH, WSD), with different strategies: pre-procurement (ECCH), randomised control trial (WSD, Telescot) and telehealth/telecare convergence (WSD, London). All these initiatives were recently launched (2008-2009), which shows that large scale RMT deployment is a new phenomenon. Further they all plan to scale-up the number of patients included in the RMT scheme incrementally, which points to the complexity of deploying RMT solutions.

Apart from the above cases, regional and/ or local pilots tend to target small numbers of patients. Examples include about 300 UK telecare services provided by local authorities or housing

associations for various chronic diseases, the Koala study in the Netherlands scaled up from originally 155 patients to 1000 across the country, or the Costa del Sol pilot in Malaga started with 15 CHF patients. Industry-led pilots include the Roche diabetes RMT initiative in Spain, the Orange Health care mobile pilot in Austria and the GE Health care RMT pilot in Hungary.

The reviewed activities show that RMT technology innovation is incremental, enhancing existing products or devices (implants, vital sign monitoring, and communication devices), software (e.g. intelligent data processing, decision support software), infrastructure (telecommunication networks, protocols, standards) and systems (integration with EHR). Further the research and innovation focus is currently moving towards innovations of a different type, like process innovation (e.g. innovative closed-loop approaches), organisational innovation (e.g. "integrated care" models) or institutional innovation (reimbursement models). At its broadest, Integrated Care may encompass preventive care, social care, and care and support in the home, recognising that social conditions impact on health and vice-versa. It imposes the patient's perspective as the organising principle of service delivery. It is presumed that chronic care management can be most effective when established within a wider system of integrated care.

However in most European countries today social and health care are two separate entities with separate budgets and different infrastructures, which very often do not "talk to each other". This makes convergence and integrated care in Europe look like a distant dream. Major efforts are therefore needed to ensure that the radical innovations required and tested in some pilots and projects can unfold at the right pace and in the right scale. Unfortunately while RMT is thought to contribute best to the much praised paradigm shift towards patient-centred services and out-of-hospital care, which should help health care systems adapt and cope with demand in the future, not enough is being done at national level to push for the radical changes needed to care practices. If nothing is done at organisational and institutional level projects and pilots alone will not succeed in transforming health care at the pace that is needed.

**Slow progress from R&D to sustained services.** Summing up the evidence gathered, we can conclude that the landscape is dominated by pilots and programmes with very few isolated cases of sustained long-term services. So, from a different perspective we corroborated the picture emerging from the analysis of companies. Additionally this analysis shows that 10 years of top level funding for R&D and pilots have failed to break the strong barriers that impede reasonable scale viable RMT service provision. One major hindrance for moving from R&D projects and from pilots to production seems to be the lack of funding for the transition period towards full deployment, leading many projects and pilots to stop after funding has dried out. Projects followed by pilots, that may be used to identify and correct implementation problems mostly to do with scaling up to thousands of patients, may be the most efficient route towards sustained service provision (as well as being a sound basis for building business cases). It remains to be seen whether successful pilots can lead to service deployment in countries not involved in the initial experiment, as this would speed up RMT take-up in Europe. However to date, it seems that each new initiative requires its own pilot thus delaying time to market.

### **3.4 Europe vs. US market trends**

Having looked at detail at the RMT market size estimates, a brief comparison with equivalent estimates for the USA will help us understand whether the situation in Europe is particular to conditions in Europe or safely attributed to challenges in relation to the deployment of RMT. A report on mHealth and home monitoring by Berg Insight provides interesting comparison between market value and growth for the US vs. Europe, as summarised per segment below in Figure 10:

**Figure 10 – Home Medical Monitoring market value by segment (world 2008-2013)**

Segment	Market value	Projected CAGR
Diabetes monitoring	US\$ 9,000 m	10 %
Blood pressure monitoring	US\$ 800 m	8 %
Cardiac monitoring	US\$ 300 m	3 %
Other	US\$ 500 m	7 %
<i>Total</i>	US\$ 10,600 m	10 %

Source: Berg Insight, 2009

According to Berg Insight<sup>74</sup> the market for home health monitoring – roughly corresponding to RMT – was worth USD 11 billion (€7.84 billion)<sup>75</sup> with diabetes monitoring by far the leading segment, although 90% of sales relate to strips and only 10% to actual monitors.

On the glucose monitoring segment Europe has the lead with a share of the global market estimated at USD 4.9 billion (€3.5 billion<sup>76</sup>) against USD 3.3 billion (€2.35 billion) for the North American market, out of a global market of USD 9 billion (€6.4 billion). Interestingly, European growth rates are foreseen to be 10% annually for the period 2010-2014 against 6% for the US.

The total North American market for home cardiac monitoring today is worth USD280 million (€200 million) while the European market is only worth USD 10 million (€7.1 million). Berg Insight concludes on the significant potential for growth in Europe in that segment. In particular "home arrhythmia monitoring is likely to be adopted in Europe in a few years" in their view. For the US, 90% of the market value comes from services with only 10% related to the sale of devices.

According to the same study, the North American market for out-of-hospital blood pressure monitoring is worth USD300 million (€214 million) while the European market is estimated to account for USD250 million (€178 million), out of a global market of USD 800 million (€570 million). Berg Insight foresees an annual growth rate of 8% worldwide until 2014.

As to air flow monitoring, the market is estimated to be worth USD 50 million with an expected growth of 9% annually until 2014. Berg Insight foresees the sales of home spirometry devices for COPD patients as likely to increase, leading to the appearance of monitoring services in that segment.

In conclusion Berg Insight underlines that remote monitoring has given rise to a substantial market only in one of the nine segments they have examined, namely the glucose monitoring segment, for which growth rates are expected to reach 8-10% after 2011 with a wider deployment in Europe in the future. Berg Insight stresses that there is a significant untapped potential for remote monitoring both in the US and in Europe, and estimates that 25% of the people suffering from diseases that may

<sup>74</sup> mHealth and Home Monitoring report, second edition 2009.

<sup>75</sup> Exchange rate taken from Berg Insight's conversion, e.g. p.63.

<sup>76</sup> As was also commented when sizing the RMT market, estimates and forecasts from various consultants differ widely: for instance the Berg report estimate of the 10% of European Glucose market, effectively addressing monitoring services, would be €350 million which is of the same order of magnitude but significantly larger than the F&S estimate (see footnote 64 on page 30). This is only to be expected as described in detail on page 36 and 37).

require home monitoring would benefit from existing wireless solutions, while another 50% could benefit from integration of existing medical devices.

Berg Insight also foresees a migration of cardiac monitoring towards wireless networks from existing solutions mostly provided over fixed lines, with added flexibility and user friendliness. For other segments they predict an evolution towards the consumer market with the convergence of medical and mobile technology. Data centres for home medical monitoring is likely to open new business opportunities for network providers and mobile operators.

In summary the position of Europe vs. the US varies depending on the segment considered, as Europe is significantly ahead of the US market on the glucose monitoring segment but lagging behind dramatically on the home cardiac monitoring segment (the European market value is only 3.5% of the US market value) and somewhat behind on blood pressure monitoring. As to COPD and air flow monitoring, there is no comparative data between Europe and the US so all that can be said is that it is the smallest segment of the above four in terms of value globally albeit with long term growth expectations.

### **3.5 Summarising the evidence**

The key empirical findings, fully corroborated by the country studies (see Annex III, Section 8) can be summarised into the following three blocks:

- **Market data.** Market data show that the market size is very small, in its infancy; market data are also of dubious reliability and raise a number of conceptual issues to be discussed;
- **An R&D and pilot subsidised market.** There have been and continue to be pilots of varying scale and ambition. Most of them are abandoned once the funding mechanism is stopped. (The UK demonstrators and the CIP Pilot Renewing Health<sup>77</sup> are the most ambitious ones.). A lot is still done under R&D and in form of pilots;
- **Unclear and shaky context for market players.** There are small SMEs and large companies, which find this a high potential market but do not see ways to develop it. Setting up an RMT service requires a heavy upfront investment and the ROI only comes from long-term deployment and only if this is done on a sufficiently large scale (i.e. with enough patients). As a result there are very few specialised companies, since business sustainability requires diversification. Large players are in a “wait and see” mode and keep investing to have a presidium on the market in case it eventually takes up.

Further more detailed analysis on barriers justifying the various findings that we collected directly from stakeholders and experts will be reported on these in Section 5.

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<sup>77</sup> A CIP funded large scale activity started in March 2010 (see details at <http://www.renewinghealth.eu>).



## **4 Evidence on RMT outcomes and the potential of higher deployment**

### **4.1 The importance of evidence on outcomes**

Considering the need for RMT and the relative absence of deployment as evidenced by the findings in sections 2/3, it is reasonable to wonder whether the evidence on the outcomes of the RMT services that are under trial exists, is positive or whether it is visible enough among the stakeholders. Producing evaluation and measurement indicators in a multi-stakeholders perspective is of strategic importance for the wider adoption of such services and the challenges of realising it in practice have been analysed in full depth in Section 3 of the Deliverable D1.1 “Report on the Overall Structure of the Strategic Intelligent Monitor”. Methodological implications for producing robust and convincing evidence of outcomes that can be causally attributed to RMT or any other PHS application is also reported in detail in Deliverable D1.1; a few important points are re-iterated here, for the sake of clarity.

**Evidence on positive role of ICT on clinical outcomes is required more than in other fields.** Remote monitoring and treatment, as any other ICT enabled service in the health care sector, deals with the most precious of all values: life itself. It is, thus, clear that evidence on clinical outcomes and patient safety is a pre-condition for the acceptance of the technology by medical professionals and patients alike.

**Different groups of beneficiaries and stakeholders shall be convinced.** Evidence on RMT should prove positive outcomes for different audiences:

- **Users/ patients (plus relatives and their associations/ advocates).** Patients are the primary beneficiaries and their relatives are the secondary beneficiaries of any RMT service provision. First, naturally robust evidence that RMT can safely improve patients' health status; and second, evidence on patients improved quality of life, autonomy, control over their daily lives is needed to create confidence and overcome any resistance to the application of the technology;
- **Broadly defined health care professionals.**<sup>78</sup> Assuming RMT deployment produces the foreseen benefits, medical professionals will also benefit *ex post* as they will be required to concentrate their efforts to the patients that mostly need help. RMT will also provide medical professionals with more comprehensive data (from more regular recordings of patients' health status) to make more accurate decisions, thus offer better care to their patients. *Ex ante*, however, they are stakeholders in need of being convinced that RMT: (a) generates clinical outcomes responding to medical guidelines; (b) does not damage doctor-patient relations or creates risks of malpractice lawsuits<sup>79</sup> and (c) induces improved working conditions and optimisation of workload and not increased workloads which in addition are not duly compensated by appropriate incentives);
- **Management of health care producing units (i.e. hospital, laboratory, GP practice).** The managers of producing units as a second tier of intermediate beneficiaries (naturally taking for granted that they also care about patient safety and clinical outcomes) may be also interested in improving the efficiency of the production processes and of the allocation of

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<sup>78</sup> This general category represent a simplification we make for the sake of brevity for it should be further broken down into nurses and doctors, and among the latter between primary, secondary, and tertiary level professionals.

<sup>79</sup> The risks often raised by professionals include: a) inappropriate treatment or delay in care (inaccurate/inappropriate information may confound or complicate treatment decisions and delay care); b) unintended errors; c) inappropriate use of applications or information or unintended diffusion of sensitive information may undermine trust and prompt conflicts and motivate consumers to seek care from questionable providers.

resources since this means that they will be able to increase the quality and quantity of output with the same level of input. However, also in this case, *ex ante* as stakeholders they have concerns that home care for an increasing number of chronic patients without an adequate alternative economic scheme or new structure of incentives may lead to a net decrease of the funds provided to their organisations;

- **Broadly defined institutional stakeholders/third party payers<sup>80</sup>** are interested in containing the rising cost of health care for chronic patients while at the same time, coping with increasing shortages of professionals, meeting growing demands and increasing the level of satisfaction and trust on the side of the citizen with respect to the European health care system. Naturally, though from a different perspective, also institutional stakeholders would like to avoid issues of malpractice, privacy violations, etc. Moreover, when deciding to invest public funds into such services, decision makers require proof that these funds are not wasted and that such services do not drain resources that may be better employed for other purposes.
- **Broadly defined industry stakeholders (suppliers)<sup>81</sup>**. Naturally suppliers are not indifferent to clinical outcomes and patient safety, also for the simple reason that errors and malpractice lawsuits affect them as well. They are interested in providing quality services and demonstrable outcomes in order to consolidate and expand this market opportunity. Naturally they are interested in generating revenues and profits from such activities and, in this respect they may want to accelerate the process. Indeed, there are differences of opinions among the various stakeholders as to whether the evidence gathered so far is enough, as well as when and under what conditions the evidence collected will be considered sufficient<sup>82</sup>.

**State of the art.** Certainly there is no dearth of RMT evaluation studies (and related meta-studies) that try and formally test some or all of the potential outcomes mentioned above. Such studies are selectively considered in the next paragraphs and systematically reviewed in summary tables reported in Annex IV (Section 9). More in general there are plenty of evaluation studies in telemedicine and others areas of eHealth; a single meta-analysis article, for instance, identified 612 different studies focussing on the evaluation of telemedicine outcomes.<sup>83</sup> There are also hundreds of case studies reporting evidence on various outcomes,<sup>84</sup> etc. Yet, there is a lack of widely used and standardised approaches and particularly of institutionally approved and applied systems of evaluation and measurement.

The field is still characterised by a lack of consistency between studies in terms of evaluation frameworks used, outcome indicators and measures available and adopted, and tools available and applied.<sup>85</sup> In brief, the shortcomings of analysed evaluation studies include: (a) evaluations not based on standard methods, guidelines and toolkit to cope with the complexity of a multi-stakeholders and

<sup>80</sup> We refer here generically to policy-making and overseeing bodies, without distinguishing the various possible tiers (national, regional, local). We also join here together policy-making and funding bodies, which fits universal NHS models but not the systems where such bodies are separated (i.e. in social insurance models). This aggregation also overlooks the fact that third party payers can be private insurances. We assume they are broadly interested in the same outcomes as public third party payers.

<sup>81</sup> In this case, the treatment of industry players as a unified category simplifies the difference between those supplying strictly ICT services and those who, not belonging to the health care system proper, also provide the medical components of the RMT service.

<sup>82</sup> See minutes of SIMPHS November 2009 validation workshop, where stakeholders raised concerns on this issue: <http://is.jrc.ec.europa.eu/pages/TFS/documents/MinutesSIMPHSValidationWSfinalforpublication.pdf>

<sup>83</sup> P. Whitten et al, Systematic review of cost effectiveness studies of telemedicine interventions. *British Medical Journal*. 324 (2002), 1434-1437.

<sup>84</sup> For instance 257 of such studies are reviewed in B. Chaudhry et al, Systematic review: impact of health information technology on quality, efficiency and costs of medical care. *Annals of Internal Medicine*, 144 (2006): E12-E22.

<sup>85</sup> R. Scott et al, Telehealth outcomes. *Journal of Telemedicine and Telecare*, 13 (2007, Supplement 2).

multi-beneficiaries domain; (b) fragmentation of evaluation and measurement approaches produced in different disciplines; and (c) limited resources allocated to the evaluation process.<sup>86</sup>

**A hierarchy of validity.** The above difficulties are also related to the intrinsic methodological difficulties of causally attributing an outcome (i.e. reduced mortality) to an output (i.e. number of patients treated with RMT) in a scientifically and empirically robust and valid fashion. Between the production of an output and the realisation of the outcomes there are several intervening variables that must be controlled for. For this reason experimental design through **Randomised Control Trials** (RCT) with patients randomly assigned to the treated groups (receiving RMT services) and to the control group (not receiving RMT services but cared according to parameters ensuring they receive adequate quality of "usual" treatment) is considered the most valid and reliable form of evaluation. The random selection should control for the different individuals and socio-economic characteristics of the patients avoiding possible bias, as patients with particularly favourable and/or unfavourable parameters and conditions should be present in both the treated and the control groups. The settings of treatment should ensure that patients in the control group do not receive an inferior level of quality of treatment compared to the treated group. While RCT are placed at the top of the hierarchy of validity, they also present shortcomings. They are discontinuous and, between one test and the other, clinicians use data that can be unreliable due to their obsolescence. Moreover, they do not provide the continuity needed for a stable and institutionally accepted system of evaluation and measurement.

Going down the hierarchy of validity we can find **longitudinal studies** of the same cohort of patients, whose parameters are steadily compared to the zero measurement (before they started the RMT treatment) and year-by-year. The parameters for the RMT treated cohort are also compared to those of patients not receiving RMT services. Yet, in this case, the equality of treatment settings is not ensured. Moreover, patients who are part of the cohort may over time develop very specific and favourable motivation and lifestyle behaviours, which would set them aside from the population of average patients. Due to these two characteristics the results from such studies are considered as providing weaker evidence as compared to that of **RCT**.

At the bottom of the hierarchy we find **case studies**, the majority of which tend to show positive outcomes (here we do not refer only to RMT but to eHealth in general). Yet, case studies do not allow attribution of ICT supported output to observed effects as it is not possible to apply randomisation or case-control design to the evaluation study. Moreover, it is difficult to generalise from the particular study to the broader context since in many instances the cases concern leaders and best practices and are much less representative of usual practice.<sup>87</sup>

## **4.2 Evidence on clinical and cost-effectiveness outcomes: selected examples**

As anticipated, evaluation studies of RMT are treated more systematically in Annex IV while here we only selectively discuss some of them. One of the better known cases is that of the Veteran Health Administration (VHA)<sup>88</sup> summarised in Table 8.

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<sup>86</sup> E. Ammenwerth et al, (2004). Vision and Strategies to Improve Evaluation of Health Information Systems. *International Journal of Medical Informatics*. 73 (2004): 479-491.

<sup>87</sup> OECD, *The Contribution of ICT to Health System Productivity and Efficiency: What Do We Know?* Paris: OECD, 2007.

<sup>88</sup> A. Darkins et al. Care Coordination/Home Telehealth: The Systematic Implementation of Health Informatics, Home Tele-health, and Disease Management to Support the Care of Veteran Patients with Chronic Conditions. *Telemedicine and e-health*, 14(1) 2008: 1118-26. Other articles discussing the VHA case include: R. Schofield et al. Early Outcomes of a Care Coordination-Enhanced Telehome Care Program for Elderly Veterans with Chronic Heart Failure, *Telemedicine and e-health*, 11(3) 2005: 1118-26.

**Table 8 – VHA CCHT success case**

From 2003 till 2007, VHA introduced the national home telehealth program "Care Coordination/Home Telehealth"(CCHT), which basically upgraded an existing disease management approach for non-institutional care (NIC) services with a RMT component. The number of patients treated increased from 2,000 to 31,750 and the diseases addressed included, among others, diabetes, CHF, and COPD. Data from the analysis of a cohort of 17,025 CCHT patients shows 19% reduction in hospital admissions, 25% reduction of bed days of care, a mean patients' satisfaction score of 86% with a per annum cost of \$1.600, which is about half the cost for traditional NIC services.

Disease-specific data include:

- Diabetes: 20.4% decrease in utilisation of traditional NIC services;
- CHF: 25.9% decrease in utilisation of traditional NIC services
- COPD: 20.7% decrease in utilisation of traditional NIC services

Source: see footnote 88

Indeed, the results of the VHA case are impressive and solidly documented, but they may suffer from the earlier discussed bias that characterises longitudinal studies of the same cohort of patients.

An RCT of a Home-based Telemanagement (HBT) programme (i.e. RMT integrated within a disease management programme) specifically designed to prevent hospital readmission of patients with CHF has been carried out by Fondazione Maugeri in four regions of Italy (Lombardy in two provinces, Piedmont, Campania and Apulia).<sup>89</sup> The study documents evidence in relation to hospital readmission, clinical outcomes, and cost-effectiveness. All-cause<sup>90</sup> hospital readmission in the HBT treated group was 36% lower than in the Usual Care (UC) group (HBT patients show likelihood of readmission after 1 year of 28% compared to 42% for UC patients). One-year total mortality rate was 9% in the HBT group and 14% in UC group. Lower bound mean cost for HBT group for hospital readmission was €843 versus €1298 for the UC group, and the annual cost to prevent one readmission was €638.

Positive outcomes have been demonstrated in another Italian randomised control trial concerning tele-assistance to patients with chronic respiratory failure with reduction of 36% in hospitalisation, 65% in urgent calls to GPs, and 71% in acute exacerbations.<sup>91</sup> On diabetes, research conducted by Protti in Australia shows that integrating Electronic Medical Records (EMR) with ICT enabled disease management could curb diabetic deaths by 32%.<sup>92</sup> Several others single RCT can be found that report positive outcomes.

A different strand of literature provides meta-analyses of single studies such as the above, where such a meta-analysis is not a simple review of the literature. Meta-reviews, in fact, analyse several studies and then select only those where the results can be aggregated and re-elaborated statistically

<sup>89</sup> A. Giordano et al. Multicenter randomised trial on home-based tele-management to prevent hospital re-admission of patients with chronic heart failure. *International Journal of Cardiology* 131 (2009) 192–199.

<sup>90</sup> This refers to re-admission to the hospital due to all possible causes and not only to CHF. It is important to stress that CHF patients treated with RMT may avoid re-hospitalisation for that disease but may nonetheless develop other conditions requiring inpatient care.

<sup>91</sup> M. Vitacca et al. Tele-assistance in chronic respiratory failure patients: a randomized clinical trial. *European Respiratory Journal*, 33 (2009): 411-41.

<sup>92</sup> D. Protti, The Application of Computer Technology in GP Surgeries is Beginning To Have Positive Effects on Chronic Disease Management, World View Report 5, *Connecting for Health*: <http://www.connectingforhealth.nhs.uk/newsroom/worldview/protti5>

to test the extent to which the outcomes documented in a single study hold when considered jointly with those of other comparable studies. For instance the meta-analysis by Clark *et al* looked at 234 studies focussing on remote monitoring of CHF patients, of which only 14 (for a total of 4264 patients) met the criteria for inclusion and were analysed.<sup>93</sup> Clark *et al* found that remote monitoring of CHF patients: (a) reduces all cause mortality by 20%; (b) reduces rate of admission to hospital for CHF by 21%; but (c) the evidence on reduction of all causes hospitalisation is not conclusive (patients may be re-hospitalised not for CHF but for other morbid conditions). More recently Polisena *et al* using a similar approach analysed 21 studies (still focussing on remote monitoring of CHF) for a total of 3082 patients.<sup>94</sup> Polisena *et al* confirm the above findings in that mortality is significantly lower and several studies suggest reduced hospitalisation and utilisation (but the data presented do not allow conclusive statements on all cause hospitalisation).

In the earlier quoted editorial Cleland and colleagues<sup>95</sup> comment on the findings of Clark *et al* and of two additional studies,<sup>96</sup> that there are few doubt about the fact that telemonitoring reduces mortality among CHF patients but that the evidence is not conclusive as to the reduction of all cause hospitalisation. They add, however, the following important analysis:

"Most patients with heart failure receive much poorer care than the patients included in any control group of any telemonitoring study conducted so far. Annual mortality for contemporary patients discharged from hospital after worsening heart failure in the real world is between 25% and 40%. The lack of effect on hospitalization could simply reflect a lack of benefit. However, timely hospitalization may have been the reason for the reduction in mortality and keeping patients alive means they have a chance of being hospitalized again. In this sense, hospitalization is a good outcome rather than evidence of disease progression and casts doubt on the wisdom of hospitalization as an endpoint in clinical trials."<sup>97</sup>

Indeed, if we look at the results only from the perspective of clinical outcomes in terms of reduced mortality there is no doubt that RMT produces the desired outcomes. Moreover, although the evidence from RCT is not conclusive as to reduced hospitalisation (that is its cost-effectiveness), the implications from the above quote are two: (a) if we compare the patients treated with RMT not to the control group but to the average patients probably the cost-effectiveness would be evident and also the VHA case shows that the cost of patients treated with a combination of RMT and disease management is half that of those treated in a traditional manner (not totally scientific but anyway it is a good evidence); and (b) reduced hospitalisation should not be the main parameter to evaluate RMT for its contribution is to enable an increased rate of services which reach more people with the same level of input.

So, going back to the key question: does RMT work? Is the evidence gathered so far enough? If not, what else need to be done?

The evidence is increasingly compelling but seems not yet sufficient to convince all stakeholders and lead to full acceptance and deployment of RMT. Yet, we think that this is only one side of the

<sup>93</sup> Clark RA, Inglis SC, McAlister FA, Cleland JGF, Stewart S. Telemonitoring or structured telephone support programmes for patients with chronic heart failure: systematic review and meta-analysis. *British Medical Journal*, 334 (2007): 942-945.

<sup>94</sup> A. Polisena et al, Home telemonitoring for congestive heart failure: a systematic review and meta-analysis, *Journal of Telemedicine and Telecare*, 16 (2010): 68-76.

<sup>95</sup> Cleland et al Telemonitoring for heart failure, *op. cit.*

<sup>96</sup> A. Mortara, et al Home telemonitoring in heart failure patients: the HHH study (Home or Hospital in Heart Failure). *European Journal of Heart Failure* 2009 11(3): 312-318; D. Owais, A randomized trial of home telemonitoring in a typical elderly heart failure population in North West London: results of the Home-HF study. *European Journal of Heart Failure* 11(2009): 319-325.

<sup>97</sup> Cleland et al Telemonitoring for heart failure, *op. cit.* p. 227.

picture. RMT does not take off not only because evidence is not entirely convincing but due to other sources of resistances. Having said that, naturally more can be done to better and more systematically collect evidence using widely shared and commonly accepted methodology and toolkit.

#### **4.3 Assuming evidence has convinced stakeholders: what if ...**

Certainly, more work is needed to reinforce the evidence base but we can safely state that the various forms of RMT discussed and especially those that are integrated within a wider disease management approach do seem to produce important outcomes. Should this evidence be confirmed and the use of such approaches eventually take off on a larger scale than the current one the aggregate outcomes that could be achieved would be sizeable and RMT would become an important market opportunity.

Below we first report two extrapolations of potential outcomes based on scenarios of higher level deployment that have been produced in the Swedish Presidency *eHealth for Healthier Europe* cited earlier for six Member States (Czech Republic, France, the Netherlands, Sweden, Spain and the United Kingdom). These extrapolations are based on clinical metrics gathered for each of the six Member States (number of admissions for chronic diseases, mortality rates, etc) to which the authors have applied benchmarks of benefits extracted from the literature reporting evidence on the application of ICT in the management of chronic patients.

**Reducing deaths from diabetes complications.**<sup>98</sup> The total number of deaths in the six countries that can be attributed to complications caused by diabetes are 35,000 per year. According to the figure reported earlier (see footnote 92), the application of EMR in combination with an ICT supported disease management toolkit could save up to 32% of diabetic deaths. From interviews the authors assessed that the deployment of such a solution (EMR plus disease management) in the six countries ranged from zero to 70%. Under the assumption that such technologically supported approach reached full adoption in all six countries, up to 11,000 deaths could be saved each year ( $35000 * 0,32$ ).

**Reducing hospital admissions of chronic patients.**<sup>99</sup> In the six countries about 40.000.000 hospital admissions are reported yearly, of which it is estimated that between 75% and 85% (so up to 30.000.000 admissions) are for chronically ill patients. From interviews the authors estimated that the level of adoption of Telemedicine and Home Health Monitoring in the six countries ranges from zero to 10%. Assuming full adoption and applying the 20% benchmark of reduced hospitalisation as a result of Home Health Monitoring (taken from one of the many publications about the VHA case seen earlier) they estimate that up to 5.6 million hospital admissions could be avoided annually in the six countries.

While scientifically questionable, these estimates can nonetheless be considered good enough to at least reflect the order of magnitude of the potential aggregate outcomes.

**An extrapolation on CHF patients.** Described below, is a set of extrapolations on the potential value of the market and the potential benefits from higher deployment of RMT for CHF patients only. In paragraph 2.2, when we presented the data available on prevalence, costs, and other parameters, we also cited a number of disclaimers as to the scientific validity of these extrapolations that apply here as well. As illustrated there, there are few standardised and comparable ready to use metrics. Having not had the resources to thoroughly collect clinical metrics and interview experts in all of the European countries for which we present the extrapolations, we relied on the following

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<sup>98</sup> *eHealth for a Healthier Europe*, op. cit. p. 34.

<sup>99</sup> *eHealth for a Healthier Europe*, op. cit. p. 36.

available data: (a) various type of information gathered from the literature; (b) the comparable and standardised data contained in OECD Health Data 2009 only for EU19;<sup>100</sup> and (c) the interviews conducted during the country studies (from which we extract our main hypothesis of CHF addressability through RMT).

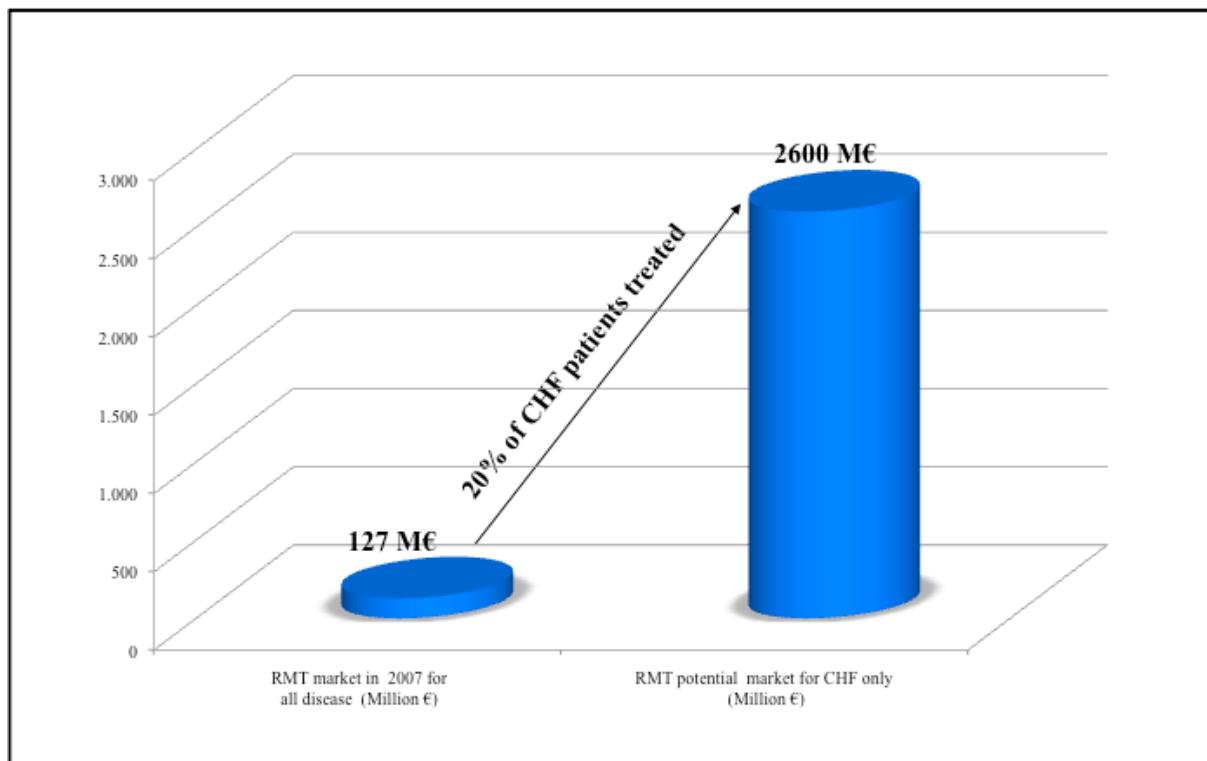
As a result, we could not find, for instance, the number of yearly admissions due to Chronic Heart Failure. We know from the literature that CHF patients account for 5% of yearly hospital admissions but we could not find anywhere (not even in the OECD 2009 Health Data) the total number of yearly hospital admission in EU27 or EU19 or EU15. We also could not find any reliable and comparable benchmark on the average cost of one hospital day for CHF patients; although we know from OECD Health Data 2009 that in EU19 CHF patients (once admitted) stay on average in the hospitals 10.2 days. All limitations and assumptions that were taken into account when developing the extrapolations below (2 scenarios for cost and 2 for cost savings), are transparently described in Table 9 and the corresponding explanatory notes (see pp.54 and pp. 55).

Considering only data for CHF, assuming a prevalence of 2% over the entire European population and that only 20% of the CHF patients in EU19 are able to be treated with RMT and applying a benchmark price to the service (4 Euros per patient, per day) we can extrapolate a growth in the value of the RMT market/expenditure depicted in the graph below: from only 127 M€ for all diseases (as was estimated by F&S) to 2.6 B€ for CHF only (see all details of estimation procedure in Table 3 and related explanatory notes).

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<sup>100</sup> As illustrated earlier the OECD EU19 do not include: Bulgaria, Cyprus, Estonia, Latvia, Lithuania, Malta, Romania, Slovenia. Total population of EU19 in 2007 (according to OECD 2009 Health Data) was 451 million, which is 91% of total EU27 population.

**Figure 11 – RMT market/expenditure potential growth: CHF segment only**



Source: estimate from F&S and authors' extrapolation see Table 9 and related explanatory notes

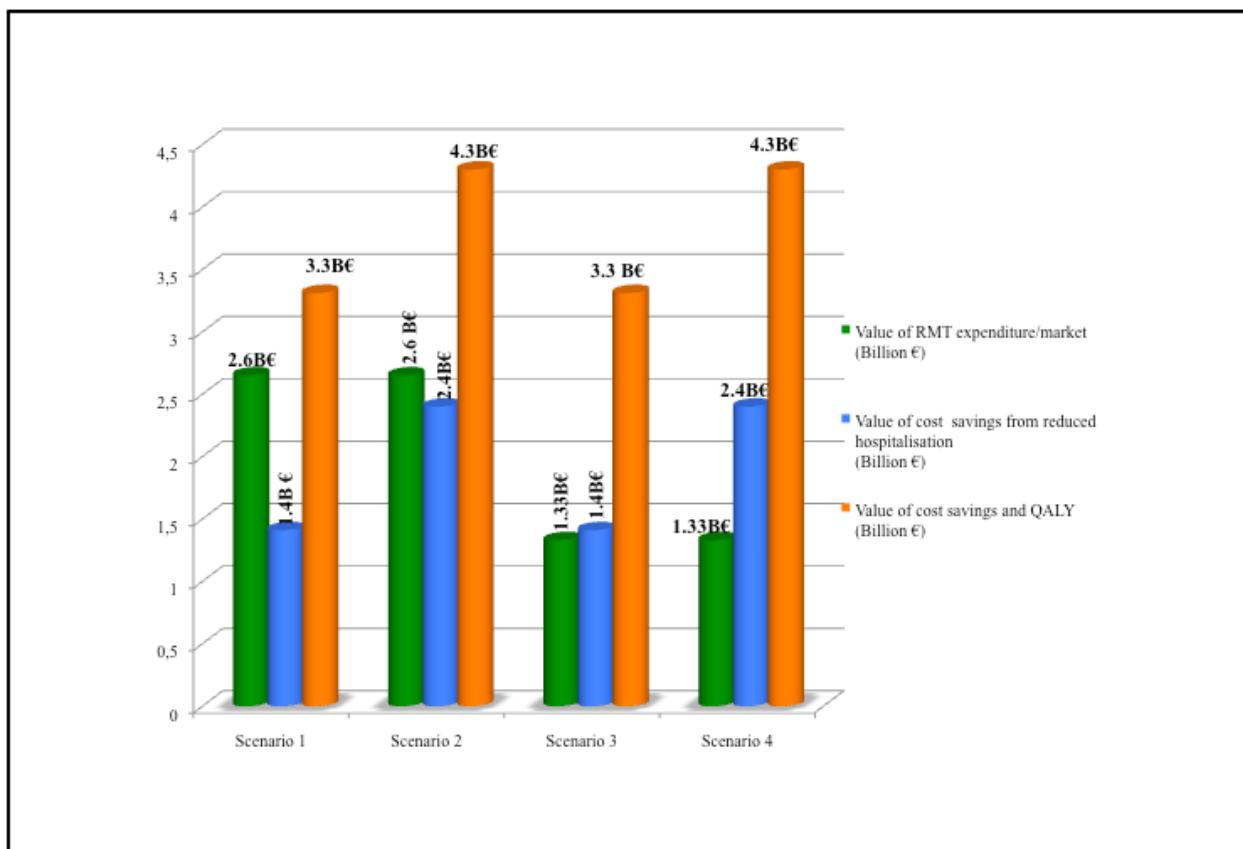
We used above the expression “RMT market/expenditure” since the money for paying RMT services will come from third party payers or from public funding (see details in Annex I of Deliverable D1.1). Some of this money will go directly to pay market players and some will be used to reimburse the health care producing units for the work of their professionals involved in RMT service provisions. At any rate, regardless of whether we look at it as market or as expenditure, the value of €2.6 B represents the potential cost of RMT under the assumption of deployment to 20% of CHF patients in EU19 and must be compared to the potential benefits.

**The likely benefits.** Using benchmarks for the relevant literature as reported in section 2.2 and also in Annex IV (section 9) we estimated the potential reduction of deaths for CHF over a year to amount to 90832. Assuming these patients will live only one extra year, the aggregate value we calculated for the corresponding QALY measure of this extra year is about €1.9 B.<sup>101</sup> We could also

<sup>101</sup> Given the lack of a market price for healthcare services paid for from the public budget, governments need to find ways to measure the benefits associated with alternative allocations of scarce resources from the perspective of the patients (in the market the price is a direct measure of consumers willingness to pay, which is assumed to reflect their appreciation of the quality of the good or service they decide to purchase). To obviate to this health economists have tried to measure, from the perspective of the recipients, the benefits associated with a possible intervention in healthcare. One solution is the development of Health-Related Quality of Life (HRQoL) indexes that are used to calculate Quality Adjusted Life Years (QALY). Through objective (from clinical evidence and surveys of clinical experts) and subjective (from patient surveys) parameters it can be measured how much having a disease subtract to the quality of life. Very simply this can be understood as follow: good health (both objectively and subjective) = 1 QALY whereas death = 0 QALY. Using parameters on the disabling impact of CHF (from disability weights by disease category published by the WHO [http://www.who.int/healthinfo/global\\_burden\\_disease/GBD2004\\_DisabilityWeights.pdf](http://www.who.int/healthinfo/global_burden_disease/GBD2004_DisabilityWeights.pdf)), thus, we can establish that 1 year of extra life as a results of RMT can be measured as equal to 0.7 QALY, which multiplied by the total number of avoided deaths (90.832) make 63.582 QALY. This is the QALY benefit in volume produced in our RMT scenario. The next more complicated issue is to give it a monetary value. Intuitively, one extra year of life can have a value for society (individual continue to work, produce, pay taxes), naturally for the patient and for his/her relatives and friends. The literature on this issue is vast and contains a wide range of variation in the monetary value to assign to QALY (ranging from €10.000 up to €100.000 depending on the different methodologies and the corresponding assumptions). The monetary value of a QALY is of great

estimate that treating 20% of CHF patients with RMT could reduce/avoid 2.779.459 hospital days. Assigning a monetary value to these saved hospital days turned out to be more difficult (for some of the reasons explained earlier); so we produced two possible estimates of the cost of one hospital day for CHF treatment: €508 that we consider more robust, and €864 that we consider less reliable. Using the first estimate the total saving would amount to about €1.4 B, whereas using the second it would reach 2.4 B€. It is important to note here that in both cases, these more tangible (compared to the QALY) monetary measures of benefits would be lower than the cost (2.6 B€). In Figure 12 below, we developed four possible scenarios crossing the two estimates of the cost of one hospital day (€508 versus €864), with two different pricing for one patient day of RMT: €4 per patient per day (used to calculate the value of €2.6 B reported above) and €2 per patient per day (assuming economy of scale will lead to lower cost of services).

**Figure 12 – RMT potential expenditure and benefits: CHF segment only (four scenarios)**



Source: authors' elaboration see Table 9 and related explanatory notes

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importance for the cost-effectiveness analysis that should support decision to invest scarce resources for new treatment and/or new technology. In this respect it is useful to notice that in the UK the National Institute for Health and Clinical Excellence (NICE, *NICE Guidelines to the Method of Technology Appraisal*, NICE, UK, 2008) established that it is worth investing in treatment and/or technologies that have a cost per QALY ratio of about €30.000. Given our scope in this extrapolation, we can reverse this and use it the average value of a QALY. So, we used 1 QALY= €30.000 to estimate the monetary value of the reduced mortality outcome of RMT for CHF. On the other hand, it is interesting to point out that if we divide the total expenditure for RMT of 2.6 B€(scenarios 1 and 2) by the total volume of QALY produced (63.582) we have a cost per quality ratio of €41.714, which is higher than the NICE threshold. If the cost of RMT goes down (as in scenarios 3 and 4), however, we would get the much more favourable cost per QALY ratio of about €20.857.

By comparing scenarios 3, 4 it is clearly visible that only under a reduced pricing for RMT (2 Euros per person per day<sup>102</sup>), the value of savings from reduced hospitalisation is higher than the costs. On the other hand, if we consider also the QALY value, the benefits far outset costs. Actually the value (benefit) of the reduced number of deaths is in itself greater than the costs incurred from applying RMT.

From this and in light of what we discussed earlier in paragraph 4.2, on the non-conclusive evidence on reduced hospitalisation and on the assumption that this is probably not a correct measure to assess the contribution of RMT, our conclusion is that the cost of providing RMT should be weighted almost entirely against the clinical outcomes. As a matter of fact, the Swedish Presidency study cited earlier, reports potential benefits expressed in volume metrics and does not contain a single estimation of the monetary value of the reduced costs.

We can conclude that, regardless of the scientific accuracy of such extrapolations, the order of magnitude clearly conveys the message that we stand to lose large potential benefits if the deployment of RMT remains at the current very modest level.

In the next two pages, a table and subsequent notes explain in detail the assumptions and limitation of the extrapolations presented above.

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<sup>102</sup> The price used for the extrapolation is an average based on a couple of real instances that we came across through our interviews. It depends on many parameters, such as the cost of the monitoring devices, the communication charges, the quality of the medical team monitoring as well as that of the emergency service offered. Depending on how many of the above charges are subsidized and/or paid out of pocket, the cost to the public Health Care sector could be even lower than the 2 Euros per patient per day used in the extrapolation.

**Evidence in support of the extrapolations on CHF presented above.**

**Table 9 – Data, benchmarks and assumptions used in the extrapolations**

<b>Value of RMT expenditure/market under 20% addressability/deployment assumption for patient with CHF</b>	
1. Total EU19 Population	454.160.000
2. Prevalence of CHF over total population	2%
3. Total CHF patients in EU19	9.083.200
4. % Of CHF considered suitable for RMT	20%
5. # Of CHF patients treated with RMT under 20% deployment	1.816.640
6. Average cost per patient per day	4€
7. Days of treatment	365
8. Value of RMT expenditure/market	<b>2.652.294.400€</b>
<b>Number of reduced death at one year and QALY value applying benchmark from RCT to 20% assumption</b>	
9. Lower bound yearly average mortality rate at one year	25%
10. Baseline deaths out 1.8M patients CHF patients at one year	454.160
11. Average reduction of mortality rates for RMT treated patients	20%
12. Reduction in number of deaths at one year	90.832
13. Assumed value of 1 Quality Adjusted Life Year	30.000€
14. Aggregate QALY value of 1 year of extra-life (assuming average 0,7 value of QALY for the extra year of life (CHF will not enjoy full health status)	<b>1.907.472.000€</b>
<b>Value of reduced utilization applying benchmark from RCT to 20% assumption</b>	
15. Average length of stays in hospitals for CHF patients (number of days per patient)	10.2
16. Re-hospitalisation benchmark rate at 3 months	50%
17. Baseline # of re-hospitalised patients out of the 1.8M patients	908.320
18. Hospital days occupied by re-hospitalised patients out of the 1.8M patients	9.264.864
19. Benchmark of reduction in utilization	30%
20. Reduction in hospital days from RMT treatment to 1.8M patients	2.779.459
21. Average full cost of one hospital day	508€
22. Value of reduced hospitalisation through RMT under 20% scenario	<b>1.411.965.274€</b>
23. Net cash benefits (without considering QALY)	<b>-1.240.329.126€</b>
24. Net benefit considering QALY	<b>667.142.874€</b>
<b>Estimation of average cost of one hospital day for CHF patient in EU19: method 1</b>	
25. Total number of CHF patients in EU19	9.083.200
26. If 50% hospitalised at least once and stay 10.2 days, then total hospital days=	46.324.320
27. Total Health care expenditure in EU19	1.177.000.000.000
28. Total health care expenditure for CHF (2% of total health care expenditure)	23.540.000.000€
29. Cost per hospital day	508€
<b>Estimation of average cost of one hospital day for CHF patient in EU19: method 2</b>	
30. Yearly acute per capita bed-days in EU19	1,2
31. Total acute bed-days in EU19	544.992.000
32. CHF absorbs 5% of them	27.249.600
33. Average cost of 1 hospital day for CHF patient	864€

### **Detailed explanation of the contents (source or calculation formula) of Table 3**

#### **Value of RMT expenditure/market under 20% addressability/deployment assumption for patient with CHF**

1. OECD Health Data 2009;
2. Average extracted from the relevant literature reported in paragraph 2.2<sup>103</sup> and in Annex IV (Section 9);
3. Row1\*Row2;
4. Obtained from interviews with physicians conducted during the case studies;
5. Row3\*Row4;
6. Average of various pricing found during the work on companies and on projects/pilots/programmes;
7. Here it is assumed that, even if the actual patients may change, in any given day of the year for 365 day 1.8 million patients will be under RMT treatment;
8. Row5\*Row6\*Row7;

#### **Number of reduced death at one year and QALY value applying benchmark from RCT to 20% assumption**

9. Lower bound benchmark extracted from the relevant literature reported in paragraph 2.2;<sup>104</sup>
10. Row3\*Row9. This is the baseline number of death among the 1.8M patients if they were not treated by RMT;
11. Average extracted from the relevant literature reported in paragraph 2.2 and in Annex IV (Section 9);
12. Row10\*Row11;
13. International benchmark of the value of one QALY in US \$ converted into Euro;
14. Row13\*Row12\*0.7 (to reflect that the extra year of life will not be in perfect health and that the disabling impact of CHF require to subtract 0.3 from each additional year of life that so corresponds to 0.7 QALY);

#### **Value of reduced utilization applying benchmark from RCT to 20% assumption**

15. OECD Health Data 2009;
16. Average extracted from the relevant literature reported in paragraph 2.2 and in Annex IV (Section 9);
17. Row17\*Row3. This is the baseline number of re-hospitalised patients out of the 1.8M if they were not treated by RMT;
18. Row17\*Row16. This is the baseline number of hospital days absorbed by patients out of the 1.8M if they were not treated by RMT;
19. Average extracted from the relevant literature reported in paragraph 2.2 and in Annex IV (Section 9);
20. Row19\*Row18
21. See 25 through 29;
22. Row21\*Row20;
23. Row22 minus Row8
24. Row22 plus Row14 minus Row8;

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<sup>103</sup> We applied the 10% prevalence benchmark to an estimate of the population 75 and older and the lower bound of 1% prevalence to the rest of the total population and the total number of patients obtained is roughly equal to 2% of the total population in EU19.

<sup>104</sup> As reported in the editorial by Cleland et al mortality of CHF patient at one year range between 25% and 40%. On the other hand, mortality at 5 years can be up to 75%. To remain conservative we used only the lower bound estimate for mortality at one year.

**Estimation of average cost of one hospital day for CHF patient in EU19: method 1**

- 25. Equal Row3;
- 26. Our assumption based on benchmark extracted from the literature reported in paragraph 2.2 and in Annex IV (Section 9);
- 27. OECD Health Data 2009;
- 28. J. Mc Murray and S. Steward, *The Burden of Heart Failure*, op. cit.;
- 29. Row28/Row26;

**Estimation of average cost of one hospital day for CHF patient in EU19: method 2**

- 30. OECD Health Data 2009
- 31. Row30\*Row1;
- 32. Applying by analogy to bed-days the benchmark that CHF are responsible each year for 5% of all admissions to hospital (the latter is also from J. Mc Murray and S. Steward, *The Burden of Heart Failure*, *op. cit.*).



## 5 Barriers to innovation and ways to overcome them

In this section we report on the barriers to RMT deployment as collected from the experts and stakeholders we interviewed during the course of our research. These barriers have been presented in November 2009 in the Discussion Paper<sup>105</sup> distributed prior to the Brussels Validation workshop (see footnote 73). This analysis of barriers coincides to a large extent with that contained in part II of the latest OECD report on ICT and health care.<sup>106</sup> This is a further confirmation of the robustness and validity of our findings. This is then followed by a model of Innovation dynamics that would explain a few of the challenges in this complex multi-stakeholder environment. A set of preliminary recommendations closes this section of the report.

### 5.1 Barriers: views from the field

Since this is a multi-stakeholder market, barriers are reported and prioritised differently depending on whether market players or medical professionals are mostly affected. The main barriers reported by market players are the following:

- **Lack of reimbursement.** The issue of reimbursement is one of the major roadblocks on the path to PHS/RMT market deployment and has been mentioned virtually by each of the experts and stakeholders interviewed. Some of the market players interviewed have managed to negotiate agreements with insurances (e.g. in Germany, Netherlands) or public health care (e.g. in the UK, Italy or Spain) but all these attempts are the results of longstanding, resource consuming individual efforts. Industry experts told us that without some clear and standardised financing and/or spending decisions from the relevant health care bodies the market will not take up (i.e. on the basis of out of pocket money or of services acquired for their clients by private insurances). For market players, the lack of transparency on reimbursement models and the complexity of national frameworks and legislation make it difficult to get an overview of what services may be reimbursed where and to what extent;
- **Buyers' fragmentation.** The institutional set up of health care systems shapes how companies try to sell their products or services for RMT. For instance, in Germany, companies try to cooperate with social insurance, in Spain they address the local level providers of health and social care, in Italy they talk with the Regions for health care RMT but then have to talk with municipalities if they want to enter through the door of social care. As a result, companies were concerned of this fragmentation: both as regards the level of public decision-making authority and the lack of a clear procurement process. The landscape is, thus, populated by many local initiatives and opportunistic small companies, which usually die down after R&D or pilot funding money dries out;
- **Difficult to be accepted by health care organisations.** Many market players encountered clear resistance from health care providers to accept an end-to-end RMT service provision by an "outsider" supplier, even when the latter integrated state-of-the-art technology with very professional and well trained call centre operators and its own medical experts and nurses. Not surprisingly a few market players told us that they have at least one major health care institution among their shareholders and most often provide B2B2C services: that is they provide the technology, the call centre, and also partially the medical components of the

<sup>105</sup> Available at: <http://is.jrc.ec.europa.eu/pages/TFS/documents/SIMPHSbackgroundpaperforvalidationworkshop.pdf>.

<sup>106</sup> OECD, Achieving Efficiency Improvements in the Health Sector through the Implementation of Information and Communication Technology, Paris: OECD, 2010, pp. 35-44.

service to a hospital, which in turn owns the relation with the patient and with the third party payers and compensates the suppliers;

- **Constraints to market scale.** The fragmentation referred to earlier is also reflected in the lack of cross-border operations. Both SMEs and large companies operate in a "strong home base" before seeking to expand to other countries and generally the extent of cross-border operation even for larger player appears to be very limited. However, the mobility of patients imposes that solutions are implemented.

In sum a number of factors contribute to create uncertainty for market players who must cope with unclear business models and shaky revenue streams.

The main barriers reported either by individuals operating within health care systems (professionals and/or representatives of health authorities/payers) or by neutral third party experts (i.e. health economists, organisational scholars, and eHealth experts) are the following:

- **Unfavourable structure of incentives.** Regardless of differences in EU country institutional public systems, both external experts and health care professionals (those involved in, and in favour of, RMT) are of the opinion that the structure of incentives in place in health care delivery and financing run against RMT. Health care reimbursement and financing oscillates between two models: fee for service (i.e. DRG based reimbursement) or capitation (fee for patients treated, regardless of activities, typical for GPs). Keeping patients out of the hospital through RMT reduces exactly the fee for services the hospital may receive (so it is not an incentive to adopt RMT). On the contrary GPs paid on a capitation basis for managing a pool of patients (that cannot increase) perceive the work they may have to undertake within an integrated pathway RMT service as an extra and unpaid load. Even if RMT would eventually enable them to work more efficiently it would not translate into economic gains in systems where the overall quota of patients that can be treated is fixed and cannot be increased. Even if these opportunistic considerations sound ethically inappropriate, we must realistically accept that health care, as any other social system, needs the correct structure of incentives in place to make things happen. The only other alternative would be to impose strong top-down mandatory obligations; however, this is not always feasible. It is thus appropriate to consider how to make ICT supported work attractive economically or in general beneficial in other ways to managers of health care institutions and to health care professionals;
- **RMT: where does it belong?** RMT, especially if integrated into a HBT delivery models, is the quintessential form of what is called in the US NIC (Non Institutional Care) and in others Territorial Medicine (in brief all that happens outside of hospitals, *extra muros*). According to many of the interviewees, much talk has been made about the importance of this form of care delivery for the future sustainability of health care but still the issue has not been placed in a clear policy "box". It is not clear who the institutional sponsors really are. eHealth applications are successful and take off when there is a clear decision maker pushing them. In the field of RMT, with noticeable exceptions, it is difficult to localise where such decision maker might be. Interviewees reported not seeing a feeling of "urgency" to deploy RMT in health care since there are other more important challenges that get the attention of politicians and policy makers;
- **Primary, secondary, and social care.** The cases of success we encountered were to a large extent linked to the personal motivation of actors in primary and/or secondary care – i.e. GPs and specialists such as cardiologists - who believe in the benefits of implementing RMT solutions or are forced to find solutions to service physically remote patients. Yet, some of

these motivated professionals told us that the fragmentation between primary and secondary care acts as a bottleneck; also because of the different incentives they are subject to, in their national health care systems. In particular professionals argued that, if hospitals are not always ready to launch RMT for various reasons related to incentives, the key push for it could and should come from the GPs. Since RMT is part of Non Institutionalised Care (NIC) or territorial medicine, it should be within the responsibility of GPs to identify and recruit patients who are more suited for RMT, especially in view of the fact that many hospitals especially during certain period of the year (when they face full bed occupancy) tend to early discharge chronically ill patients without acute conditions. These should be identified by GPs as the key target for RMT, recruited, and treated through a seamless and joined up collaboration between GPs and institutions of secondary care. The input from GPs could break hospital resistance. This is not happening, not only because of lack of incentives, but also as a result of insufficient GPs e-Readiness and of the well-known fragmentation and "turf war" between primary and secondary care. Strictly related to this issue is the problem of identifying and selecting the appropriate target of patients to be recruited for monitoring. Exchange of data and information between different tiers of the health care and between the health care and the social care departments is crucial. The success case of Veneto (reported in post-it 7) confirms that a strong drive from higher-level health authorities can overcome such bottlenecks. Yet, according to the more pessimists among our interviewees, new systems like PHS/RMT add transparency and remove professional control, which is why they are met with resistance. According to this view, in the end the main driver will be the patient who wants the service. Unfortunately patient awareness of RMT solutions - let alone of their benefits - is still limited to say the least.

- **Lack of evidence, awareness, education.** There is an increasing body of evidence supporting the claim that RMT can make a difference even if not fully conclusive. More work in this direction is certainly needed to fully ensure health care authorities/payers are aware about clinical outcomes and cost-effectiveness. Yet, more awareness raising activities targeting decision makers and insurances (social or private) should disseminate the evidence from journal articles that are usually not accessible in their jargon for the non experts and especially about "champions of success". Currently, in fact, many interviewees think that we are in a "chicken and egg" stalemate. Lack of standardised evidence or of awareness on existing evidence delays decisions on reimbursement and funding. This in turn reduces the numbers of treated patients available for control trials and, thus, further delays the point in time when more robust and conclusive evidence will be available. As a result, market players in turn cannot fully deploy their services and lack of market scale keep prices high. As was suggested before, by raising the awareness of the patients to likely benefits will put pressure on the system from the bottom-up.
- **Strategic leadership for structural change.** According to some of the interviewed experts, all of the issues reported above are very important but are of a tactical nature, in the sense that they could be solved if there is a strategic leadership and decision to use RMT and PHS within a major organisational restructuring of care delivery processes. Decision makers who understand that RMT and PHS can be an opportunity to introduce such changes as a way of making health care delivery both more effective and efficient (doing more and better while containing the cost) can act upon most if not all of the bottlenecks discussed so far. In other words the experts suggest that a longer term vision and a new strategy for how health care services should be organised and reimbursed is needed to take advantage of what modern medicine can do and ICT can enable. The linear piecemeal approach to RMT/PHS, based on the optimistic/deterministic assumption that sooner or later technology is adopted, may never

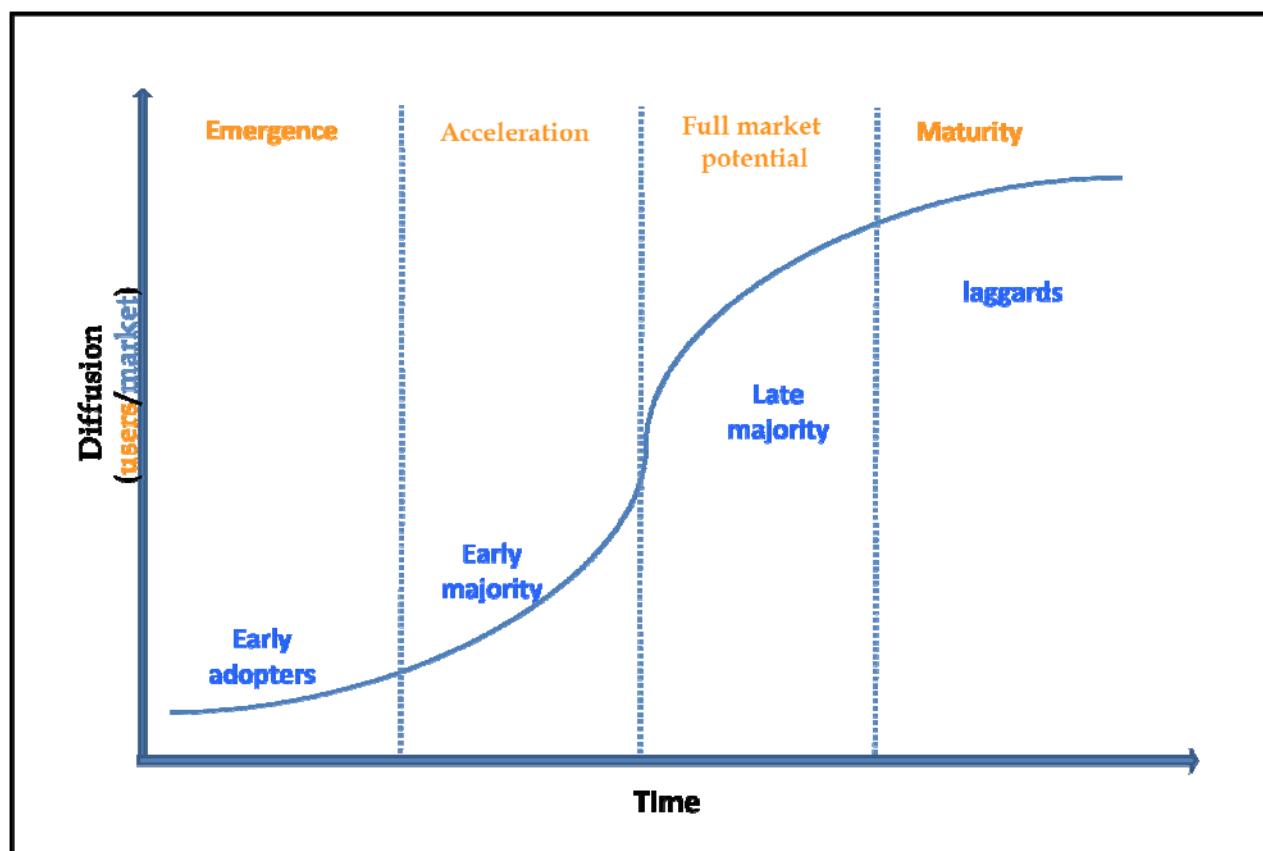
work. As one of the interviewees stated: “the mere push of technology represents a Ptolemaic approach not capable of producing durable and large effects. What is needed is a Copernican revolution where PHS are part of major institutional and organisational restructuring”.

Finally, most stakeholders and experts affirmed that there are also some technological gaps mainly due to inter-operability bottlenecks. Some also thought that the RMT technology is not yet mature in the sense that the solutions available in the market are too basic and require still too much the intervention of professionals. More sophisticated approaches (i.e. ones produced by R&D efforts) are needed and also integrated into alternative disease management systems; however, these are either not yet proven in terms of reliability or are too expensive.

## **5.2 Innovation dynamics within a complex ecosystem perspective**

Trying to bring together the views on barriers and of most of the empirical evidence discussed in the previous section, we will briefly and selectively present some insights from the literature on technological and institutional change and innovation. This is instrumental also to look in the end, at RMT as a complex ecosystem. The one depicted in Figure 13 is an S-shaped curve typically used to describe the dynamic of technology and innovation adoption from the perspective of diffusionist theories.

**Figure 13 – Traditional S-Shaped innovation and diffusion curve**

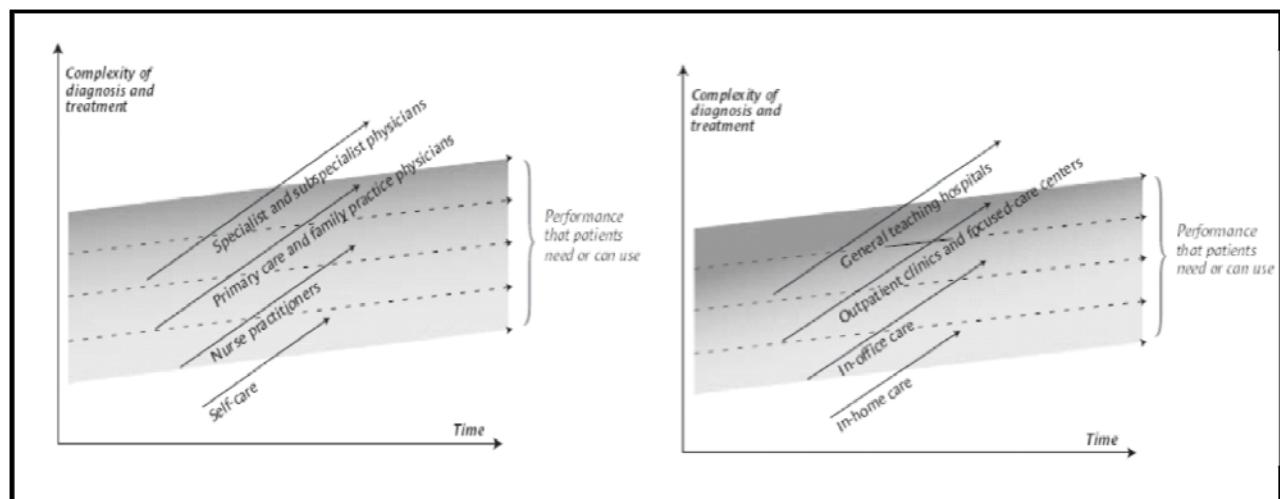


Source: Authors' elaboration on literature as presented in footnote 107

However, such a way of looking at the diffusion of innovation<sup>107</sup> provides a practically useful but merely descriptive tool, which has two clear limitations for our purpose. First, it can be used to input data into the underlying calculation algorithm and passively let the data speak but it does not provide an explanation of why a curve may be more or less steep and especially how and why a particular technological innovation moves from one phase to the other or simply becomes "history" as it has happened to many innovations that never took up. In our case we have little data to plot and qualitatively placing the RMT market somewhere in the graph does not help much in making sense of the evidence gathered and envisaging what and how could happen next. Second, it presupposes a sort of technological optimism that may fit well the trajectories of self-contained technological products but is not entirely appropriate for complex technology-driven services entailing additional and complex cross-complementary organisational and institutional changes as in the case of RMT.

Clearly more directly relevant insights to facilitate the understanding of innovation dynamics in RMT comes from the theory of disruptive innovations developed by Christensen and colleagues,<sup>108</sup> which has also been specifically applied to health care.<sup>109</sup>

**Figure 14 – Disruptive innovations of health care professions and institutions**



Source: C. Christensen et al, Will Disruptive Innovations cure Health Care? op. cit., pp. 105-106

<sup>107</sup> While popularised in the marketing literature by E. Rogers, (*Diffusion of Innovations*, New York: The Free Press, 5th edition 2003 – 1st edition 1965) and refined in the neo-Schumpeterian analysis of the "ICT revolution" (as presented for instance by the seminal work of C. Perez, *Technological Revolutions and Financial Capital - The dynamics of bubbles and golden ages*. Cheltenham, UK: Edward Elgar; 2002), the curve was first plotted at the turn of the 20th century in a sociological analysis of imitation processes (see G. Tarde, *The Laws of Imitation*, trans. by E. Parsons, New York: Holt, 1903), and the - by now standard - typology going from early adopters to laggards comes from a 1943 article on the diffusion of "hybrid seed" among Iowa farmers (see B. Ryan, and N. Gross, The diffusion of hybrid seed corn in two Iowa communities. *Rural Sociology*, 8 (1943): 15-24).

<sup>108</sup> See for instance in chronological order: J. Bower and C. Christensen, Disruptive Technologies: Catching the Wave, *Harvard Business Review*, January–February 1995; C. Christensen, *The Innovator's Dilemma*, Harvard Business School Press, Boston, 1997; C. Christensen, and M. Raynor, *The Innovator's Solution*. Harvard Business School Press, Boston, 2003. The typical formulation of the Christensen model focuses on the two concepts of "overshot consumers" and "low end disruptive innovations". At some point market incumbents overshoot their customers, since the rate at which products improve exceeds the rate at which the customers can absorb the new performances. At this point, a disruptive technology may enter the market and provide a product which has lower performance than the incumbent's one but which exceeds the requirements of certain segments, thereby gaining a foothold in the market. The disruptor can then progressively move up-market. In particular Christensen shows that powerful innovations disrupting industries did so by enabling a larger population of less skilled people to do more conveniently and less expensively things for which earlier they needed specialists in centralized locations. Minicomputers first and personal computers later, for instance were disruptive to mainframe producers and we no longer need to bring our punched cards to mainframe computer centres.

<sup>109</sup> C. Christensen, et al, Will Disruptive Innovations Cure Health Care? *Harvard Business Review*, Sept-Oct (2000), 102-112.

In the seminal article of 2000 Christensen et al argue that health care has devoted so many resources to the treatment of the most acute problems and thus to overshoot the majority of less complex needs many patients have. Additionally, since the system must treat also less demanding needs, very specialised institutions and specialists have been forced "down market". This means that they have to deal with problems that could instead be addressed through a combination of less expensive carers (nurses) and enabling technologies, in other words through disruptive innovations along the lines depicted in the Figure 14 above.

We can explain the reasoning underlying the two figures above applying it to the specific case of RMT. As specialist physicians continue to concentrate their efforts on the most acute situations and on "the most incurable of illnesses for the sickest of patients", less-skilled and less-expensive practitioners either employed by NHS or by market players suppliers could take on more complex roles and deal with ever larger numbers of chronically ill patients through RMT integrated into disease management programmes. This is exactly what happened in the VHA case and in other success cases. The same logic in parallel - still according to the Christensen model - should happen to health care institutions. Research clinic and large hospitals concentrate their efforts on the high-end of the market (most acute conditions) but must also serve the lower end. In this respect they have tended to opportunistically use to some extent the lower end to finance the high-end segments. This, however, is increasingly unsustainable and signs of changes are already visible: "patients that occupied hospital beds 20 years ago are now being treated in more-focused care centres and outpatient clinics, doctors' offices, and even at home".<sup>110</sup>

RMT, thus, following the logic of the Christensen model would be the final multiplier of such a process eventually evolving into closed loops allowing full self-caring chronic patients. Christensen criticised, for instance, regulation preventing nurses from taking more responsibility in the delivery of care and compared it to as if regulators "in the early 1980s had decreed that because microprocessors were inferior in computing power to wired logic circuits, all personal computers had to be equipped with wired logic boards, not microprocessors".<sup>111</sup> Hence, Christensen's view in the end was that such processes eventually cannot be stopped even within health care. The matter of the fact is, however, that dealing with patients and substituting a physician with RMT plus a nurse or with a self-managed RMT is not exactly the same thing as substituting a wired logic circuit with a microprocessor. Moreover, in health care it is not easy to move resources to better serve overshot patients. Apart from these objective factors, the health care system is more complex than any comparable industry and characterised by overlapping and conflicting incentives and vested interests. Change within such a system cannot be brought by disruptive technologies alone. Indeed, Christensen in his later work on the *Innovator Solution*<sup>112</sup> done with Raynor replaced disruptive technology with the term disruptive innovation because he recognized that few technologies are intrinsically disruptive or sustaining in character. It is the strategy or business model that the technology enables that creates the disruptive impact. In order to understand how such innovations can occur within a complex ecosystem such as health care an understanding of the social, institutional, and economic underpinning of innovation is needed.

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<sup>110</sup> Christensen, et al, Will Disruptive Innovations Cure Health Care? op. cit, p. 106.

<sup>111</sup> C. Christensen, et al, Will Disruptive Innovations Cure Health Care? op. cit. p. 107.

<sup>112</sup> C. Christensen, and M. Raynor, The Innovator's Solution, op. cit.

When an innovation becomes spread through such a process<sup>113</sup> it is then incorporated into a new accepted institutional template of action. Networks effects and the emergence of hub of innovators play an important role in unleashing this mimetic innovation process. In this respect, also within management and organisational studies and not only within sociology, it has come to be accepted that innovation does not occur in isolation but within a social systems and especially within networks and hubs seen as loci of sharing strategies and pooling resources, with the aim of developing new products or of exploring new technologies.<sup>114</sup>

The RMT field has already witnessed the emergence of champions and of a few hubs of innovator but no large-scale mimetic process has taken place. One possible and simple explanation is that the number of champions and the intensity and scope of the innovators networks is not yet sufficient to unleash a mimetic process. Alternatively, it is possible that awareness and dissemination about champions and success cases has not been spread enough or lack convincing evidence backing the positive results reported. These two reasons certainly provide part of the explanations to the current situation of RMT. Yet, there are additional elements to be considered that can be understood from standard and basic economic analysis of strategic and competitive behaviours and of players' structure of incentives. We illustrate this reasoning hypothetically on the diffusion of innovation X within non-specified business-to-business market involving private firms. According to mainstream economic reasoning:

- If innovation X is thought/shown to eventually increase the profitability of firms buying X (henceforth simply buyers) either by increasing revenues or by reducing costs, competitive pressures may produce mimetic processes leading to bandwagon effects among them (at least until the extra returns will be brought back to zero as all competitors adopt the same tools) and boost the market for firms producing X (henceforth simply sellers);
- Yet, different dynamics can have negative effects stopping such bandwagon processes:
  - If sectoral dynamics tend to be characterised by an important strategic advantage for 'first-mover' among buyers, this then reduces the room for adoption of X by many other competitors;
  - The same 'first mover' advantage may limit the number of sellers, which in turn slow down the spiral of decreasing prices and limit adoption by buyers;
  - If there is a lag time between adoption of X and increased profitability, the investments in X could come to be perceived as risky among buyers and bandwagon effects stopped;
  - Finally, specific powerful enough functional units within buyers may be threatened and/ or have no incentive to adopt X and succeed in resisting adoption
- The factors above could, however, be reversed and bandwagon effects could be positively supported as a result for instance of:

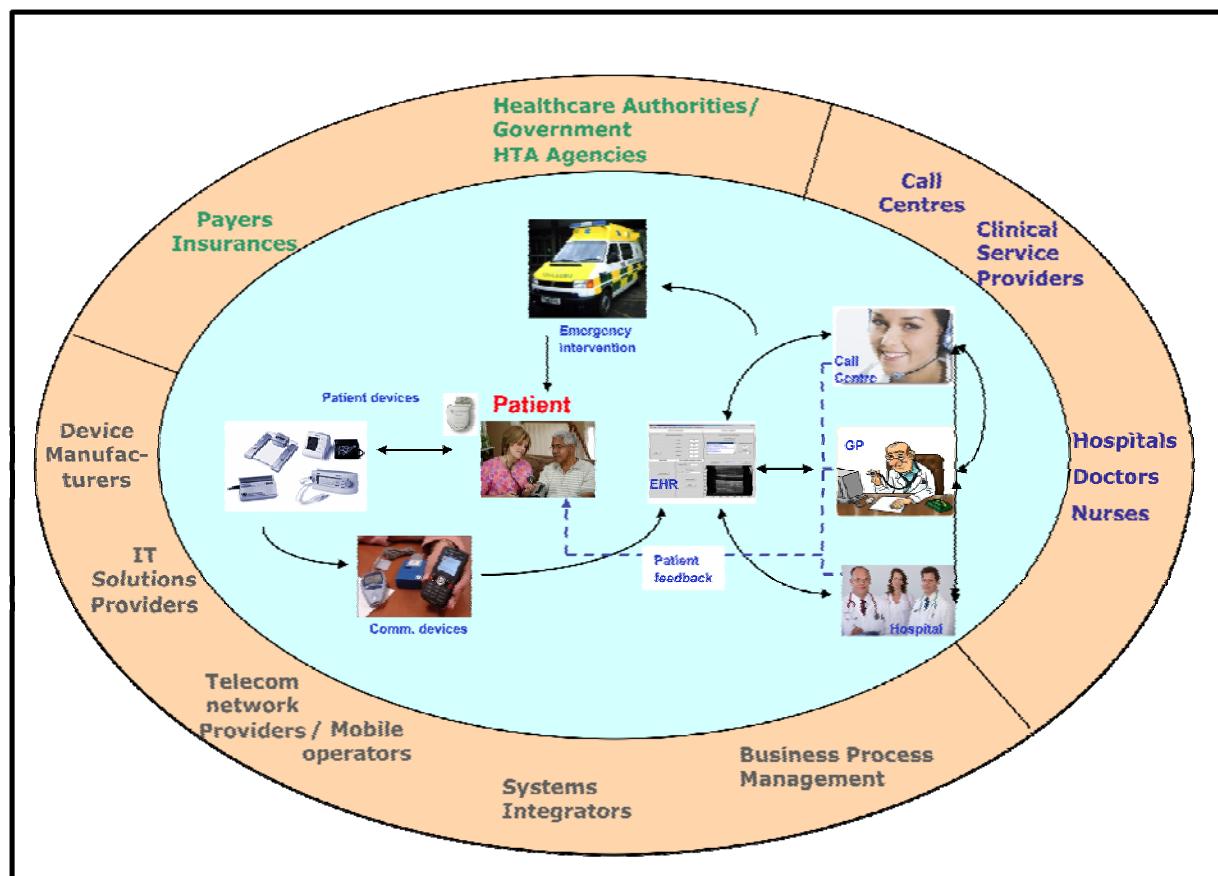
<sup>113</sup> Innovations occur at micro-organisational level, also on the basis of strategic and competitive considerations captured in standard economic reasoning. They face institutional inertial resistance, but they spread and become mainstreamed only as a result of mimetic institutional processes facilitated by network effects. The way activities are carried out within a given population of organisations is shaped by institutionalised practice. In particular "institutional isophormism" is a process of "convergent inertia or change", whereby organisations do or try to do what is considered legitimate in their own institutional environment. While institutional inertia is strong, organisational evolutionary change occurs (On organisational evolutionary theory see for instance: R. Nelson, and S. Winter, An Evolutionary Theory of Economic Change, Cambridge, MA: Belknap, 1982; M. Tushman, and E. Romanelli, Organizational Evolution: A Metamorphosis Model of Convergence and Reorientation. *Organizational Behaviour*, 7 (1985): 171-222) and is then spread through a mimetic process in which each single organisation/institution tends to imitate the most legitimised and/or successful players in their population of reference (a sector or an entire industry), in order to become legitimised too, and to reduce uncertainty about their future (see P. Di Maggio, and W. Powell, *The New Institutionalism in Organizational Analysis*. Chicago: University of Chicago Press, 1991).

<sup>114</sup> See for instance: L. Lengrand, and I. Chatrie, *Business Networks and the Knowledge-Driven Economy*, Brussels: European Commission, Brussels, 1999; N. Noria and R. Eccles (eds.), *Networks and Organizations: Structure, Form, and Action*. Boston, MA.; Harvard Business School Press, 1992; R. Pouder, and C. John, *Hot spots and blind spots: Geographical clusters of firms and innovation*. *Academy of Management Review* 21(4), 1996: 1192-1225.

- Selected government incentives that reduce uncertainty and risk of investments;
- Raising awareness with patients on the benefits of out-of hospital care and cure;
- Policy research and awareness on activities demonstrating and heralding the benefits of Innovation X;
- Public discourse and hype pushing buyers to make investments even under conditions of uncertainty about their ROI, simply to “keep up with their neighbours”.

The reader by now can probably already envisage how this sort of dynamic applies to the RMT seen as a complex socio-technical ecosystem where: a) to a large extent factors inscribed in different sub-systems affect one another, shaping different possible outcomes and lines of development for the system as a whole; and b) the non-technical (broadly conveyed by the adjective ‘social’) and the technical elements are continually evolving on their own while continuously interacting with each other in ways that cannot be overtly controlled and easily predicted.<sup>115</sup> The one depicted for RMT in Figure 15 below is only an impressionistic snapshot.

**Figure 15 – RMT ecosystem: snapshot**



Source: Authors' elaboration

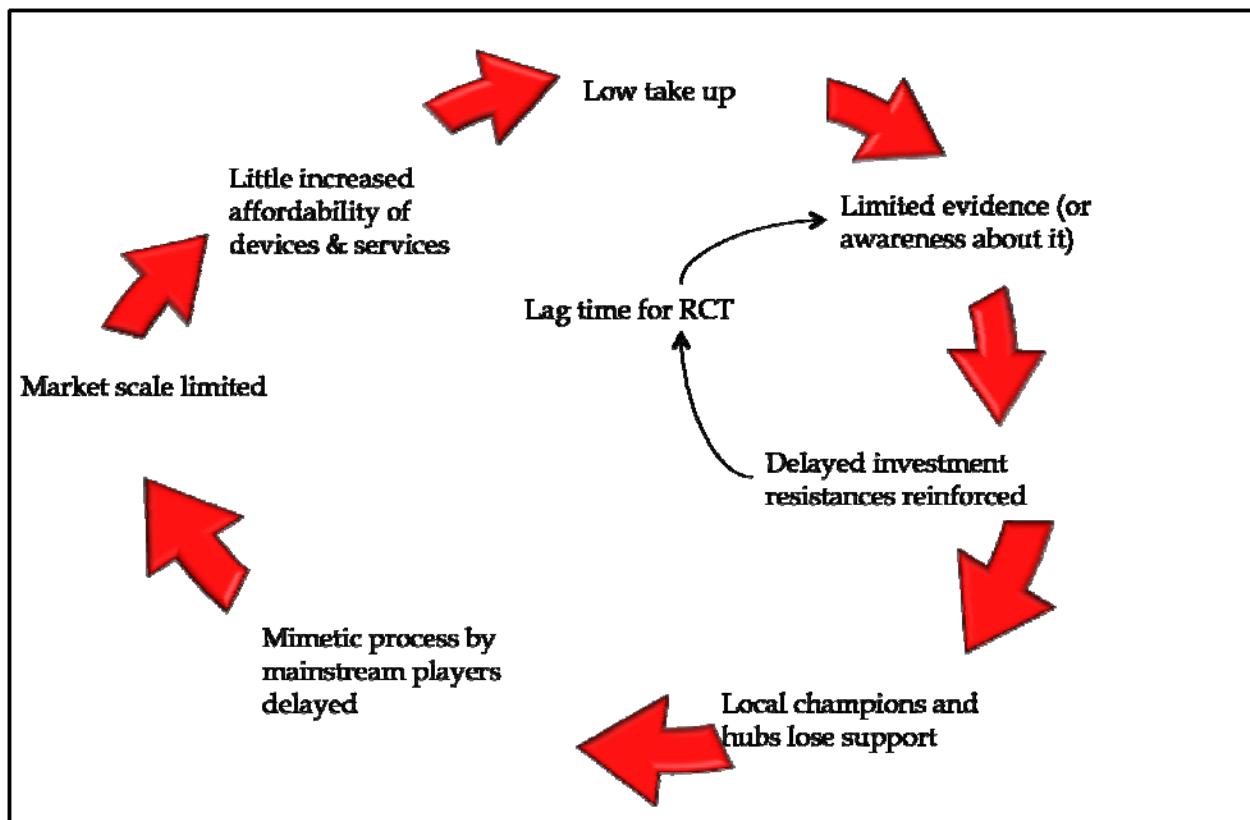
In a more structured and aggregated fashion, also in view of the contents of the previous paragraphs we can identify four macro sub-systems: Users/patients (their relatives and their advocate organisations), Health care providers (including together both professionals and management of

<sup>115</sup> Rooted in classical works on socio-technical systems such as for instance: J. Forrester, *Industrial Dynamics*. Cambridge, MIT Press, 1967; J. Thompson. *Organizations in Action*. New York: McGraw Hill, 1967; E. Trist, *The Evolution of Socio-Technical Systems*. In: Ven, A.H., Joyce, W.F. (eds.) *Perspectives on Organization Design and Behavior*. New York: John Wiley, 1981.

producing units), Health authorities / payers, Suppliers (see discussions of different objectives and expectations presented earlier in section 5.1).

The structure of incentives, interests, needs, aspirations and expectations from this complex and fragmented set of players and sub-systems have so far only rarely coincided to produce successful and self-sustained RMT service provisions. In general the reciprocal and complex interaction among all these sub-systems and players is producing and re-producing most of the barriers discussed above and hindering the kind of mimetic process whereby champions are emulated leading to progressive bandwagon effects and full market uptake. We can now apply to RMT the economic reasoning developed generically and hypothetically earlier in this section.

**Figure 16 – The vicious circle that needs to be broken**



Source: Authors' elaboration

**Lack of evidence increases gap for response.** RMT is not yet consensually recognised by all stakeholders as an application producing an increase in quality (clinical outcomes) and cost-effectiveness of health care delivery. There is both a lack of more conclusive evidence and a lack of awareness about the existing evidence and the success of the increasing number of champions. In general the economic literature has shown that even in a less complex realm such as the adoption of ICT within private firms there is a time lag between the moment of investments and the time when productivity outcomes show up. The famous quip by Nobel Prize Robert Solow that “You can see the computer age everywhere but in the productivity statistics”<sup>116</sup> also known as “productivity

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<sup>116</sup> R Solow, We'd better watch out. New York Times, July 12, 1987, p. 36.

paradox”<sup>117</sup> has reigned unchallenged for a decade before empirical evidence has started to show that ICT was boosting productivity but with a substantial lag time.

This lag in RMT is compounded because: (a) Randomised Clinical Trials are time-consuming and additional time lag is built into it by the process of scientific publishing; and (b) Once evidence from RCT is available and accepted, continuous long-term services may be launched, and eventually concrete and tangible results may surface. This slow process has negative impacts stopping the potential mimetic process that can lead first to market acceleration and eventually to realisation of full market potential. Additionally, there is an equally negative “elective affinity” between this time lag generating uncertainty as to the appropriateness of RMT and the resistance springing deliberately and opportunistically for the defence of vested interests or in a less intentional way by mere lack of incentives.

**Gap contributes to uncertainty leading to low-take-up.** This slow down in adoption by mainstream players reduces market scale and revenues, contributing to create uncertainty for market players. The latter in turn either leave the market or continue to “wait and see” and in this way they will not be able to make their product and services more affordable. Lack of affordability can potentially block even the more enthusiastic innovators and champions, which may further feed into strengthening the forces of resistance. It is a negative closed-loop that needs to be broken.

While this explanation may seem overly pessimistic, it only provides logic and empirically backed understanding of how barriers block innovation dynamics. It can be looked upon from the optimistic perspective of how such a loop can be broken and innovation dynamics jump-started. Alternatively this negative loop can be mapped against best practice cases to identify the key success factors that prevented the barriers to reinforce each other so as to replicate them in other contexts. So such a stalemate can be broken down either as a result of spontaneous socio-economic and market processes and/or of policy actions as we discuss very briefly and tentatively in the next section.

### **5.3 Conclusive recommendations**

A tentative and preliminary set of policy measures that may help break the stalemate is presented below. The barriers loop described earlier can be broken through policies, regulations, and standardisation aimed at reducing uncertainty, providing selective incentives, raising awareness, and supporting networks and hubs of innovation. Evidently, some of these policy and regulatory interventions rest with Member States and pertain more to the realm of public health than to that of Information Society. Some, however, are more directly actionable from the perspective of eHealth policies.

Member States willing to jump-start RMT may take one of two broadly defined approaches: a) traditional command and control regulatory measures: make RMT mandatory; b) provide selective economic incentives integrated with soft measures aimed at persuading the key stakeholders (awareness campaign, education and training, benchmarking for “naming and shaming”, etc).

Not considering the command and control measures, we believe that working on changing the incentives structure can be the most effective approach. This is so because we have to acknowledge that the adoption of RMT (as for other eHealth applications) is not necessarily advantageous for all stakeholders in the same way. Objectively under a “fee for service” payment model, leaving aside the question of clinical outcomes benefits, the possible economic benefit of RMT may accrue

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<sup>117</sup> As was renamed by Brynjolfsson in his widely cited initial article Brynjolfsson, Erik "The Productivity Paradox of Information Technology", Communications of the ACM, December, 1993.

overwhelmingly to the payers and only marginally to the health care provider. For instance, a hospital using RMT may see their funding simply reduced. A possible incentive may be that of allowing the hospital to retain 50% of the cost-saving produced by RMT: a hospital saving for instance €1 million a year in bed-occupancy costs through RMT disease management programme, the following year would be granted at least €500.000 to spend into innovation research in important clinical areas, so that a win-win situation is realised between the payer and the provider.

The earlier mentioned 2010 OECD report has showed that incentives for the adoption of eHealth applications are in place in several countries, as summarised in the following table:

**Table 10 – Type of incentives adopted to boost adoption of ICT in health care**

Incentives	Australia	Canada	Netherlands	Spain	Sweden	United States
Payment Differentials	Yes	Yes	Yes	No	No	Yes
Grants and Subsidies	Yes	Yes	Yes	Yes	Yes	Yes
Reimbursement	No <sup>118</sup>	Yes	No	No	No	Yes
Share withholds	Yes	No	Yes	No	No	Yes

Source: OECD, *Achieving Efficiency Improvements in the Health Sector*, op. cit., p. 58

Or in other words, the following as a direct result of the analysis of Table 10.

- Grant programmes and subsidies are used in all six countries to encourage adoption of eHealth applications by GPs;
- Bonus and add-on payment (payment differentials) are granted to reward providers for adopting and diffusing ICT (Australia, Canada, Netherlands) or for improved quality through eHealth applications (United States);
- Reimbursement for eHealth services (Canada and United States and partly Australia);
- Withholding payments to providers for non-compliance (Australia, Netherlands, United States).

Considering all of the above and specifically aimed at fostering the take up of RMT we mention tentatively the following policy options:

- Riding the wave of policy consensus, on both sides of the Atlantic on the need for governance in eHealth in general and Telemedicine in particular as was expressed by the ministerial conference in Barcelona (March 2010)
- Increased and sustained awareness-raising and dissemination activities, especially focussing on spreading the knowledge about local champions, about the increasing evidence of RMT with respect to clinical and cost-effectiveness outcomes, as well as through methodologically robust modelling and simulation of the potential benefits under different take-up scenarios;
- Further financial support to studies and research aimed at further reinforcing the evidence on outcomes and at moving towards increasingly standardised and accepted evaluation methodologies;

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<sup>118</sup> Only in the case of Glucohealth there is reimbursement as evidenced by the OECD report mentioned as source of this table.

- Design innovative mechanisms to support networking and the emergence of hubs among RMT champions and innovators (i.e. creation of centres of excellence for chronic disease management);
- Explore synergies between eHealth and eInclusion policies and supporting instruments to bring about health care and social care joined up research and innovation pilots;
- Explore the potential of consumer driven policies in support of Wellness / AAL services as a way to also boost healthcare and social services. For instance, conditional cash transfer to the elderly or to any group in need to be used to pay for such services (i.e. The Dependency Law in Spain will provide the elderly with 600 euro per year that can be used to buy such kind of services or other forms of assistance) may work as a driver for the growth of the market in this area. On the other hand, if economy of scale is reached in such domain this could have positive spill over effects in other ones (i.e. industry can bring to the market more affordable services that can then be acquired by the public buyer in the field of remote monitoring and/or social care)
- Consider revising the EU value chain of R&D, pilots and validation as to increase the chances of moving to the final stage of sustained service production and delivery;
- Leverage the new window of opportunity that may be opened in the post i2020 framework with the envisaged strong investment into broadband making sure that RMT and more in general PHS are the priority type of services to be supported through these new platforms.

## PART TWO: ANNEXES

### 6 ANNEX I: Innovative activities in RMT

#### 6.1 Scoping of research

A great variety of activities can be discerned throughout Europe aiming at the creation of an RMT market. The starting point of our research on innovative activities was the general scanning of more than 200 EU-funded projects in the area of eHealth and pilots, so as to take stock of the state-of-the-art of innovation in the field. We have identified initiatives specifically focusing on PHS or RMT, as well as some of their key characteristics such as the medical conditions addressed, the positioning of RMT innovation in relation to the RMT value chain (e.g. development of devices or systems, analytical tools, patient platform, medical platform, patient management system) and the scale of the initiative both in terms of number of patients and coverage (e.g. local, regional, national, multi-site). Next we selected a sub-set of projects and pilots focusing on PHS/RMT for more in-depth research with the objective to identify the goals, means and outcomes of these initiatives and understand how projects and pilots may contribute to the innovation dynamics of the RMT market as a whole. Our analysis is presented in this section and assesses the benefits of RMT to different user groups (such as patients, and medical staff including nurses) as well as the evidence on their cost/effectiveness.

#### 6.2 Analysis of EU-funded activities

Since 1989 EU research funding in the area of eHealth has exceeded the €1 billion mark with more than 500 eHealth projects funded. Personal Health Systems and Remote Patient Monitoring and Treatment have been present in research activities in the area of eHealth for more than 10 years e.g. under Framework programmes 5, 6 and 7<sup>119</sup> (1999 – 2013) the IST/ICT<sup>120</sup> Thematic Priority as well as through policy and support to deployment activities under eTEN and its successor CIP ICT PSP.<sup>121</sup> The table below gives an overview of the type and number of initiatives identified under various EU funding instruments. In addition Living Labs have been included in this table as some of them deal with eHealth and to a lesser degree with PHS and RMT. The latter focus on monitoring, prevention and home care, in particular within the e-Wellbeing cluster, and these Living Labs have started to network and scale-up, or to transfer their ICT-supported services to larger national markets.

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<sup>119</sup> <http://cordis.europa.eu/fp7/dc/index.cfm>

<sup>120</sup> [http://cordis.europa.eu/themes/home\\_en.html#cloud](http://cordis.europa.eu/themes/home_en.html#cloud) (Information and Communication Technologies).

<sup>121</sup> Competitiveness and Innovation Framework Programme ICT policy Support Programme.

**Table 11 – Overview of EU funded activities**

EU-funded activities	FP5 <sup>122</sup>	FP6 <sup>123</sup>	FP7 <sup>124</sup>	eTEN <sup>125</sup>	CIP <sup>126</sup>	LL <sup>127</sup>
No. eHealth projects	133	55	9	64	7 (eHealth services & Ageing Well <sup>128</sup> )	129 (23 in Wellbeing & Health cluster)
Of which No. of RMT projects for CDM <sup>129</sup>	16	5	5	10 <sup>130</sup>	4	4
RMT Project names	@Home AMON CHRONIC CHS DIAFOOT E-CARE EPI-MEDICS HEALTHMATE HEARTS M2DM MOBIHEALTH TELECARE TeleMedicare TOPCARE U-R-SAFE WEALTHY	MyHeart Heartfaid PIPS Saphire Oldes	Chronious HeartCycle Metabo Perform Diadvisor	FOR ALL (ICAROS) HealthService24 HealthWare iCare Linkcare Health-eLife (doc@Home) Interlife HealthOptimum  Better Breathing MCC	Dreaming Nexes CommonWell  Renewing Health	Laurea LL Skagen LL i-City Living Lab Salud Andalucía

Source: Authors' elaboration from data available on the CORDIS server

**Health condition perspective.** The analysis of the content of the selected projects shows that the focus spans from monitoring and early prevention to home care. Chronic Heart Failure (CHF), diabetes and pulmonary conditions (COPD) are the most recurrent chronic diseases addressed by the projects, followed by Chronic Kidney Disease (CKD), renal insufficiency and neurodegenerative diseases like Parkinson. In addition, co-morbidity, which refers to the condition of patients suffering from more than one major multiple diseases at the same time, is a thorny challenge for clinical medicine as one disease may affect the evolution and response to treatment of the other. Co-morbidity is also addressed in a number of EU funded RMT initiatives such as METABO (FP7) which deals with chronic diseases related to metabolic disorders.

**Technology and service innovation.** Most EU-funded projects address the complete value chain of the PHS/RMT markets. BY examining the PHS/RMT value chain, a number of technological advances have emerged from these projects and are briefly described below. Integration of health-monitoring tools into textiles has been talked about for some time. The European Commission has invested in research efforts in this field throughout FP5 and FP6. In terms of projects that address these developments and focus on physiological monitoring for prevention of cardiovascular risk, is

<sup>122</sup> <http://cordis.europa.eu/ist/ka1/health/>

<sup>123</sup> Information available at [http://ec.europa.eu/information\\_society/activities/health/research/fp6projects/index\\_en.htm](http://ec.europa.eu/information_society/activities/health/research/fp6projects/index_en.htm)

<sup>124</sup> [http://ec.europa.eu/information\\_society/activities/health/research/fp7phs/index\\_en.htm](http://ec.europa.eu/information_society/activities/health/research/fp7phs/index_en.htm)

<sup>125</sup> [http://ec.europa.eu/information\\_society/activities/eten/cf/opdb/cf/project/index.cfm](http://ec.europa.eu/information_society/activities/eten/cf/opdb/cf/project/index.cfm)

<sup>126</sup> [http://ec.europa.eu/information\\_society/activities/health/cip\\_ict\\_psp/index\\_en.htm](http://ec.europa.eu/information_society/activities/health/cip_ict_psp/index_en.htm)

<sup>127</sup> <http://www.openlivinglabs.eu/>

<sup>128</sup> [http://ec.europa.eu/information\\_society/apps/projects/index.cfm?theme\\_id=12](http://ec.europa.eu/information_society/apps/projects/index.cfm?theme_id=12)

<sup>129</sup> Chronic Disease Management (COPD, Chronic Heart Failure, Diabetes).

<sup>130</sup> Relatively recent projects i.e. after 2005.

Wealthy (FP5) and then My Heart (FP6) which have developed wearable electronics and body sensors to detect and measure body vital signs, as well as a signal processing algorithms used to extract ECG data from the wearable electronics. HeartCycle (FP7) also researches new bio-sensors (mainly for the continuous monitoring of blood pressure, blood oxygen levels and heart function).

The development of innovative closed-loop approaches for chronic disease management is the focus of many projects: for instance, in HeartCycle (FP7) for coronary heart disease and heart failure patients, in Metabo (FP7) for diabetic patients, in Chronious (FP7) for Chronic Obstructive Pulmonary Disease (COPD) as well as Chronic Kidney Disease (CKD) and Renal Insufficiency. In some cases the platform connects to electronic patient health records, as is the case with Heartfaid (FP6) or Linkcare (eTEN). The systems developed are intended to report automatically to clinicians, in order for them to adapt therapies and make lifestyle recommendations (medical loop), as well as involve the patients themselves in the management of their disease (patient loop).

Remote communication of data is ensured by either wireless, mobile communications including use of PDAs and mobile phones, internet technologies, home-interactive TV as well as agent technologies. One example of home-interactive TV system is the Caring TV channel, a Finnish innovation developed by the Laurea Living Lab<sup>131</sup> that offers a new way of delivering health care and welfare services directly to the home through interactive TV. The pilot project started in 2006 and several Caring TV projects are underway today, led by Laurea, for different user groups. Mobile trans-European services for chronic disease management have been researched into by a number of projects such as FOR-ALL or HealthService24 (eTEN). Agent technologies are promising improved chronic disease management systems, in the form of a personal assistant ubiquitous in the daily life of a patient with a continuous support for chronic disease management, allowing compliance support, interfacing with monitoring devices, real-time medical advice (PIPS,<sup>132</sup> Saphire,<sup>133</sup> FP6projects).

Robotics is the research areas<sup>134</sup> with most potential in home patient monitoring. However, a barrier in the commercialisation of robotics for care is the way health care systems are currently funded as well as the need for more user involvement in order to develop efficient robotic application.

"Integrated care" services (i.e. the combination of social care and health care) for effective management of chronic diseases can be found in a large number of projects. A series of "integrated care" projects led by Hospital Clinic of Barcelona since 2000 shows<sup>135</sup> the high potential of this approach. Examples are Health-Life, Linkcare, FOR-ALL, and Better Breathing (eTEN), as well as CommonWell and NEXES (CIP). The European CIP ICT-PSP Programme in particular promotes the deployment of ICT solutions supporting integrated health and home care management. The aim of the NEXES (Supporting Healthier and Independent Living for Chronic Patients and Elderly) project is to deploy, integrate and validate services targeting prevalent chronic disorders and addressing the areas of well-being and rehabilitation, enhanced care support of unplanned hospitalisation, home hospitalisation and early discharge, support of diagnostic and/or therapeutic procedures and the identification of strategies for the success of extensive and sustainable deployment of services.

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<sup>131</sup> [www.activelife.fi](http://www.activelife.fi)

<sup>132</sup> See:

[http://cordis.europa.eu/fetch?CALLER=FP6\\_PROJ&ACTION=D&DOC=3&CAT=PROJ&QUERY=1192711569763&RCN=71245](http://cordis.europa.eu/fetch?CALLER=FP6_PROJ&ACTION=D&DOC=3&CAT=PROJ&QUERY=1192711569763&RCN=71245)

<sup>133</sup> [http://cordis.europa.eu/fetch?CALLER=PROJ\\_ICT&ACTION=D&CAT=PROJ&RCN=79482](http://cordis.europa.eu/fetch?CALLER=PROJ_ICT&ACTION=D&CAT=PROJ&RCN=79482)

<sup>134</sup> Dutch innovation agency, TNO, has published a 'robo roadmap' on the way forward for robotics in medical and health arena. The agency developed the roadmap as part of an EU funded study to provide policy recommendations for the application of robots in the future, including in health care. The study available at [http://www.tno.nl/downloads/TNOKvL\\_report\\_RoboticsforHealthcare1.pdf](http://www.tno.nl/downloads/TNOKvL_report_RoboticsforHealthcare1.pdf)

<sup>135</sup> [http://www.betterbreathing.org/documents/Integrated%20Care%20Programmes%20at%20HCB\\_AlbertAlonso\\_HCB.ppt](http://www.betterbreathing.org/documents/Integrated%20Care%20Programmes%20at%20HCB_AlbertAlonso_HCB.ppt)

**Validation with real users.** The scale of the EU projects, in terms of number of patients served as well as geographical coverage (local, regional or national) is diverse. Trials typically begin with tens of patients, then scale up to hundreds of patients and in some cases thousands of patients (large scale). Most of the projects considered in our review and analysis have foreseen clinical trials with 'real' patients but outcomes are still under assessment except in the following cases: Heartfaid<sup>136</sup> (FP6), Better Breathing<sup>137</sup>, Health-eLife,<sup>138</sup> and HealthService24<sup>139</sup> (eTEN) or the HHH<sup>140</sup> study. Examples of observed benefits identified in such assessments are described in. Observations made in these pilots strongly emphasise the need for further confirmation of findings by means of large scale randomised intervention (clinical) trials, at European scale, such as the one recently launched (2010) funded by the CIP programme (RENEWING HEALTH<sup>141</sup>).

**Table 12 – Multi-site trials and validations (examples)**

<b>MyHeart (FP6) – 200 patients in 6 sites</b>
In October 2008 a clinical study was launched as part of the MyHeart Heart Failure Management project. The aim of the study was to determine if daily measurement of vital signs obtained by the MyHeart system can help predict worsening heart failure. Up to 200 patients at 6 clinical sites (Aachen, Madrid, Heidelberg, Malaga, Murcia and Bad-Oeynhausen) were included in the study, which is jointly organised by Medtronic and Philips.
<b>Heartfaid (FP6) - about 20 patients</b>
The HEARTFAID platform prototype has been tested by the consortium clinical partners (University "Magna Graecia" Catanzaro (Italy), Jagiellonian University Medical College (Cracow, Poland), University Milan-Bicocca (Italy), Istituto Auxologico Italiano (Milan, Italy)) in two settings i.e. hospital and home settings. In home care settings, the system prototype transmits by means of various sensors most commonly monitored home data in heart failure patients.
<i>Clinical stabilization at home of the HF patients and lower incidence of acute exacerbations at home, were some of the benefits observed together with costs reduction. Improvement of patient's care through an easier and better management of the disease. In addition, the HEARTFAID platform increased interest towards a better care and awareness of the disease among CHF patients improving self-control.</i>
<b>Metabo (FP7)</b>
The validation foreseen in the Metabo project will involve patients with diabetes in Italy, Spain and Czech Republic.
<b>Dreaming(CIP) – 360 patients in 6 sites</b>
The DREAMING solution is being piloted in Denmark, Estonia, Germany, Italy, Spain and Sweden (multi-centre randomised trials with 60 users per site, in total over 300 users, both elderly as well as chronic patients). The aim of the pilots is to assess the impact of the service on the quality of life of elderly people, their formal and informal caregivers and their relatives and on economic and clinical indicators, verify its financial sustainability and check user satisfaction.
<b>NEXES (CIP) – 3000 patients in 3 sites</b>
Large scale randomised clinical trials (up to 5000 patients ) are foreseen through deploying four integrated care programs for chronic patients in three sites (Catalonia, Norway, Greece). In Catalonia, all of the Nexes services will be deployed in several local health areas, namely three districts of Barcelona and one medium size city in the suburbs of Barcelona. In each area, deployment will be coordinated by the Hospital Clinic of Barcelona. In Norway, all of the Nexes services will

<sup>136</sup> <http://www.heartfaid.org/>

<sup>137</sup> Presentations of results in the final conference at [http://www.betterbreathing.org/public\\_document.html](http://www.betterbreathing.org/public_document.html)

<sup>138</sup> [http://ec.europa.eu/information\\_society/activities/eten/cf/opdb/cf/project/index.cfm?mode=detail&project\\_ref=ETEN\\_NM7](http://ec.europa.eu/information_society/activities/eten/cf/opdb/cf/project/index.cfm?mode=detail&project_ref=ETEN_NM7)

<sup>139</sup> <http://www.healthservice24.com/Internet/external/cms/index0ed6.html?healthservice24>

<sup>140</sup> A. Mortara, et al Home telemonitoring in heart failure patients: the HHH study (Home or Hospital in Heart Failure). *European Journal of Heart Failure* 2009 11(3):312-318.

<sup>141</sup> Also mentioned in footnotes 73 and 77 <http://www.renewinghealth.eu>

be deployed in the area of the city of Trondheim (St Olav hospital), while in Greece, the Nexes services will be deployed in the metropolitan area of Athens by several partners (Sotiria Hospital, Santair and ISPM).

#### **Better Breathing (eTEN) – 4 sites**

Four pilot sites in Better Breathing carry out market validation of the eServices for the care of chronic patients in Catalonia, Denmark, Norway and Wales. In Catalonia, the field trials are conducted with patients from the Hospital Clinic Provincial Barcelona. In Denmark, the market validation takes place at the Funen Hospital (validating eCare and eLearning), in Norway in the University Hospital of North Norway (eCare, eRehabilitation, eLearning and ePatient Community services). The patient groups consist of COPD patients. In Wales, the market validation takes place in co-operation between the Prince Philip hospital in Llanelli, Carmarthenshire, the Carmarthenshire Trust and IHC (validation of eCare, eRehabilitation and eLearning).

*Evaluation of impacts on medical staff showed increased workload, but "reassuring for them to be able to monitor vulnerable patients remotely".*

#### **Health-eLife (eTEN)**

The Health-eLife project is validating the Doc@Home™ service in the context of typical European hospital outpatient service and is also conducting a review of previous socio-economic studies in the management of chronically ill patients at home, undertaken in Portugal, Estonia and the UK. The study demonstrated the service competence to manage patients at home across a range of clinical dimensions and disease conditions

*The use of remote monitoring for COPD showed promising results for quality and cost-effectiveness .The use of remote monitoring also caused patients to sub-consciously adjust their life styles .*

#### **HHH study (Home or Hospital in Heart Failure) (Action line 10.1)- 461 patients in 11 sites in 3 countries**

HHH is an EC -funded, multi-country, randomised controlled clinical trial, conducted in the UK, Poland, and Italy, to assess the feasibility of a new system of home telemonitoring (HT). The HT system was used to monitor clinical and physiological parameters, and its effectiveness (compared with usual care) in reducing cardiac events in heart failure (HF) patients has been evaluated. From 2002-2004, 461 HF patients were enrolled in 11 centres.

*Over a 12-month follow-up, there was not observed a significant effect of HT in reducing bed-days occupancy for HF or cardiac death plus HF hospitalisation (a trend towards reduction of events was observed in Italy).*

#### **RENEWING HEALTH (REgioNs of Europe WorkINg toGether for Health) (CIP)**

A large scale pilot on Telemedicine has just been launched by Call 3 of CIP ICT-PSP programme (“ICT for patient-centered health service”) to validate in real life settings the use of existing PHS for innovative types of Telemedicine services and to prepare for their wider deployment. The initiative is expected to build up the largest multi-centre clinical trial ever deployed in Europe to measure the effectiveness and cost effectiveness of Telemedicine solutions.

*Source:* Authors' elaboration from data collected from the CORDIS database or project web-sites

### **6.3 Analysis of pilots and programmes<sup>142</sup>**

Pilots and programmes are spanning from small scale (dozens of patients) to medium scale (hundreds of patients) to large scale (thousands) at local, regional or national levels. Most advanced countries in relation to RMT, in terms of **scale as well as degree of integration or 'mainstreaming'**, are USA, United Kingdom, then Germany, Spain, Italy and the Netherlands. The most commonly addressed conditions are COPD, CHF, diabetes and combinations. Tunstall and HomMed Honeywell, Intel, Philips and BOSCH (Health Buddy by Health Hero, since late 2007 – see section 7.2 on companies) are amongst the main companies providing technologies/solutions mostly used in RMT pilots.

<sup>142</sup> We call “programmes” commercial activities. They may be the outcome of pilots going into “real” service production.

Innovative developments under so-called "integrated care" services (social/health care combinations) can be seen in nationwide initiatives like the Veterans Health Administration's programme in the US, regional initiatives like Scotland's Telecare Development Programme (TDP programme) and Telescot, Connected Health & Care Northern Ireland strategy (ECH), or the HTN Lombardy in Italy. Also some pilots and trials involve a combination of telecare and home telehealth applications, such as the KOALA study in the Netherlands.

**Large scale initiatives.** Despite the fact that there is a plethora of PHS/RMT activities, there are only few large scale initiatives amongst them. The most integrated/mainstream example of home telehealth internationally is considered to be the **Veterans Health Administration's Care Coordination/Home Telehealth** programme in USA (VHA's CCHT) with more than 30,000 (mostly elderly) patients currently served. The medium-term implementation strategy foresees the enrolment of 50,000 patients with chronic Spinal Cord Injury (SCI), depression, mild dementia, multiple sclerosis (MS), or Parkinson's disease. Subject to the outcome of the short- and medium-term implementation, VHA will consider a long-term implementation programme that will support the 41% of the chronic-disease population with low or limited activities of daily life. CCHT was developed as part of the VHA's efforts to provide home care services to cater for the rising number of elderly veterans with chronic care needs.

Care coordination<sup>143</sup> has been explicitly designed to meet the changing health care needs of the veteran population that is ageing and coping with the limitations imposed on their lives and longevity by chronic diseases and conditions, e.g., diabetes, chronic heart failure (CHF), spinal cord injury (SCI), posttraumatic stress disorder (PTSD), depression, chronic obstructive pulmonary disease (COPD), stroke, multiple sclerosis (MS), and hypertension. An economic analysis of the CCHT outcomes by the VHA has shown reduced hospitalisations, 30% fewer emergency room visits, 30% reduction in the average number of bed days of care, improved health-related quality of life and benefits in terms of satisfaction, clinical outcomes and costs.<sup>144</sup>

Another large-scale initiative in the US is the National Association for Home Care and Hospice (**NAHCH**) pilot. Sponsored by Philips Home Health care Solutions and co-sponsored by the NAHCH and Fazzi Associates, the study is considered the largest technology and telehealth study in the history of home care (it involved 976 Home care associations across the country). The study addressed four major home care technology areas, including telehealth and Remote Patient Monitoring Technology. Study results show<sup>145</sup> that nearly one third of large agencies are currently using a telehealth system and that industry use of telehealth is expected to double over the next two years, mainly as a means of managing patients with chronic disease. In addition, over 88% of agencies report that deployment of telehealth services led to an increase in quality outcomes, as evidenced by the reduction in unplanned hospitalizations and Emergency Room visits, and over 71% report an improvement in patient satisfaction.

In the UK, telecare and telehealth form part of a **major randomised control trial** across three demonstrator sites aiming at a recruitment target of up to 6,000 people in the three WSD pilot sites: Kent, Cornwall and Newham. WSD is considered the biggest single telecare/ telehealth convergence

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<sup>143</sup> VHA defines care coordination as- *the use of health informatics, telehealth, and disease management to enhance and extend care and case management activities to facilitate access to care and improve the health of designated individuals and populations with the specific intent of providing the right care in the right place at the right time* <http://www.va.gov/occ/>

<sup>144</sup> Adam Arkins , MD, Chief Consultant for Care Coordination, Department of Veterans Affairs, Changing the location of care: Management of patients with chronic conditions in Veterans Health Administration using care coordination/home telehealth, at <http://www.rehab.research.va.gov/jour/06/43/4/darkins.html>

<sup>145</sup> <http://www.medical.philips.com/wpd.aspx?p=/Resources/News.wpd&id=1619&c=main>

pilot in the Europe.<sup>146</sup> An important aim of the **Whole System Demonstrator (WSD)**<sup>147</sup> trial is to build the evidence base for the use of these technologies as part of integrated health and social care support for people with long term conditions. Criteria for enrolling patients in the WSD telehealth trial are those diagnosed with one or more of the long term conditions such as CHF, type 1 or type 2 diabetes, COPD or co-morbidities, and, people that have had at least one or more unplanned events in the last 12 months in relation to their long term condition, such as: unplanned hospital admission, intermediate care, rapid response service use, treatment following call out of ambulance services or accident and emergency visit. The WSD Programme will run for over two years with all participants recruited during 2009 and results foreseen to be published in late 2010. A WSD Action Network (WSDAN) has been established to disseminate the lessons learned on the three sites and to become a source for the collected worldwide evidence on the effectiveness of telehealth and telecare (a database of evidence on the benefits of telehealth and telecare).

Scotland NHS Lothian Telehealth programme (**Telescot**) is considered one of the largest of its kind in the UK and will provide in-home care for patients with COPD and other chronic conditions. The NHS Lothian programme is part of an ongoing collaboration between NHS Lothian and the Scottish Government, implemented by Intel and Tunstall (it is using the Intel Health Guide personal health system, launched in the UK in November 2008). It follows a small-scale pilot of 30 patients with COPD launched in March 2008, also using the Intel Health Guide. The large-scale programme<sup>148</sup> started with 200 COPD patients and will later include those with other chronic conditions including cardiac diseases and diabetes across Edinburgh and the Lothian regions. A number of patients included in the programme will be enrolled in a randomised control trial conducted by the University of Edinburgh. Results of this research will be available in 2010. The project<sup>149</sup> is being evaluated through the TeleScot suite of randomised controlled trials; it is exploring the role of telemonitoring in the management of long-term conditions and whether telemonitoring of COPD affects hospital admissions or quality of life for people with moderate or severe COPD in comparison with usual care. Recruitment of patients has recently started for several randomised controlled trials, using the Tunstall telemonitoring technology. Telecare/telehealth convergence pilots are the focus of the renewed telecare strategy<sup>150</sup> for 2008-10 implemented through the **Telecare Development Programme (TDP)**. The evaluation of the first phase of implementation<sup>151</sup> shows that a number of outcomes and efficiencies have been achieved.

One of the European examples that has raised a lot of expectation, mostly because it was a combined shared standards and central procurement of technology, is the Northern Ireland **Connected Health & Care strategy (ECCH)**.<sup>152</sup> It represents a major investment in chronic disease management and public procurement of a remote telemonitoring service for 5,000 people (heart disease, COPD, diabetes) by 2011. ECCH was set up and funded in January 2008 by the Department of Health, Social services and Public Safety (DHSSPS), following a feasibility study carried out in 2007, to develop, procure and implement a remote monitoring service for chronic disease patients in Northern Ireland. This is a system-wide solution that actually goes beyond pilots. The strategic focus of the ECCH initiative is to embed technology in health care so as to leverage its potential to catalyse change, bridging the gap between market solutions that are available and which offer significant potential for improving the quality and efficiency of services and the lack of awareness about these

<sup>146</sup> [http://ec.europa.eu/information\\_society/events/cf/document.cfm?doc\\_id=7253](http://ec.europa.eu/information_society/events/cf/document.cfm?doc_id=7253)

<sup>147</sup> [http://www.dh.gov.uk/en/Health%20care/Longtermconditions/wholesystemdemonstrators/DH\\_084255](http://www.dh.gov.uk/en/Health%20care/Longtermconditions/wholesystemdemonstrators/DH_084255)

<sup>148</sup> [http://www.shsceventsbookings.co.uk/event\\_316/documents/BrianMcKinstry.pdf](http://www.shsceventsbookings.co.uk/event_316/documents/BrianMcKinstry.pdf)

<sup>149</sup> <http://www.jitscotland.org.uk/downloads/1248342434-Newsletter%20TELESCOT%20July%202009%20FINAL.doc>

<sup>150</sup> Telecare Strategy 2008-2010 sets out the Scottish Government's expectations of further development in telecare; <http://www.jitscotland.org.uk/downloads/1219664870-94-Telecare%20Strategy%202008%20-%202010.pdf>

<sup>151</sup> <http://www.jitscotland.org.uk/downloads/1235404195-B59058%20Final%20Report%20low%20res.pdf>

<sup>152</sup> <http://www.eu-cch.org/>

solutions among practitioners and policy makers. Pre-procurement for services in relation to CHF, COPD and diabetes patients, both home-based and mobile is currently ongoing<sup>153</sup> and service implementation is planned for 2010. In the future further disease conditions may be tackled such as stroke prevention, hypertension, telecare services (e.g. fall detection), medicinal compliance or dementia, depending on the results of the evaluation of the current services. ECCH also aims to build an evidence base in relation to the use of remote monitoring in support of the management of chronic disease, which will be used to assess its operational outcome and impacts. ECCH is so far the only large scale, system-wide initiative with pre-procurement.

**Regional initiatives.** Beyond the above mentioned large scale initiatives, many other smaller scale but equally regionally implemented initiatives have been identified and studied during the first phase of SIMPHS. The **Health Telematic Network (HTN)**<sup>154</sup> in Lombardy gradually extended the initial telecardiology service, set up in 1998 for the Boario Home Care Project (applying new models of disease management and technology) to more locations in Lombardy to convert evidence from clinical trials and research into benefits for everyday practice.<sup>155</sup> The **Lombardy Region authorities** have commissioned an expansion of the service from 2006 on, to cover the whole region with new "disease management" services. The benefits reported so far were: (a) faster and more appropriate access to health care for citizens who are unaware of their emerging chronic heart disease; (b) fewer unnecessary hospital visits; (c) faster GPs' response to changes to the therapies that are needed by their patients; and (d) economic benefits which were exemplified by: (i) increasing and sustainable net benefit to patients, GPs and hospitals; (ii) economic return (net benefits to cost ratio) over 15 years of 230%; (iii) estimated annual cost benefit ratio 3.3 to 1 by 2012. eHealth impact project evaluates 31% of direct benefits are for citizens versus 69 % for health care provider organisations.<sup>156</sup>

Overall, the **Lombardy region** is leading the process of wide diffusion of RMT services, starting from initial experimentation through pilots towards the introduction of reimbursement of RMT for CHF operationally. Early experimentation funded by either the Italian Ministry of Health or the European Commission, such as for instance Criteria<sup>157</sup>, Piano Urbano,<sup>158</sup> and Radici,<sup>159</sup> has eventually led to operationally reimbursed RMT services for CHF (and also for other chronic diseases, see *infra*). Even before these projects and pilots were launched, the Region had set up a group of clinicians to discuss what could be appropriate targets and type of diseases, the kind of therapeutic paths to be followed (six months versus sine die, versus various other solutions). All this experience has then been transformed into a self-standing programme of the Region going under the name of **Nuove Reti Sanitarie (New Health care Networks)**<sup>160</sup> in the context of which the protocol for the reimbursement of RMT services for patients with CHF has been defined and is currently managed. The Region has introduced regional protocols (it is not formally a DRG, but it comes close

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<sup>153</sup> There are four short listed providers selected Candidates for the Remote Telemonitoring Northern Ireland (RTNI) Managed Service : Robert Bosch GmbH with McElwaine Smart, British Telecommunications plc (BT) with Home Telehealth Limited, Hewlett Packard Limited with Honeywell HomMed, Intel and Home Telehealth Limited and TF3 consortium comprising Tunstall Health care (UK) Limited (Tunstall), Fold Housing Association Limited (Fold) and Silicon and Software Systems Limited (S3); info at <http://www.eu-cch.org/index/remote-monitoring-service.htm>

<sup>154</sup> <http://www.e-htn.it/home.htm>

<sup>155</sup> Three different types of services are available: (a) a service to provide a rapid second opinion for general practitioners; (b) a service to provide home tele-nursing for chronic patients; (c) a service to provide a call centre service for hospitals. The service centre provides technological and organisational support, while the hospitals' cardiologists and nurses manage the health care activity.

<sup>156</sup> [http://www.medetel.lu/download/2008/parallel\\_sessions/presentation/day2/good\\_ehealth.pdf](http://www.medetel.lu/download/2008/parallel_sessions/presentation/day2/good_ehealth.pdf)

<sup>157</sup> <http://www.cefriel.it/criteria>

<sup>158</sup> <http://www.cefriel.it/pianourbano>

<sup>159</sup> <http://www.radici.regionelombardia.it/>

<sup>160</sup> <http://www.cefriel.it/nrs>

to it<sup>161</sup>) for three services, managed within Nuove Reti Sanitarie. Two protocols target cardiovascular patients: (a) Home Telemonitoring protocol for patients with CHF; and (b) Post-cardio-chirurgic home-based assistance. Later, in 2008 a new protocol was launched for Home based palliative assistance (for terminally ill cancer patients) making use of ICT enabled solutions. The Region, through a number of regional level regulations,<sup>162</sup> has identified, defined and priced the three protocols (see data reported earlier in Figure 9 on page 38) and subsequently authorised the health care structures of the region requesting the reimbursement for the provision of such services to implement them with another set of Regional regulatory acts.<sup>163</sup> The reimbursed tariffs have been defined on the basis of a preliminary simulation of costs but will be steadily adjusted since the protocol mandates that the health care structures receiving reimbursement must provide detailed information on the usage of resources, which will serve to adjust the tariffs for reimbursement.

Another Italian region, which has a long-standing experience of home care, European level experience in Telemedicine (it currently runs 19 European projects in the area of health including telemedicine)<sup>164</sup> and enjoys strong leadership and vision at regional level is **the Veneto Region**. One of the recent European projects lead by the Veneto Region is HEALTHOPTIMUM (eTEN) aiming at deploying telemedicine services, geographically (e.g. roll-out of neurosurgical tele-counselling in all Local Health Authorities of the Veneto Region), and also to new specialties (e.g. the application of the HEALTH OPTIMUM services to stroke management where the Veneto Region has selected three hospitals equipped with neurology and neuro-radiology services). The region has recently procured a service for tele-assistance and remote monitoring of basic vital parameters ensuring for five years the capability of reaching everyday a total of 25,000 users. Overall, the region shows innovative and visionary initiatives towards the integration of health and social care. The Region elaborated a multidimensional fiche (known as SVAMA) where individuals are assessed along three dimensions: economic capabilities, social conditions, and health status. Looking at these three dimensions a local Committee composed by the Local Socio-Health Unit (USSL), the hospitals, and the local GPs will decide which patients should be enrolled in the offered tele-assistance and remote monitoring services and request that the provider, who cannot object to the decision, offers them a service. The service provision consists of a collection of a number of vital signs (ECG, blood pressures, and others), their automatic preliminary analysis and the transfer of the output to the Distretto Socio-Sanitario (an intermediate body between the USSL and the hospitals) where a specialist full time employee (not a cost charged by the provider) periodically looks at the data. In case of abnormal patterns (but not in case of full blown emergency when the patient is immediately brought to the hospital) the specialist may decide either for a change in the pharmacological therapy (she/he triggers the GP responsible for the patient) or for a short hospitalisation. The fact that all the health and social care human components of the services are ensured by the personnel of the USSL explains the lower price for the tele-assistance and remote monitoring service (see data reported earlier in Figure 9 at page 38), compared to those of other Italian regions.

RMT services to treat CHF, Diabete, and COPD patients living in remote areas in the mountains has been recently procured by the **Piedmont Region** (see data reported earlier in Figure 9 at page 38). The services foresee, besides the standard remote monitoring activities, the periodic visit of nurses, the interventions of physicians and also sophisticated video-conference equipment and services. The level of the offered services explains the higher price per patient per day reported for this region.

<sup>161</sup> The detailed illustration available in the documentation received is summarised in the Country Profile Italy.

<sup>162</sup> DGR N. VII/20592 of 11.02.2005, DGR N. VIII/1375 of 14.12.2005, DGR N. VIII/6410 of 27.12.2007 and DGR N. VIII/7180 of 24.04.2008.

<sup>163</sup> DGR N. VIII/2471 of 11.05.2006 and with DGR N.VIII/7933 of 06.08.2008 and with the recent DGR N. VIII/10072 of 7.8.2009.

<sup>164</sup> Presentation of Veneto Region at [http://www.synthesisproject.ro/Presentation\\_230209\\_Veneto%20Region.pdf](http://www.synthesisproject.ro/Presentation_230209_Veneto%20Region.pdf)

In Canada, **The Ontario Telemedicine Network (OTN)** is one of the largest telemedicine networks in the world. OTN was created through the April 2006 merger of three provincially funded telemedicine networks: CareConnect (Eastern Ontario), NORTH Network (Central & Northern Ontario) and VideoCare (Southwestern Ontario). The Ontario Telehomecare Phase One Program (March 2007 to October 2008) provides care and monitoring to 600 patients with chronic diseases. Eight Family Health Teams supported phase One across Ontario in collaboration with local Community Care Access Centres – all of whom play key roles in chronic disease management activities. The Telehomecare project is currently expanding into the thousands of patients in 2009.<sup>165</sup>

Besides the WSD programme and regional initiatives, **in the UK**, there are also over **300 telecare services** provided by local authorities, housing associations, independent, voluntary and third sector organisations as well as commercial providers. A small number of primary health trusts have been testing telehealth systems that can monitor respiratory and heart conditions at home. These services include regular home monitoring of blood pressure, blood sugar, weight and other vital signs. If these measurements are outside of certain levels, health care professionals (e.g. specialist nurses, community matrons) are alerted and will take appropriate follow-up action. In 2008, the Commission for Social Care Inspection (CSCI) collected information from 150 social care authorities<sup>166</sup> and reported on telecare outcomes and mainstreaming.<sup>167</sup> For instance, a highly successful pilot employs telecare to deliver services to 35 people with COPD with the aim to reduce hospital admissions and increase self-care across Blackpool (the scheme if successful will be extended to 200 people). Lancashire is in the process of setting up a telehealth-monitoring pilot in partnership with East Lancs Primary Care Trust & Housing Pendle. Eighteen patients with long-term conditions (6 CHD, 6 COPD & 6 Diabetes) will be identified to have vital signs monitoring in their homes. In addition to this, a second telehealth-monitoring pilot is under discussion in partnership with East Lancs Primary Care Trust & Housing Pendle. The intention is to mainstream telecare in the region by taking it up into a standard care package like any other treatment (2009).

There is also a **Chronic Care Management (CCM) programme** (comprising three projects) **operating across Wales** – Carmarthenshire, Cardiff and North Wales – launched in 2008 and focused on chronic conditions such as arthritis, COPD, diabetes and CHF. Each of the three projects is focused on different aspects of health care and social care. The first annual report<sup>168</sup> outlines improvements in care for patients with chronic conditions such as a reduction in emergency medical admissions in Carmarthenshire over a three year period by almost: (a) 40% for COPD; (b) 30% for CHF; and (c) 10% for diabetes. Admission avoidance figures attributed to the CCM team show a drop over 2008-2009 by 10% (to 528 patients), whilst patients have benefitted from a rapid increase in the number of telecare installations over 2008 – 2009 from 240 to 751, handling 1146 referrals. In addition, **the Scottish Centre for Telehealth** is supporting a number of developments.<sup>169</sup> Some actual and foreseen pilots are ongoing for example in South/North East Scotland and Lanarkshire (hyper acute stroke care), and in Lothian, Lanarkshire, Moray (COPD). The demonstrators are also expected to be extended to cover a wider range of conditions, including diabetes, hypertension, coronary heart disease and asthma for example in Lanarkshire. Also in the UK, a major two-year pilot programme has been announced by the Department of Health to test and evaluate a range of models of integrated care. The programme which consists of **16 Integrated Care Pilots (ICP)** is designed to explore different ways in which health and social care could be provided to help drive

<sup>165</sup> <http://exweb.otn.ca/telehomecare/files/Telehomecare%20Fact%20Sheet%20FINAL%20Sept192007.pdf>

<sup>166</sup> <http://www.networks.csip.org.uk/telecareprofiles>

<sup>167</sup> Telecare performance reports from social care authorities (2008) at:

<http://www.dhcarenetworks.org.uk/IndependentLivingChoices/Telecare/TelecareOutcomes/>?

<sup>168</sup> Details of the first annual report at [www.ccmdemonstrators.com](http://www.ccmdemonstrators.com)

<sup>169</sup> <http://www.sct.scot.nhs.uk/index.html>

improvements in local health and well being. Integration refers to partnerships, public and third sector organisations, systems and models – crossing boundaries across primary, community, secondary and social care. The pilots<sup>170</sup> vary from developing new models of long-term condition management to help patients choose their end-of-life care, to enable people to self-manage COPD care. A number of these pilots also deal with innovative approaches for chronic disease management.

In the **Netherlands**<sup>171</sup>, some major regional initiatives have been launched recently (not more than 3 years ago), such as IZIT, BHI and ZIF. The main focus of these initiatives is health care change and the role/position of the patient. IZIT<sup>172</sup> is a leading regional initiative in the **Twente region** aiming to establish an information system for integrated care in Twente that facilitates the exchange of information between GPs in the region. IZIT has become an best case example of ICT developments in health and social care, for other regions. IZIT cooperates with insurer Menzis and regionally operating home care organisations in the successor of the KOALA project and with the regional Innovation Platform Twente in developing a programme, called INNOTEL, which will develop solutions for well-being (home care services and chronic disease management for the elderly). The **KOALA**<sup>173</sup> project is a combination of telecare and home telehealth applications, coined as services for "Care en Cure" which involves about 1000 patients **from all parts of the country**. The first KOALA study involved 155 CHF patients, 25 diabetes patients and 58 COPD patients. The objectives were to reduce the number of visits to physicians and cardiologists. Trials will be continued with roughly 300 patients with CHF, diabetes and COPD and an additional 300 patients with intensive nursing care needs.<sup>174</sup> **Brainport Health Innovation (BHI)**<sup>175</sup> is a regional initiative, part of Brainport Development, around **the region of Eindhoven** with the aim to improve independent living. On the basis of a shared vision regarding the focus and orientation of BHI a programme has been developed, called 'Connected Client, Connected Patient'. It now consists of some nine projects, ranging from elderly remote care to a health service portal and a coach for patients with chronic diseases. BHI also participated in the Interreg IIIC project 'Telemedicine and Urban Planning'<sup>176</sup> and is involved in its successor 'Healthy Workforce' (under preparation). Seven cities throughout Europe were connected to this initiative (Eindhoven, Den Haag, Barcelona, Southampton, Bologna, Genoa and Parma). **Zorg Innovatie Forum (ZIF)**<sup>177</sup> is a regional innovative centre in **the northern part of the Netherlands (province Groningen)**. It has formulated four 'showcases' of which one is in the domain of RMT. The showcase 'Care for the future' will contribute to the successor of the KOALA project in the eastern part of Groningen.

**Local initiatives.** In addition to the regional initiatives, there are obviously many more company-driven local initiatives, three of which we report on are in Spain, Austria and Hungary. **Emminens**, a subsidiary of pharmaceuticals giant Roche runs a number of initiatives in Spain. **Saludnova**, a spin-off from the University of the Basque Country and part of the Cooperativa Mondragón, is involving three hospitals of the Regional Health care System **in the Basque country** in running pilots on telemonitoring<sup>178</sup> for chronic patients. In June 2009, **Orange Austria** and charity Arbeiter-Samariter-Bund Österreich (Workers Samaritan Federation Austria) announced<sup>179</sup> a trial to pilot a **mobile e-health solution** for monitoring blood sugar levels and blood pressure, using Alcatel-Lucent

<sup>170</sup> [http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/documents/digitalasset/dh\\_098912.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_098912.pdf)

<sup>171</sup> Based on information provided for in the Dutch Country report carried out by IPTS.

<sup>172</sup> [www.izit.nl](http://www.izit.nl)

<sup>173</sup> [http://www.koalaweb.nl/documents/april%202007%20Koala\\_En.pdf](http://www.koalaweb.nl/documents/april%202007%20Koala_En.pdf)

<sup>174</sup> ICT&Ageing country profile at <http://www.ict-ageing.eu/>

<sup>175</sup> See <http://www.brainporthealthinnovation.nl/> (download section; programme 'Connected Client, Connected Patient').

<sup>176</sup> See <http://www.telemedicine-europe.net/index.php?id=1>

<sup>177</sup> See <http://www.zorginnovatieforum.nl/>

<sup>178</sup> [http://www.saludnova.com/index.php?option=com\\_content&view=article&id=178&Itemid=146&lang=en](http://www.saludnova.com/index.php?option=com_content&view=article&id=178&Itemid=146&lang=en)

<sup>179</sup> Via [http://www.ehealtheurope.net/news/4970/orange\\_austria\\_targets\\_mobile\\_e-health](http://www.ehealtheurope.net/news/4970/orange_austria_targets_mobile_e-health)

TeleHealth Manager solution, an off-the-shelf e-health platform, in Austria. **GE Health care** is part of a consortium leading a major telemonitoring initiative, in the framework of the **3-year Hungarian Assisted Living Programme**, initiated and majority-funded by the Hungarian government. The initiative (also backed up by GE Health care investment) aims to research and develop remote telemonitoring systems that monitor both activity levels and vital signs such as blood pressure and heart rate, alerting caregivers to changes that may signal potential health problems or emergency situations. Evidence collected will likely focus on the potential benefits of home health monitoring for elderly patients with chronic health problems such as stroke, depression and dementia. The Consortium aims to identify activity patterns and physiological symptoms that may remotely predict onset of disease, diagnose a condition earlier, identify problems such as a relapse or detect a worsening of a condition.<sup>180</sup>

#### **6.4 Lessons on innovative activities**

Innovative activities, mostly undertaken as projects and pilots, but also taking place in programmes, are spanning from small scale (dozens of patients) to medium scale (hundred of patients) to large-scale (thousands) at local, regional or national levels. As far as EU-funded projects are concerned, large scale and multi-site trials and validations have been funded by the CIP and eTEN programmes. Most advanced countries in relation to RMT, in terms of scale as well as degree of integration or 'mainstreaming', are the US, the United Kingdom, Germany, Spain, Italy and the Netherlands.

Most innovative initiatives identified relate to pilots not to sustained long-term services. Instances of the latter supported by reimbursement models can be seen only in very few cases like in Germany (Vitaphone) or Italy (HTN). In Germany, a number of health insurance actors offer large-scale home telehealth service programmes as part of their integrated health care programmes, while other actors are involved in trial phases with a rather low number of participants. The experience with HTN Lombardy shows how reimbursement strategies might assist in moving from innovation perspectives to real markets – albeit with still a fraction of the possible patients being served. Recommendations on reimbursement of home telehealth and remote monitoring were recently made by the American Telemedicine Association.<sup>181</sup> These recommendations, although not yet implemented by payers even in the USA, provide an insightful analysis of how Tele-homecare reimbursement can be addressed as part of mainstream approaches.<sup>182</sup>

Most innovative activities studied included data collection tasks to satisfy the need to build evidence related to the clinical outcomes, cost effectiveness, impacts on services utilisation, and acceptance by health care providers.<sup>183</sup> Since thus, telemedicine as an alternative to disease management is not generally accepted, there are a number of possible approaches to commissioning telecare and telehealth, all of which have associated risks (e.g. "Go for it – initiate major programme, phased implementation", "Stay with controlled pilots and projects", "Wait for the money", "Wait for the evidence", or "Do nothing – it's not a priority"). While a few innovators and early adopters are using RMT technology, a "waiting game" is taking place until the evidence on clinical outcomes and cost-effectiveness would be available.<sup>184</sup> The EU is trying to address this challenge by launching what is hoped to be the largest multi-centre clinical trial (9 countries, over 1000 patients each) ever deployed in Europe to measure the effectiveness and cost-effectiveness of Telemedicine solutions (CIP

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<sup>180</sup> GE-Health care presentation during the 2009 eHealth Ministerial Conference in Prague and news at: [http://www.ehealtheurope.net/News/4365/hungary\\_signs\\_e-health\\_deal\\_with\\_ge\\_health\\_care](http://www.ehealtheurope.net/News/4365/hungary_signs_e-health_deal_with_ge_health_care)

<sup>181</sup> Virginia and eleven other states have adopted mandates legislating that health insurers pay for telemedicine services. The other states are: California, Colorado, Georgia, Hawaii, Kentucky, Louisiana, Maine, New Hampshire, Oklahoma, Oregon and Texas.

<sup>182</sup> [http://www.americantelemed.org/files/public/policy/Home\\_Telehealth\\_Policy\\_ver3\\_5.pdf](http://www.americantelemed.org/files/public/policy/Home_Telehealth_Policy_ver3_5.pdf)

<sup>183</sup> Systematic Review of Home Telemonitoring for Chronic Diseases: The Evidence Base: JAmMed Inform Assoc. 2007; 14:269–277

<sup>184</sup> [http://www.wsactionnetwork.org.uk/news/features/the\\_challenges\\_for.html](http://www.wsactionnetwork.org.uk/news/features/the_challenges_for.html)

Renewing Health, see footnote 141). This pilot will produce large scale, measurable, comparable and statistically significant results, regarding the effectiveness of the solutions tested, using a commonly agreed and scientifically sound assessment methodology and develop sustainable business models.

One of the main challenges on accessing required evidence is raising consensus on the population at risk, mainly as a result of difference in definitions. In the UK for instance, 5% of patients account for 49% of in-patient bed days in hospitals (and associated costs) and just 2% of patients with long-term conditions account for 30% of unplanned admissions and 80% of visits to a general practitioner. Many hospital admissions can be prevented provided "at-risk" population can be predicted. In the UK, since 2005, the King's Fund and BUPA/Health Dialog have developed predictive<sup>185</sup> models such as *PARR ++ (People at Risk of Readmission to Hospital)*. These predictive models seem to be more accurate when making forecasts for the future e.g. in predicting which patients will be a high cost in 6-12 months time as well as those patients that will have an avoidable event. Some examples are the PARR model used in WSD programme or in the doc@Home<sup>186</sup> project.

From a health condition perspective, chronic heart failure (CHF), diabetes and pulmonary conditions like COPD are the most important chronic diseases addressed by both EU-funded projects and pilots, together with co-morbidity.

Most EU-funded projects address the whole value chain of the personal health systems and remote patient monitoring markets, from development of monitoring & measurement devices (sensors) including protocols & analysis tools to patient platforms & patient management systems (patient and medical loops). In some cases the platform connects to electronic patient health records.

Funding is needed at the start of the service procurement as well as for the transition period towards full deployment. Most of successful implementations seem to happen when funding is made available by public authorities. ECCH in Northern Ireland is so far the only large scale, system-wide initiative with pre-procurement. Interesting cases with private funding are Saludnova (Cooperativa Mondragon) and Rehabitic (Telefonica) in Spain. Mixed approaches (public/private funding) can be seen in some cases e.g. in USA -Home Care and Hospice with Fazzi Associates and Philips, Hytmobile in Spain (MMC and Hospital de la Paz, Madrid), GE Health care in Hungary.

In conclusion, innovation in RMT is happening all over Europe. There are various models for RMT reimbursement that are currently being tested and USA-based recommendation that may be applied in the EU. A sound assessment methodology is being tested in various pilots to collect and make visible appropriate evidence of quality of treatment, clinical outcomes and cost-effectiveness as well as models for predicting patients at-risk. As a consequence the sustained funding of small or large pilots is required if the much needed innovative activities are to bear their much anticipated fruits.

## **6.5 Role of pilots and projects in spurring innovation dynamics**

RMT pilots and projects address innovation at different levels. Based on our review of pilots and projects in EU member states and beyond, we have identified a number of innovation trends which each in their own way may contribute to RMT market uptake. These innovation trends are summarised in this section.

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<sup>185</sup> Based on the DH presentation to be found at:

[http://www.aok-gesundheitspartner.de/imperia/md/content/gesundheitspartner/bund/dmp/evaluation/konferenzberlinjuni2009/dmp\\_konf29\\_30\\_06\\_09\\_goodwin\\_engl.pdf](http://www.aok-gesundheitspartner.de/imperia/md/content/gesundheitspartner/bund/dmp/evaluation/konferenzberlinjuni2009/dmp_konf29_30_06_09_goodwin_engl.pdf)

<sup>186</sup> Docobo presentation at SIMPHS Workshop.

As a result of the over 10-year sustained R&D efforts, examples of incremental innovation in technological components, resulting in new or improved products, include devices (implants, vital sign monitoring, communication devices), software (e.g. intelligent data processing, decision support software), infrastructure (telecommunication networks, protocols, standards) and system integration (integration with EHR). In terms of newest developments, textile-sensing platforms for instance are being used to address cardiovascular diseases. These systems are cost-effective in helping physicians e.g. to monitor cardiac patients during periods of rehabilitation, resulting in decreased hospitalisation time. Finally, by providing direct feedback to the users, they improve their awareness and potentially allow better control of their own condition. Projects that have developed such platforms and devices include HealthWear, MyHeart, Wealthy and Heartcycle.

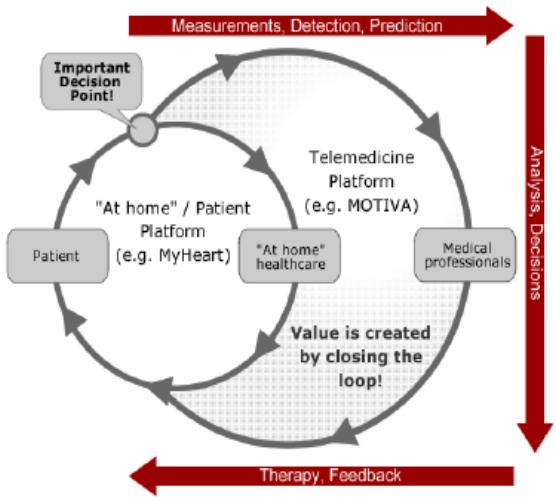
Besides technological innovation aimed at enhancing product features, a number of projects and pilots increasingly address processes, an acknowledgment that there is a paradigm change towards patient-centred services, and out-of-hospital care, which requires a radical change with existing practices. Service delivery in the future will be radically different from today's care services, with its focus on care processes controlled and delivered by medical practitioners. Most of the EU-funded activities as well as pilots we studied seem to increasingly address process innovation, including chronic disease management systems such as intelligent closed-loop approaches. Some examples are provided in Figure 17 below. HeartCycle for instance tackles closed-loop management by multi-parametric monitoring of vital signs and other parameters, physiological and statistical modelling of medication and lifestyle effects, motivating patients towards treatment compliance by feeding back the short- and long-term effects of their treatment. It provides decision support through a patient loop (interacting directly with the patient to support the daily treatment) and a medical loop (involving medical professionals, e.g. alert so as to dynamically adopt the care plan). Closing the loop towards integrated disease management is still to be made though and HeartCycle will use the results of the MyHeart project and the MyHeart clinical heart failure studies to develop a closed-loop disease management strategy.

Other innovative approaches are close to reaching market deployment like Medtronic's "semi-closed loop" -the first diabetes technology to make automated treatment decisions in extreme situations<sup>187</sup>. This system, sometimes referred to as an "artificial pancreas", would emulate a healthy pancreas by using technology that continuously monitors glucose levels and automatically adjusts insulin delivery in patients with diabetes.

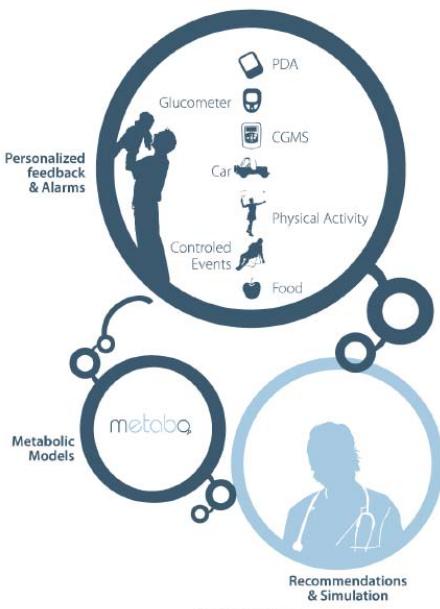
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<sup>187</sup> [http://www.medtronic.com/Newsroom/NewsReleaseDetails.do?itemId=1244301588079&lang=en\\_US](http://www.medtronic.com/Newsroom/NewsReleaseDetails.do?itemId=1244301588079&lang=en_US)

**Figure 17 – Examples of closed loop approaches**



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**17a – HeartCycle closed-loop**

**17b – Metabo long loop**

Source: mentioned inside figure

"Integrated Care" reflects another recent trend in projects and pilots, the goal being "seamless" care for patients with acute and chronic health problems at any point in the health care system. At its broadest, Integrated Care extends to encompass preventive care, social care, care and support in the home, recognising that social conditions impact on health and vice-versa. It imposes the patient perspective as the organising principle of service delivery.

The term "Integrated Care" means different things to different stakeholders<sup>188</sup> though:

- To the user, it means a process of care that is seamless, smooth, and easy to navigate.
- To the provider, it means working with professionals from different fields and co-ordinating tasks and services across traditional professional boundaries.
- To the policymaker, it means merging budgets, and undertaking policy evaluations which recognise that interventions in one domain may have repercussions on those in other domains, and thus should be evaluated as part of a broader care package.

Integrated Care is not yet widely implemented in any EU Member State as currently, in most EU countries there are separate social and health care systems with separate budgets, and different infrastructures that very often do not 'talk to each other'. The lack of communication between the two makes it difficult to reach convergence and current regulatory frameworks do not allow for instance medical personnel to attend medical issues in the social services area.<sup>189</sup> However innovative developments under integrated care supporting the effective management of chronic disease can be

<sup>188</sup> Lloyd J, Wait S.; "Integrated Care. A guide for policymakers"; International Longevity Centre and the Alliance for Health & The Future, London: 2006.

<sup>189</sup> Tunstall assessment (SIMPHS WS minutes: <http://is.jrc.es/pages/TFS/documents/SIMPHS16JuneWorkshopsummaryfinal.pdf>).

seen both in EU-funded activities like the CommonWell project (CIP) as well as in national or regional initiatives like VHA in USA, WSD in the UK or Scotland's telehealth/telecare programmes.

In the UK, a major two-year pilot programme has been announced by the Department of Health to test and evaluate a range of models of integrated care. The programme which consists of 16 Integrated Care Pilots (ICP) is designed to explore different ways in which health and social care could be provided to help drive improvements in local health and well being. Integration refers to partnerships, systems and models as well as organisations crossing boundaries across primary, community, secondary and social care. The pilots<sup>190</sup> vary from developing new models of long-term condition management to help patients choose their end-of-life care, to enabling people to self-manage COPD care. Pilot sites are working across primary, secondary, community and social care services, public and third sector organisations to forge new partnerships, systems and care pathways. A number of these pilots also deal with innovative approaches for chronic disease management.

In terms of new services for a specific disease innovation may open up new market segments or lead to improving existing ones. Especially with respect to ICT-driven innovation the user is able to influence design processes<sup>191</sup> and plays a crucial role as a group<sup>192</sup> in the adoption of new services. There are many examples of what user-centric service innovation means in RMT in particular stemming out of the many Living Labs projects that are being funded by the European Commission. For instance, the LL Skagen and maXi projects both in Denmark or the i-City in Belgium, involving users in testing and evaluating solutions. LL Skagen<sup>193</sup> focuses on services for chronic patients with diabetes. In another example, as part of i-City in Belgium, the IM3 Interactive Mobile Medical Monitoring<sup>194</sup> project, is an interesting example in relation to remote monitoring for CHF patients focused on the context and indirect change by using technology (a first target group of 12 patients with CHF, now being scaled up to 100 patients). Recent developments in the market such as the new "game-care" services recently launched for a specific disease may lead to opening new markets. In this respect, an interesting example is Bayer Didget gadget for Nintendo DS<sup>195</sup> for telemonitoring of diabetes in children that was developed together with the parent of a child with type 1 diabetes.<sup>196</sup>

There is evidence of institutional innovation in the RMT market as in reimbursement provision. In the US, despite strong evidence of RMT benefits, provided by the VHA programme, health care payers still remained resistant to providing reimbursement for remote patient monitoring.<sup>197</sup> After a 2005 study,<sup>198</sup> showed that only about half of state Medicaid programs reimburse for telemedicine, policy options were implemented and the American Telemedicine Association recently made recommendations on reimbursement of home telehealth and remote monitoring (see footnote 182).

In Europe, successful implementations of RMT with reimbursement can be seen in two cases: one in Germany and the other in Lombardy, Italy. In Germany, main providers include commercial

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<sup>190</sup> [http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/documents/digitalasset/dh\\_098912.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_098912.pdf)

<sup>191</sup> Silverstone, R. & Haddon, L.; "Design and the domestication of information and communication technologies: Technical change and everyday life"; in R. Marshall and R. Silverstone (eds.), Communication design: The politics of Information and Communication Technology (pp. 44-74). Oxford: Oxford University Press (1996).

<sup>192</sup> Surowiecki, J. "The Wisdom of Crowds"; Anchor Books, ISBN 0-385-72170-6 New York: 2005.

<sup>193</sup> [http://www.bth.se/ha/halsoteknik.nsf/bilagor/living\\_lab\\_Skagen\\_2008.pdf/\\$file/living\\_lab\\_Skagen\\_2008.pdf](http://www.bth.se/ha/halsoteknik.nsf/bilagor/living_lab_Skagen_2008.pdf/$file/living_lab_Skagen_2008.pdf)

<sup>194</sup> <http://projects.ibbt.be/im3>

<sup>195</sup> <http://www.bayerdidget.co.uk/About-Didget/Didget--Diabetes-Management>

<sup>196</sup> Paul Wessel, the parent, noticed that although his son Luke was constantly losing his blood glucose meter, he could always find his Nintendo Game Boy. It was this observation that inspired Paul Wessel and Bayer to work together to develop the first and only blood glucose meter that connects to the Nintendo DS and Nintendo DS Lite gaming systems to reward children for good testing habits.

<sup>197</sup> Report from SpyGlass Consulting [http://www.spyglass-consulting.com/press\\_releases/SpyglassPR\\_RPM\\_2009.pdf](http://www.spyglass-consulting.com/press_releases/SpyglassPR_RPM_2009.pdf)

<sup>198</sup> 'Telemedicine for CSHCN: A State-by-State Comparison of Medicaid Reimbursement Policies and Title V Activities' <https://www.ichp.ufl.edu/documents/Telemedicine%20in%20Medicaid%20and%20Title%20V%20Report.pdf>

monitoring services (for chronic diseases), non-profit organisations for chronic diseases (such as the Stiftung Telemedizin) and selected hospitals, clinics or GPs who provide outpatient services for elderly people. Vitaphone's system is an example of company –driven initiative that negotiated the inclusion of its system in reimbursement structures with each insurance company separately in Germany (Betriebskrankenkasse), however most of the subscribers to the service pay for the device and the service privately.<sup>199</sup> An example of up-and-running programmes, according to a recent report from the ICT& Ageing project,<sup>200</sup> is BKK Taunus<sup>201</sup> in cooperation with PHTS Telemedizin<sup>202</sup> that provides home monitoring of patients with chronic heart conditions and diabetes. The services have been tested in several states and are now offered nation-wide to all members of the Taunus BKK.<sup>203</sup> As of 2007, 2000 patients with chronic heart problems and 200 with diabetes were monitored through a BKK Taunus telemedicine system at home, in the German state of Hessen.

The experience with HTN Lombardy<sup>204</sup> shows how reimbursement strategies might assist in moving from innovation perspectives to real markets. Following the introduction of a testing reimbursement for a telemedicine service for the home telemonitoring of Chronic Heart Failure patient in 2006, in the next future Regione Lombardia will test a reimbursement for a second telemedicine service- the home telemonitoring of the Chronic Obstructive Pulmonary Disease patient. Two telemedicine projects (Telemaco in a rural area, and NRS in a more populated area) serve as testing grounds (500 patients in 1<sup>st</sup> phase of Telemaco and a few hundred in NRS which will increase in the near future -5 to 6 years to a total of 5 – 6,000). They show differences in the break-up of reimbursement cost due to different cost structures of hospital and telemedicine services.

Other models are experimented in the Netherlands or Northern Ireland. According to the ICT&Ageing project, financial support of smart home technology was available in the Netherlands till the end of 2008. Afterwards, care organisations will be able to ask for reimbursement of extra costs for smart home technology, as far as it is within the giving budget for new housing. The measure will be put in place during 2009 and 2010. After 1st January 2011 smart home technology will be calculated within certain exploitation schemes.<sup>205</sup> In Northern Ireland, the nursing time at night is being used for registering RMT services.<sup>206</sup>

## **6.6 Overview of RMT-related projects and pilots in the EU**

### **6.6.1 EU-funded projects**

The tables presented in the following sub-section give a complete overview of EU-funded research projects sorted per type of activity, i.e. FP5, FP6, FP7, eTen and CIP. For each project, information is provided on the start and end date of the project, the health condition addressed, the main focus of the research, the expected outcomes and the part of the value chain covered by the research.

In summary the following are the main findings (also described in the main part of this report:

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<sup>199</sup> Vitaphone presentation in SIMPHS ws minutes: <http://is.jrc.es/pages/TFS/documents/SIMPHS22AprilWorkshopsummaryfinal.pdf>

<sup>200</sup> [http://www.ict-ageing.eu/?page\\_id=403](http://www.ict-ageing.eu/?page_id=403)

<sup>201</sup> <http://www.taunus-bkk.de/>

<sup>202</sup> <http://www.phts.de/>

<sup>203</sup> [http://www.ehealtheurope.net/news/telemedicine\\_growing\\_in\\_use\\_in\\_germany](http://www.ehealtheurope.net/news/telemedicine_growing_in_use_in_germany)

<sup>204</sup> SIMPHS Feb.09 ws presentation at: <http://is.jrc.ec.europa.eu/pages/TFS/documents/090206MinutesPHSworkshopfinal.pdf>

<sup>205</sup> [http://www.ict-ageing.eu/?page\\_id=509](http://www.ict-ageing.eu/?page_id=509)

<sup>206</sup> SIMPHS WS June 2009 <http://is.jrc.ec.europa.eu/pages/TFS/documents/SIMPHS-AIMBrux090615final.pdf>

1. Fifteen (about 40%) of the 38 projects that we report on are dealing with the part of the value chain that includes monitoring of vital signs and its data transmission; that is not entering in the part that deals with the patient (medical platform).
2. Fifteen (about 40%) of the 38 projects that we report on are dealing with the whole value chain including a medical platform in some cases also including a link to an EHR.
3. In contrast, only 3 projects deal with the monitoring device only (a more recent one researches a multi-parametric monitoring device) and 5 projects with the medical loop without offering any particular device solution.
4. Most of the projects deal with chronic conditions in various forms (mostly cardio-vascular) and only 10 projects (about 26%) deal with elderly people or rehabilitation needs.
5. There is a recent trend to deal with neurodegenerative diseases which has not been researched as widely in the past.

**Table 13 – EU-funded projects**

Name	Type of activity	Start & end date	Health Condition	Focus	Expected Outcomes	Part of the value chain addressed
@Home	FP5	1/01-04/03	Chronic patients (cardiac and psychiatric)	Development of a telemedicine platform for real-time, wireless, remote monitoring of patients	@Home platform comprising wireless medical sensors, patient monitoring module and clinic monitoring module	Monitoring, patient & medical platform
AMON	FP5	1/01- 04/03	-	Monitoring of vital signs using a wearable personal health system	A wrist monitor device, expert system that analyses and monitors the patients' condition, data link, multilingual interface	Monitoring
CHRONIC	FP5	01/00 01/04	- Chronic (respiratory, neurological) patients cardiac,	Development of an Integrated care platform	Development and validation of Integrated care platform in different settings (hospital, home care, emergency, post-surgery)	Integrated care
CHS	FP5	01/00-07/04	Chronic patients (CHF	Telemedicine services for home care	Development and validation of telemedicine services for home care (clinical trials in 5 hospitals in 4 countries)	Monitoring of vital signs, data transmission, teleconsultation

Name	Type of activity	Start & end date	Health Condition	Focus	Expected Outcomes	Part of the value chain addressed
DIAFOOT	FP5	01/01-07/02	Diabetes	Remote Monitoring of diabetic foot	Development of a wireless system, for measuring plantar pressure and temperature for patients with diabetic foot	Monitoring of vital signs, data transmission
E-CARE	FP5	01/00-01/03	Recovery and long-term illness, elderly and people predisposed to diseases	Medical expert system for continuity of care	E-care Platform	Monitoring, data communication, patient and medical interfaces, link to EHR
EPI-MEDICS	FP5	01/01-01/04	Cardiac patients	Mobile system for early detection and analysis of cardio syndromes	Development of a Personal ECG monitor	Monitoring, data communication, link to EHR
HEALTHMA TE	FP5	01/01-06/03	Support to variety of health problems i.e. care of chronic patients, of acute patients and tele-assistance	Personal health mobile system for telecare and tele-consultation	Development of a personal health mobile system	Monitoring, data communication via mobile
HEARTS	FP5	01/02-01/04	Heart diseases	Early alarm recognition and telemonitoring system	Development and testing of a HEARTS System prototype (in a hospital setting)	Monitoring, data communication via mobile, alarm recognition
M2DM	FP5	01/00-01/03	Diabetes	Telemedicine for service care to residential and mobile diabetic patients	Development and validation of a M2DM telemedicine service in 3 sites	Data analysis

Name	Type of activity	Start & end date	Health Condition	Focus	Expected Outcomes	Part of the value chain addressed
MOBIHEALTH	FP5	01/02 07/03	- Disease prevention, diagnostic & management, remote assistance, clinical research	Development of mobile services	Development and large scale trials of mobile services	Monitoring of vital signs
TELECARE	FP5	01/01- 06/04	At-risk citizens, post-surgery, chronic patients	Development of a Telecare service system	Development of a telemonitoring service via mobile	Monitoring, patient & medical interfaces, feedback
TELEMEDICARE	FP5	01/00- 06/03		Open Platform Telemedicine solution	Development of telemedicine solution and testing of a prototype	Monitoring, patient & medical interface , feedback
TOPCARE	FP5	01/01- 01/04	Patients that need infusion therapies, controlled ventilatory support and monitored medication adjustment and adherence control	Development of a telematic Homecare platform	Development and evaluation of a telematic Homecare platform; TOPCARE system has been evaluated in 3 home care scenarios (home ventilation, infusion therapy support, coagulation monitoring)	Vital signs monitoring, communication via mobile, link to EHR,
U-R-SAFE	FP5	01/02 01/04	- Elderly patients with respiratory and/or cardio pathologies	Universal Remote signal acquisition	Development of a Telemedicine service concept	Vital signs monitoring, medical interface, feedback
WEALTHY	FP5	09/02 03/05	-	Wearable health care system	Remote monitoring using intelligent wearable	Vital signs monitoring, medical interface, feedback

Name	Type of activity	Start & end date	Health Condition	Focus	Expected Outcomes	Part of the value chain addressed
MyHeart	FP6	01/04 12/08	– Chronically ill patients disease management is one of the four application concepts (more specifically cardiovascular disease)	Monitoring of vital body signs with wearable technology. Intelligent clothes with an integrated wireless link to user feedback devices and to professional medical centers make up the MyHeart system.	Development of wearable electronics & body sensors AND disease management system	Prevention, monitoring of vital signs , patient platform
HEARTFAID	FP6	02/06 01/09	– Chronic heart failure	Innovative technological platform (HEARTFAID) that integrates biomedical data with EHR systems; provides services such as patient telemonitoring, signal and image processing, alert and alarm systems and supports clinical decision in the HF domain.	Development of HEARTFAID platform	Spanning across whole value chain (from monitoring, patient&medical platform, feedback)
PIPS	FP6	01/04 12/07	– Prevention (one of the case-based scenarios involves diabetes management)	Creation of a new Health and Life Knowledge and Services Support Environment, improving current health care delivery models	New health care delivery model	PIPS agents as interfaces with monitoring devices and for real-time medical advice
OLDES	FP6	01/2007- 2010	diabetes & heart diseases	User entertainment services, through easy-to-access thematic channels and special discussion groups supported by animators, as well as health care services based on established Internet and tele-care communication standards.	The OLDES system will include wireless environment and medical sensors linked to health care providers.	Monitoring, medical loop
Saphire	FP6	01/2006 12/2008	– Cardiovascular diseases	Intelligent health care monitoring and decision support system	Platform integrating the wireless medical sensor data with hospital information systems.	Patient monitoring (by using agent technologies)

Name	Type of activity	Start & end date	Health Condition	Focus	Expected Outcomes	Part of the value chain addressed
HeartCycle	FP7	03/2008 – to 02/2012	Cardiovascular disease (coronary heart disease and heart failure patients), as well as co-morbidities	Research into new multi-parametric bio-sensors and analysis of vital signs (e.g. for the continuous monitoring of blood pressure, blood oxygen levels and heart function; a closed-loop disease management solution serving HF and CHD patients, including possible co-morbidities hypertension, diabetes and arrhythmias.	New Sensors and closed-loop disease management	Multi-parametric monitoring of vital signs, analysing the data , patient loop and medical loop
Chronious	FP7	02/2008-07/2011	The Chronic Obstructive Pulmonary Disease (COPD) and Chronic Kidney Disease(CKD) and Renal Insufficiency	Intelligent wearable platform, based on multi-parametric sensor data processing, for monitoring people suffering from chronic diseases	Platform for chronic disease management	Multi-parametric monitoring, telecare (the system generates alerts in case of invalid medical data or if current activity and behaviour lay outside the well-established activity patterns )
Metabo	FP7	01/2008 - 06/2011	Diabetes	Integrated interoperable platform for the continuous effective monitoring of metabolic levels and parameters, for the generation of predictive personalized models and for their application in care processes for diabetes.		Monitoring of vital signs, management platform; data produced by METABO will be integrated with the clinical data and the history of the patient
Perform	FP7	02/2008-02/2011	Neurodegenerative diseases (e.g. Parkinson)	System for remote health status monitoring, the qualitative and quantitative assessment and the treatment personalisation for people with neurodegenerative diseases and movement disorders, such as Parkinson's.	New sensors, intelligent wearable system to be tested in four phases of experiments	Multi-parametric monitoring
DIAdvisor	FP7	03/08-02/12	Chronic patients (diabetes, insulin dependent type I and II)	Development of a prediction based tool which uses past and easily available information to optimise the therapy of type I	improved diabetes control and QoL using control and risk management theory,	Monitoring, data communication, patient and medical interfaces, system feedback

Name	Type of activity	Start & end date	Health Condition	Focus	Expected Outcomes	Part of the value chain addressed
				and developed type II diabetes. The application is not dependent on specific sensor technologies and can be adapted to technologies like standard strip sensing, minimally-invasive continuous glucose sensors and emerging non-invasive methods.	physiological modelling, identification theory, medical device technology, sensor science and user understanding	
FOR ALL	eTEN	06/2006 – 11/2007	Heart chronic diseases	Market validation of an existing pilot system deployed as a result of the eTEN ICAROS project.	Mobile European pilot of ICAROS	Monitoring, chronic disease management
HealthService 24	eTEN	02/2005 - 07/2006	Chronic diseases (COPD , cardiac Patients) and High risk pregnancies	Continuous Mobile services (market validation of FP5 Mobihealth)	Mobile Monitoring System	Integrated health care services platform
HealthWear	eTEN	11/2006 - 04/2008	elderly people, patients with chronic diseases, convalescent people and patients during their rehabilitation	Remote Health Monitoring with wearable non-invasive mobile system	Market validation of Wealthy prototype system	Monitoring vital signs with wearable mobile system
iCare	eTEN	06/2006 -02/2008	Cystic Fibrosis , asthma, COPD, diabetes, chronic heart pathologies	eService improving mobility and autonomy of patients with chronic disease	Market validation of an eService based on remote auscultation	Monitoring
Linkcare	eTEN	09/2005 – 02/2007	Chronic diseases	Integrated health care service for chronic patients	Pilot evaluation, platform ; a business case for the adoption of novel integrated care services by EU health care systems.	Integrated care model
Health-eLife	eTEN	03/2005 – 06/2006	Chronic diseases	Doc@HOME Home Based chronic disease Management	Market validation of the Doc@Home™	RPM platform for chronic disease management

Name	Type of activity	Start & end date	Health Condition	Focus	Expected Outcomes	Part of the value chain addressed
					service in the context of typical European hospital outpatient clinics	
Interlife	eTEN	03/2005 – 06/2006	Chronic diseases	New health care services, based on a technological platform, for continuous home monitoring service ;the development of a transeuropean network for home care delivery	Contact centre platform	Home care delivery
HealthOptimum ID	eTEN	06/2007 -05/2009	Chronic diseases	Market validation of HEALTH OPTIMUM services (one of them is tele-care)	HEALTH OPTIMUM Deployment phase 1 and preparation for Full Deployment	Telecare
Better Breathing	eTEN	06/2007 – 11/2008	COPD	New care model for COPD patients by ICT- supported home hospital services	Market validation of eServices for the care of chronic patients	New care model
MCC (Medical Care Continuity)	eTEN	02/2005 - 05/2007	elderly persons and patients suffering chronic diseases.	New service for at-home medical care	The market validation of the MCC service will also identify expected benefits, its acceptance by the users and beneficiaries and its effectiveness and efficiency.	New Medical Care service
Dreaming	CIP	05/2008- 05/2011	Elderly and chronic patients (diabetes, COPD and heart failure)	Large scale pilot project to demonstrate new services to support independent living of elderly people	New services for large scale deployment of Dreaming including health/safety monitoring & assistance at home.	Monitoring

Name	Type of activity	Start & end date	Health Condition	Focus	Expected Outcomes	Part of the value chain addressed
Nexes	CIP	06/2008 - 06/2011	Chronic diseases	Deploying four integrated care programs for chronic patients addressing prevention, health care and social support and validating the deployed programmes in large scale RCT studies.	Four integrated care programs for chronic patients	Integrated care
CommonWell	CIP	01/10/2008 -01/10/2011	COPD & CHF (also independent living)	Integrated services to provide independent living and improve the quality of life for older people and those with long-term conditions.	Provision of integrated services for effective management of chronic disease	ICT-enabled health and social care services

*Source: authors' elaboration from data collected on CORDIS database*

### **6.6.2 Overview of pilots in European Member States**

The tables presented in the following sub-section give an overview of the pilots identified in the field of PHS/RMT in European Member States. For each pilot, the overview provides information on the type of activity, whether national, regional or local, the start and end date of the activity, the geographical scope, the focus and type of innovation addressed as well as the number of patients served. Where possible we also provide a short description of the pilot activities.

**Table 14 – Pilots**

Name	Type	Start & end date	Geo. scope	Condition	Focus incl. type of innovation	Nr. of patients	Short description of pilot
Care Coordination/Home Telehealth (CCHT) national programme operated by the Veterans Health Administration (VHA)	national	2003-	USA	The main conditions served are diabetes, hypertension, congestive HF and COPD, as well as smaller numbers with depression and post-traumatic stress disorder.	Telehealth monitoring service	more than 30,000 (mostly elderly) chronic patients currently served	CCHT was developed as part of the VHA's efforts to provide non-institutional care (NIC) services to cater for the rising number of elderly veterans with chronic care needs. First introduced in 2003, CCHT is now a routine NIC service that uses home telehealth and disease management technologies in care management as adjuncts to VHA's existing health information technology (HIT) infrastructure.
Virtually healthy: Chronic disease management in the home	national	2000-2002	USA	COPD, CHF, diabetes & combinations	Home care	790 (out of 8,704) veterans and control group of 772 patients set up to enable cross comparisons, with clinically similar but non-enrolled users.	5 demonstration projects to test disease management principles, the role of the care coordinator and the effective use of technology to maintain veterans in their homes.
NAHCH: National Association for Home Care and Hospice	national	9 months in 2007	USA	Chronic diseases		976 Home care associations	
Whole system long term conditions demonstrator program (WSD)	Regional Large-scale pilot (three areas : Cornwall, Kent and Newham)	2008 -	UK	COPD , CHF and diabetes	Telehealth /telecare	Over 1000 patients/users for telehealth and over 1,000 patients/users for telecare.	Randomised Control Trials, focusing on individuals with Chronic Pulmonary Disease (COPD), Heart Failure and Diabetes, and adults with social care or health and social care needs at risk of hospital admission. The evaluation will look at the impact on emergency admission rates & bed days, patient/carer experience and quality of life and the impact on Primary Care.

Name	Type	Start & end date	Geo. scope	Condition	Focus incl. type of innovation	Nr. of patients	Short description of pilot
Northern Ireland Connected Health Pilots	Regional large scale	2008-	Northern Ireland	Heart diseases, diabetes, COPD, dementia		5000 by 2011	As of July 2008, over 800 patients across Northern Ireland have benefited from participation in a range of eHealth pilot schemes including: Remote monitoring of implantable Cardiac Devices; Video conferencing for Paediatric Congenital Heart Disease; Remote Telemonitoring of chronic diseases including COPD; Diabetes and Dementia; and Telecare projects to support independent living.
Home tele-monitoring in HF patients: the HHH study (Home or Hospital in Heart Failure)	EU	2002-2005	11 centers in UK, PL, I	heart failure	Telehealth monitoring service	461	European Community-funded, multinational, randomized control clinical trial, conducted in the UK, Poland, and Italy, to assess the feasibility of a new system of home tele-monitoring (HT). The HT system was used to monitor clinical and physiological parameters, and its effectiveness (compared with usual care) in reducing cardiac events in HF patients was evaluated.
NHS Lothian	Local small scale pilot	2008-2011	UK	COPD and/or CHF	Telehealth monitoring service	400 patients in Edinburgh and Lothians	Large scale (400 patients) randomised controlled trial conducted by Edinburgh University, which aims to report in 2010.
NHS Swindon	Local small scale pilot	2008-2010	UK	COPD (and diabetes if successful)	Telehealth monitoring service		Telehealth monitoring service to support COPD patients following a small scale tele-health pilot in 2007 that has shown increased quality of life and reduced hospital admissions for COPD patients.
NHS Sheffield primary care trust	Local small scale pilot	2008 (5 months)	UK	COPD	Telehealth monitoring service	30 patients in Sheffield	Telehealth monitoring service to support COPD patients in Sheffield
Home-HF study	local (3 hospitals North West London)		UK	heart failure	Tele-monitoring	142 patients discharged for follow up	HOME-HF study to determine if home tele-monitoring of typical HF patients, recently discharged from hospital, could reduce the risk of all-cause re-hospitalization, when compared with usual specialist care, and at what cost.

Name	Type	Start & end date	Geo. scope	Condition	Focus incl. type of innovation	Nr. of patients	Short description of pilot
HTN (Health Telematics Network) tele-medicine project	Regional large-scale	2006 onwards	IT	Chronic heart failure	Home tele-monitoring of HF patients		HTN and Regione Lombardia participated in several projects with the Ministry of Health, focused on the effects of the use of tele-medicine in the management of chronic HF patients at home. As of 2006 Regione Lombardia introduced reimbursement for a telemedicine service.
Medic4all telemedicine services	company pilot	2008	RO	Chronic disease	Mobile tele-medicine for prevention		Telemedicine services launched by Orange and Medic4all in Romania. The Wrist Clinic, a health monitoring device, is monitoring health indicators like blood pressure information, pulse, EKG, temperature, breathing, blood oxygen levels and other medical parameters. Measurement results are transmitted automatically via Bluetooth to the customer's mobile and then to their online medical record, via the Orange network.
Home care of elderly through tele-monitoring	Company & national pilot	2008-2011	HU	elderly people & chronic diseases (stroke, dementia and depression)	Integrated care		GE Health care and the Hungarian national Health system developed an integrated system for the remote monitoring of the health of elderly citizens, particularly those who suffer from neurological diseases such as stroke, dementia and depression.
Roche pilot in Costa del Sol	Local small scale pilot		ES - Malaga region	diabetes type 2 patients	Remote monitoring for diabetes management	162	
Hytmobile	Local small scale pilot Hospital la Paz Madrid	2009 -	ES	Remote control of anticoagulant treatment (ACT)		13	Clinical trials started on January 2009 and have recruited 13 patients by now. The aim is to get 20% of total ACT patients.

Name	Type	Start & end date	Geo. scope	Condition	Focus incl. type of innovation	Nr. of patients	Short description of pilot
Saludnova	Regional large scale pilot (3 Basque Region hospitals)	2009 -	ES	on chronic disease (in general)	telemetry		Create a platform for Telemetry, (primary and secondary care) not focussing on any specific disease, but rather on chronic patients that may need support during the evolution of their disease. The sensors already connected are: blood pressure, oximetry, cardiac rate, weight, breathing rate, EKG and temperature.
Rehabitic	Local small scale pilot ( Telefónica with Hospital La Esperanza in Barcelona)		ES	remote rehabilitation			Telefonica I+D is currently carrying out a broad-ranging clinical study with real patients having a knee prosthesis. A clinical evaluation of the platform is on-going at La Esperanza Hospital (IMAS), in Barcelona. It includes an interactive software-hardware platform designed to facilitate rehabilitation therapies, carried out remotely, for numerous pathologies and also include a videoconferencing function and access to the Electronic Clinical Record.
Queensland trials telehealth project (AUS)	Regional small scale pilot		AUS	chronic diseases		100	Pilot to improve the efficiency of treatment for patients with chronic disease.- using HomeMed device (100 people in first stage in Queensland). It could become a regular part of Medicare, Australia's health insurance programme.
Health Buddy	Local small scale pilot in 4 NL hospitals		NL	COPD	Tele-monitoring	100 COPD patients	An evaluation of the effects of telemonitoring COPD-patients on aspects of quality of life, care consumption, and patient satisfaction.
St. Lucas Andreas Hospital in Amsterdam-West	Local small scale pilot	2007 -	NL	CHF	Tele-monitoring HF patients supported by NL health insurers	100 CHF patients	Tele-monitoring of HF patients at home using the Philips Motiva system based at the St. Lucas and Andreas Hospital in Amsterdam-West; a similar pilot launched in the US as well.

Name	Type	Start & end date	Geo. scope	Condition	Focus incl. type of innovation	Nr. of patients	Short description of pilot	
LifeStat™ Remote Monitoring and Health Management <sup>207</sup>	International	2008-	Case studies in Canada, Austria and France	Blood sugar levels and blood pressure.	Telehealth monitoring service and feed-back	n/a	tele-monitoring solution combining intelligent end devices as well as the necessary infrastructure to provide remote monitoring and care. The application can also deliver alarms, notifications and reminders to patients and their caregivers using text messaging (SMS), e-mail or telephone interactive voice response (IVR) systems.	
Living Skagen <sup>208</sup>	Lab	2008	Local (experimental)	The Skaw, Denmark	Diabetes	Telehealth diabetes monitoring	Eight participating families (30 users)	Focuses on supporting information for the blood sugar level in relation to food, insulin and physical activity of the diabetic through a laptop supported software

Source: Authors' elaboration from data collected from CORDIS database

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<sup>207</sup> [http://enterprise.alcatel-lucent.com/private/active\\_docs/RMK7526090608\\_TeleHealth\\_Manager\\_healthcare\\_market\\_EN\\_Brochure.pdf](http://enterprise.alcatel-lucent.com/private/active_docs/RMK7526090608_TeleHealth_Manager_healthcare_market_EN_Brochure.pdf)

<sup>208</sup> [http://www.bth.se/hal/halsoteknik.nsf/bilagor/living\\_lab\\_Skagen\\_2008.pdf/\\$file/living\\_lab\\_Skagen\\_2008.pdf](http://www.bth.se/hal/halsoteknik.nsf/bilagor/living_lab_Skagen_2008.pdf/$file/living_lab_Skagen_2008.pdf)

## 7 Annex II: RMT Company Analysis

Annex II focuses on the companies operating in the PHS/RMT market and describes the empirical evidence supporting the analysis presented in § 3.2 and **Section 5** of the core part of this report. The Annex reports the findings of the different research activities (desk research, semi-structured interviews, and experts' workshop) on RMT/PHS company data that, after identifying a large set of 200 companies, focussed on a sample of 50+ companies. In the first introductory section a general illustration of how the work has been carried out is presented (§ 7.1.1 and § 7.1.2), followed by a summary of the main findings (§ 7.1.3). Next in § 7.2 all the findings of the desk research activities, are presented in an integrated overview broken down according to several parameters. In § 7.3 we provide detailed examples from both the desk research analysis and the key insights from the interviews and workshops on the 50+ companies and thus contribute to raise evidence from the field on emerging market conditions and their likely impact. Finally, § 7.4 contains the list of the 50+ companies and a brief profile for each one of them. A set of market indicators and their value (where data were available), were proposed for the 50+ companies in Deliverable D1.1 (see D1.1 Annex II).

### 7.1 *Introduction*

#### 7.1.1 A two step approach

The empirical work carried out for the company analysis entailed two steps. First, we carried out some desk research in the first half of 2009 with the aim to identify companies active in the PHS/RMT market. We did so by reviewing specialised conference attendance lists, market reports and health IT newsletters and websites. A general review of 200 companies helped us identify key characteristics of the PHS market and get a better understanding of its current state of development. Out of these 200, we identified 50+ companies for in-depth research, in order to understand better the dynamics of the market, the various parameters that may define emerging business models, and the activities of different types of players.

Second, in parallel to studying RMT/PHS company data, we contacted representatives of the selected 50+ companies, as well as other experts (e.g. health care providers, procurement etc.) for in-depth interviews and workshop-like discussions (between February and June 2009). The aim was to complement the desk research with more first hand insights from the field such as: a description of companies' role in the value chain, as well as the perception of companies' representatives and experts on market growth, barriers and drivers. Data of qualitative nature were thus collected which enabled us to extract the key insights that have been presented earlier in the core part of this report (§ 3.2 and, especially, **Section 5**). As part of this line of activities we have organised the following events:

- a) A large stakeholder's workshop<sup>209</sup> with ca. 30 participants from industry, health care, insurances, academia etc.;
- b) Three restricted workshops with 3-4 participants each;<sup>210</sup>
- c) One-to-one meetings or phone interviews with experts – i.e. semi structured interviews with 7 experts (note that these exclude the interviews carried out in the framework of country studies, see **Annex III** included as **Section 8** for more details);

<sup>209</sup> See <http://is.jrc.ec.europa.eu/pages/TFS/documents/090206MinutesPHSworkshopfinal.pdf>

<sup>210</sup> See <http://is.jrc.ec.europa.eu/pages/TFS/documents/SIMPHS17AprilWorkshopsummaryfinalrev1.pdf>  
<http://is.jrc.ec.europa.eu/pages/TFS/documents/SIMPHS22AprilWorkshopsummaryfinal.pdf>  
<http://is.jrc.ec.europa.eu/pages/TFS/documents/SIMPHS16JuneWorkshopsummaryfinal.pdf>

### 7.1.2 50+ companies: selection criteria, benefits, and limits of the approach

The 50+ analysed in more detail were chosen according to the following criteria:

- Companies playing a significant role on the PHS market;
- Overall sample covering as many products and services as possible;
- Companies with a clear European focus;
- Overall sample covering all parts of the PHS value chain.

In terms of companies playing a significant role we included in particular those with existing or emerging presence in the RMT/PHS market, taking into account the size of the company, the types of products and services offered, and the level of activity in the market. The term presence in the market is taken to mean that the company is directly active in the RMT/PHS market itself – not in markets that only support or are linked to it (i.e. companies with the most direct participation in the RMT/PHS market itself). We included large companies but also a significant number of SMEs as these play an important role in the market development.

As to products and services, an effort has been made to select companies that offer relevant and economically significant products for various aspects of PHS, thus illustrating the range of products and services on offer. As to the level of activity, the companies chosen are the most active in driving the development of the RMT/PHS market through participation in pilots or projects, alliances, those investing large sums of money in R&D, and contributing generally to innovation in the market.

As to our third criteria, the focus is on companies operating in Europe, i.e. those having their home base or a major part of their activities in the EU27 area. Many large companies that operate predominantly in the US or the Japanese market have not been included in the scope of this review. However, a few companies from outside Europe, e.g. from Israel and the USA, have been included since they have a significant level of activity in Europe besides representing geographical areas with the most developed PHS markets, and hence with some of the most innovative products and business models.

According to our fourth criteria, a variety of companies covering as many parts of the value chain as possible, were included. In some parts of the value chain, many more active companies can be found than in others: for instance, the devices segment is well supplied by a large number of actors, whereas there seems to be fewer companies offering system integration or other high-end services, or the latter may be more difficult to identify. In spite of these differences, we have chosen a sample of companies that represents all the various parts identified. Finally, it should also be kept in mind that this list is only an attempt to characterise the market, and it cannot be fully representative, given the limited sample size.

By focusing on the company location, size, number of years in business, geographical focus areas, the type of products and services these offer and most importantly, the market segments they focus in, and where in the value chain they are placed, we were able to get an overview of the evolution of the RMT/PHS market, the active stakeholders, and the wide variety of products and services on offer.

Our approach of sampling 50+ companies for in-depth analysis has enabled us to identify and categorise the various types of players, and to describe the key characteristics of each category or cluster. The analysis also shows some of the connections that exist between the players and the roles played by each cluster in the PHS value chain, thereby giving us an overall understanding of the composition and functioning of the value chain. Moreover, the

analysis of companies has facilitated the description of a number of business approaches used in the industry, some of which focus on fulfilling the needs of a specific part of the value chain, others on integrating the different parts or the whole of the value chain. The analysis also demonstrates the possibility of utilising existing infrastructure as part of a company's business model: for example by using mobile phone networks for communication and transfer of patient data. The use of existing infrastructure enables the launch of targeted products and services for niche markets, by making it possible for a company to develop new products or services which provides them with a competitive advantage while they can use existing means and technologies for performing more standard functions like data transmission. We have thus been able to create a good overview of the EU market and its general level of development, and acquire an insight into the activities of the players and the industry trends / developments.

The semi-structured interviews and restricted workshops have been useful in complementing the desk research analysis, providing insights into individual companies' strategies and business models characteristics. They have helped us understand better the variety of business models present in the PHS/RMT market and the current state of development of the market, confirming the findings emerging from the desk research and enabling further conclusions. The interviews have also given us insights on reasons for the slow market uptake as well as on drivers and barriers in general, which could not be brought to light by desk research alone.

However, since the analysis is limited to a sample of companies, it is not possible to analyse the market in quantitative terms or make predictions regarding its future development. In addition, it should be pointed out that the availability of quantitative data is often quite limited. Furthermore, the analysis is limited to Europe, and as such cannot be used to make conclusions on a global scale, as important markets such as the USA are not within the scope of the study. In spite of our efforts to include companies from all EU27 Member States, we could only identify relevant companies from older Member States that does not make it possible to draw any conclusions on the new Member States, except for noting an apparent lack of PHS activity in this geographical area. It is obvious that, enlarging the sample of companies and collecting more quantitative data – if they exist – would enable us to draw statistically significant conclusions from the analysis, which would represent a significant improvement in terms of the level of insight we would be able to provide. However, it could be very difficult to achieve, as little data is currently available on the RMT/PHS markets.

### 7.1.3 General overview of findings

A first look at the health care industry gives the impression that a large number of companies operate in the RMT/PHS market; however, this is only partly true. Although the boundaries between companies' activities are sometimes difficult to define, many companies operate in an eHealth or Health IT related area, but relatively few are pure RMT/PHS market players. Narrowing down from Health IT to the PHS market, we have found evidence of companies operating in different segments such as system integration, devices, and remote monitoring, but there are limited signs of the market functioning as an integrated whole.

In addition, many of the identified companies offer relatively few products or services or parts of services for the PHS market, while most of their activities are targeted in other areas. Furthermore, many companies in the market are more generic service providers, for example of imaging and data management solutions, and their activities cannot be classified as PHS. For all these reasons, the PHS market as a whole can be described as relatively immature, and fragmented in the sense that various companies operate in different parts of the value chain that are not necessarily integrated.

Current large players in the health care industry seem to place a 'wait and see' attitude toward the RMT/PHS market. This may be due to its relatively low state of development and high fragmentation, both of which make it difficult for large players to gain significant revenues and leverage economies of scale. On the other hand, the still cautious approach from larger players means that there is quite a large playing field for SMEs. This is confirmed by the significant contribution of SMEs in terms of novel products and services we have found. Even if the economic impact of SMEs remains somewhat limited, their activities are important for driving the market and preparing the ground for further developments.

Large traditional IT and Telco companies provide "traditional" ICT services such as network infrastructure, connectivity and hardware in the RMT/PHS market. Moreover, several have entered the market by expanding their portfolio: some offering PHS (e.g. Bosch, Ericsson, and Orange), some offering hospital information management and system integration services (e.g. Intel, Cisco, Nokia). This active role, taken by ICT companies that are strong players in their base markets, but are newcomers in the Health IT and PHS market, represents an important development as it raises growth expectations. Moreover, many telco companies seek to find new revenue streams as their traditional markets (voice, messaging) are becoming saturated, and PHS represent for them the opportunity to offer new value-added services.

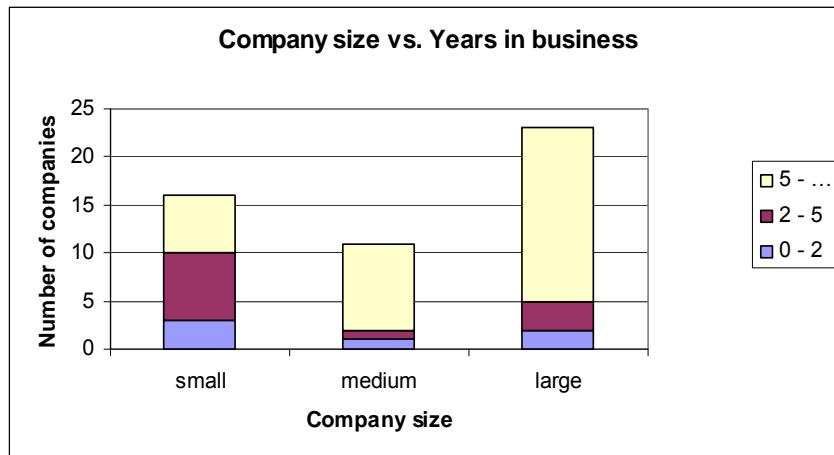
## **7.2 Companies Review: a snapshot of the PHS market**

The evidence gathered through desk research on the 50+ companies has been structured and analysed according to a set of parameters that allowed us to produce several descriptive summary statistics. These are reported in the various graphs and charts below, which are only briefly commented. As anticipated, our sample does not allow deriving any quantitatively based generalisation and, thus, the numbers and comments below are merely indicative.

### **Company Type**

Figure 18 below gives an overview of the number of companies according to their size and how many years they have been in business, showing that the majority of the sampled companies have been operating for at least 5 years whether small or large. The relative lack of medium-size companies in the sample could indicate that right now it is difficult for an SME to consolidate activities and grow in size while large companies can afford to invest in R&D and maintain their 'wait and see' presence in the RMT/PHS market due to their strong market position in other market segments (e.g. wider health IT).

**Figure 18 – Company size vs. years in business**

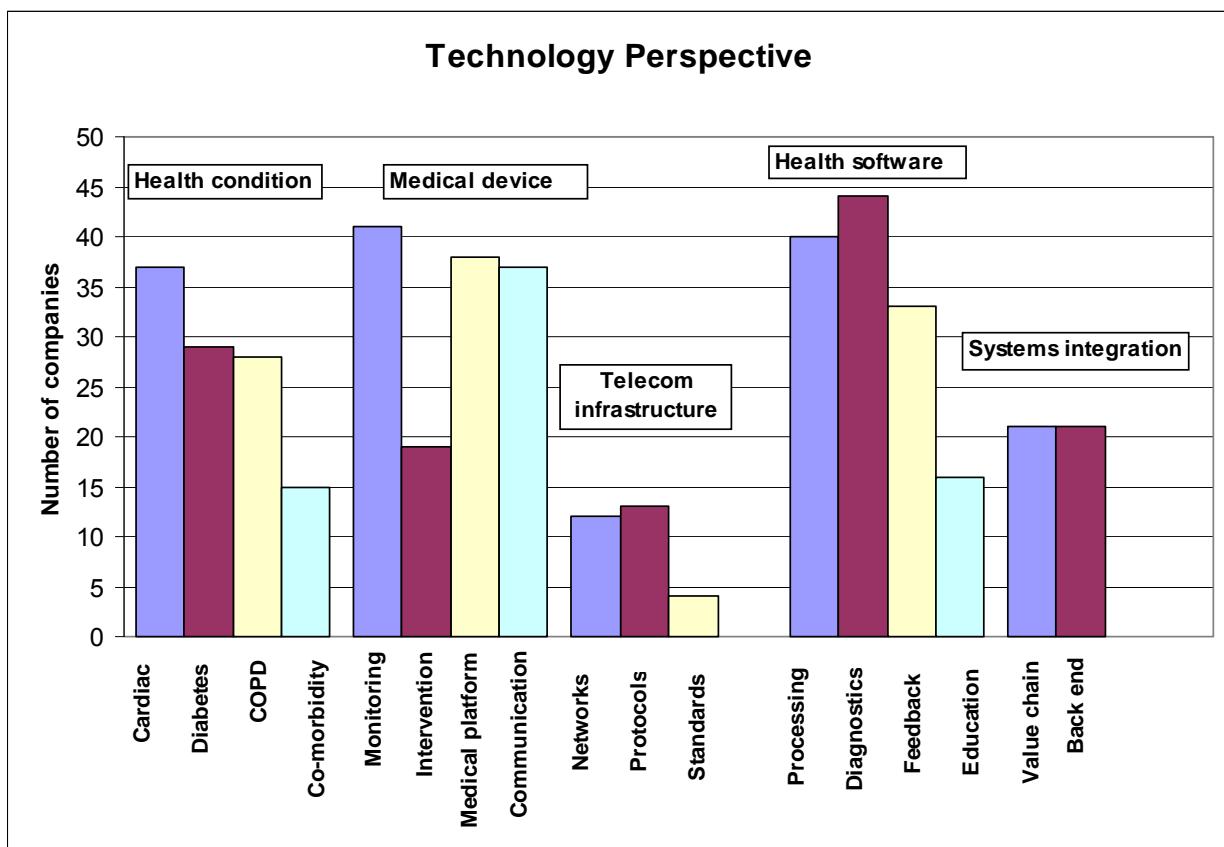


Source: authors' elaboration from collected data

## Technology focus

Figure 19 shows the type of health conditions addressed, the medical device, infrastructure, software and systems integration segments for the companies reviewed. As to the diseases addressed, these include primarily cardio-vascular, diabetes, and respiratory diseases, with a few instances where the co-morbidity of these three main groups of chronic diseases are treated. As to the devices, we can see that monitoring, medical platforms and communication devices are widely offered, but intervention devices are offered by less than 40% of the sample. Only a small part of the sampled companies offer related telecom infrastructure; with regard to the services offered, networks and protocols are offered by about 25%, standards by less than 10% of the sample. Health software, especially data processing and diagnostics, are offered by more than 80% of the companies, while some kind of personalised feedback is provided by slightly more than 60% of the sample. Finally, as many as 42 companies (84%), provide some form of systems integration, divided equally between value chain (though not necessarily all of it) and back-end integration, while education services are the least common.

**Figure 19 – RMT companies and technology focus**



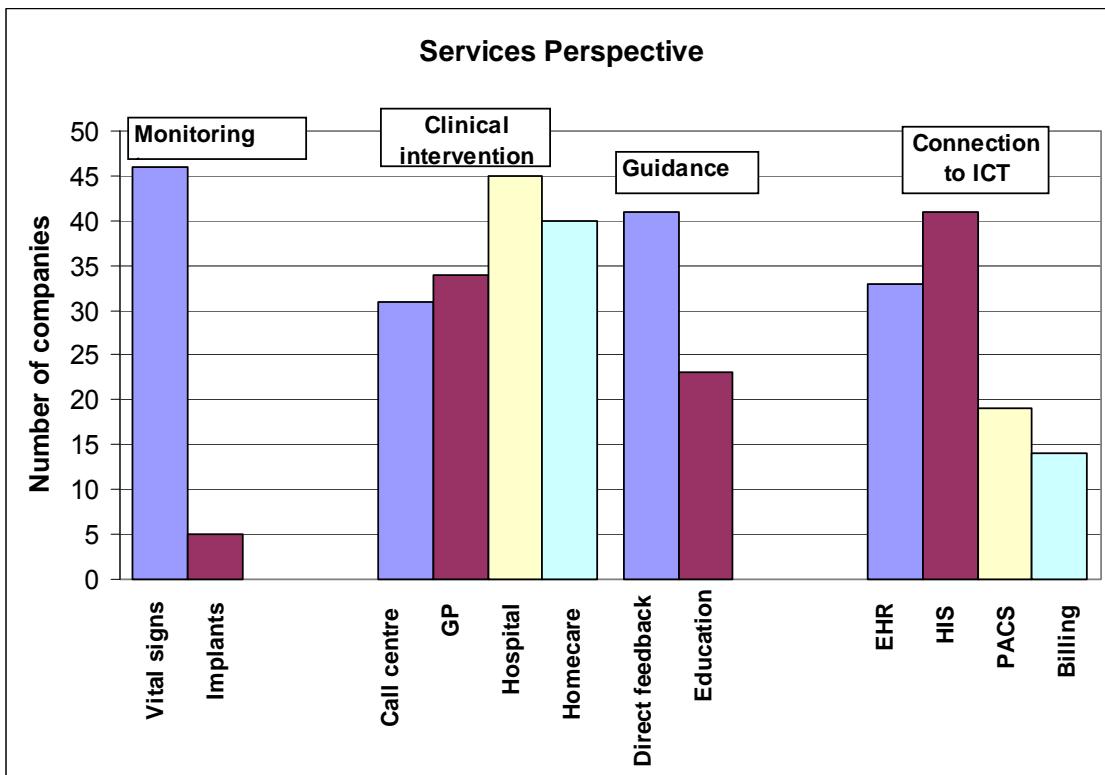
Source: authors' elaboration from collected data

## Service focus

Figure 20 gives an overview of the various types of services provided by the companies reviewed. In terms of monitoring, vital signs are by far the focus of most of the services provided compared to implants, which seem to be a niche market. In the area of clinical intervention, services for hospitals or home care lead even though services to GPs and call centres are also common among the companies reviewed. Overall, every type of connection to clinical infrastructure is serviced by more than 60% of the companies. In the area of guidance

offered by remote PHS systems, feedback is more commonly offered than education. As to ICT systems' connections, the most common service is access to Hospital Information System followed by EHR (electronic health records including patient and clinical records), while PACS (Picture archiving and communications system) and billing connections are less common. One explanation may be that the first two are easier to integrate to new solutions, whereas connections to PACS and billing would require more specialised software.

**Figure 20 – RMT companies and service focus**

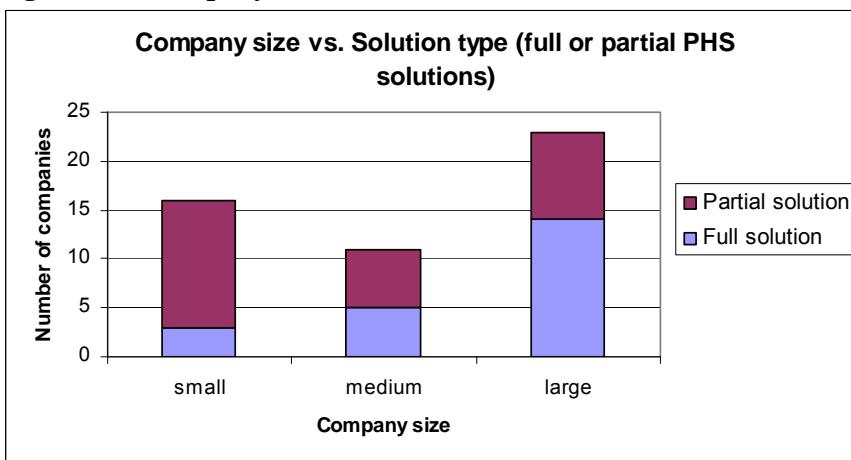


Source: authors' elaboration of collected data

#### Full vs. partial solution

Figure 21, displays the correlation between the size of the company and whether its solution offering is a full or a partial one. A full solution encompasses all parts of the value chain, whereas a partial solution is limited to some of them.

**Figure 21 – Company size vs. solution extent**



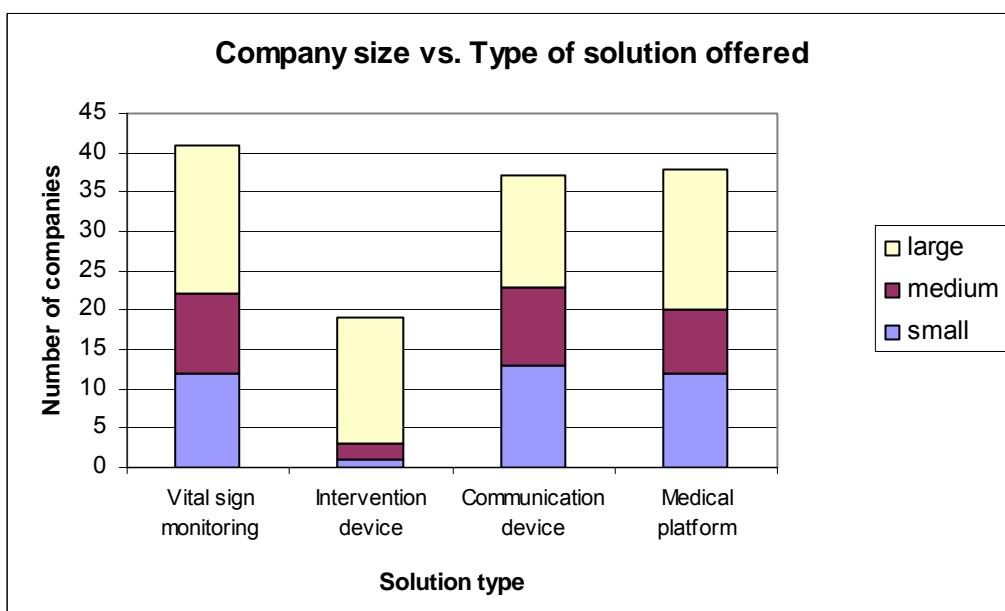
Source: authors' elaboration from collected data

As the chart shows, most of the solutions offered by SMEs are partial ones, although many medium-sized companies also offer full solutions. On the other hand, the majority of large companies seek to offer full solutions. This difference between SMEs and larger players is to be expected: given the larger resources (time, personnel, and finance) and product portfolios of the larger players, they are often better positioned to offer full solutions. Furthermore, the large companies may also have better visibility on the various parts of the value chain, making it easier for them to understand the needs of various stakeholders and thus to develop solutions that encompass all parts of the value chain.

### Type of solution offered

Figure 22 summarises the types of solutions offered by companies of different sizes. This mapping is a relatively rough one, and only counts the companies in the segment of the value chain they are most active in although most companies are active in several segments.

**Figure 22 – Company size vs. solution type offered**



Source: Authors' elaboration of collected data

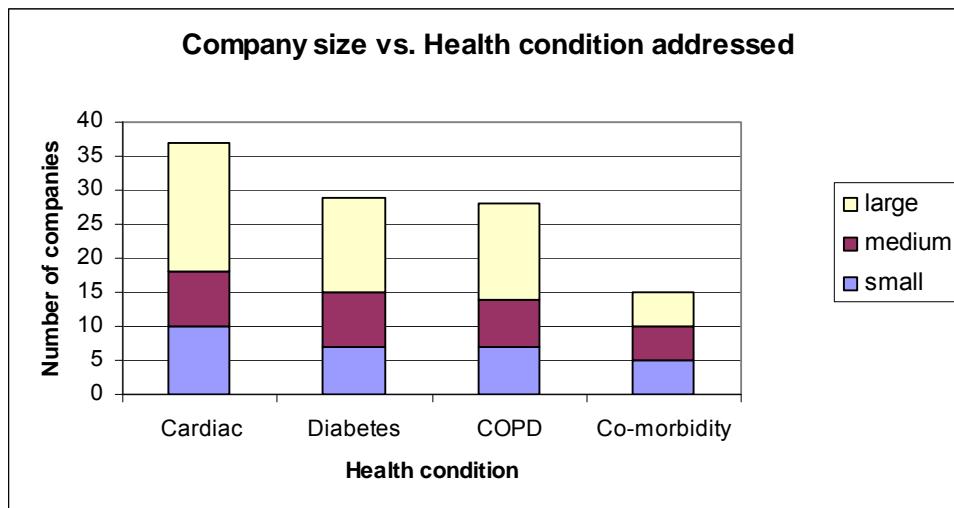
Large companies are visible in all the segments, with a roughly equal number of companies providing different types of solutions. SMEs are visible in three of the four segments, but offer intervention devices only to a very limited extent. As a result of this, the overall number of companies serving this segment is smaller than for the other ones. There may be at least two explanations for this: intervention devices may take more resources to develop and maintain than other solutions (which makes them less attractive to SMEs) and there are more risks (health, legal) involved with providing intervention devices (which SMEs may be less willing to take).

### Health conditions addressed

The chart below, Figure 23, displays how many companies, by company size, address the main different disease conditions. To sum up the results, cardiac conditions are addressed by 70% of the companies, diabetes and COPD by slightly more than 50%, and co-morbidity by 30%. Only a small minority of the sample addresses the other conditions. If we compare

company size and health condition, the distribution of large, medium and small companies seems to be not dependent on the disease condition.

**Figure 23 – Company size vs. health condition addressed**

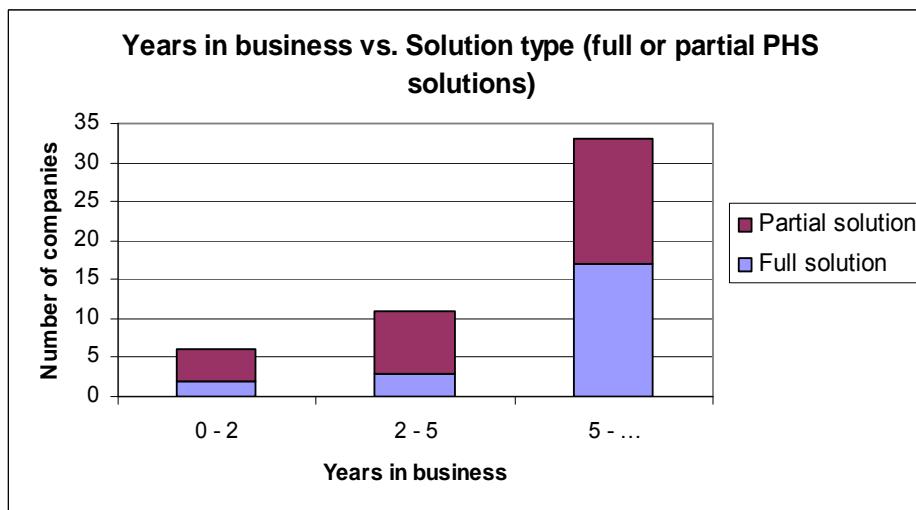


*Source:* Authors' elaboration of collected data

#### **Solution offered vs. years in business**

The chart below, Figure 24, shows the years in business vs. the solution offering of the companies in the sample. More than 30 companies have been in the business for more than 5 years, although in some cases there may be doubts as to whether they have been in an RMT/PHS segment during the last 5 years. If we take a closer look at the data, we can see that the established companies offer full solutions more often than the newly started ones. This is to be expected, given that the more recent market entrants have not yet had the time to develop more sophisticated solutions or to integrate all parts of the value chain with their solution. However, there may be a small bias in this result: many of the more established companies are large ones with more than 500 employees, which means that they have had more possibilities to offer full solutions in the first place.

**Figure 24 – Years in business vs. solution offered**



*Source:* Authors' elaboration of collected data

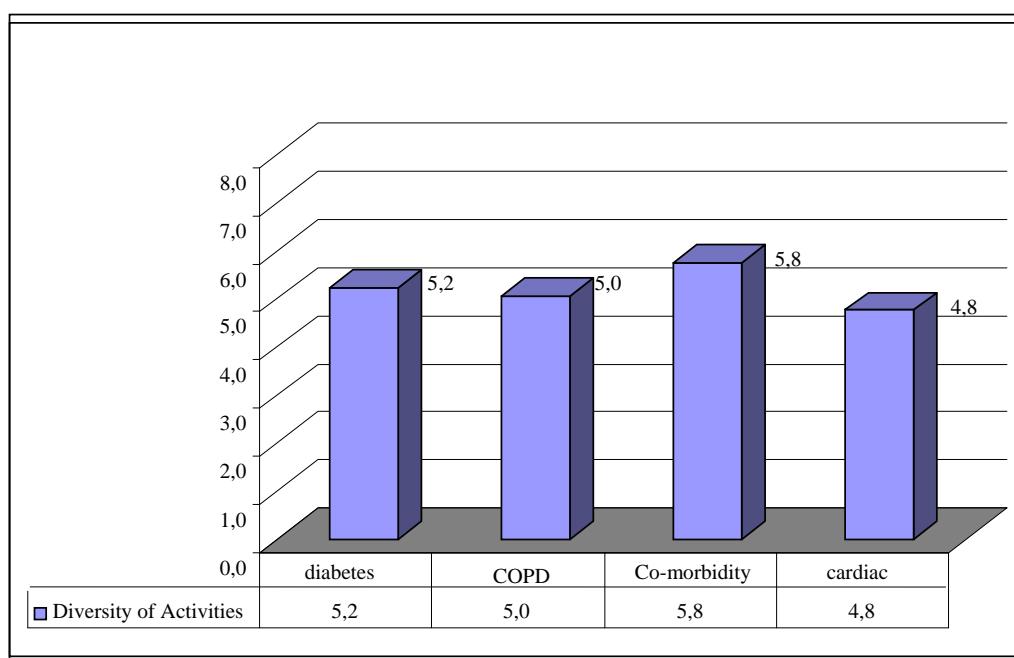
## Diversity of activities

Finally one question of interest when looking at companies on the RMT/PHS market is to understand how diversified their activities are. We have made an attempt to get a quantifiable view of this by composing the following indicator. We counted the activities of a single company together with the conditions addressed by the products or services it offers. As a nominal variable each item has been scored with one point, and we took the following 10 items to start with:

- 4 conditions: diabetes, COPD, cardiac and co-morbidity
- 6 technology perspectives: vital sign monitoring device, intervention device, medical platform, communication device, patient platform and network provision.

The maximal score possible according to the above is 10. The actual indicator is the mean of the values counted for each company, sorted by either health condition or company size.

**Figure 25 – Diversity of activities indicator per health condition**



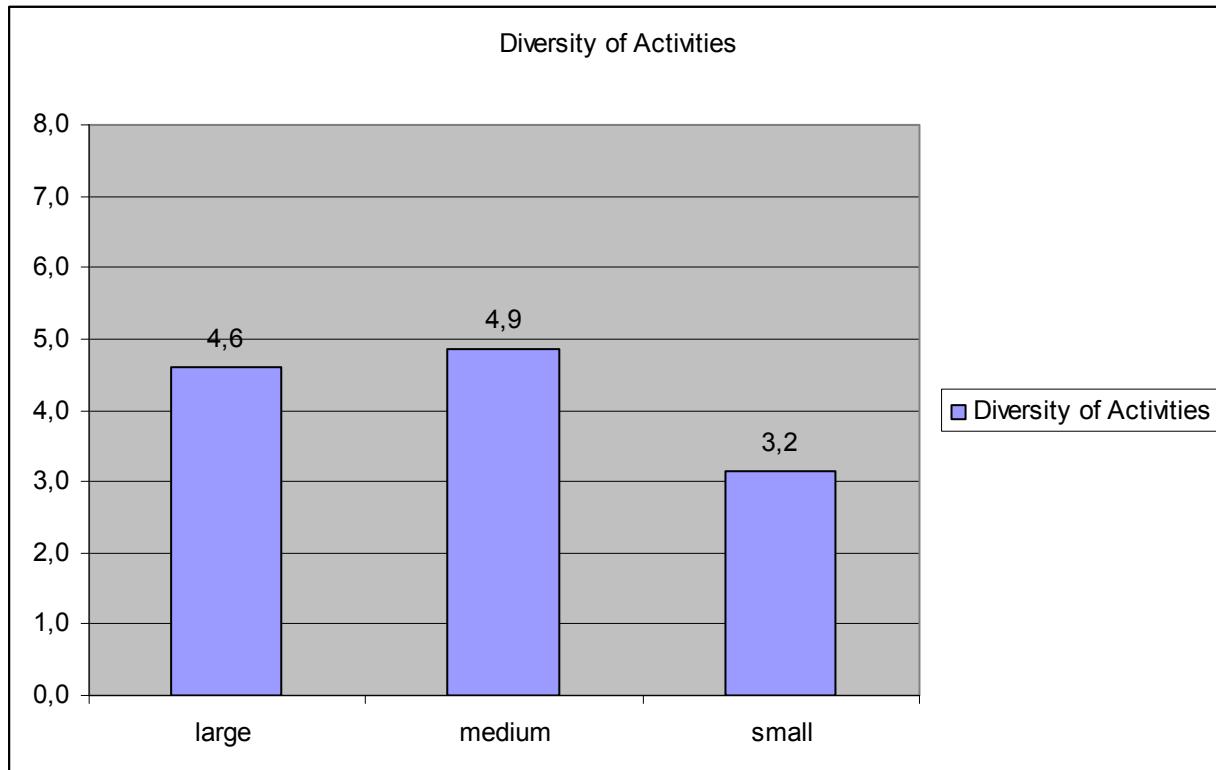
Source: Authors' elaboration of collected data

The outcome, in Figure 25, shows that companies in activities related to cardiac conditions are the most specialised companies. The qualitative research mirrors this finding, companies offering tailor-made solutions for heart patients started offering remote monitoring and other services based on their previous experience in the medical cardiac field. One larger, non-European example would be St Jude Medical, the US based company which strives to utilise its experience from cardiac rhythm management, arterial fibrillation, cardiovascular and neuro-modulation treatments in the development of PHS. A European company following that pattern is the Swiss based Schiller Medizintechnik that is specialised in cardiac conditions. On the other hand companies that offer support for patients suffering from co-morbidity do score the highest in the diversity of activities factor. Also, companies offering solutions related to diabetes appear to be covering a broader spectrum of activities.

If one takes a closer look at the indicator for diversity of activities (Figure 26) one sees that actually small companies are the most specialised. Surprisingly medium sized companies are those which cover most activities, they score slightly higher in the indicator for diversity of

activities than large companies. The focus and specialisation of the small companies can be explained by the limitation in resources. This mirrors as well observations from the qualitative interviews with experts and stakeholders, who pursue an organic growth from one product before diversifying their activities. In order to gain ground and offer a broader spectrum of solutions larger players entering the market often purchase small or medium sized companies.

**Figure 26 – Diversity of activities indicator vs. company size**



Source: Authors' elaboration of collected data

### **7.3 Analysis of the evidence from the field on company strategies, the RMT/PHS market conditions and their likely impacts**

This sub-section analyses the data collected by the desk research and in the field, aiming at highlighting evidence that shapes stakeholders decisions mainly in relation to prospective market conditions and foreseeable implications.

#### **Company size and presence**

In terms of company size and presence, the interviews revealed that small and medium-sized companies, such as for instance Vitaphone, Docobo, and HeartLinkOnline, are generally rather open about their current areas of operation, their actual plans for expanding their geographical base and their market share, if not always in terms of revenues at least in terms of patients served, i.e. number of patients connected to their systems.

As to larger companies like Philips, Honeywell, Bosch etc. while it is much more difficult to obtain a clear picture of where their activities start and stop on the RMT/PHS value chain, it is also more difficult to assess the extent of their presence across Europe as well as get even a rough estimate of their market share. This is likely due to: (a) the confidentiality of the information type, especially in a market that is far from being well established; and/or (b) the

reluctance to give access to market figures that show a very immature stage of development. The situation is similar for telcos or mobile operators active in the PHS market: while some companies have developed clear business cases the extent of their market presence is less obvious. For instance, Ericsson seems to be at the forefront among mobile or telco operators; its mHealth solution was planned (in 2009) to be provided in Belgium, Netherlands, Spain, Portugal, Switzerland, Italy and Singapore.

SMEs are often only active in the country in which they were established and seek to first establish a sound business case in their home base before seeking expansion into further regions. Three examples follow: (a) Docobo, a UK start-up in 2006, is an SME with 14 employees which very recently opened a sales representation in the Baltic, Portugal being next in line; (b) Saludnova, a small company that came into existence at the end of 2008, has established its operation in the Basque Country region of Spain and intends to extend to other Spanish regions before crossing the national boundaries; and (c) HeartLinkOnline, a Belgian start-up created in September 2007, is also working on establishing its business operations in its home base first as is the Belgium based Niko group which acquired both Vitalsys and Vitaltronic, indicating a move into the digital assisted living and home care market.

With slightly different objectives in mind, the multinational pharmaceutical company Roche also started offering remote monitoring solutions in Spain, the country in which it acquired Carpe Diem, an SME that had already started providing remote monitoring services in Spain. In that sense the Roche subsidiary Emminens that resulted from Roche's move into this market is also mainly active in Spain, its home market, for remote monitoring solutions, while expansion into other countries is in the pipeline.

Tunstall with over 1000 employees is a large company that has had long established business in the UK and expanded into telecare solution from its social care activities. Its main market is the UK but it is also active in countries like Spain, Netherlands etc. Its expansion to other countries is closely linked to the health care/social care institutional set-up in these countries.

The relative lack of cross border operation from an SME perspective shows that the market is far from being developed. Besides, most of the SMEs, that we came across, have been created in the last couple of years which confirms the nascent nature of the remote monitoring market. While this may seem in contradiction with the fact that remote monitoring and telemedicine technologies have been available for at least the last 15 years, it shows that it takes a long time for mature technologies to make the step into full market deployment.

In terms of larger companies, as mentioned before, the extent of their geographical coverage is somewhat difficult to assess. For instance, Bosch acquired the well established and widely used Health Hero network serving mainly Veterans of the United States with the rebranded Health Buddy which has the highest installed patient base of the companies in the sample. However the discussions with representative of large multinationals indicate that their market presence is not as developed as they would wish and they are more or less in a waiting position, whereby they may withdraw from the market altogether if revenues do not start to flow as the investment made in RMT/PHS solutions are rather high and may become increasingly difficult to justify in light of weak market sales.

Finally, both with regard to the 50+ companies sample and the companies interviewed, it should be noted that most companies are from Western Europe or USA, with the exception of some key global players originating from Israel (e.g. Aerotel, SHL Telemedicine). There is scarce evidence of companies from prospective EU Member States, except for Vamstec

(Croatia), not only in the RMT/PHS market studied, but in the Health IT sector in general. This seems to indicate that these countries are just a market for PHS and remote monitoring systems implementation rather than PHS innovation centres, though the situation could change.

### **Role of SMEs vs. large players in the value chain**

Looking at the SMEs, we can see that some of them (MeTeDa, SHL Telemedicine, Docobo) provide full solutions, but that most focus on one part of the PHS value chain. This is quite natural, given the more limited resources, technical capabilities and number of staff SMEs have. SMEs therefore typically aim to fulfil the needs of one part of the value chain as well as possible, often based on a novel technological solution or business model, and connect their solution to other parts of the value chain. Furthermore, SMEs often have one key product or set of products, which forms the cornerstone of their business, and which can be modified or tailored to suit different sets of requirements that arise in various use cases and environments. SMEs, such as Vitaphone, often cooperate with larger companies, which enter the e-health market without prior medical knowledge.

We can also see that quite a few of the SMEs utilise existing infrastructure as part of their service offering. For example, companies such as Kiwok, T+ Medical and SHL Telemedicine make use of existing mobile networks as part of their business model. Further, many companies use existing IT infrastructure and hospital information systems as building blocks in their system.

In contrast to the SMEs, large medical companies tend to cover a much wider spectrum of products and services. Some of those (e.g. Boston Scientific, GE Health care, Philips Medical) are able to leverage their existing product offerings to cover all parts of the PHS value chain. What's more, large players not only offer products in all or most of the segments, but often actively seek to connect the various parts of the value chain and make the entire chain more efficient, thus functioning as system integrators. Within larger companies the units responsible for e-health can appear to conduct their business rather like an independent medium sized company, HomMed/Honeywell, for instance, only employs around 100 people; nevertheless such a business unit has the opportunity to tap into the resources of the parent company.

### **Funding**

The main difference in funding approaches is linked to the size of the company. In general, for larger companies, funding is less an issue from the outset as engaging in PHS/RMT are investment decisions based on market returns expectations, like in other domains, but the time it takes for PHS/RMT revenues to start flowing may endanger these investments, as stressed by the larger players interviewed. For example, for a large company like Bosch or Intel or for telcos and mobile operators investment decisions, to participate in telemedicine markets in general and RMT/PHS markets in particular, are made based on market growth perspectives at medium to long term and may be seen as market diversification opportunities. Smaller companies belonging to large multinationals like HomMed/Honeywell, Emminens/Roche or Tunstall a medium-sized company, also enjoy the financial backing from long established businesses and can draw into the R&D resources from the mother company that makes the issue of, initial or ongoing, funding less critical. At the same time, decisions to withdraw funding for such activities may happen at short notice if different priorities appear to be more promising to management and/or shareholders. It is therefore crucial for the PHS/RMT

market that barriers are removed fast if one does not want to risk losing larger players, as some expert put it. This could delay market growth even further or even kill the market, as both small and large companies are required for a healthy, competitive market and PHS/RMT ecosystem to develop. What currently motivates both small and large players to remain active in the market in spite of slow uptake is the societal and economic trends, i.e. projections on the exponential growth of chronic diseases, ageing of EU population and depleting public health care resources (both human and financial).

The situation is very different for SMEs. Some of the SMEs, we talked to, have not come across too many difficulties in securing funding to start or pilot run their activities: Vitaphone for instance, has received the financial backing from one of the co-founders of SAP, which allowed for the initial investment in infrastructure and operation or HeartLinkOnline which also managed to convince initial investors. Docobo, on the other hand, reported having had to struggle to secure funding, surviving on EU Framework programme funding in addition to its CEO having had to renounce any form of emolument for the first year or two of operation. The case of HTN in Italy, a company born in 1998 out of the Boario Home Care project, a regionally-funded project, is also typical of the way SMEs or young spin-offs have to struggle to get their activities off the ground. HTN needed significant funding at the start to develop its IT Platform and had to rely on cash flow from pilot and projects for some years. Today cash flows from projects still finance a large amount of its operating activities and this situation may be reversed in 5 years from now, according to its CFO depending on the pace of reimbursement uptake as well as type and number of services reimbursed. In other words, by then R&D and operation would be funded mostly by reimbursement. Saludnova, a spin-off from the University of the Basque Country mentioned earlier, is part of Cooperativa Mondragón, a group of 264 companies from various sectors whose promotion centre aims to support the development of new locally based businesses in different areas. Although its funding is currently secured, Saludnova reported having to work hard on convincing its counterparts to plan funding for the following years so as to ensure continuity of its operation.

Eventually larger players foresee a consolidation process on the PHS market with a few large players and a number of small players. Big players are needed as small companies would not be able to scale up to the same extent. The picture may look like that of the automotive industry, with large players and a myriad of local/smaller providers and funding may not be a problem in this case. As a result, the decisions for either a large multinational, a well established mother company, a venture capital firm or a private investor to financially commit to the creation of business operations in the RMT/PHS market is linked to the availability of evidence as well as to the general health and demographic trends in Europe:

- The projected increase in chronic disease occurrence across Europe (and worldwide)
- The financial burden this will impose on health care systems
- The proof of concept that remote monitoring technology works

These have all been mentioned as reasons for going into business in that market segment.

### **Health conditions addressed**

While directly addressing various health conditions, almost all companies operating in the market also offer services for the management of chronic diseases. This can be explained by the fact that these conditions are becoming increasingly common due to aging populations and lifestyle issues, are predicted to increase exponentially over the coming decade and as such represent significant market opportunities.

The chronic disease management systems are often linked to hospital information systems, and to the patient data clinicians and general practitioners have access to. These services generally focus on long-term patient management and care, often through specialised disease management software and patient information databases. Another type of service, from a health condition perspective, is the broad spectrum of tele-consultation, tele-nursing, tele-radiology, and other remote treatment or consultation services. They are enabled by new telecommunication services, which make it possible to efficiently transmit and process patient data. Remote consultation services in the case of limited patient mobility are very valuable.

When considering remote monitoring and management of chronic conditions, companies like Vitaphone focus on delivering the full value chain of products and services for chronic heart failure. But, most others, including both SMEs and larger companies offer solutions that can be applied to a varying degree to each of the three most common chronic conditions, namely CHF, diabetes and COPD, with asthma, mental disease and co-morbidity rapidly becoming important segments. Some market players further indicated interest in the weight management or wellness part of the market: Ericsson is one example. Their product offer is targeted at lifestyle as well as chronic diseases and besides applications for hospitals (mobile discharge), home and elderly care and public health care (mobile disease management), it also addresses pharmaceutical companies with solutions for mobile clinical trials. Companies like St Jude Medical that operate on the cardiac implant market are for logical reasons starting to develop remote monitoring solutions with implants on the cardiac segment, which they see as a niche market at the moment. On the other hand Medtronic, a leader with cardiac implants, which has a long experience with insulin pumps and diabetes monitoring targets both heart and diabetes remote monitoring.

Moreover, interviews revealed, the interest of PHS/RMT players in the wellness part of the market (not obvious from the desk research). Some of the products available on the market may already be marketed with this broader target customer group in mind. However the bulk of the companies interviewed have not tackled this segment yet, focusing on getting their business case right with RMT of chronic conditions first. What may happen in the future though, as stressed by some players, is that the RMT market gets a push from the consumer side, i.e. from the more general wellness and prevention market which is in a much better position to become a mass market than RMT.

### **Targeted segments in the value chain**

Both small and large companies interviewed seem to be capable of covering the full value chain of PHS/RMT in terms of offered services (see Figure 8 on page 34 of this report). The interviews revealed that most if not all companies considered, provide full and adaptable solutions, i.e. from providing patient devices to ensuring connection from the home to the medical platform and the various clinical systems. Only in few exceptions RMT providers run their own call centre, a function which is normally outsourced. The data communications happens through existing infrastructures, and partnerships with specific operators, especially in case of mobile applications, are not uncommon. Where the offer from the various companies differs most is probably in the service provision segment. Companies in the RMT market seek to provide distinctive features so as to gain a competitive edge e.g. by offering more and more sophisticated analytical tools, user-friendly patient or medical platforms, or putting the stress on the mobility features of their offer.

Looking more precisely at the type of products and services available in the PHS market, based on the 50+ company sample, we can point out several "clusters" of companies. First of

all, many companies focus on the remote monitoring segment (e.g. Aerotel, Biotronik, Bmeye, CardGuard, IEM, Kiwok, SHL Telemedicine), providing systems that include various measurement devices as well as vital signs processing and analysis tools. Some of their products only process and transmit the patient data and vital signs, but more often these products also enable some kind of vital signs analysis, usually taking place at the clinic or the hospital. The key health segments addressed by the remote monitoring devices, and the wider personal health systems sector, are the cardiac, diabetes, and COPD conditions. Furthermore, many vital sign monitoring products can be used to monitor several of the chronic diseases (only the niche market of implantable cardiac devices is a truly separate market). Overall, the level of competition in the remote monitoring market is already quite significant, but there seems to be potential for further growth, as there are no signs of saturation.

A second cluster of companies consists of those that offer different patient data management solutions (e.g. Docobo, GoodIT, T+ Medical, Viterion). Most commonly these solutions consist of a software package that can be linked to hospital information systems; in some cases the software also connects to electronic patient health records. There is less direct evidence of connections to PACS (image management) and billing systems, though many products either enable this connection or can be tailored to include it. Nearly all companies that offer data management solutions seek to improve the current information management process by making it more efficient, allowing for better updating and/or consolidation of patient data thus improving the overall patient data management process.

A third, related cluster is made up of more conventional ICT providers. Several companies (e.g. InterComponentWare, ISPro, Vamstec) offer ICT and communications solutions specifically for the medical industries, consolidating data from various sources and enabling a more efficient flow of information. In some cases, the dividing line between patient data management and ICT infrastructure provision is blurred; this is understandable, given that consolidating patient related information involves both the management of clinical data and improving the communications infrastructure.

Finally, we can also identify a cluster of telecommunication companies that have entered the PHS market. Some of them have developed new business models, whereas others merely bring in their communications capabilities (which are not analysed in this report). Organisations such as Orange are an example of the former: they act as a service provider that offers turn-key communications solutions for the lower layers of the network. This is a new business for telecommunications companies that require new knowledge and expertise. Moreover, some communications companies (Ericsson, Intel) are becoming active in the PHS market itself by offering information consolidation and data management services. These are aimed both at professionals (clinicians, general practitioners, hospitals) and patients, with specific features tailored to both segments. As for Nokia, one of the main reasons for its interest in the PHS market seems to be the fact that its smartphones offer a platform for transmitting patient data. For the moment, we have not been able to find evidence of Nokia directly offering health related products or services. However, Nokia has been very active in financing small companies in PHS (eHIT, LifeChart). Nokia is also a promoting member of Continua Health Alliance.

### **Products, services and technical solution**

Most of the companies studied offer a mix of products and services that are often characterised by a high degree of flexibility. In other words depending on the specific needs of the health care provider for whom they implement the remote monitoring system, their

offer will be tailored to each case delivering as much or as little of their solution as required. This is the case for both SMEs and large multinationals.

One exception may be Vitaphone that provides all elements of the value chain from the equipment on the patient's side to the call centre manned by their own cardiologists. Their service provision ends at the point of care when the patient is handed over e.g. to a hospital or when emergency services have to be involved. Most companies consulted do not provide call centre facilities, but subcontract that function if needed. Their service offer therefore stops a little earlier on the value chain.

### Patient devices

All the companies provide one or several devices to be used by the patient. These devices can take different shapes depending on the condition to be monitored and whether they measure vital signs or collect qualitative information. Examples include:

- ECG belt (from 2 to 12 points) for cardiac signs measurement (e.g. HeartLinkOnline)
- ECG card worn around the neck for registering ECG (e.g. Vitaphone)
- Peripheral devices such as weight scale, blood pressure cuff, blood glucose meter, pulse oximeter, peak flow meter, and PT/INR<sup>211</sup> (e.g. HomMed, Saludnova, Tunstall, Ericsson), packaged per chronic condition and connected to a monitor (HomMed, Tunstall) or mobile phone/PDA (Saludnova, Ericsson)
- Handheld monitor capable of reading vital signs (Docobo), through the use of built in sensors, which for example record twenty-second rhythm strips of ECG, as well as capable of collecting other qualitative data
- Handheld or laptop style monitors which: (a) enable a qualitative assessment of the patient health status, by for instance displaying questions which patients can answer by pressing buttons or using a touchscreen; (b) may be equipped with audio/video capabilities allowing for educational content to be diffused; and (c) may be capable of connecting to vital signs measurement devices.

While the above are proprietary solutions, some companies like HTN use devices from manufacturers like Aerotel or CardGuard; Docobo also provides a connection to third party devices alongside its HealthHub. Together with the measurement of vital signs, most devices facilitate the collection of qualitative information, whereby questions are displayed to the patient who can key in simple answers (e.g. yes/no). Qualitative data collection modules are generally based on decision-trees that constitute the intelligence of the system. This goes both for devices offered by small companies (e.g. Saludnova or Docobo) and large ones like (e.g. HomMed's monitor, Bosch's Healthbuddy, Intel's Health guide). The systems typically draw on a vast pool of questions that can be tailored to the needs of a specific condition in a specific health care setting and in the required language.

### Processing/Communications

Once the measurements are registered on the patient's device, they need to be transmitted to a server for further processing. In some cases like for Saludnova the data is processed in a mobile device or PDA locally, thanks to the intelligence built in the software with which the

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<sup>211</sup> PT/INR is the prothrombin time (PT) measured as prothrombin ratio (PR) over international normalized ratio (INR).

mobile phone or PDA is equipped. In the case of HeartLinkOnline, a smartphone gateway is used which has a GPS function so as to locate the patient while the intelligence is built-in in the measuring device i.e. the chipset on the ECG belt has an algorithm which cardiologists can pre-program by indicating which ECG exception of the patient should be immediately transmitted to the clinic's permanent cardio-monitoring centre.

The data transfer from the measurement device to a mobile, PDA or gateway is often done via Bluetooth<sup>212</sup>, but also via cable, infrared and increasingly through Near Field Communication, which does not require power like Bluetooth and is faster/easier to set-up. Further transmission from the gateway to a server or central database happens via fixed line, Internet or mobile networks. From then on, the data may be routed into clinical information systems, connected to EHR or other applications. In case the data transmitted exceeds given thresholds, an alarm is triggered and emergency services are alerted.

A number of companies in the remote monitoring market team up with Telco or mobile operators, as is the case for Saludnova that works exclusively with Vodafone. Telefonica is another example of a Telco cooperating with remote monitoring solution providers (e.g. Costa del Sol remote monitoring project). Roche originally worked on exclusive terms with Vodafone in Spain but opened up to all Telco in 2005. Orange recently launched a remote monitoring initiative in Austria in partnership with remote monitoring solution providers while Ericsson's mHealth solution has been tested in a number of trials since 2001.

#### Service provision

Services provided generally include the storage/processing of data, the provision of decision support tools and applications as well as some form of technical support and training. Docobo does so through its clinical database Doc@HOME that can be accessed by clinicians via a web interface. It is based on open standards and is fully interoperable so that it can connect to EHR. Saludnova's offer includes service maintenance of the system e.g. web services, alarms management, medical personalization, ontology in real time. Tunstall provides similar types of services. Roche also provides access to its database via web interface that allows the viewing of patient data and generation of graphical representations of the data. Bosch's HealthBuddy system also enables clinicians to create trend charts and patient reports. The Intel® Health Care Management Data Services and Application Suite enables the clients' IT departments to deploy/manage the telehealth programme within the health care organisation. HomMed/Honeywell provides different level of service depending on clients' requirements.

Except for Vitaphone and HTN that run their own call centres staffed with specialists, most companies outsource the medical/specialised part of the service provision or cooperate with a university clinic or hospital. This is the case of HeartLinkOnline that works with the Belgian Imelda (Bonheiden) hospital (a renowned hospital in the domain of cardiac diseases), which staffs a medical call centre, located in the cardio centre of the clinic, that has been monitoring heart patients for over 10 years. That cardio centre receives alarm data from HeartLinkOnline patients. Saludnova can provide access to a medical call centre and add further services upon request through the involvement of external parties. Intel in contrast has set up a team of clinical experts to provide professional services to health care organisations, facilitating the integration of the PHS into their current disease management programs and care settings.

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<sup>212</sup> Bluetooth is also the first connectivity standard accepted by the Continua Health Alliance.

## **Market focus, market size**

Different strategies are being followed depending on the company offering and the country concerned. Specifically the health and social care set up play an important role for companies when defining their strategy to deploy remote monitoring services in a given country.

In Germany, Vitaphone focuses on cooperating with insurers (Betriebskrankenkasse) but also targets private patients who pay for the service from their own pocket. In Spain, Roche works with hospitals i.e. the public Health care. Roche actually uses remote monitoring services as a marketing tool to increase its market share of diabetes strips; the sales representatives for diabetes strips promote the remote monitoring solutions towards hospital managers. Saludnova also built its business model around its close cooperation with public hospitals, but deliberately does not address private insurances. Tunstall, a company with a long history of social care/telecare, works closely with social care providers in the UK and has started establishing similar connections with social care services in Spain.

The strategy from larger companies like Intel, HomMed/Honeywell or Bosch is, however, less clear. Both the health care and consumer markets seem to be within their possible focus. Nevertheless, as reimbursement is mentioned as a key issue by some of these players, i.e. a condition for market uptake, they are likely to pursue negotiation with health and social care actors as well. On the other hand such players also foresee a market push from the consumer side. Their product offering seems to be capable of fitting both types of market segments.

While some companies focus on one condition only, such as heart for Vitaphone or HTN, diabetes for Roche (since Roche is a market leader in diabetes diagnostics), others like Saludnova, Intel, Bosch, HomMed and others cater for any of the most common chronic diseases. Although more empirical data would be desirable in order to draw sound conclusions, at first sight it seems that the market focus of a company is closely linked to the following elements:

- The country of origin of the company seems to influence the way a company develops its business model focusing on some specific stakeholders e.g. health care vs. social care vs. private insurance
- Whether a company covers the full value chain including manning a specialised call centre seems to limit the focus of the activities to one particular condition e.g. only cardiac disease management (HTN, Vitaphone). This can be explained by the complexity and costs of running an in-house medical centre with several specialties.
- A further element explaining the business choices made by companies on the remote monitoring market is the origin of the company in terms of medical vs. technology development. In other words, when a company is created around a technology, its offer is likely to be wider as technology can in principle be applied to various diseases. On the other hand when a company originates from the medical sector, (e.g. Vitaphone is co-founded by a cardiologist), or the company was specialised in one condition before providing remote monitoring applications (e.g. St Jude Medical, Roche), then its offer will logically concentrate on that one condition.

In terms of market size, it is very difficult to access reliable and comparable data. Smaller companies tend to be more open about the number of patients they serve, as well as on revenues or service pricing in some cases. For example, Vitaphone declares to have more than 30,000 users in at least 3 countries, HTN serves some 500 patients from 12 hospitals in Regione Lombardia and SaludNova have an annual budget of 150,000 Euros for as many

patients (70 currently, 2009) as possible served by 2 hospitals in the Spanish Basque region. For larger companies, it is both unclear which EU countries they actually operate in and how many patients they serve through remote monitoring services, as opposed to other telehealth services they may run. For example HomMed declares to serve 40,000 patients worldwide. In general, small and very small companies especially those which started operating a year or two ago generally have small-scale activities. Large companies or those that started earlier on the remote monitoring segment tend to have a wider customer base as could be expected.

## Business models

Most of the evidence presented in this section, are relevant for defining emerging business models. A separate EC funded study, the Rand/Cap Gemini report on "Business Models for eHealth",<sup>213</sup> dealt with this topic and elaborated a conceptual and theoretical framework for defining business models in this area. From this report we can recall that, although "a common definition on the notion of business models" is lacking, their key elements include:

- "Description of key components defining a specific business idea",
- "Roles and relationships among a firm's customers, allies and suppliers, major flows of product, information and benefit for all participants",
- "Tools that links the technical potentials of an organisation to the realisation of full economic value".

In addition, the Rand/Cap Gemini report stresses that the current approaches to the analysis of business models are inward looking, not taking account the dynamics of factors outside of an organisation. The report considers these approaches nevertheless interesting in the area of eHealth where a business model is required to orchestrate the interests of the various stakeholders involved in pursuing a specific strategy. The report concludes by underlining the difference between strategy and business model where a strategy is about why an eHealth system should be implemented by a health care provider, while a business model is about how the system is to be implemented.

All the supporting evidence presented here can be compared against the model presented by the Rand/Cap Gemini report, and while we have not provided a full analysis of business models according to one or the other definition, we have sought to identify the various dimensions that characterise the companies interviewed and the determining factors for success or failure.

## Revenue streams

Very little information could be gathered on how remote monitoring products and services are priced and how revenues are generated. Further information can be found in the country studies (see Annex III, **Section 8**).

Some companies seem to offer devices for a lump sum and services for an affordable monthly subscription, thus also enabling private patients to use the services along side those that are members of insurance schemes. Other companies have concluded agreements with certain hospitals and costs are borne by the public health care system. Vitaphone indicated that revenues come from: (a) the device provided to the patient for a cost of approx. 200 Euro and

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<sup>213</sup> "Business Models for eHealth", Rand/Cap Gemini, June 2010, published by European Commission, last accessed at: [http://ec.europa.eu/information\\_society/activities/health/docs/studies/business\\_model/business\\_models\\_eHealth\\_report.pdf](http://ec.europa.eu/information_society/activities/health/docs/studies/business_model/business_models_eHealth_report.pdf)

a monthly subscription fee of 10 Euro which covers the service provision consisting of connecting the patient to a central registration centre. The patient sometimes pays this privately, in other cases this cost is reimbursed by an insurance company.

Ericsson's model is based on sharing the benefits of early discharge along the value chain, as is the case with the German Red Cross Hospital Group, Munich. The hospital bears the investment (and optionally the running costs), as it will save on each early discharged patient and distributes parts of the savings to members of the value chain (i.e. doctor, Ericsson, health service provider, operator). Furthermore, Ericsson has developed a process for identifying the business case for m-health (mobile health) solutions; it identifies quantifiable business case variables, measures them, puts them into scenarios, and develops a cost calculation and a model to distribute the costs and benefits over the value chain stakeholders. This last step is essential to a fair distribution of costs and benefits (i.e. it prevent that some parties bear the costs but do not get the benefits while others receive benefits even though they bear no costs).

Saludnova negotiates yearly contracts for providing services for a given number of users with each hospital in the public health care system. Dependency on health budgets makes it difficult to secure steady revenue streams.

While no figures were given by most companies, their revenues may be derived from comparing the cost of providing and installing devices, developing software, processing and storing data as well as carrying out technical and clinical triage for the provision of care services, and providing call centre services.

## **Reimbursement**

Reimbursement is a teething issue for market players on the PHS/RMT market. The difficulties encountered in relation to having products and services taken up in a reimbursement scheme are one of the most important factors slowing market uptake. Only one company (Vitaphone) mentioned having private patients paying themselves for the RMT services although this is not the main bulk of its client base. All companies interviewed mentioned having agreements with public health care authorities or with health insurances.

However the level of reimbursement is often not sufficient to sustain a business as underlined by SMEs like HTN and Docobo. The extent of and modalities for reimbursement of remote monitoring depends on the country where the services are deployed and the health care and social care settings. (see Annex III: **Section 8** on Countries study for more details). The lack of trust in or awareness about evidence on the benefits of PHS/RMT solutions on the side of payers contributes to this state of play. In addition even when there is a will to implement PHS/RMT solutions in e.g. a public health or social care settings, the inadequacy of the legal framework makes it either impossible to implement these solutions, or requires to circumvent the system until a permanent solution is found.

## **Evidence**

While there seems to be a lack of awareness about evidence among payers and health care providers on the benefits of PHS/RMT, many of the companies interviewed stressed that there is more than sufficient scientific evidence of the benefits of remote monitoring around. These companies have often commissioned their own study to prove the benefits of their solution or have cooperated with research institutes to bring evidence about the benefits of remote monitoring solutions (see paragraphs 9.3 to 9.6 on scientific evidence for more details).

However, there is very little being done from the companies' side to raise awareness on the bulk of evidence to the medical professionals (usually the primary care medical professionals) and even less towards the patient. The issue is clearly about disseminating scientific results and making such results more comparable, promoting a common approach in that field.

## Certification

A couple of companies referred to certification as an important tool to convince insurance companies and other parties of the benefits and quality of remote monitoring systems. In particular Vitaphone has invested in setting up a quality infrastructure for the managed care model with the German VDE (Verband der Elektrotechnik, Elektronik and Informationstechnik) that resulted in the production of a Quality Handbook of more than 900 pages (2007) which details the set-up and quality assurance regulations for such a Teleservice<sup>214</sup> centre. Any system fulfilling the requirements of the Handbook will be acknowledged as VDE Certified Management System. Saludnova also reported carrying out a pilot at the Hospital de San Sebastian, to demonstrate that the technology requirements of the Regional Health System (Osakidetza) are fulfilled so as to obtain certification from the Basque government.

## Research and innovation activities

Larger companies like Roche, HomMed, Intel and Bosch can draw on their own R&D resources and facilities to pursue innovation in the RMT field. Both, small and large are engaged in local, regional or national projects as well as EU projects. Besides the obvious R&D goals pursued with these activities, in particular larger players underlined that their interest in being involved in innovative developments and EU projects is not only about getting research funding but is also a means to keep up with market evolution and be aware of potential new business opportunities.

This is confirmed by a recent statement from the German Minister for research and education commenting on Germany's participation in EU projects:

*"Apart from the plain numbers this level of engagement offers other advantages for German researchers," said Annette Schavan, the German minister for research and education. "The value of participating in European projects lies in building networks, exchanging knowledge and reaching out into new markets."*<sup>215</sup>

As to smaller companies, they often use EU projects as a means of funding both research activities and business operation. This shows how difficult it is currently for smaller companies to sustain a viable business model based on revenues/reimbursement only.

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<sup>214</sup> <http://www1.vde.com/WBB/PMM/Publikationen/Anwendungsempf+TeleMonitoring.htm>

<sup>215</sup> See <http://www.bmbf.de/press/2661.php> - English Translation of the statement in Research Day Europe Issue 3266 08 Sep 09.

The following examples illustrate the type of research and innovation activities the companies interviewed participate in:

1. Vitaphone is involved in a number of national and international research projects like:
  - EasyCare,<sup>216</sup> dealing with nurse call services for care at home and Motivation60+<sup>217</sup> for Sports and activities, two national projects focusing on the consumer market;
  - EmotionAAL<sup>218</sup> (diabetes) and AMICA<sup>219</sup> (for patients with COPD, two international projects focusing on managed care models).
2. Tunstall participates in various projects and pilots including the UK Whole System Demonstrator, regional projects like NHS Lothian, NHS Sheffield and NHS Swindon, and the EU funded CommonWell project, a large-scale project aiming at delivering integrated care services for COPD and CHF patients as well as in the context of Independent living.
3. HTN was born out of an Italian project, the Boario Home Care project (1998-2003). It still participates in national and international projects in the Telemedicine area in order to be able to fund and pursue its own innovation activities.
4. Docobo was also born out of EU FP projects. It is currently involved in a 2007 - 2010 EU FP 6 project called ‘ENABLE’ dealing with the development of wearable systems. It also participates in the 2008-11 TSB ALIP project ‘PEACE’ (Personal Care Environments) and the 2009-12 TSB ALIP project ‘PEACE EVERYWHERE’ Community.

## Partnerships

There are examples of partnerships at different levels on the RMT market. Telco and mobile operators seek partnerships with technology solution providers in order to enter the market. Vodafone is an example in Spain as shown by the Saludnova and Roche cases. Beyond the companies that are reviewed in this section, Orange has recently announced a partnership with Alcatel Lucent in Austria for mobile eHealth service provision.

For companies capable of providing full solutions, or with already established services, insurance companies are interesting candidates, giving access to large bases of patients. Vitaphone recently announced that they signed a partnership agreement with ADAC thus aiming to address their services (telemedicine-supported prevention programme) to 16 million insured members and 8200 employees. Vitaphone also announced in July 2009 its cooperation with Biotronik – a market leader in the cardiac implant segment – for the monitoring of patients with heart failure in Germany.

On a scientific level, companies also seek cooperation with research organisations so as to validate the efficiency and benefits provided by their solutions.

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<sup>216</sup> <http://partner.vde.com/bmbf-aal/AAL-Steckbriefe/Documents/BMBF%20Förderprojekte/easycare.pdf>

<sup>217</sup> <http://partner.vde.com/bmbf-aal/AAL-Steckbriefe/Documents/BMBF%20Förderprojekte/motivation60plus.pdf>

<sup>218</sup> [http://www.aal-europe.eu/calls/funded-projects-call-1/copy\\_of\\_ecaalyx](http://www.aal-europe.eu/calls/funded-projects-call-1/copy_of_ecaalyx)

<sup>219</sup> <http://www.amica-aal.com/index.php>

## 7.4 50+ company list and company profiles

Table 15 – List of the 50+ companies

<b>Implants</b>	<b>Service providers/Product vendors/SMEs</b>
Biotronik	Aerotel
Boston Scientific	Vitalsys
Medtronic	Aiperman
St Jude Medical	Tunstall
Sorin Group	Docobo
<b>Large players</b>	Vitaphone
Philips	Saludnova
GE Health care	Heart Online
Agfa Health care	E-HTN (Lombardy)
Honeywell	Bmeye (cardiovascular)
Bosch	IEM (blood pressure)
<b>Newcomers in the PHS market</b>	Goodit (diabetes, other remote monitoring)
Intel	Kiwok (ECG)
<b>ICT providers</b>	T+ Medical (disease management systems)
Nokia	Vamstec Croatia (image and data management systems)
Ericsson	eHIT (system integration)
Vodafone	GEM-MED (measuring and monitoring, patient platforms)
Orange	Schiller Medizintechnik (telemonitoring, medical platforms)
Telefonica	Vitaltronic (vital data real-time management)
Cisco	SHL Telemedicine (cardiac monitoring, other remote monitoring)
DGN Service (hospital information systems)	MeTeDa (teleanalysis and outpatient management)
InterComponentWare (electronic personal health records, other data systems)	TMA Medical (mobile care unit: multi-device examination system designed for mobile and stationary operation)
ISPro (ICT and telematic solutions for hospitals)	
<b>Frost &amp; Sullivan report</b>	<b>Pharma</b>
Omron	Roche
Cardguard	Bayer
Viterion	<b>Other</b>
Healthhero	Institut fur Angewandte Telemedizin (implementation of telemedicine systems)
Bodytel Scientific	

## Brief description of 50+ company profiles

**Aerotel** is an Israel-based, medium-sized company with activities throughout the world. They mostly operate as a product vendor, with devices for the measuring of blood pressure, ECG, blood glucose, weight, SPO2, respiratory peak line via telemonitoring, wearable alarms, and remote monitoring software. They provide full-service solutions for telehealth applications, offering an inpatient monitoring system that consists of a medical call centre software and monitoring devices that transfer vital, medical or lifestyle data over the telephone, the Internet or wireless networks. The patient information and the transmitted data can be viewed locally or via the Internet. Their most important product is the Heartlink ECG monitoring system, which is specifically designed for various diagnostic, emergency and monitoring applications. It consists of a range of personal 1 to 12 lead transtelephonic or digital ECG devices for remote diagnostics. The recorded data can be transmitted through the phone to Aerotel's Heartlink Receiving Station (HRS) for immediate diagnosis.

**Agfa Health care** offers solutions such as Hospital Information Systems (HIS), Clinical Information Systems (CIS), Radiology Information Systems (RIS), Picture Archiving and Communications Systems (PACS), Laboratory Information Systems (LIS), Cardiology Information and Image Management Systems (CVIS), solutions for reporting, enterprise scheduling, decision support, and data storage as well as Digital Radiography, Computed Radiography, print solutions, film and associated products. According to discussions with experts from the company Agfa Health care wishes to apply this knowledge as a hub for eHealth and telecare solutions.

The Luxemburg-based **Aipermon GmbH & Co. KG** is active in the field of telemedicine and monitoring of physical activity. The AiperCoach Home system enables the patient to transmit vital data such as blood pressure, physical activity and weight conveniently from home to the doctor, to the hospital or to a telemedical centre. Furthermore the company offers devices with a display to monitor the energy intake and physical activity level of patients, who are as well guided for the change in behaviour. The company cooperates with the Charité University clinics in Berlin and various distributors, their products are available mainly in EU countries and other developed nations.

**Bayer Health care** is the subsidiary of the Germany based Bayer AG. Bayer Health care operates through four divisions: Animal Health (veterinary drugs); Consumer Care (OTC meds); Diabetes Care; and Pharmaceuticals (represented by Bayer-Schering Pharma and Bayer Health care Pharmaceuticals). Diabetes Care's Viterion 200 telehealth monitor transmits patients' vital signs taken at home, saves the measurements and transmits them to the General Practitioner. Bayer offers analytical software to analyse the data both for patients and health care professionals. Note that Bayer through its subsidiary MEDRAD offers products including vascular injection systems, magnetic resonance scanner coils, and computed tomography injection systems, as well as syringes and disposable tubing.

**Biotronik** is a large German company that focuses on cardiac monitoring devices and systems. They concentrate on two distinct business areas, electrotherapy and vascular intervention. In electrotherapy, they offer diagnostic tools and options for treating arrhythmias. The products offer a range of diagnostic features for remote processing and analysis of data from implanted cardiac rhythm management devices. In this way, the implants provide access to relevant technical and clinical data, while allowing systematic and continuous patient surveillance. The implanted defibrillators and pacemakers transmit encrypted messages, which can be automatically analysed in Biotronik Home Monitoring Service Centre and sent to the physician. In the field of vascular intervention, Biotronik offers guide wires, balloon catheters, and stents, but these are less relevant for the purposes of PHS.

**Bmeye** is a small Dutch company that offers products for monitoring cardiac and pulmonary conditions. Their main product in the remote monitoring field is the BMEYE monitor, available in two basic configurations: Nexfin Continuous Blood Pressure Monitor, and Nexfin HD Continuous Cardiac Output and Blood Pressure monitor with Real-time Hemodynamics. Their product enables a full patient analysis including stroke volume, cardiac output, systemic vascular resistance, and various blood pressure metrics.

**BodyTel** is a German based company that specialises in comprehensive telemedical monitoring and management systems for chronic diseases, particularly diabetes, obesity and blood pressure. On the patient site its products are designed to simplify home monitoring for patients and to enable communication of measured body values between patients, health care professionals and caregivers. Their products can send alarms to caretakers in case of hyperglycaemic or hypoglycaemic episodes, mobile phones are used for the communication.

**Bosch Health care** is a subsidiary and umbrella brand of the Bosch Group. It encompasses a full range of telehealth products and services. This newly established subsidiary built around Health Buddy, a monitoring device made by Health Hero Network, which was acquired by Bosch in 2007, includes all international operating units in the area of telehealth, which aims to extend health care outside the traditional institutional walls of health care systems, and into individuals' homes and lives. It incorporates ViTelNet telehealth systems, which produce robust telehealth hardware, including touch screen-based systems. The ViTelNet telehealth system also offers flexible integration with customer systems. In Germany, a first pilot study has been launched with the hospital operator Asklepios. The objective of this project is to use telehealth solutions to monitor patients suffering from chronic obstructive pulmonary disease (COPD), type 2 diabetes and Parkinson. For more than two years, Bosch has been involved in the "Partnership for the Heart" project, together with the Charité Medical School in Berlin and the Robert Bosch Hospital in Stuttgart. This study - the most extensive of its kind, encompassing more than 600 congestive heart failure (CHF) patients - hopes to scientifically substantiate the benefits of telehealth for this condition. Additional cooperation projects in the U.K., the Netherlands, and the Middle East are currently also in the pipeline. Practical application of the Bosch telehealth system has so far been highly successful. Last January, the U.S. Department of Veterans Affairs published an analysis of data from over 17,000 patients whose care was coordinated using telehealth systems, particularly the Health Buddy System and ViTelNet's product offerings, from 2004 to 2007. The study showed an average 20 percent reduction in hospital admissions across a wide variety of conditions.

**Boston Scientific** is a large US-based medical company with an annual global turnover of \$8.3 billion. This revenue is generated over multiple product lines and services, and does not represent PHS alone. In the area of PHS, they are nonetheless a major player, with offerings in all the major product categories (cardiac, COPD, blood pressure, co-morbidity, and so on). Additionally, they are a major provider of implants and associated monitoring systems. Their services aim to connect the various kinds of personal health systems, and they can thus be described as a value chain integrator, even if most of their products and services can also be used on a stand-alone basis.

**CardGuard**(renamed LifeWatch in May 2009) is a Swiss company focusing on vital signs monitoring and data analysis. They have an extensive product portfolio that covers the cardiac, COPD and blood pressure segments, and also offer devices for transferring information between the patient and a call centre. Remote monitoring remains their most important market, with revenues of \$12.82 million in the fourth quarter of 2007.<sup>220</sup> They have also signed a long-term agreement in 2004

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<sup>220</sup> Europe Remote Patient Monitoring Markets, Frost & Sullivan, June 2008.

for a strategic alliance with Samsung Electronics Co., Ltd. in Korea. According to the terms of this agreement, Card Guard will develop, manufacture and sell to Samsung Electronics various medical software applications and devices, which will be used in Samsung mobile handsets.

The United States based Company **Cisco** is a market leader worldwide for IP-based networking equipment, the company provides routers and switches used to direct data, voice, and video traffic. It uses its expertise in these fields to expand into the eHealth market. In cooperation with the UnitedHealth Group the company is building United States-wide network, which will give patients access to physicians and specialists when in-person visits are not possible. It will be called "Connected Care" and will combine audio and video technology and health resources to greatly expand physicians' reach into rural, urban and other underserved areas. Cisco's products are furthermore used to build responsive support communities for patients with different conditions. The company is active as well in the field of medical images.

The Germany based **DGN Service GmbH** specialises in medical intranets; it runs the health network for doctors *Deutsche Gesundheitsnetz D/G/N*, the network for pharmacists *aponet Professional* and the network for dentists *DZN*. The company is one of the systems integrators in Germany providing the technical infrastructure for telehealth solutions, including trusted computing for RMT/PHS.

**Docobo** is a small UK-based company specialising in medical platforms. Their main product is called doc@Home, which is an integrated telehealth solution for the remote management of patients with a range of long term conditions. Through doc@Home, essential patient related data is collected and analysed, which permits the management of chronic conditions through interaction between clinicians and patients at home. To complement the doc@Home patient management system, Docobo offers the HealthHUB product, which is similar to a PDA and, using the principle of "store and forward", records and transfers vital signs measurements, changes in symptoms, side effects, and quality of life indicators to the centre of care.

The Finland based company **eHIT**(bought by Mega Electronics Ltd in October 2009) specialises in the field of mobile solutions within the health care and wellness industries. It provides software products and implements customer projects dealing with integration of eHealth solutions. Its products and services consist of eHealth and eWellness solutions in which the end users actively participate in the maintenance of their own health. eHIT's products focus on self care, home care, and occupational health. The products offered by this SME include the seamless integration of real-time patient-doctor communications with the patient's medical record, vital sign monitoring and nursing support via a mobile device which acts as a gateway for different sensors, as well as a medical platform for data analysis.

**HTN** is an Italian company that was established by a small group of cardiologists, who, through the Boario Home Care project, started providing 24 hours a day telemonitoring for patients with cardiovascular diseases, using a mobile electrocardiograph. The project took place in the Boario region of northern Italy. The successful results led to expanding the project to other northern Italian regions and HTN subsequently participated in several projects of the Ministry of Health and the Lombardy region, which were focused on the effects of using telemedicine in the management of chronic heart failure patients at home. The projects helped demonstrate the positive impacts of telemedicine, in terms of diagnostic accuracy, quality of life and spending optimisation. As a consequence, in 2006 the Lombardy region introduced reimbursement for the home telemonitoring of Chronic Heart Failure patients on a test basis. HTN offers medical platform and communication services, specialised teleconsulting, medical assistance over communication networks, personalised monitoring and vital signs monitoring. They also provide teleconsulting and ECG referrals,

multispecialty second opinion for general practitioners, home telenursing for chronic cardiac diseases, telediagnosis for arrhythmia, and call centres for hospitals.

**Ericsson** is a global Swedish telecommunications company that has recently entered the personal health systems industry. Their main product in the PHS market is Ericsson Mobile Health, a hosted solution for remote monitoring and patient follow-up. The system has been designed to be as easy to use as possible, with no manuals for the patient to read and a single button to push to transmit the medical information relevant to the patient. The system also enables mobile monitoring and follow-up of large numbers patients, and has a fixed monthly fee for the hospitals and clinics that choose to use it. The system works as an information hub, integrating information from patients, clinicians and insurance companies.

**GE Health care** is a major US-based player in the medical industry with a global turnover of \$17 billion, of which only a minor part comes from PHS products and services. GE Health care offers a variety of remote monitoring, medical information, and vital signs collection and analysis systems. GE health systems are also connected to hospital information systems, PACS imaging systems and billing solutions. As they offer a full service package to connect the different parts of the value chain, GE Health care can be considered a system integrator from the PHS point of view. As announced in April 2009, GE Health care and Intel have also signed an alliance to deliver personal health care products and services to patients in their homes. Both companies will invest \$250 million in the products and research over the next five years. GE Health care is also a promoting member of the Continua Health Alliance.

**Gem-med** is a Spain-based company working at the crossroads of ehealth and cardiology. gem-med designs, develops and sells eHealth equipment, it offers telemedical services and diagnosis through the net. Its products focus mainly on health services in a professional environment and are specialised in the field of electrocardiography. The company designs and develops diagnostic equipment for cardiology and carries out research on the use of medical methods and protocols of prognosis and diagnosis for interpreting cardiologic tests. The products and services are offered in two lines of complementary business. One line consists of electrocardiographic diagnostic equipment, which includes a range of electrocardiographs and Holter. The other is a line of telemedicine services which includes virtual diagnosis, the renting of equipment, and the development of customised projects and specialised training.

**IEM** is a small German product vendor focusing on COPD treatment. They offer various blood pressure measurement products as well as educational content related to COPD and blood pressure issues in general. Their products enable both the measurement and analysis of patient data.

**GoodIT** is a Finnish SME whose main focus is diabetes. They offer ICT solutions for management of diabetes, alongside remote management of mobile medical devices, accounting and billing systems for mobile medical services, and medical and health care process models and platforms. In addition, they offer a significant amount of educational content, both for hospitals and patients.

**Health Buddy System** is a United States Based company that serves as the interface between patients at home and care providers, facilitating communication of historical patient data of and self-management support for patients with chronic conditions. Originally developed in California by Health Hero Network, the Health Buddy System was acquired by the Bosch Group in Dec.07 (now part of Bosch Health care). The Health Buddy Appliance connects patients in their homes to their care providers. The health management programmes within the Health Buddy system cover more than 30 health conditions and provide interactive scripted content based on standard practice

guidelines. A web-based patient management tool enables care managers to analyse the data and take appropriate actions.

**Heartlink Online** (HLO) is a Belgium based start-up whose offering currently consists of a belt equipped with a two point ECG device used to remotely monitor ECG's for emergency and routine monitoring. Furthermore it offers accompanying service for the arrangement to transmit the data to the cardio centre of the patient's clinic, via a Smartphone gateway equipped with GPS facilities. The belt that can be pre-programmed contains an algorithm which enables specialists to define exceptions that should trigger an alarm. HLO also provides data storage facilities and connection to EPHR using Secured Software as a Service. Next to cardio-data which is HLO's current focus, a variety of other vital sign data can be transmitted through the Smartphone gateway and into the EPHR, such as glucose data, spiroometry, combined blood pressure and heart rhythm, oxygen saturation of the blood, weight and other measurement.

**Honeywell HomMed** is a United States medium sized company and part of Honeywell's Life Safety business unit. It is active in telehealth and remote patient monitoring. It has a large home health customer base serving over half a million patients globally. Within the EU the company serves over 40,000 patients in the UK (1,400 patients per WSD site). HomMed is also active in Italy, Germany and in the Netherlands. Its biggest customer in the US, Kaiser Permanente (a closed system run by a centrally funded health insurer) represents over 60,000 monitors, and 600 customers, serving over 600,000 patients. Its products measure vital signals, support and remind in-home user in taking care of them selves, HomMed also provides software to analyse the data.

The **Institut für Angewandte Telemedizin** is part of the Heart and Diabetes Center North Rhine-Westphalia in Germany. It is active in the fields of cardiac, circulatory and metabolic diseases. A device enables the patients to monitor their vital parameters. Patients can record their ECG and call the Medical Service Centre in case of symptoms. After an anamnesis an ECG is transmitted. The situation is then evaluated by medical personnel with special training, supervised by experienced cardiologists from the Clinic for Thoracic and Cardiovascular Surgery.

**Intel** is a global ICT company that has recently entered the PHS market. Their main product in the PHS market is the Intel Health Guide, which is intended to be a powerful care management tool for health care professionals who manage patients with long-term (chronic) conditions. The Intel Health Guide seeks to provide a higher level of patient engagement and more efficient care management by enabling communications between patients and health care professionals, and providing clinicians with access to the most current, actionable data. This personal health system combines an in-home patient device – the Intel Health Guide PHS6000 – as well as an online interface – the Intel Health Care Management Suite – allowing clinicians to monitor patients and remotely manage care. Intel and GE Health care have also agreed on a €183 million technological alliance to develop and promote new products and services for personal health.

**InterComponentWare** is a German company that provides ICT solutions for the medical industry. Their product range encompasses electronic personal health records, data systems, and technology platforms. Their business model is about integrating stand-alone IT systems through hardware and software products, making information flows more efficient and consolidating data from various sources. Some of their key products include the LifeSensor personal health record, solutions from ICW Professional Suite, and the ICW eHealth Framework as a development environment and base technology. They are also actively involved in standardisation activities.

**ISPro** is a small German ICT provider for hospitals and clinics. Their most important products include the Jesaja.net Zuweisерportal, a user portal for clinicians and general practitioners, and the

Cordoba communications platform for networks of clinicians. These can also be coupled with remote monitoring systems. At the moment, more than 200 hospitals in Germany and elsewhere are using ISPro systems.

**Kiwok** is a Swedish company focusing on cardiovascular measurement and transmission of ECG data over mobile phone networks. Their product portfolio is built around the BodyKom Series ECG solution, which enables doctors and care personnel to receive the ECG of heart patients via an ECG sensor and a cellular phone. The system operates in all locations worldwide, as long as there is mobile phone service coverage. The caregiver receives diagnosis data as soon as the patient registers abnormality in his monitoring. Customised measures (e.g. sending of notification to doctor and relatives) can be deployed automatically. With added functionalities, the BodyKom Series can also be applied in other areas which require monitoring, such as diabetes and blood pressure.

**Medtronic** is a large US-based company with a global turnover of \$13.5 billion. In common with other global medical companies, only a small share of their revenue comes from PHS and remote monitoring businesses. Nevertheless, they are a very active player and leader in the PHS market, where their key activities are focused on new-generation implants with remote connection capabilities. They also offer a range of other remote monitoring and homecare devices. The health conditions they address in the PHS and remote monitoring markets include cardiac rhythm disease management, cardiovascular conditions, and diabetes.

**MeTeDa** is a medium-sized Italian company that focuses on vital signs monitoring and analysis. The core of their activity is the production of managerial medical software, with an emphasis on clinical data elaboration and the development of innovative technologies of telemedicine and teleconsultation. Managing and analysing clinical data, especially the data provided by remote monitoring systems, is their main focus area in the PHS market.

**Nokia** is a Finnish telecommunications company with a total turnover of over 50 billion Euros. Recently they have become active in the personal health systems and remote monitoring markets. One of the main strategic advantages for Nokia's presence in the PHS markets is their ability to provide patient platforms (or communication platforms) which enable the transfer of patient data. With a smartphone they can evaluate and assess the data before sending it towards a medical platform. Nokia also actively supports and finances smaller companies in the area, such as the Finnish company eHIT and the e-Health company LifeChart (jointly funded by Nokia and Johnson & Johnson), which monitors and manages patients with chronic heart conditions. In addition, Nokia is an active member of Continua.

**Omron** is a large Japanese hospital equipment manufacturer with global revenues of 60 billion Yen. They are also active in the PHS and remote monitoring markets, for which they supply products such as blood pressure monitors, non-invasive vascular monitors, and portable ECGs. In these markets, they can be characterised as a device manufacturer, though the company as a whole works more as a system integrator whose products and services encompass the whole value chain.

**Orange Health care** is the health care division within the France Telecom group. It focuses around 3 priority areas, at the hospital, at the doctor's office and at the patient's home. It enables and facilitates hospitalisation and care at home by connecting health care professionals and their patients. The company cooperates with partners for the provision of medical and care knowledge, the exchange of medical information, the coordination of action and diagnosis, and the provision of a kind of "working area on the move". Furthermore Orange strives to offer electronic payment, electronic transmission and data storage services. It targets remote assistance of patients suffering

from chronic disease and the provision of data systems and intelligent software adapted to specific conditions.

**Philips Medical** is a global medical systems provider whose product offering includes diagnostic imaging systems, health care information technology solutions, patient monitoring and cardiac devices. In the PHS market, they address the cardiac, diabetes, COPD as well as co-morbidity conditions. As a company that connects the different parts of the value chain through a comprehensive product and service portfolio, they can be considered a systems integrator for PHS. Philips is also a member of Continua.

**Roche** is a large Swiss company with an annual turnover of 46 million Swiss francs. Their main interests are in the pharmaceutical market, but they also operate as a provider of diagnostic products for the PHS market. Roche has been one of the first companies to offer tailored products for different patient groups. Roche also has a subsidiary called Emminens, which offers telemedicine services (teleconsultation, processing patient data, monitoring patient status) for diabetes patients in Spain and other parts of Europe. Roche is a member of Continua.

The Spain based **Saludnova** is a young start-up within the Cooperative Mondragon Group, which originated at the University of Bilbao. It provides ubiquitous solutions for monitoring of biometric variables and the real-time detection of alarm situations, triggering the necessary medical care measures. Saludnova offers two distinct streams of solutions in the remote monitoring market, the **Careline Home**, more focussed on preventive medicine and social care and **Careline Pro** focusing on monitoring of in-out patients e.g. by hospitals. The product targeted at professional users comprises additional functions compared to the standard one such as transmission of graphics, photos and comments. It contains automatic sensors for measuring hypertension, respiratory, heart and co-morbidity vital signs, and transmission is via Bluetooth. In addition qualitative questions allow capturing data manually about the person's condition (e.g. how they slept etc.) and a manual sensor is used for transmitting temperature and glucose levels. The Saludnova products and services are targeted at chronic patients. Saludnova sees clear opportunities in this market, as technology will be needed to face the sheer volume of chronic diseases, which will require more efficient health care in the future.

The Swiss based Company **Schiller** manufactures and supplies electrocardiographs, long-term pocket sized ECG and blood pressure recorders, spirometers, medical IT solutions, patient monitors and external defibrillators. The company portfolio also comprises small portable vital signs monitoring devices to be used in PHS, which they produce themselves. Even though the Schiller's product are predominantly used within hospitals, the company is an example of a larger group of highly specialised SMEs active in the field of medical devices for patient monitoring, which have the potential to enter the PHS market.

**SHL Telemedicine** is an Israeli company that focuses on cardiac monitoring and its integration in the PHS value chain. They concentrate on developing and marketing advanced personal telemedicine systems as well as providing their end-users a comprehensive telemedicine solution that includes medical call centre services. Their solution includes the transmission of medical data by an individual, from a remote location to a medical call centre via communication networks. Using computer systems, the medical call centre staff uses the data to diagnose and monitor patient health and to respond to their needs.

**St. Jude Medical, Inc.** is incorporated in the United States and is also present in Europe. The company develops, manufactures and distributes cardiovascular medical devices for global cardiac rhythm management, cardiology and cardiac surgery, arterial fibrillation therapy as well as

implantable neurostimulation devices for the management of chronic pain. St. Jude Medical markets a wireless transmitter called Merlin@home, which has been introduced in Europe in 2008 at pilot centres. This system communicates automatically by radiofrequency with the implantable device, sends data to the physician using an analogue landline system and alerts if necessary the physician or the patient. The latest version of the Merlin.net Patient Care Network (PCN) gathers and stores data from the implant procedure, in-clinic follow-up visits and from subsequent remote transmissions sent from a patient's home. Remote transmissions can include both patient-initiated and automatic follow-ups and monitoring transmissions sent via the Merlin@home remote transmitter. The system gives doctors more timely access to important patient and device data, allowing them to get a more complete patient record by easily transferring cardiac device data into EHR systems.

**T+ Medical** is a medium-sized UK based company with large-scale operations also in the USA. They specialise in remote monitoring and health care management over mobile networks. Their telemedicine solutions utilises existing network infrastructures, mobile phone and web technologies for ubiquitous access and direct communication to people with chronic diseases. T+ Medical's service offering consists of disease management, remote monitoring and wellness solutions for disease management organisations, hospitals, group practices, health plans, employers and government organizations. The company cooperates with Vodafone in providing them medical know-how and services

The Spain-based company **Telefonica** provides fixed and mobile telecommunications services across Europe and Latin America. The company has set up a special division called eHealth that will develop and implement proposals specifically related to health and welfare. In Spain, the Ministry of Health of the regional government of Castilla and León trusted automation of its first level care appointments to Telefónica, through which patients can make an appointment through different channels: phone, SMS and internet. USP Hospitales and Telefónica signed a strategic alliance to work together on developing eHealth, telemedicine and tele-radiology solutions. Furthermore the pilot project Remote Service Platform (Plataforma de Teleasistencia) is a platform intended to facilitate the care of dependent people, reducing the number of trips needed to check their health status. Telefonica is also participating in the Home Telecare project together with the Hospital Costa del Sol. In this project that started in December 2008 and is targeted at heart patients and terminal patients, It is designing the communication platform in cooperation with health care professionals.

**TMA Medical** is an Austrian SME whose main product in the PHS market is called the Mobile Care Unit (MCU). Designed for stationary or portable use within telemedicine applications, the MCU is a stand-alone multi-device examination system operated and controlled by a dedicated personal computer. The MCU enables a wide range of examinations. A homogeneous electronic medical record is created and will be transmitted using various Internet connectivity methods (Lan, WLAN, 3G, WiFi, PSTN, satellite). The MCU can be customised and interfaced with existing telemedicine platforms. In addition, by using video-conferences, the MCU can be used as a medical tool for remote areas, emergency and prevention.

**Tunstall** is a UK based company which is one of the world's leading providers of telecare and telemedicine solutions, with a global turnover of more than €180 million. Tunstall has a number of different devices in its product portfolio for PHS. These include RTX monitors and peripherals with disease specific packages and clinical systems organisers (CSO). Over 2,500 monitors and CSO's are deployed and used by over 65 NHS partners in the UK. The objective of the technology is to reduce the amount of time doctor/nurse needs to spend with patients: measuring is done at home, an alarm is triggered and medical intervention is arranged only when certain parameters are exceeded which saves patient visits. The information transmitted is stored in servers, and medical experts can access the database for trend analysis purposes.

**Vamstec** is a small Croatian company that specialises in image and data management systems. They process and distribute medical images in electronic form, and combine them with patient examination data, thereby aiming to make existing health care services more efficient and more attuned to patient needs. Their products provide scalable, secure, and relatively economical patient management systems for day-to-day use in clinics and hospitals.

The Belgium based Start-up **VITALTRONICS** is a subsidiary of the telemedicine specialist Vita, it develops medical technologies in order to allow doctors to follow the vital parameters of their patients in real time. In this context, VITALTRONICS has already developed prototypes of telemonitoring devices, in collaboration with various technological partners like CETIC and Verhaert New Products & Services. It sub-contracts the technical design and the production to other companies. Its products include an automated external defibrillator (CardiAid) and a fall detector.

**Vitalsys** is a Belgium based company specialised in Telemedicine Integration systems and services for Telemedicine combined with the distribution of medical technologies in the Benelux Region. The company promotes existing validated medical vital sign monitoring systems for hypertension, heart diseases, respiratory problems, diabetes and other conditions. The core of these systems is the Vitalsys telemedicine platform named VitalCare for processing of medical data. The company belongs to the Niko Group together with Vitaltronics.

The German based company **Vitaphone** offers integrated systems for the acquisition and transmission of biological signals with the help of modern communication devices. These are part of telemedicine monitoring and care systems. The telemedical concepts encompass both top of the line technology and a medical service centre, which is staffed with physicians, and is available around the clock. **Vitaphone** provides comprehensive patient care solutions to care suppliers and health care insurers and targets patients suffering from chronic heart failure.

**Vodafone**, a leading mobile communications operator, is directly active in the field of e-health in cooperation with the Rockefeller Foundation and the United Nations Foundation, offering mobile health solutions for developing countries. Furthermore, the company is cooperating with T+Medical (see above), a provider of mobile phone-based technology, and focuses on transferring biometric data of patients with chronic diseases, recording details about their condition and treatment, using mobile phones. Vodafone Spain has developed a service that enables people with diabetes to effectively control their sugar levels. A monitoring device measures the level of sugar in their blood, displays the reading on their mobile phone and transmits this information to their doctors. With the support of the Vodafone Portugal Foundation, a system has been developed to remotely monitor epilepsy in children. Neurologists and paediatricians at the West Lisbon Hospital Centre use mobiles and specially developed software to monitor medical diagnostics remotely via the Internet. The Vodafone Care service in Germany, offered in partnership with Vitaphone, provides elderly people with instant access to the Vitaphone Service Centre (24-hour support by doctors and health care specialists), enabling health care specialists to make decisions quickly in an emergency. Vodafone is also a partner of Saludnova (see above) for the provision of telemonitoring services in the Basque Country.

**Viterion** is a German SME owned by Bayer Health care (see above). They work as a system integrator, combining and consolidating different types of patient data and managing it over communications networks. Their products offer features such as patient specific alerts, communication between health care providers, a library of disease management protocols, streamlined clinician workflow and management of patient data, managing access to patient data (e.g. according to its confidentiality), and the ability to integrate with other hospital information systems.

## **8 Annex III: Summary of Country Reports**

### ***8.1 Study design and reliability***

The SIMPHS activity, in fulfilling its objective to get field data, planned to carry out country studies. VTT Technical Research Centre of Finland was subcontracted by IPTS to help build a picture of the RMT/PHS market and provide an analysis of the roles and strategies of the market stakeholders in France, Germany, Sweden and United Kingdom, by interviewing key stakeholders and experts from the field in these four EU countries. Furthermore, IPTS elaborated two additional country studies for the Netherlands and Italy.

Stakeholder interviews were used as the means to gather both qualitative and quantitative data from various key stakeholders in each respective country, so as to fill the “knowledge gap” that currently exists, since there is little public data about the RMT/PHS market in most European countries. Filling the gap is the first step in determining: (i) how innovation in RMT/PHS emerges and impacts market growth; (ii) whether innovation and changes take place top-down through health care systems and GPs, bottom-up through industry players or through health care policy at national, regional or local level. Different stakeholders’ interests were covered such as policy makers, payers, health service providers, users, large-scale procurement, technology and IT service providers.

A total of 68 interviews were conducted in the six countries (7 in France, 10 in Germany, 13 in Italy, 18 in the Netherlands, 7 in Sweden and 13 in the UK). The number of persons interviewed per country could have been larger and was only limited by the strict timeframe and available resources. Stakeholder's willingness to participate in the survey and provide expert information varied by country; participants willing to provide evidence were found rather easily in Germany and the UK, while it turned out a bit more challenging to awake the stakeholders' interest in France and Sweden, for instance. Interviews were conducted both face-to-face and by telephone and were structured using sub-sets of the questions presented in § 8.6. Before the interview, additional material and the questionnaire were sent to each interviewee to enable preparation for the interview. The list of the interviewed experts can be found in § 8.7. Most of the experts and stakeholders interviewed were working in the RMT/PHS domain; on the one hand this meant that they were well versed into this domain, however on the other hand, it meant that there could be some bias in their responses. To balance this we also interviewed stakeholders that were not directly involved in the domain.

The data collected via interviews was complemented with data from other sources to build the most comprehensive picture of the RMT/PHS market as possible in each respective country. The study results were presented and validated at the SIMPHS Validation Workshop in Brussels on 17-18 November 2009. A full report presenting a detailed country report for each of France, Germany, Italy, the Netherlands, Sweden and the UK is provided separately.<sup>221</sup> Each country report gives an account of the overall health care system, its funding, the policy context in which it is set, the management of chronic conditions and the RMT/PHS market situation. Each report also includes a discussion chapter addressing issues like RMT in a social care context and patient empowerment, and includes a concluding section summarising the main findings of the respective country study.

In the following sections we discuss the key findings of the country studies and compare the state of development in the six countries. But before going into this we first introduce two concepts as a frame of reference that will allow us to assess the position of the countries and the RMT market.

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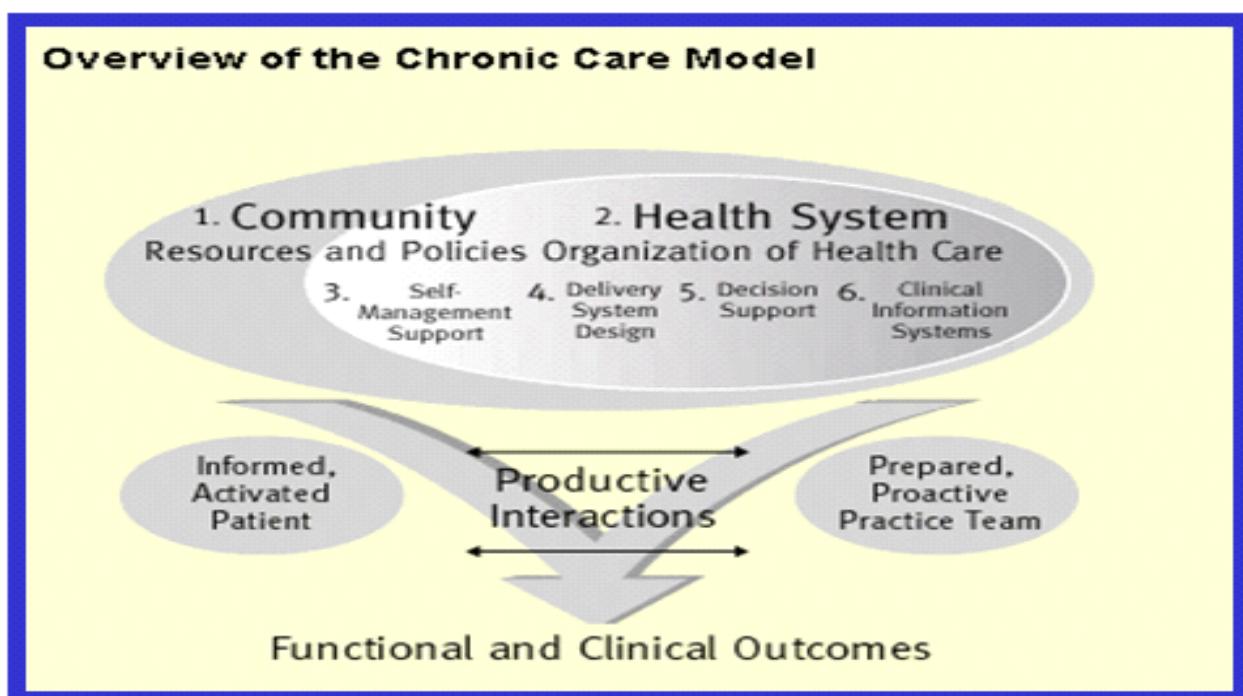
<sup>221</sup> <http://is.jrc.ec.europa.eu/pages/TFS/documents/VTTcountryreps>

## 8.2 Chronic Care Model and disruptive innovation

The widely accepted "golden standard" in disease management is the Chronic Care Model (CCM) developed by Wagner and colleagues.<sup>222</sup> It comprises six interacting components (see Figure 27 – Overview of the Chronic Care Model) that are needed to provide high-quality care for chronic health problems:

- (1) the community with the resources and policies,
- (2) the health care system, which is organized to enable the interaction of its four components:
  - a) self-management support,
  - b) delivery system design,
  - c) decision support, and
  - d) clinical information systems.

Figure 27 – Overview of the Chronic Care Model



Source: Developed by the MacColl Institute – ACP-ASIM Journals and Books (see footnote 134)

The core idea of the CCM is the facilitation of the interaction between the informed and activated patient and the prepared care team. Patients have the motivation, information, skills, and confidence necessary to effectively make decisions about their health and manage it. Similarly, the care team has the patient information, decision support, and resources necessary to deliver high quality care. In the CC Model the patient is no longer an object that is being cared for but an active participant of the care process, a *co-producer of care*. Another term that is often used to illustrate the role of the patient is *patient empowerment*.

The role of the clinical information systems is to:

- Provide reminders for providers and patients.
- Identify relevant patient subpopulations for proactive care.

<sup>222</sup> Chronic care model: <http://www.improvingchroniccare.org/>

- Facilitate individual patient care planning.
- Share information with providers and patients.
- Monitor performance of team and system.

Note that the CCM although it emphasises the interactions between patients and care teams does not include any remote monitoring technologies as such. RMT is a recent add-on to the model and the value added by RMT has yet to be demonstrated in clinical trials.

Although the model has been shown to provide improved health (functional and clinical) outcomes its implementation in clinical routine has been difficult. The main barrier for successful disease management programs is the current reimbursement incentive framework and integration of independent providers when providing care. Most health care systems are organized in a way that do not reward practitioners, care teams and providers if they manage the health of their patients better and thus reduce the workload and/or visits to care facilities. A well-documented example of successful disease management systems comes from the USA, where Kaiser Permanente and the Veterans Health Administration have provided incentives for disease management by rewarding health outcomes, not number of transactions (fee for service) or capitation. In this case, another key enabler is that both are integrated providers not a group of interacting but separate providers.

The difficulties in implementing disease management programs are just one example of the problems of current health care systems. National health care systems have developed in a piecewise fashion over tens of years. Although enormous progress has been made in medical knowledge and medical technologies, health care systems are still based on the same, original principles. Michael Porter from Harvard Business School when speaking on a report done on the Finnish health care system<sup>223</sup> summarized his view of the current state of national health care systems with the following sentence: “*Today, 21<sup>st</sup> century medical technology is delivered with 19<sup>th</sup> century organization structures, management practices, and pricing models*”. Clayton Christensen (also from Harvard Business School) has elaborated the above statement and proposes to reorganize health care based on four service models:<sup>224</sup>

- *Coherent solution shops* (to sort out disorders that are still in the realm of intuitive medicine);
- *Retail clinics* (to care for our everyday rules-based disorders);
- *Value adding process clinics* (to process needs after a definitive diagnosis has been made);
- *Facilitated user networks* (to help patients service their behaviour-dependent chronic ailments).

Each service model needs to have its own set of incentives in order for the business models to work and produce the desired outcomes. Christensen’s argument in putting forward this proposal is that the current health care systems need to be disrupted in ways similar to what we have come to witness in most other industry and business domains. The problem of the current health care systems is that the four service models co-exist as an entangled mesh. They need to be separated and for each an incentive scheme has to be set up that rewards "correct behaviour". In the case of the CCM the two last mentioned service models need to be implemented: facilitated user networks as the treatment in most chronic diseases is to change the patient’s behaviour and value adding process clinics for the care teams to interact with the patients.

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<sup>223</sup> Juha Teperi, Michael E. Porter, Lauri Vuorenkoski and Jennifer F. Baron. The Finnish Health Care System: A Value-Based Perspective, 2009 (PDF: <http://www.sitra.fi>).

<sup>224</sup> Clayton Christensen et al. The Innovator’s Prescription – A disruptive solution for health care. McGrawHill, 2008.

## **8.3 National frameworks for RMT**

### **8.3.1 Health reforms are the norm – not the exception**

The health care systems in the six countries are complex. All provide health services to all citizens. But underneath, there are a myriad of policies, agencies and interacting incentives and disincentives that make it nearly impossible to understand how the system actually works<sup>225</sup> (see Christensen's argument on the need to disrupt the Health care systems, on page 135). In the country reports we provided an overview of the respective systems; however, the overviews are "biased" towards RMT systems within the health care environment.

Coinciding with OECD and WHO report findings, the 6-country study results identify that EU health care systems are fighting several concurrent and interdependent challenges such as: cost containment, innovation in medicine, life sciences and technology and demographic change due to ageing populations. Consequently, continuous health reforms have become common place in almost all EU countries. As such, RMT/PHS is competing for the attention of policymakers and other key stakeholders in this environment. It should not come as a surprise that RMT is not accepted as a central means to tackle the challenges that health care systems are facing; as one of the interviewed experts put it "*there is no urgency for RMT*".

### **8.3.2 Reimbursing health outcomes – incentives for integrated care**

To make a justified case for RMT/PHS one would need to convince policymakers that what is needed is policy that sets incentives for providers to offer integrated services in chronic care and that rewards providers for the improved health outcomes. With that in place, we would only need to demonstrate that the deployment of RMT in CCM does indeed improve health outcomes.

With current lifestyles projected to further increase the incidence of certain chronic diseases, such as cardiovascular diseases, diabetes and certain cancers, the need for the deployment of the CCM is more than clear, as it has been estimated that up to 70% of health care expenditure derives directly and indirectly from chronic diseases. All six countries have recognised this challenge and have designed policies that address the management of chronic diseases. However, while the approach is according to the golden CCM standard, most countries are not making it attractive for providers and general practitioners to work for improved functional and clinical outcomes.

More explicitly, the health care systems of the countries we studied do not reward services that keep patients away from doctors' offices or hospitals; instead providers are reimbursed based on fee for service and/or capitation.<sup>226</sup> Neither mechanism encourages providers to keep patients away from hospitals or outpatient clinics. Moreover, in most systems there are no incentives that reward providers and GPs for improved functional and clinical outcomes when treating patients with chronic diseases. As a result, DM programs, which are facilitated by RMT and offered by service providers (ICT, triage centre and health care), have to: (a) be adjusted to reward improved outcomes in general; and (b) find a formula that enables the sharing of rewards among providers in a way that also encourages all value chain members to strive for better performance i.e. functional and clinical outcomes.

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<sup>225</sup> More information and detail on how the EU health care systems are organized, health reforms implemented and topical themes, such as chronic care management are reported by OECD [www.oecd.org](http://www.oecd.org) and WHO Observatory <http://www.euro.who.int/observatory>.

<sup>226</sup> In Germany physician practices get a (small) bonus for deployment of the DM programs but this not connected to health outcomes.

The important thing to notice is that it is not enough to reward providers for results; what is also needed is that the patients are provided with *truly integrated care*. Otherwise providers can shift work and cost between themselves at the cost of the patients. In other words, the focus of the service provision should be on the patient and not the disease and health outcomes should be appropriately measured on this. The findings of the 6-country study demonstrate that incentives for integrated care outcomes are not yet in place.

With DM programs based on best practice and appropriate incentives in place, the next step is to determine the best way to deploy RMT in disease management. RMT services could add value to DM programs by providing a better connection between the patients and care providers. Returning to the urgency comment referred to above the challenge is "*to connect the dots between DM programs and RMT*". In other words, provide evidence that RMT adds value to disease management and set up incentive systems that reward health outcomes over capitation and fee-for-service. One clear finding in the 6-country study is that the relevant stakeholders have not yet made this connection.

### 8.3.3 RMT/PHS market – Innovation dynamics

The RMT market is still in a formation stage; evidenced by the RMT activities (projects) that are currently ongoing in the six countries. The countries differ quite a lot in this respect. France seems to be most behind, as we couldn't identify any push for RMT. In Germany DM programs have been recognized and physician practices are encouraged to apply a CM model. The role of RMT in this, however, is not widely recognized. The same more or less applies to Sweden, that is DM programmes are considered important but RMT is not part of the recognized solution. In Italy, eHealth, as health care in general, is regionalised, and as a result RMT deployment is emerging only in the richest regions (Lombardia, Emilia-Romagna, Toscana, Veneto and Piemonte). In the Netherlands, where important reforms encourage market developments in health care, RMT still remains a niche market. Of the six countries the UK is the only one where there are large-scale Randomized Clinical Trial (RCT) pilots in Telehealth and advanced Telecare (i.e. in RMT). In the other countries there are many local projects but their level of ambition is much lower than for those in the UK.

Although the 6-country study did not supply us with any hard market data, the market projections (done by consultancy companies and others) which were collected seem to be based on statistics on disease prevalence provided among others by OECD Health Data. As an example, in the UK report the number of people with Long Term Conditions (LTCs) and the percentages that could benefit from RMT services are estimated. The former is derived from the relatively recently introduced Quality of Outcomes Framework (QOF) as part of the remuneration system for GPs in the UK but the latter are subjective estimates reflecting a wide range of awareness across the medical community. The low reliability of market data is a barrier to 'connecting the dots' which has serious negative implications for the sustainability of market mechanisms.

The problem of embedding the technology into a service that will improve health outcomes is central to the creation of sustainable business models in this area. Even then, the organisational changes needed to deliver ICT support for DM programs are practically not defined. Firstly, any such changes should only positively impact the patient/doctor relationship (i.e. by improving and facilitating it). Secondly, the cost of the initial investment in setting up an RMT service, which will deliver and install the RMT system at the patient's location (home a/o mobile patient), as well as the required further investment for the education and training in using the system require logistics support that needs to be built-in into RMT systems. Also, a help-desk would be needed to troubleshoot usage problems both trivial and complex. All this means that an RMT service needs a lot of users (patients and health care providers) in order to deliver services at an affordable cost. The suggestion made by

several interviewees was that a virtual Care Management Centre be set-up, one which runs 24/7 and provides clinical triage and the basic logistical services. The question that arises from this is whether the centre should be in-house (with respect to the RMT service provider) or provided externally; and the question thereafter is whether the services could be provided by extending the existing Call (Contact) Centres that are quite common place today even in health care.

Moreover, governance of any RMT solution proposed is not clear. For example, clinicians may not easily accept (as initial evidence seems to indicate) that an intermediary (Contact Centre/Care Manager) runs the regular service and only exceptional cases (patients whose clinical condition is not within the preset boundaries) are brought to their attention. Secondly, and more importantly, clinicians are less likely to trust vital signs monitoring and reporting done by the patients on their own. For example, blood pressure readings are highly dependent on whether the patient is standing or sitting, or has been exercising etc. Similarly blood glucose readings are quite different before and after meals. It is highly important that patients are trained and understand how and when the vital signs measurements are to be taken. Another concern that was expressed is that patients may knowingly feed erroneous readings of their vital signs.

Within the countries studied, innovation seems to be applied on different levels. For instance, through participation in EU or national or regional programmes, projects and initiatives as well as through company related innovation activities. The problem, though, is that (the UK being the exception) there does not seem to be an overall vision of what RMT could offer. Indeed, some experts pointed out the need to develop a longer term vision of how health care services should be organised and reimbursed to take advantage of what modern medicine can do and how ICT can enable this. Their point was that it is not enough to push RMT/PHS or eHealth but rather push for a systemic change across the health system<sup>227</sup> as it has happened in other business domains where ICT has disrupted existing business models and created new opportunities.

The traditional route for larger diffusion of new technologies in health care has been for the industry to engage *medical opinion leaders* as first users and through them convince and gradually provide evidence that the new technology can be used to provide improved services to patients. In the case of RMT (and any ICT system in health care for that matter) the problem is that there are few opinion leaders to be found in the medical profession. The purpose of the technology is to facilitate interaction across the whole care team that includes the patient as a co-producer. In spite of the difficulty in identifying a business owner on the health care side technology industry should work to engage relevant stakeholders in order to produce success stories that ultimately will lead to diffusion. The basic rule in medicine is that you need to show that it works. The large-scale demonstrators in UK and elsewhere are in that respect highly important for the development of the RMT/PHS market.

### 8.3.4 Embedding RMT into care processes – integrating patient data

The 6-country study has revealed a somewhat lukewarm demand for RMT/PHS services although there was overall consensus on its potential. In essence, this evidence sheds light on why a mix of market (creation of new markets), organisational (creation of new ways of doing the same job), and institutional innovations (creation of new norms, rules, habits) is required, beyond the already available product (new goods, medicines and devices, new services) and process innovation (new ways of using products), if the transition (or disruption) of health care to a system with a stronger emphasis on DM, long-term care, home care and prevention is to materialise. It is also for this reason that extensive experiments and pilots are required before RMT can be embedded in the day-to-day

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<sup>227</sup> The ideas put forward by Michael Porter, Clayton Christensen and Regina Hertzlinger (all from Harvard Business School) are good examples of how current health care systems should be disrupted.

structure of health and social care organisation and practice. Experiments and pilots, testing new ways of delivering health care, play a vital role in this.

The countries studied each have an ongoing infrastructure development programme that seeks to provide an integrated electronic medical record (EMR) that care providers and citizens (patients and family, informal carers) can access and use. The implementation of the national EMR programs, however, has turned out to be more challenging than originally anticipated. Sweden and the UK are implementing a nation-wide care summary record system. In Spain a similar system is being implemented in a strongly regionalised institutional environment. In Germany the EMR program seems to be delayed because of privacy/security concerns. In France a program was underway but was stopped and is being refocused. In Italy, electronic Health Records (EHR) is one of the four priorities of an ambitious eGov 2012 Action Plan, but progress toward its implementation has been slow. Many proof-of-concepts are running in the Netherlands in relation to the large-scale implementation of at least parts of a national EHR, but they have also been affected by many delays. Several interviewees considered that the delays in these EMR programs form one barrier for RMT diffusion, as an integrated EMR/EHR is a necessary prerequisite for RMT services.

Patient acceptance of RMT is however, essential. Acceptance relies on whether patients will be willing and able to use RMT to their benefit (there is emerging positive evidence from UK pilots). Patients are expected to take vital signs measurements with the devices and transmit the results to the clinicians. Some parts of this can be automated but not all (at least not today).<sup>228</sup> Yet another, essential part of the trust chain is the privacy of personal health data exchanged during RMT processes. It is of high importance that industry takes a proactive role in this issue and respects the relevant legislation and rules concerning the privacy of confidential personal health data in implementing RMT/PHS systems.

The interviews revealed also that the readiness to re-evaluate the role of the patient and to shift towards the co-producer approach is not yet there. Service providers are more comfortable in their current roles of managing patients that comply with their instructions. Overall, there are justified concerns about the co-producer model; in an ideal world, the patient is willing to take on the responsibility for his own care and has the tools and abilities to be an active member of his own care team. In a real world, care must be exercised to build and maintain trust across the whole value chain for the co-producer model to work.

### 8.3.5 Creating awareness and evidence

The 6-country study identified evidence that the relevant stakeholders (policy makers, industry, professional groups etc.) do not know what RMT/PHS is or what it can enable. Also as already revealed "there is also no feeling of urgency" to deploy RMT in health care (see sub-section 8.3.1) since other more important challenges get the attention of stakeholders. Whether these are more important or whether RMT really is the technology, that when deployed appropriately (disruptively!), can bring savings while at the same time improve health outcomes, is an issue that the RMT stakeholders themselves need to address. They need to showcase: (a) scientific proof of the improved outcomes of the application of the technology; (b) the added value of the technology towards all stakeholder groups; (c) the likely benefits of the application of the new vision of health care to society as a whole; and (d) the contribution to jobs and growth for the EU. Most of all they need to bring the evidence closer to the patient so that 'demand pull' can be in effect exercised.

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<sup>228</sup> Remote monitoring of intelligent implanted cardiac pacemakers is an example of RMT that exists today and is found to be useful.

Although RMT pilots are being carried out only a few of them are done at a level where scientific proof can be obtained and reported. Major improvements in clinical status and decrease in use of hospital and outpatient clinic services, have been reported in pilot deliverables published. The problem though is that turning these into cost savings would require re-organisation in health care services in the style suggested by Christensen's value-added process clinics and user facilitated networks. This means that in addition to working towards producing evidence of benefits, effort is needed in educating decision makers and other key stakeholders (including patients). In conclusion, there is ongoing some degree of awareness but as stated above this does not translate into action.

The full country report lists the activities that were identified during the study. There must be many more that did not come up in the interviews or from the material collected for the study. The problem with most of these is that their ambition level reaches only to a "proof-of-concept" level. Implementing many small proof-of-concept projects is counterproductive. It spreads limited resources into small projects that will not produce hard evidence that can move the market forward. Proof-of-concept projects are also the result of the fact that public funding agencies seem to be overly focused on technology and rely on the fact that market mechanisms will carry good ideas forward. Again UK stands out as a good example of what the other countries should follow, i.e. fund large-scale pilots that can produce hard evidence. In general, for EU health care systems, the requirement that RMT satisfies is implicit or latent. Working with large-scale pilots and publishing scientific evidence is necessary to create and justify this need.

### 8.3.6 Standards, innovation cycles and need for integration

Although several interviewees were aware of international standards development organizations (SDOs) for technical and semantic interoperability of RMT systems, it was a bit surprising to note that this was not more common. This finding is aggravated by the fact that most of the persons that were interviewed were experts and stakeholders in this domain and therefore one would have expected that almost all would know of for instance, the Continua Health Alliance and Integrating the Health care Enterprise initiatives.<sup>229</sup> This finding is indicative of the need of sharing information.

The 6-country study shows that the RMT/PHS market is still being defined. The first generation of RMT products and services are being tested and piloted to gather evidence of value. One could compare this with the situation with the first CT and MRI scanners and minimally invasive surgery in the early 80's. It took several innovation cycles with intensive interplay between the technology developers and the users (clinicians and surgeons) to transform (disrupt) medical imaging and surgery into what they are today. We need to get the cycle of innovation into motion also for RMT. In the above examples the key innovators were industry and medical opinion leaders. In the case of RMT a much larger network of innovators is required as argued by Christensen.

One possible route to speed up these cycles is if the needs of the elderly both in terms of staying independent and coping with their environment (Ambient Assisted Living, Advanced TeleCare in UK terminology) and RMT/PHS (TeleHealth in UK terminology) can be served through one integrated channel. Integration of the service channels makes sense not only from the patient perspective but also from the service perspective. The interviews showed that there is awareness of the integration need in the four countries. In reality, though, wheels are turning slowly.

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<sup>229</sup> [www.continuaalliance.org](http://www.continuaalliance.org) and [www.ihe.net](http://www.ihe.net)

## **8.4 Summary of country findings**

### **8.4.1 French RMT market summary**

**Table 16 – France country study, main findings**

- No RMT market to date. There is a growing interest and awareness about market possibilities, but development has been slow. Market growth is anticipated to happen in the future, but prior estimates of growth rates have been recently toned down. A strong shift of interest from devices to services has also occurred.
- In France market actors tend to partner, since they believe that value chains amongst various providers are the best way to attain results and awareness that no actor alone can achieve.
- The availability of market data is very limited. Also, scattered data is difficult to find and analysing its reliability is often difficult. There is a strong need for better data, with data concerning evidence on RMT benefits and potential contacts interested in partnering, especially needed. Also information of reimbursement possibilities and success stories of RMT are needed.
- The RMT market barriers heavily outweigh current drivers. Main drivers include an ageing population, increasing prevalence of chronic conditions and the uneven distribution of medical professionals. The most important stakeholders driving change are policy makers, medical professionals and citizens themselves. Also, interviewees expressed the need for both bottom-up and top-down diffusion of RMT.
- There was some information on a newly formed agency called CNR, which according to initial limited information may have great potential in driving the market forward.
- On a general level it seems RMT is hard to implement into current health care structures. Many potential market barriers were identified such as on organizational, cultural, social and financial aspects. Technology is not seen as a barrier although certain technological advances could facilitate market growth (interoperability & EPR). Main barriers included lack of education, lack of reimbursement possibilities and lack of aligned incentives. Also the role of medical doctors was seen as problematic due to possible fear of loss of power if RMT is implemented.
- The potential for RMT in a social care setting is clearly recognised but organizational boundaries are major barriers for implementation. There is a need for inter-organizational co-operation and continuum of care.
- Patient empowerment seen as very important, but actual empowerment is still rare. Patients generally are more interested in health information, but this has not realized into demand for RMT services. Education about RMT is needed.

## **Conclusions**

The main finding from the French RMT market could be summarized as: there currently is no RMT market. Although RMT is receiving more and more attention, projects in general do not seem to pass the project phase and pilots remain as pilots due to a number of barriers that hinder growth. For sustainable business opportunities to arise, the following major barriers would have to be overcome: lack of reimbursement possibilities and incentives to adopt RMT. Although estimates concerning

RMT growth in the number of years it would take until market reaches a more mature phase were mostly missing, all French stakeholders felt that the market would grow in the future.

Generally speaking RMT does not seem to fit the current health care system in France. As a consequence, market growth has not materialised and current barriers remain unresolved. Until the "rules of the market" are set stakeholders will find it hard to deploy RMT and find their place in the new value chains RMT services would enable.

#### 8.4.2 German RMT market summary

**Table 17 – Germany country study, main findings**

- No real market has yet materialized and supply-side success stories are very rare. Since action remains mostly project-based pilot studies, the critical mass to make things happen is still missing. Partnering has become more common among actors, but market consolidation is still strongly needed.
- The estimates about when the RMT market will be mature were usually in the range of 2 to 3 years, but interviewees said it could take up to 10 years before the market became mature.
- Availability of market data is currently low. Data is also extremely scattered with quantitative data almost unavailable and its reliability questionable. There is a clear need for more data concerning many areas of RMT that the SIMPHS could facilitate. Success stories and evidence-based proof of concepts were most needed; however, turning data into action should be the focus.
- Main market drivers include an ageing population, increase in chronic diseases, and increase of rural areas with scarce services. Technology is not a market driver – it could offer possibilities, but it is not being adopted.
- Current barriers heavily outweigh market drivers as on a policy maker level RMT does not need to happen now; in other words there is no long term strategy on RMT on a political level and the market is "on hold" until the German elections with stakeholders waiting to see where the next round of possible reform points. The whole concept of RMT and how it should be integrated in current health care structures is fuzzy which has led to unresolved roles and responsibilities amongst key stakeholders. Finally, the innovation process, from innovation to reimbursement and market, concerning RMT is unclear.
- Other main barriers include lack of leadership, lack of industry consolidation, RMT services that do not fit the current health care structure, lack of reimbursement possibilities, organizational boundaries that make implementing services difficult, a physician culture that is not used to RMT services (loss of power), lack of patient interest due to lack of knowledge about RMT.

### Conclusions

Talking about an RMT market in Germany seems to be optimistic at the moment. Although progress is happening in the form of pilot projects and partnering among interested stakeholders and actors, many of the key issues hindering growth are still unresolved. Although some actors have managed to create business through their RMT services, the scale of business is still very small. There is a general interest towards RMT and even acceptance that it could be a possible solution for creating a sustainable health care system in the long term in light of acknowledged pressures the current system is facing. However, action and leadership are currently missing. The whole field of RMT is fuzzy, and the perceptions of various stakeholders on the roles and responsibilities of others are unclear.

The rules of the market seem to be missing with no clarity in who is responsible in making them. Also the urge to tackle RMT is not as acute as many other problems currently on the table.

The ongoing reforms of the German health care system have not targeted RMT issues. Neither have these reforms changed the structure of the system drastically which is difficult to do in practice. The key question is whether widely adopted RMT services can be moulded to fit the current structure of the German health care system in a manner that enables wide scale adoption of RMT services or will the system itself have to change. If it is down to the latter, it is still unclear who will take the first step in making this happen and how long this change would take. Stakeholder views were mainly quite optimistic, believing the market would be ready in 2 to 3 years. With the German national election round the corner key stakeholders are eagerly waiting to see what comes next with regard to RMT. Although RMT has not as of yet found its place in the German health care system, Germany's DM programs can prove to be a potential platform where RMT solutions could be implemented if suitable business models are found to justify the initial up-front investment cost and adequate incentives between physicians and health insurance funds are met.

#### 8.4.3 Italian RMT market summary

**Table 18 – Italy country study, main findings**

- In Italy, the RMT market does not exist and RMT is not an integrated part of care pathways. But, there are successful cases of RMT deployment (Lombardy/Veneto), albeit with a slow uptake.
- The RMT market in Italy is characterised by: (a) a few large companies, a minority of which has RMT as their core business, most making revenues from other eHealth services or services like tele-surveillance or telecare; (b) a few medium sized companies structurally positioned to take advantage of RMT market; (c) many small localised and opportunistic companies whose lifespan is short; (d) a handful of insurance companies providing RMT as part of added value services.
- Strong regional disparities with some of the richest regions providing RMT activities, with a push from regional authorities and public procurement initiatives, but little to no RMT activities in significant parts of the country.
- RMT solutions offered today are very simple (e.g. static measurements) and require significant involvement of health care professionals since more complex RMT solutions may be met with resistance by users and may be too costly.
- Main barriers to RMT deployment include: (a) lack of a favourable incentive framework which means that until RMT is included for reimbursement at national level no take up of the market can be expected; (b) lack of awareness, culture and capacity to introduce a "Structured Tele-medicine" approach which may only be achieved through major institutional and organisational restructuring; (c) closed regional systems with some regions like Lombardia, Toscana, and Emilia-Romagna having invested into their own broadband network to inter-connect health care units and players, making it difficult for new players to get into the market; (d) lack of evidence on and of awareness of potential benefits of RMT; and (e) resistance of practitioners (both GPs and specialists) and hospitals, mainly for financial reasons.

### Conclusions

The RMT market in Italy remains a niche market, with some examples of successful undertakings albeit limited in scale. The lack of political push and of a specific strategy for RMT combined with the strong regional differences in terms of health care organisation and financing make it a difficult

market for industry players. Most of them try to be present in the market, drawing revenues from other eHealth activities, to be in good position should RMT take up in the future; however, in the past few years, even those have had to revise their business plans and scale down their expectations, and have diversified their activities to be able to survive.

One of the main barriers to RMT uptake is the lack of a clear incentive framework that would encourage the implementation of RMT services. Instead, GPs, specialists and hospitals alike resist the introduction of RMT that undermines their existing revenues streams. The lack of awareness about what RMT offers and the perceived lack of evidence on its benefits also play against market uptake. The fragmentation of the health care organisation combined with the funding mechanisms organised at regional level contributes to the fragmentation of the RMT market itself. There is a trend towards moving the competence for eHealth away from the Regional Innovation Department into the Health Department but only few regions are sufficiently active in the eHealth domain to give RMT market players confidence in future growth.

In other words in spite of a number of successful projects and large scale pilots, particularly at regional level, and despite the emergence of successful Italian companies on the local /regional RMT markets, the prospects for growth do not lead to much optimism as the current health and social care framework is not adapted to the specificities of RMT.

#### 8.4.4 Dutch RMT market summary

**Table 19 – Netherlands country study, main findings**

- There is evidence of some 'viable-business-model' market developments in the Netherlands with RMT services embedded in home care or offered as stand alone, either reimbursed by insurance schemes or paid out of pocket. However, there are a limited number of companies active in the RMT field, which is still a niche market.
- There are several experiments and pilots on new ways of delivering health and social care funded via EU, national and regional programmes and projects, as well as by industry actors (e.g. on remote care, long term care, home care, independent living etc.).
- Patient empowerment, although still in its infancy, is increasingly seen as one of the main drivers of innovation in the health care system.
- There is scarce availability of both qualitative and quantitative data about the RMT market. Most actors have no comprehensive view of the RMT field, and in addition, there is limited exchange of information among actors.
- Main market drivers include an increasing elderly population, the forecasted lack of health care professionals, and the need for new models for care of chronic diseases in the future.
- In spite of profound reforms calling for new models of care, the role of RMT is still limited although it is believed to have the potential to help in the transformation process.
- Main barriers are those of financial nature: lack of incentives for GPs (paid per visit and not per outcome), difficulties with budget reallocation between primary and secondary care, as well as between health and social care.
- There is increasing awareness on a political level of likely benefits of RMT deployment, but there is no short term strategy for RMT. The increasing importance of regions in the health care organisation may help push RMT services introduction.

## **Conclusions**

The market for RMT services is still limited in the Netherlands which appears to be a young, niche market with only few active players. However ongoing reforms and power given to insurers and to the regions could become important drivers for RMT diffusion. Different approaches adopted to date include the cooperation between health and social care organisations in projects and pilots, the stand-alone services offered as a market product and the embedding of RMT services in existing insurance packages. The next generation of projects (Koala, CommonWell, Health Buddy) with a larger number of patients involved (up to a few hundred per project) is underway. This could lead to the elaboration of the evidence needed to prove the added value of RMT services. Evidence on benefits is so far scattered but points in the direction of patient satisfaction, enhanced self-management by patients, enhanced autonomy and independent living as well as beneficial impact on hospital re-admissions and bed days of care (BDOCs). Coordination and co-operation at national level to help combine the efforts undertaken in the various projects could mean a quantum leap in terms of producing evidence which is statistically significant. Meanwhile, the market will continue to grow by absorbing further RMT solutions but growth will be sub-optimal in view of the absence of clearly defined and shared evidence. Since the new projects have an international component results may also be used for international comparison.

Finally, the patient is often mentioned as the single actor who can promote the diffusion of RMT, by demanding access to RMT services. In reality patients or patient organisations are not sufficiently organised in that field but working on their mobilisation would help foster dissemination of RMT systems. Raising patient awareness by organising national campaigns might be one option; media attention for RMT systems another.

### **8.4.5 Swedish RMT market summary**

**Table 20 – Sweden country study, main findings**

- The Swedish RMT market does not exist, and successful business cases are very rare. There is growing activity, mostly project-based pilot studies with an increasing trend for partnering among stakeholders but with insufficient critical mass despite the very advanced IT infrastructure in Sweden. The market is seen as possessing all the potential to grow during the next 2-5 years.
- There is increasing awareness towards the need for new services to support health and social care and collaboration among different organizations. Integration of RMT into the health care system seen as possible and desirable.
- Patient empowerment is increasingly happening and is the focus of the national health strategy.
- Market data are extremely scattered, and qualitative and quantitative data are scarce. There is a need for more data concerning successful examples and evidence-based proof of concepts.
- Main market drivers include increasing elderly population and need for new models for care of chronic diseases in the future.
- There are currently more barriers than drivers for market development: (a) lack of funding and changes in the current reimbursement mechanisms; (b) lack of leadership; (c) lack of information and knowledge about RMT; (d) users and patients are not aware of the possibilities of RMT.
- While eHealth in general, is seen as one of the lead markets for Sweden, and there is increasing awareness on a political level of the importance of RMT, there is no specific strategy yet.

## **Conclusions**

There seems to be widespread interest among different stakeholders in the development of RMT. However, action requires clear leadership, which is still missing among stakeholders. As a result, developments are embryonic and a lot still needs to be done to enable market growth in spite of the common vision of and belief in the potential the RMT market holds. Establishment of the market also requires government action to involve county councils and municipalities in its development; the government, as the guiding actor, would need to set up common rules and regulations while the implementation itself will be the responsibility of the county councils and municipalities. The roles in general are still not defined between different stakeholders. There is also need to change the current reimbursement mechanisms, which are likely to not give further incentives to the development of new RMT applications. Progress is currently happening in the form of increasing discussions, pilot studies and projects but also in partnering among interested stakeholders and actors in the field. However, several key issues remain unsolved. Although some companies have managed to stay in the market and create business for their RMT services, success stories are rare.

### **8.4.6 The UK RMT Market**

**Table 21 - United Kingdom country study, main findings**

- The market is currently very small (well below 5% penetration) and still being defined.
- There is growth potential during the next 5 years in the market.
- This growth is dependent on positive outcomes from current major trials, pilots and demonstrator projects and from the clinical acceptance of RMT and related services for a wider range of ‘long term conditions’.
- Strong evidence of long-term ‘infrastructural’ actions to enable growth but some concerns regarding adequacy of future broadband local access networks.
- An increasing focus on the convergence of health care and social care delivery with considerable attention being given to underlying process management and organisational models.
- Further supplier development required in technical and clinical triage processes at RMT hubs.
- Significant investment in health care informatics and vastly improved demand data flowing from the (Primary Care) Quality and Outcomes Framework.
- Patient empowerment beyond service choice will benefit from imminent implementation of Summary Health care Records.
- Market drivers include demographic trends, chronic care management costs, growth of life-style-related conditions, citizen expectations (early adopters), strong policy leadership and a combination of economic and sustainability pressures.
- Market barriers include a *perceived* lack of evidence-based investment rationale (clinical and economic), uncertainties around information governance, challenges for procurement processes and a generally low level of citizen/media awareness of the scale of required health care transformation.
- Good and growing awareness across all Administrations within the UK in terms of policy development. Legislation is planned to expand remote home-care services for the elderly.

## **Conclusions**

After more than three decades of debate, infrastructure evolution and cautious experimentation, the UK market for Personal Health Systems and Remote Monitoring & Treatment is still at a formative stage. There is, as yet, no commonly agreed or widely understood nomenclature to describe this emergent market and its segments. The words Health, Medicine and Care are variably prefixed by, ‘e’, ‘Tele’ and ‘digital’, and used together (e.g. TeleHealth care) or with other descriptors to differentiate between segments (e.g. social/community care), or, alternatively, to provide all-embracing ‘umbrella’ descriptions such as ‘Connected Health’ and ‘Assistive Technologies’ – this latter term being preferred by informatics specialists at the UK Government’s Department of Health.

There is an increasing recognition across the Primary Health care and the Social Care professional communities of a ‘continuum’ that stretches from reactive medical interventions to individual attention to wellbeing. This recognition reflects a realisation that many of the same, or similar, technology-based care delivery systems and techniques can be applied across disciplines that have, for most of the UK, been developed over the past 60 years under distinct budgetary and management regimes, each with their own culture and customer relationships.

There is, within these professional communities, a growing realisation that current practice is unsustainable in the context of demographic trends and the exponential growth of life-style-induced Long-Term-Chronic (LTC) conditions. Professionals to be yet fully embedded in public consciousness to the same extent as, say, do, not believe this general realisation, and its direct implications for citizens and the UK economy, climate change.<sup>230</sup>

The scale of the future challenge (and thus potential market for Assistive Technology solutions) is directly related to population size, age-demographic trends and the emergence of new and conveniently deployed technologies.<sup>231</sup> Of the UK’s 61.4million citizens approximately 30% are known to have one or more ‘Long Term Conditions’ (>16 million in England alone) and this is expected to grow by a further 20% in the period to 2025. The average age of the UK population (in 2008) is now 40 – two years higher than a decade previously – with around 20% over age 65. There are regional variations in age demographics with the Northern Ireland (population 1.77 million) having a higher than UK average proportion of older citizens.<sup>232</sup>

Evidence to support the clinical and economic cases for investment remains limited but is expected to be clarified (in 2010 and 2011) by results from demonstrator projects in England and Wales, by the eHealth programme in Scotland and the major procurement exercise in Northern Ireland.

The economic case for process changes and services innovation may expect to gain further support from a recognition of complimentary values – particularly in areas of environmental sustainability (‘green NHS’) and a ‘systems view’ that can embrace secondary and tertiary impacts such as anxiety reduction amongst carers. The speed with which process changes and services innovation are accepted and taken forward by clinicians and other stakeholders (in what are large and sometimes cumbersome organisations) will reflect the success of engagement and knowledge transfer programmes.

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<sup>230</sup> The recent report that more than half of all children born in the UK this year may survive beyond 100 years was treated by the media as ‘a good news story’ celebrating advances in medical practice. There was correspondingly little comment that over the period 1950-2050 the ratio of those below age 65 to those above (the ‘potential support ratio’) will have fallen from 12:1 to 2:1.

<sup>231</sup> As an indicator of growth, the global market for wearable wireless body sensors for health (not sports/fitness) applications is predicted (ABI Research) to grow from near zero to 60 million units per annum by 2014.

<sup>232</sup> The relatively higher proportion of elderly citizens in Northern Ireland is attributed to past phases of emigration and lower recent rates of immigration.

## **8.5 Final conclusions**

### *PHS/RMT market*

- There is no market today. It is still being defined. The available market data are based on projections from statistics on prevalence of e.g. chronic diseases and ageing populations.
- There have been and continue to be pilots of varying scale and ambition. Most of which are abandoned once the pilot project is over. The UK Whole System Demonstrators are the most ambitious ones and have faced a lot of problems getting started but are now ongoing.
- There are small SMEs and large companies who understand the market potential but are still defining ways to develop the market. Consequently, a lot is still done under R&D and as pilots.

### *Lack of incentives and viable business models*

- One major barrier holding RMT / PHS back is the current incentive framework that does not reward services that keep patients away from doctor's offices or hospitals. What is needed is large-scale deployment of the Chronic Care Model and financial incentives that reward functional and clinical outcomes.
- The other major barrier is lack of evidence of clinical benefits and cost savings. Although pilots are ongoing only a few are done at a level where evidence can be obtained and reported scientifically. Pilots that have published their evidence have reported major improvements in clinical status and decrease in use of hospital and outpatient clinical services. However, turning these into cost savings would require reorganization of health care services.
- In order to facilitate deployment, a new service provider between the patient and the health care system that runs the service 24/7 and acts as an intermediary triage centre is proposed. In addition, a longer term vision of how health care services should be organized and reimbursed to take advantage of what modern medicine can do and what ICT can enable, ought to be developed.
- Yet another barrier refers to knowledge of what PHS/RMT is and can enable. Education of stakeholders is an issue that needs to be addressed. There is awareness but it does not translate into action. There is no feeling of "urgency" to deploy RMT in health care. There are other more important challenges that get the attention of politicians and health policy makers.

### *The way forward*

- Provide leadership and as the first priority develop a strategy that addresses the barriers to market development. A good starting point would be the "Manifesto for Connected Health" that was written by the 1<sup>st</sup> Leadership Summit of the European Connected Health Campus in May 2009 in Belfast.<sup>233</sup>
- The European eHealth Action Plan should more clearly address the need for countries to develop a long-term vision of how health care should be organized in view of what we know today. The current health care environment needs to be disrupted in order for PHS/RMT to work

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<sup>233</sup> Manifesto for Connected Health ([www.echcampus.com](http://www.echcampus.com)).

- Create a clearing-house that collects evidence from PHS/RMT pilots and creates awareness of progress in the domain.

In closing, the need for collaboration and engagement cannot be overemphasized. No company can succeed alone. They need to work close to the patients and health care providers. They need to cooperate with other players in the market, including the social and professional organizations, and users as well as intermediate users. They need to combine resources, competencies and create dynamic capabilities.

## **8.6 Interview questionnaire**

### **Facts on PHS/RMT market:**

1. Main perspective of the stakeholder on the market of PHS/Remote monitoring, now and in the near future.
2. Type of market data or business information the stakeholder is aware of and/or uses with the aim of supporting activities in the PHS market, and accessibility of such data.
3. Type of qualitative data the stakeholder is aware of and/or uses with the aim of supporting activities in the PHS market and accessibility of such data.
4. Type of activities, products and/or services deployed in the market on PHS/Remote Patient Monitoring.
5. Role of the stakeholder in the health care delivery chain with regard to PHS/ Remote Patient Monitoring implementation.
6. Established or planned partnerships among actors.

### **Analysis of stakeholders' roles and strategies:**

7. Key factors for successful PHS implementation according to the stakeholder, including known examples of successful business approaches or business cases.
8. Factors (demographics, economics, disease occurrence, technology etc.) influencing the stakeholder's PHS procurement/deployment decisions.
9. Stakeholder's strategy in getting its activities running (business as usual, seizing new opportunities, allying with other businesses/public authorities, etc.).
10. Business models behind the stakeholder's activities and funding models for PHS.
11. Drivers (business, political, social) as perceived by the stakeholder as key for the realisation of a full-fledged PHS-market.
12. Barriers perceived as impeding the realisation of a full-fledged PHS-market.

### **Stakeholders' views and perceptions:**

13. Successful innovation models and perceived role of the various actors within these models (medical practitioners, public authorities, industry, patients, etc.).
14. Kind of activities, initiatives, measures etc. seen as necessary to realise a full-fledged PHS-market.
15. Role the stakeholder thinks he/she should have in such activities, initiatives, measures etc.
16. Lessons to be learned from the introduction of PHS in other markets (for instance the US-market).
17. Lessons to be learnt from other health markets (e.g. the pharmaceuticals market).
18. Views on usefulness of the Strategic Intelligence Monitor and focus it should have.

## 8.7 Stakeholders interviewed

Table 22 – List of stakeholders interviewed in the six countries

FRANCE (7)		
Stakeholder segment	Name	Role/Organisation
Policy makers	Laurent Debenedetti	International Relations Director, Agence pour les Systèmes d' Information de santé Partagés (Agency for shared health Information systems) ASIP/GIP-DMP
Payers	Yves Masson	CEO, AXA Assistance
Health service providers	Norbert Noury	Professeur, University of Lyon, Institute of Nanotechnology, INSA Lyon
Health service providers	Michel Amiel	President, Association pour la Télésanté en Région Rhône Alpes (ASTRHA)
PHS/RMT integration aspects	Alain Franco	Professor, Université & CHU de Nice
Technology and service providers/PHS/RMT integration aspects	Charles Parisot & Berzsenyi Agnes	General Manager Home Health & Manager, Interoperability Standards and Testing, GE Health care
Technology and service providers	Lyse Brillouet,	Marketing director, Orange Health care / France Telecom
GERMANY (10)		
Stakeholder segment	Name	Role/Organisation
Policy makers	Mathias Perleth	i. A. PD Dr. med., The German Health Care System and the Federal Joint Committee, G-BA
Policy makers	Kirsten Steinhausen	Federal Ministry of Education and Research (BMBF, Ref. 615)
Payers	Christoph Gries	Geschäftsbereich Produktmanagement, Deutsche Angestellten-Krankenkasse (DAK )
PHS/RMT integration aspects	Prof. Dr. Hans-Jochen Brauns	Chairperson, DGTelemed - Deutsche Gesellschaft für Telemedizin e. V. / alpheios
PHS/RMT integration aspects	Thomas Norgall	Senior Engineer, Fraunhofer Institut fuer Integrierte Schaltungen - BMT
Health service providers/ PHS/RMT integration aspects	Prof. Otto Rienhoff	Arzt, Med. Informatiker, The German University Medicine/ Verband der Universitätsklinika Deutschlands e.V. (VUD)
Technology and service providers	Stefan Schraps	Managing Director, Founder, Bodytel GmbH
Technology and service providers	Stefan Jentsch	Product manager, Weinmann GmbH
Technology and service providers	Florian Herrmann	Medical Sales, StollmannEntwicklungs- und Vertriebs-GmbH
Technology and service providers	Michael Bruhnke	Business Development Manager, Aipermon GmbH & Co. KG
ITALY (13)		
Stakeholder segment	Name	Role/Organisation
Policy makers	Paola Tarquini	Department for Digitalisation and Innovation, Italian Ministry of Public Administration, Head of eHealth Sector
Policy makers	Claudia di Minco	Department of Health, Italian Ministry of Welfare, Head of SIS (Health Information Systems)
Technology and service providers	Marco Romani	Project and Market Developer, TELBIOS SpA (Telemedicine company)
Health service providers	Professor Mariano Corso	Milan Polytechnic University, Department of Management Engineer, Head of Observatory on ICT in the Health Sector
Health service providers	Gabriella Borghi	Lombardia Regional Administration, Department of Health, Coordinator of Programme Nuove Reti Sanitarie (New Health Networks)
Health service providers	Professor Cristina Masella	Milan Polytechnic University, Department of Management Engineer, Head of eHealth Sector
Technology and service providers	Prof Simonetta Scalfini (founder)	Health Telematic Network (telemedicine company)
Technology and service providers	Prof Paolo Glisenti (founder)	Health Telematic Network (telemedicine company)

Technology and service providers	Maurizio Nardi (CFO)	Health Telematic Network (telemedicine company)
Policy makers	Giancarlo Ruscitti	Secretary General, Department of Health, Veneto Regional Administration
Health service providers	Dr. Angelo Rossi Mori	National Research Centre (CNR), Institute of biomedical technologies, Head of eHealth Sector
Technology and service providers	Marco Mena	Director, Between Spa (Market research company), responsible for Between observatory on eHealth deployment
Policy makers	Professor Roberto Landi	Luiss University of Rome, Management School, head of eHealth sector
<b>THE NETHERLANDS (18)</b>		
Stakeholder segment	Name	Role/Organisation
Policy makers	Annemarie van Hout	Aveant
Policy makers	Walter Salzmann	CVZ
Technology and service provider	Daan Dohmen	Founder, Focus Cura
Professional organisation	Marijke van Hees; Aart Leferink	IZIT (ICT in Health care in Twente)
Health service provider	Rolien de Jong	MeaVita, Former head of Innovation
Insurer	Harry Nienhuis	Menzis, Head of the Knowledge Centre on innovation
Policy makers	Hans Haveman	Min VWS, Department of Health, Wellbeing and Sport
Policy makers	Johan Bruin	NICTIZ
Interest organisation	Marita Meulmeester	NPCF, Patient association promoting the interest of patients within care
Consultancy	Herman Pieterse	Managing Director, Profess Medical Consultancy
Technology and service providers	Jan Ramaekers	Founder, Sananet
Consultancy	Willem Schroeijers	Syntens
Technology and service providers	Pim Ketelaar	Chairman of the Dutch Association of eHealth (NVeH) and CEO of Telecom4Care (TeleHealth consultancy)
Research institute	Hermie Hermens; Mirjam Vollenbroek	Cluster Manager, Roessingh R&D and Chair in telemedicine at University of Twente /head of RMT group. Cluster Manager at RRD & part time professor University of Twente, Clinical research and feedback in telemedicine.
Technology and service providers	Ed Mos	TNO
Technology and service providers	Jelle van der Weijden	Tunstall
Health service providers	Victor Pop	Universiteit van Tilburg, Chair in primary care and GP
Technology and service provider/Health service provider	André van Oort	Vitaphone Nederland
<b>SWEDEN (7)</b>		
Stakeholder segment	Name	Role/Organisation
Policy makers	Jonas Gumbel & Michael Bergström	Swedish Association of Local Authorities and Regions (SALAR)
Policy makers/PHS/RMT integration aspects	Monica Winge	In charge of eHealth issues at VINNOVA, the Swedish Governmental Agency for Innovation Systems
Payers	Björn-Erik Erlandsson	Senior Advisor, Stockholm County Council
Health service providers	Sabine Koch	Professor, Karolinska Hospital
Large scale procurement	Mats Larsson	Senior Partner at Caritea AB, The Swedish Association of Local Authorities and Regions (SALAR)
Users	Christer Neleryd	District Manager, The Swedish National Board of Health and Welfare
Technology and service providers	Björn Söderberg	Sales and Marketing Director, Fouder, Kiwok AB

UK (13)		
Stakeholder segment	Name	Role/Organisation
Technology and service providers	Ivan Harrow	Senior product Strategist, Intel Corp.
Technology and service providers	Paul Gee	Chief Executive, Telecare Services Association
Technology and service providers, PHS/RMT Integration Aspects	Nat Billington	Managing Director, MapofMedicine
Technology and service providers	David Kelly	Managing Director, Tunstall ltd
Health Service Providers	Paul Duffy	Chief Technology Officer, Belfast HSS Trust
Policy Makers	George McGinnis	Senior advisor, NHS England
Large Scale Procurement	Tim Ellis	Project Leader, NHS, Whole System Demonstrators
PHS/RMT Integration Aspects	Dr. Mike Bainbridge	Clinical Architect, Technology Office, DH Informatics Directorate
Policy Makers	Sir Muir Gray	Director Budgetary office, Department of Health
Users	Dr. Peter Short	NHS General Practitioner, Buxton, Yorkshire.
PHS/RMT Integration Aspects	Dr Michael Wilks	Senior Advisor, British medical Association
Large Scale Procurement	Eddie Ritson	Procurement project leader, DHSS, Public health Agency, Northern Ireland
Large-scale procurement	Dr. Hubert Curran	Senior Advisor, PHA, Northern Ireland

## **9 Annex IV: Health-related data and scientific evidence**

### **9.1 Prevalence data**

#### **9.1.1 Cardiovascular diseases**

Cardiovascular diseases (CVD) are characterised by pathological changes in the circulatory system of the body, i.e. the heart muscle and the blood vessels. This group of diseases includes hypertension (elevated blood pressure); ischaemic heart disease, including myocardial infarction; cerebrovascular disease, including stroke; peripheral vascular disease; rheumatic heart disease; congenital heart disease; and cardiomyopathies.

Cardiovascular diseases (CVD) are among of the leading causes of death and hospitalization in both genders in nearly all countries of Europe. The most frequent CVD are those of atherosclerotic origin, meaning the hardening and fatty degeneration of the arteries, mainly ischemic heart disease (IHD) and stroke. CVD clinically manifest itself in middle life and older age, after many years of exposure to unhealthy lifestyles, such as unhealthy diet, physical inactivity, and smoking habit and risk factors, such as high blood pressure, high cholesterol, diabetes, and obesity.<sup>234</sup>

##### **9.1.1.1 Chronic Heart Failure (CHF)**

In medical terminology the expression chronic refers to conditions with a long duration, whereas the term "acute" indicates a rapid onset, hence Chronic Heart Failure(CHF) is a long term condition, usually with stable treated symptomatology, the combined symptoms of a particular disease.

Due to lack of a comparable and comprehensive gathering of prevalence data for chronic heart failure, different estimations deriving from a variety of sources are to be taken into consideration. The estimated overall prevalence of clinically identified CHF is based upon population studies. The variability of the estimates on CHF prevalence has already been discussed in par. 2.2 and will not be repeated here.

According to several studies CHF puts a greater burden on the patients than any other chronic medical condition. It is a fatal condition; approximately 60% of patients diagnosed with CHF will die within 5 years of diagnosis. The self-reported quality of life is impaired by heart failure significantly and affects all dimensions of quality of life. According to the European Society of Cardiology only a minority of these patients are cared for by a cardiologist, which can lead to a higher rate of incidences and the corresponding costs.<sup>235</sup>

The economic costs and personal burden of chronic heart failure are significant. Direct costs due to heart failure were (in million € per one million population in 2004 values) 26 in the UK, 37 in Germany, 39 in France and 70 in the US, respectively. For the United States the expenditures dedicated to heart failure were higher than that for the treatment of cancer and myocardial infarction in 1991. Overall, chronic heart failure consumes 1–2% of the total health care resources in the developed countries. Medication is only responsible for a small part of the costs. Bund economic burden of heart failure may become unmanageable in the

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<sup>234</sup> EUPHIX and EUphact. (2009). "Cardiovascular diseases." Retrieved 26 October 2009, from [http://www.euphix.org/object\\_class/euph\\_cardiovascular\\_diseases.html](http://www.euphix.org/object_class/euph_cardiovascular_diseases.html). European Commission (2007). Major and Chronic Diseases REPORT 2007. Luxembourg: European Commission (2007). Major and Chronic Diseases REPORT 2007. Luxembourg. 2007: pp. 18 et seq., 117 et seq., 291 et seq.

<sup>235</sup> Ibid.: D52 et seq.

setting of an ageing population indicating the need for cost-effective treatment options and preventive strategies.<sup>236</sup>

#### 9.1.1.2 Causes for CVD

Although CVD prevalence is very high, its occurrence is largely preventable maintaining risk factors at favourable level during life span. Epidemiological studies have demonstrated that cardiovascular risk is ‘reversible’, that means that by lowering the level of risk factors it is possible to reduce the number and severity of events, or delay the event occurrence.<sup>237</sup>

Even though the clinical onset is mainly acute, CVD often evolve gradually, causing substantial loss of quality of life, disability, and life long dependence on health services and medications. They also result in premature deaths. Based on a prospective cohort studies CVD are associated with adverse outcomes in the elderly people, including cognitive impairment, dementia and decreased physical performance.<sup>238</sup>

#### 9.1.1.3 Morbidity and Years of Life lost in disability due to CVD

Uniform data on the prevalence of CVD and quantifiable data on how this condition is affecting the different populations is hard to obtain. One source is the WHO Burden of Disease project,<sup>239</sup> which compiles data from their Member states. It uses the disability-adjusted life year (DALY<sup>240</sup>) measures health gaps as opposed to health expectancies. It measures the difference between a current situation and an ideal situation where everyone lives up to the age of the standard life expectancy, and in perfect health in this way it one measure the time lived with disability and the time lost due to the condition.

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<sup>236</sup> Berry, C., D. R. Murdoch, et al. (2001). "Economics of chronic heart failure." *European Journal of Heart Failure* **3**(3): 283-291. p. 285 et seq.; Bundkirchen, A. and R. H. G. Schwinger (2004). "Epidemiology and economic burden of chronic heart failure." *Eur Heart J Suppl* **6**(suppl\_D): D57-60.: p. D58.

<sup>237</sup> Tunstall-Pedoe, H., K. Kuulasmaa, et al. (1999). "Contribution of trends in survival and coronary event rates to changes in coronary heart disease mortality: 10-year results from 37 WHO MONICA Project populations." *The Lancet* **353**(9164): 1547-1557.: pp. 1547 et seq.

<sup>238</sup> Hofman, A., M. Breteler, et al. (2007). "The Rotterdam Study: objectives and design update." *European Journal of Epidemiology* **22**(11): 819-829.:pp. 820-821.

<sup>239</sup> [http://www.who.int/healthinfo/global\\_burden\\_disease/en/index.html](http://www.who.int/healthinfo/global_burden_disease/en/index.html)

<sup>240</sup> DALY = YLL + YLD where: (YLL = years of life lost due to premature mortality; YLD = years lived with disability).

**Figure 28 – Age-standardised DALYs rate for CHD, stroke and other CVD by EU country, 2002**

	Age-standardised DALYs lost per 100,000		
	CHD	Stroke	Other CVD
Austria	579	349	431
Belgium	512	356	321
Bulgaria	1.344	1.188	1.485
Cyprus	638	289	832
Czech Republic	945	629	452
Denmark	478	401	359
Estonia	1.449	819	714
Finland	687	411	299
France	259	271	360
Germany	574	338	481
Greece	620	592	454
Hungary	1.137	731	654
Ireland	671	361	359
Italy	409	335	363
Latvia	1.606	1.102	803
Lithuania	1.444	620	608
Luxembourg	403	420	397
Malta	709	365	235
Netherlands	460	329	411
Poland	949	598	657
Portugal	431	836	301
Romania	1.176	1.162	793
Slovakia	1.037	387	795
Slovenia	552	524	492
Spain	368	294	274
Sweden	506	300	284
United Kingdom	657	359	298

Source: World Health Organization (2004) The World Health Report 2004. WHO: Geneva<sup>241</sup>

### 9.1.2 Diabetes

Diabetes is a chronic condition that occurs when the pancreas does not produce enough insulin, or alternatively, when the body cannot effectively use the insulin it produces. Diabetes prevalence increases with age. It is a common disease and its prevalence is expected to increase in the future, especially in developing countries. The majority of these diabetic patients (over 90%) suffer from Type II (non-insulin-dependent) diabetes mellitus, which is by nature, a progressive disorder with a slow and insidious onset. As a consequence, the condition is frequently under reported. Most common complications include blindness, heart and blood vessel disease, stroke, kidney failure, amputations, and nerve damage.<sup>242</sup>

Data on the occurrence of Diabetes is usually collected in special, often regional, surveys and not by routine monitoring. The international Diabetes Foundation estimated in 2010 that 8.9%

<sup>241</sup> World Health Organization (2004). The World health report : 2004 : changing history. Geneva, WHO.

<sup>242</sup> Jonsson, P. M., L.-Å. Marké, et al. (2000). "Excess costs of medical care 1 and 8 years after diagnosis of diabetes: estimates from young and middle-aged incidence cohorts in Sweden." *Diabetes Research and Clinical Practice* **50**(1): 35-47.: pp. 42-46 ; Jönsson and B. Jönsson (2002). "Revealing the cost of Type II diabetes in Europe." *Diabetologia* **45**(7): S5-S12.

of the adult (20-79 years) EU-27 population is suffering from diabetes, the prevalence ranges from 4.9% in the United Kingdom to 12% in Germany.<sup>243</sup>

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243 International Diabetes Federation (2006). The Diabetes Atlas 2006. T. Edition. Brussels, International Diabetes Federation. International Diabetes Federation. (2009). "IDF Diabetes Atlas." IDF Diabetes Atlas Retrieved 7 January 2010, from:  
<http://www.diabetesatlas.org/content/diabetes-mortality>  
<http://www.diabetesatlas.org/content/europe-0>  
[http://www.diabetesatlas.org/sites/default/files/DM%202010\\_7%20regions.xls](http://www.diabetesatlas.org/sites/default/files/DM%202010_7%20regions.xls)

**Figure 29 – Diabetes Mellitus by country**

Country/ Territory	2010 Population (20-79 years) (000's)	2010 DM National prevalence (%)	2010 DM Comparative prevalence (%)	2010 DM Total numbers (000's)	2010 Type 1 incidence (000's)	2010 IGT National prevalence <sup>244</sup> (%)	2010 IGT Comparative prevalence (%)	2010 IGT Total numbers (000's)	NUMBER OF DEATHS ATTRIBUTABLE TO DIABETES (20-79 YEARS) Males	NUMBER OF DEATHS ATTRIBUTABLE TO DIABETES (20- 79 YEARS) Females	National Diabetes Program me**
<b>EU Total</b>	<b>367,283.70</b>	<b>8.87</b>		<b>32,918.10</b>	<b>441.10</b>	<b>10.69</b>	<b>8.81</b>	<b>32,374</b>	<b>140,182</b>	<b>137,718</b>	-
Austria	6,301.6	11.2	8.9	708.4	13.3	6	4.1	377.8	2300	2,225	YES
Belgium	7,643.9	8	5.3	610	15.4	6.5	4.8	494.5	2697	2,869	NO
Bulgaria	5,790.2	9	6.5	519.5	9.4	6	5	344.7	3999	4,125	NA
Cyprus	634.1	10.4	9.1	65.9	14.9	6.7	5.9	42.8	218	171	YES
Czech Republic	7,824.3	8.7	6.4	677.3	17.2	17.4	15.3	1,360.9	3414	4,129	NO
Denmark	3,907	7.7	5.6	301.5	22.2	15.2	12.4	594.4	1226	1,518	YES
Estonia	994	9.9	7.6	97.9	15.3	17.4	15.3	173.2	645	685	NA
Finland	3,863.4	8.3	5.7	319.8	57.4	8.8	5.9	339.2	1469	1,139	YES
France	44,091.3	9.4	6.7	4,164.2	12.2	7.6	6.6	3,339.6	18443	11,984	YES
Germany	62,654.4	12	8.9	7,494.3	18	6.6	4.1	4,132.6	27585	26,994	NO
Greece	8,560.7	8.8	6	754	9.9	7.4	5.9	634.5	2957	3,585	YES
Hungary	7,514.8	8.8	6.4	658.9	11.3	17.5	15.3	1,315.3	4279	5,545	NO
Ireland	3171.2	5.7	5.2	180.3	16.3	1.9	1.7	61.3	608	589	NO
Italy	44,509.9	8.8	5.9	3,926.2	8.4	6	4.7	2,654.7	13427	13,966	YES
Latvia	1,719.4	9.9	7.6	169.7	7.5	17.4	15.3	299.7	1028	988	NO
Lithuania	2,484.3	9.7	7.6	239.8	7.8	17.3	15.3	428.9	1759	1,784	NA
Luxembo urg	348.9	7	5.3	24.3	15.5	5.9	4.8	20.4	104	107	NO
Malta	306.8	9.8	6.8	29.9	15.6	7.7	6.1	23.8	93	141	NA

<sup>244</sup> All comparisons should be done using the comparative prevalence which is adjusted to the world population. The national prevalence indicates the percentage of each country's population that has diabetes; it is ideal of assessing the burden of diabetes in each country.

Netherlands	11,943.4	7.7	5.3	922.4	18.8	6.3	4.8	748	3675	4,108	YES
Poland	28,618	9.3	7.6	2,674.6	12.9	16.9	15.3	4,843.3	14150	15,126	NO
Portugal	8,033.8	12.4	9.7	997.6	13.2	13.3	4.7	1,071.6	2825	3,136	YES
Romania	16,129	8.4	6.9	1,351.4	5.4	17	15.3	2,743.4	8985	9,083	YES
Slovakia	40,74.6	7.7	6.4	314	13.6	16.6	15.3	676.2	1822	2,256	NA
Slovenia	1,546.2	9.9	7.7	152.9	11.1	17.5	15.3	271.2	618	427	NO
Spain	33,943.8	8.7	6.6	2,939.3	13	7.5	6.6	2,533.8	10969	9,581	YES
Sweden	6,618.6	7.3	5.2	484.4	41	9	7.3	597.7	1406	2,231	YES
United Kingdom	44,056.1	4.9	3.6	2,139.6	24.5	5.1	4.7	2,250.5	9481	9,226	YES
<b>Non EU</b>											
Iceland	210.5	2.1	1.6	4.4	14.7	7.3	5.9	15.5	15	19	NO
Norway	3,356.7	4.7	3.6	159.3	27.9	8.6	7.3	287.1	595	567	YES
Switzerland	5,569.1	11.3	8.9	629.9	9	6.1	4.1	339.2	1640	1,710	NO
Israel	4,495.9	7.1	6.5	318.8	10.4	5.5	5.1	248.2	1029	918	NA

Source: based on the Diabetes Atlas by the IDFs<sup>245</sup>

<sup>245</sup> <http://www.diabetesatlas.org/book/export/html/250> (accessed on the 7 Jan 2010).

### 9.1.3 COPD

#### 9.1.3.1 Prevalence of COPD

Chronic obstructive pulmonary disease is a smoking-related condition of progressive airflow obstruction, with disabling symptoms of chronic dyspnoea, cough and sputum production. The amount of patients suffering from this condition is hard to estimate due to a paucity of well-designed epidemiologic studies on COPD from most regions in the world including both EU15 and EU12. This makes it hard to estimate the number of patients in the EU27. The estimates of prevalence rates vary widely, from 0.2% to 18.3%, partly as a result of real differences in prevalence among countries and regions, and partly because of other factors. These factors include the method by which the prevalence is estimated (expert opinion, patient-reported diagnosis, symptom-based or spirometry-based), the definition of COPD that was used, age and smoking status of the population included, etc. Based upon comparison between well-designed studies and samples prevalence of COPD in Europe is estimated to rank between 4% and 10% of adults in the Member States.<sup>246</sup> Due to different categorisation and no uniform system to collect the data, data on prevalence at the level of individual countries is not included in this report.

According to Halbert, Isonaka et al.<sup>247</sup> COPD is "*a leading cause of chronic morbidity and mortality and should be a major public health concern.*" and "*Reliable COPD prevalence data are lacking for many parts of the world, despite the frequency of major risk factors for COPD, such as cigarette smoking, use of biomass fuels, and air pollution. Approximately 15% of smokers will acquire COPD.*"

#### 9.1.3.2 Mortality of COPD

The *Global Burden of Disease* Study estimates that by the year 2020, COPD will move from the sixth to the third-leading cause of death worldwide. The rates of mortality by COPD vary from less than 25 to more than 75 per 100,000 inhabitants in various European countries.<sup>248</sup>

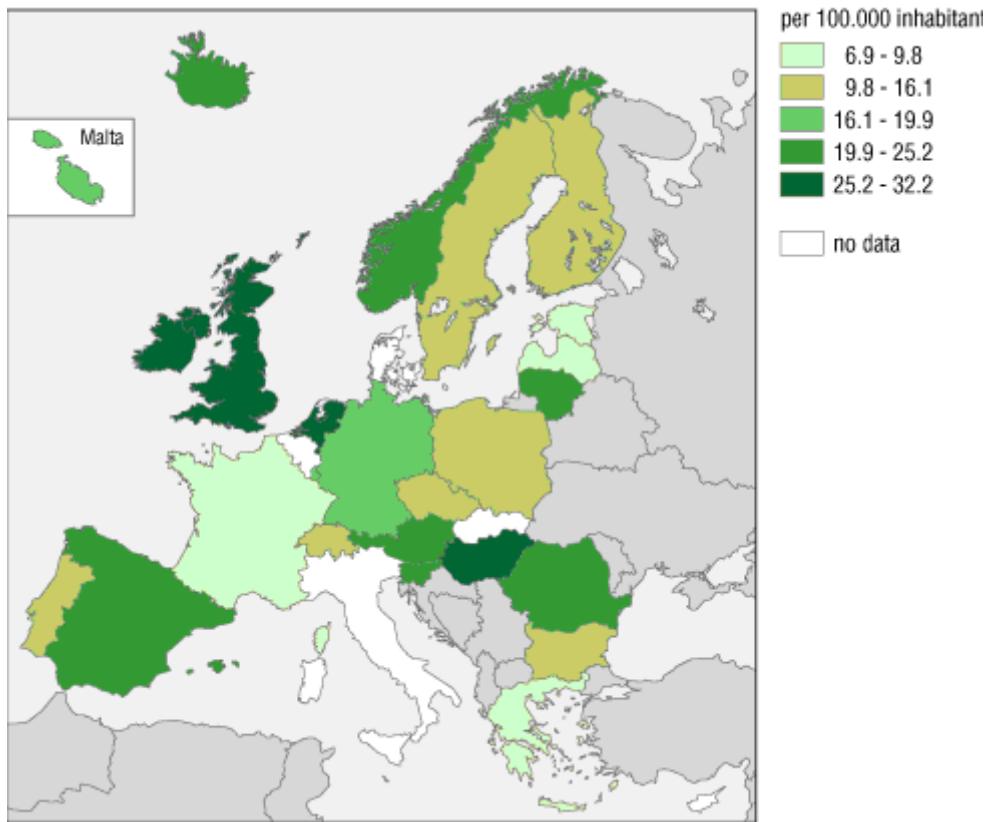
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<sup>246</sup> Halbert, R. J., S. Isonaka, et al. (2003). Interpreting COPD Prevalence Estimates\* What Is the True Burden of Disease?, Am Coll Chest Phys. **123**: 1684-1692.

<sup>247</sup> Ibid. pp. 1684-1685.

<sup>248</sup> Ibid, Loddenkemper, G. GJ, et al., Eds. (2003). European Lung White Book. TThe first comprehensive survey on respiratory health in Europe. Brussels, European Lung foundation. Wouters, E. F. M. (2003). "The burden of COPD in the Netherlands: results from the confronting COPD survey." Respiratory Medicine **97**(Supplement 3): S51-S59, Buist, A. S., M. A. McBurnie, et al. (2007). "International variation in the prevalence of COPD (The BOLD Study): a population-based prevalence study." The Lancet **370**(9589): 741-750.

**Figure 29 – Mortality (SDR) from COPD per 100,000, total in EU-27 in 2003**



Source: based upon Kaiser, S. (2007). "Mortality (SDR) from COPD"<sup>249</sup>

## 9.2 Clinical metrics (costs)

### 9.2.1 Cost of CVD

The data revealing the cost of cardiovascular diseases is using research gathered by the British Heart Foundation Health Promotion Research Group (BHF HPRG) based at the University of Oxford. According to British Heart Foundation's statistics the normal procedure of looking only at the health care costs of CVD grossly underestimates the total cost of CVD in the UK. Loss of years of productive life from death and illness in those of working age and from impact of the informal care of people with the disease contribute greatly to the overall financial burden. Furthermore the costs are also linked to illness benefits and retirement. Their research took a societal perspective to enable a wider analysis, in which all costs are considered, irrespective of who bears them or where they are incurred. It is not restricted to health care costs but also includes those costs falling outside the health care sector, such as the opportunity costs associated with unpaid (i.e. informal) care to CVD patients, or productivity losses associated with premature death or morbidity. For this analysis, a societal perspective was adopted.<sup>250</sup>

<sup>249</sup> Kaiser, S. (2007). "Mortality (SDR) from COPD." EUPHIX, 2010, from [http://www.euphix.org/object\\_map/o26n27163.html](http://www.euphix.org/object_map/o26n27163.html). The graphic is based on Data taken from the Eurostat database. It represents mortality from chronic lower respiratory diseases (ICD-10 code J40-J47) only. Mortality from asthma (ICD-10 code J45-J46) has been subtracted.

<sup>250</sup> Allender, S., Scarborough, et al. (2008). Methods for the EU cost of CVD study. Oxford, British Heart Foundation Health Promotion Research Group Department of Public Health.

From 1970 to 2000 for the age-range 45-74 years mortality has been decreasing in the majority of Western European countries but increasing in Central and Eastern Europe; during recent years mortality has also been decreasing in some Central and Eastern European countries. Those early declines could be due to changes in environmental risk factors, such as diet and lifestyle risks described above factors; more recent declines to improvements in modern cardiovascular treatments, responsible of both decreasing morbidity and increasing survival.<sup>251</sup>

#### 9.2.1.1 Cost structure for CVD

The Cost structure for CVD are based on data collected by the British Heart Foundation, expressed in 2003 prices according to their country. The categories of CVD direct health care service included were, primary care, accident and emergency care, hospital inpatient care (including day cases and cardiac rehabilitation services), outpatient care, medications.<sup>252</sup>

Other categories of health service were not included, such as school/community based prevention and health education activities, and out-of-pocket expenses incurred by patients in purchasing over the counter medications, consulting private practitioners, etc. These were not included in the study due to the difficulties of identifying them in the majority of countries. These excluded categories are likely to represent a very small proportion of the total costs identified. Categories of non-health care expenditure included in the study were the following:

- Informal care,
- Productivity costs due to mortality,
- Productivity costs due to morbidity.

Overall CVD is estimated to cost the EU Economy €192 Billion a year. This translates into a total annual cost per capita of €391. A great variety in prices can be found over different Member States from around €60 per capita per Year in Bulgaria to over 600 per capita per year in Germany and the UK. Of the Total cost of CVD in the EU, around 57% are due to direct health costs, 21% to productivity losses and 22% to the informal care of people with CVD.

#### 9.2.1.2 Health care cost of CVD in EU 27

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<sup>251</sup> Kesteloot, H., S. Sans, et al. (2006). "Dynamics of cardiovascular and all-cause mortality in Western and Eastern Europe between 1970 and 2000." *Eur Heart J* 27(1): 107-113.: pp. 107-110.

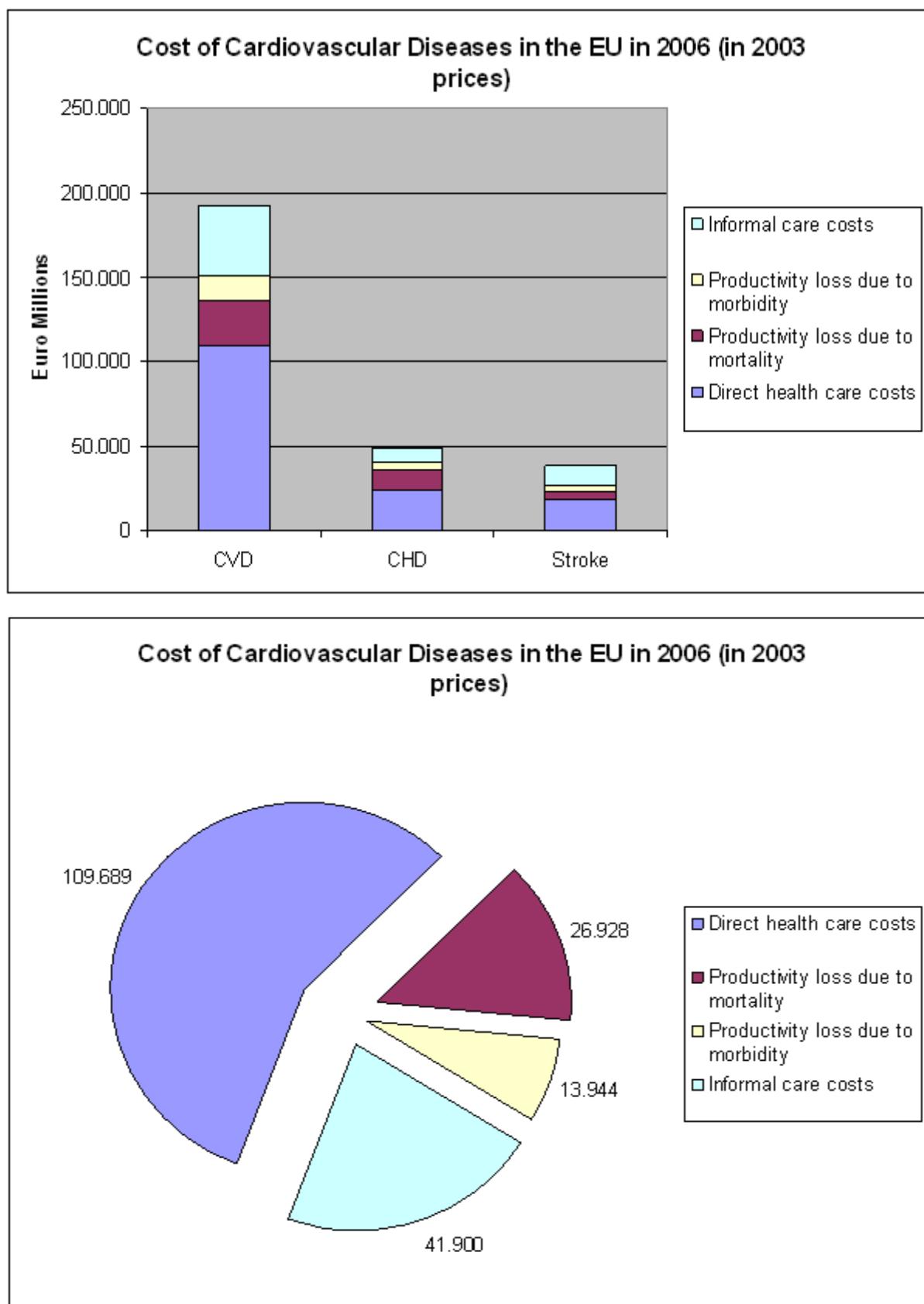
<sup>252</sup> Allender, S., Scarborough, et al. (2008). Methods for the EU cost of CVD study. Oxford, British Heart Foundation Health Promotion Research Group Department of Public Health; Allender, S., Scarborough, et al. (2009). European cardiovascular disease statistics 2008. Oxford, British Heart Foundation Health Promotion Research Group Department of Public Health.

Figure 30 – Health care costs of CVD, by country, 2006, EU

	Primary care € (thousands)	Outpatient care € (thousands)	A&E € (thousands)	Inpatient care € (thousands)	Medications € (thousands)	Total health care costs € (thousands)	Cost per capita €	Percentage of total health care expenditure %
Austria	109,234	96,853	17,518	875,423	533,837	1,632,865	198	6
Belgium	156,909	60,976	63,622	1,000,875	747,646	2,030,028	193	6
Bulgaria	32,042	32,051	5,607	132,270	71,305	273,275	35	14
Cyprus	4,321	6,608	3,182	10,559	20,727	45,397	59	5
Czech Republic	29,511	132,145	70,159	410,907	454,851	1,097,573	107	13
Denmark	55,495	63,335	13,576	619,399	238,178	989,983	182	5
Estonia	8,219	21,365	1,526	41,371	31,272	103,753	77	15
Finland	24,626	26,839	9,609	771,812	413,318	1,246,204	237	10
France	1,146,635	876,855	259,123	6,513,404	4,207,406	13,003,422	207	7
Germany	5,418,746	2,276,990	1,300,678	17,777,334	7,256,111	34,029,860	413	14
Greece	27,645	25,735	67,819	810,342	990,169	1,921,710	173	10
Hungary	48,213	73,963	6,169	174,053	449,449	751,847	75	10
Ireland	70,264	40,178	21,934	311,279	325,122	768,777	183	6
Italy	1,081,033	322,548	98,093	7,022,524	5,266,000	13,790,198	235	10
Latvia	5,694	9,793	2,242	57,460	33,189	108,378	47	9
Lithuania	19,057	13,612	2,263	94,984	71,327	201,243	59	13
Luxembourg	4,795	5,294	3,073	69,797	32,647	115,605	252	5
Malta	562	628	522	5,629	21,757	29,098	72	6
Netherlands	176,796	211,340	78,017	3,052,690	905,666	4,424,508	271	9
Poland	243,757	334,862	18,353	1,086,026	1,147,205	2,830,204	74	17
Portugal	173,348	82,802	136,535	547,579	659,087	1,599,351	151	10
Romania	24,833	115,071	9,653	366,838	209,437	725,833	34	15
Slovakia	42,314	59,617	3,475	131,791	160,639	397,836	74	13
Slovenia	12,441	12,195	6,579	65,130	85,620	181,966	91	7
Spain	439,422	579,507	259,513	1,849,545	2,566,623	5,694,611	130	7
Sweden	167,011	499,558	94,566	1,661,298	361,923	2,784,356	308	10
United Kingdom	1,098,629	390,487	88,760	13,635,293	3,698,222	18,911,391	313	12
<b>EU</b>	<b>10,621,552</b>	<b>6,371,208</b>	<b>2,642,166</b>	<b>59,095,613</b>	<b>30,958,732</b>	<b>109,689,271</b>	<b>223</b>	<b>10</b>

Source: www.heartstats.org op. cit. op

Figures 31 and 32– Cost of Cardiovascular diseases



Source: [www.heartstats.org](http://www.heartstats.org) op. cit. op.

## 9.2.2 Cost for Diabetes

Cost related to Diabetes Type II are primarily based on the study *Revealing The Cost Of Type II Diabetes In Europe*<sup>253</sup> which is an attempt to estimate the costs for Type II diabetes, which affects 90% of the patients suffering from diabetes related conditions.<sup>254</sup> It compares the costs in eight countries - Belgium, France, Germany, Italy, the Netherlands, Spain, Sweden and the United Kingdom. The total direct medical costs of Type II diabetes in the eight European countries was estimated at EUR 29 billion a year (1999 values).

Based on a Swedish study the cost profile during the natural history of diabetes is assumed to follow a 'U' or 'J' shape with relatively high costs immediately after diagnosis due to incidents during the adjustment and incidents leading to the diagnosis of the illness. This is preceded by a fall of costs and a raise with the onset of complications in the later stage of the disease.<sup>255</sup> (Jonsson, Marké et al. 2000)

In the early stage adjustments of the medication and incidents lead to higher costs, part of this cost can be reduced by interventions prior to the necessity of hospital admissions. According to a study by the U.S. Department of Veterans Affairs, continuously monitoring of chronically ill can reduce the bed days of care (BDOC) for Diabetes Mellitus by 20.4%.<sup>256</sup>

The estimated average yearly cost per patient was EUR 2,834 a year in Europe. Of these costs, hospitalisations accounted for the greatest proportion (55%, range 30-65%) totalling EUR 15.9 billion for the eight countries.<sup>257</sup>

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<sup>253</sup> Jönsson and B. Jönsson (2002). "Revealing the cost of Type II diabetes in Europe." *Diabetologia* **45**(7): S5-S12.

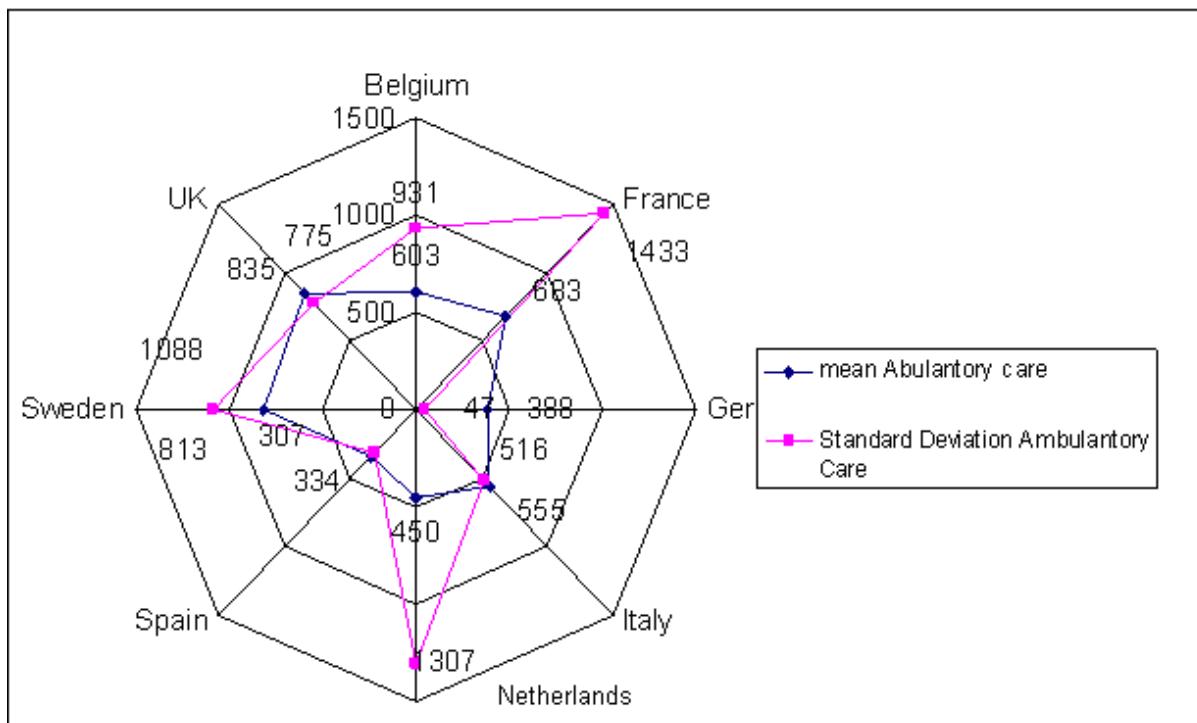
<sup>254</sup> World Health Organisation. (2008). "Diabetes Factsheet." Fact sheet Fact sheet N°312. Retrieved 7th January 2010, 2010, from <http://www.who.int/mediacentre/factsheets/fs312/en/index.html>.

<sup>255</sup> Jonsson, P. M., L.-Å. Marké, et al. (2000). "Excess costs of medical care 1 and 8 years after diagnosis of diabetes: estimates from young and middle-aged incidence cohorts in Sweden." *Diabetes Research and Clinical Practice* **50**(1): 35-47.

<sup>256</sup> Darkins, A., P. Ryan, et al. (2008). "Care Coordination/Home Telehealth: The Systematic Implementation of Health Informatics, Home Telehealth, and Disease Management to Support the Care of Veteran Patients with Chronic Conditions." *TELEMEDICINE and e-HEALTH*: 1118-1126.

<sup>257</sup> Jönsson and B. Jönsson (2002). "Revealing the cost of Type II diabetes in Europe." *Diabetologia* **45**(7): S5-S12.

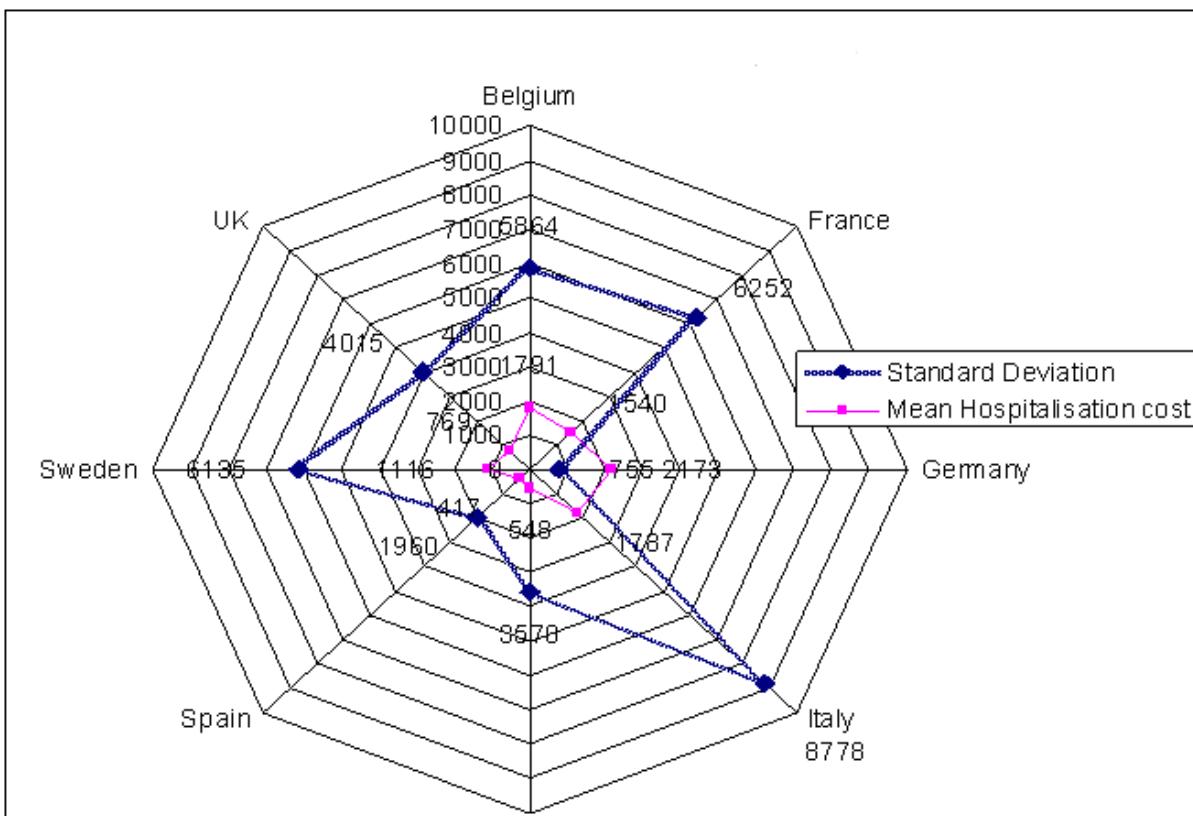
Figures 33 – Cost for ambulatory care in selected European countries related to Diabetes



Graphic: Currency € based on op. cit<sup>258</sup>

<sup>258</sup> Ibid. p. S9.

Figures 34 – Cost for hospitalisation in selected European countries related to Diabetes



Graphic: Currency €, based on op. cit. p. S9<sup>259</sup>

As seen in Figures 34 the highest mean cost for hospitalisation occurs in Germany €2,173 (data for 1999, the lowest standard deviation with €755), while the lowest mean cost for hospitalisation occurs in Italy with €1,787, but Italy had the highest standard deviation of €8,778.

### 9.2.3 Cost of COPD

Wouters<sup>260</sup> (2003) conducted an economic analysis of data from a large-scale international survey, *Confronting COPD in North America and Europe*, which covers seven countries (Canada, France, Italy, The Netherlands, Spain, the U.K and the U.S.A.) for investigating the burden of chronic obstructive pulmonary disease (COPD). The results demonstrated the high economic impact of COPD on the health care system and society in each country. The mean annual direct costs of the disease were particularly high in the U.S.A. (US dollar 4,119 [€3,647<sup>261</sup>] per patient) and Spain (US dollar 3,196 [€2,830] per patient) but relatively low in the Netherlands (US dollar 606 [€536]) and France (US dollar 522[€460]). Lost productivity due to COPD had a particularly high impact on the economy in France, The Netherlands and the U.K, accounting for 67%, 50% and 41% of overall costs, respectively.<sup>262</sup>

<sup>259</sup> Ibid.

<sup>260</sup> Wouters, E. F. M. (2003). "The burden of COPD in the Netherlands: results from the confronting COPD survey." *Respiratory Medicine* **97**(Supplement 3): S51-S59: pp. S51-S52.

<sup>261</sup> The €values in brackets are based on the interbank exchange rate for the whole year 2003, please note that some of the numbers date back earlier.

<sup>262</sup> Wouters, E. F. M. (2003). "The burden of COPD in the Netherlands: results from the confronting COPD survey." *Respiratory Medicine* **97**(Supplement 3): S51-S59.

The total societal cost of COPD per patient ranged from over US dollar 5,646 [€4,999] in the U.S.A. to US dollar 1,023 [€906] in the Netherlands. In five out of seven countries, the majority (52-84%) of direct costs associated with COPD were due to inpatient hospitalizations. As acute exacerbations of COPD are a key driver of secondary care costs, interventions aimed at preventing and treating exacerbations effectively could significantly reduce the economic impact of this disease. In all of the participating countries, COPD was underdiagnosed and undertreated. Between 9% and 30% of patients were undiagnosed despite having symptoms consistent with COPD, and up to 65% of patients did not receive regular prescribed medication. Patients reported poor symptom control and considerable use of health care resources. Therefore, reducing the burden of COPD will involve better evaluation and diagnosis of patients with COPD, as well as improved management of chronic COPD symptoms by health care professionals. The survey also demonstrated that the societal costs of COPD were 4-17 times higher in patients with severe COPD than in patients with mild COPD. Patients with comorbid conditions (accounting for 30-57% of patients in each country) were also particularly costly to society. These results suggest that a high priority should be given to interventions aimed at delaying the progression of disease, preventing exacerbations and reducing the risk of comorbidities, in order to alleviate the clinical and economic burden of COPD in North America and Europe.<sup>263</sup>

### **9.3 Scientific Evidence on RMT for Heart Conditions**

The following tables present a summary of the scientific evidence found on the impact of RMT used for patients with heart conditions, providing details on the type of study, the authors or sponsors of the study, the start and end date, the focus of the study e.g. cost/benefit analysis, clinical trial etc., the outcomes and a link to the website of the research organisation or the study itself.

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<sup>263</sup> Ibid.

**Table 23 – Scientific Evidence on RMT for Heart conditions**

Name	Type	Partners/ Authors	Start & end date	Focus	Outcome	Website
Boario Home Care Project	Regional initiative	e-HTN and other partners	Started 1998, ongoing	Italy, Lombardy region. Contains service description, stats on use of telecardiology, review of benefits of the project, costs and impact of telecardiology in the region	Telecardiology in Italy: benefits from a telemedicine network connecting chronic patients, general practitioners and health care provider organisations	<a href="#">..\SIMPHS data collection\Evaluation and assessment studies\2006 - Scalvini Boario assessment.pdf</a>
TEN-HMS Study Demonstrates Clinical and Financial Efficacy of Home Telemonitoring	TEN initiative	Philips, Cleland...	2003	World's first large-scale, randomized prospective telemonitoring trial, covering 426 Heart failure patients randomised into three groups (usual care, telephone nurse support and home telemonitoring) during 2000-2002 period	Showed that homebased telemonitoring reduced the number of days spent in hospital by 26% and led to an overall 10% cost savings compared to nurse telephone support. Home Telemonitoring also significantly improved survival rates relative to usual care and led to high levels of patient satisfaction	<a href="#">..\SIMPHS data collection\Evaluation and assessment studies\2003 - TEN-HMS Telemonitoring evidence - FINAL.pdf</a>
Remote monitoring systems for patients implanted with cardiac devices (cardioverter defibrillators and pacemakers).	Study	Australia & NZ Horizon Scanning Network,	2006	Reviews the use of remote monitoring systems for patients with pacemakers and implantable cardioverter defibrillators. Three of the more prominent systems are examined; the Carelink® Network by Medtronic, the Home Monitoring® System by Biotronik and the Housecall Plus™ Remote Patient Monitoring System by St. Jude Medical	While the remote monitoring of implantable cardiac devices offers a number of potential benefits for patients and medical practitioners, a number of questions remain unanswered. At present, it is not clear whether these systems will be financially viable in Australia, to what extent they will reduce practitioner workload and whether or not problems in the transmission of data will result in serious negative health outcomes. Large scale randomised trials involving control groups are required to further assess the financial and clinical effectiveness of remote monitoring systems.	<a href="#">..\SIMPHS data collection\Evaluation and assessment studies\2006 - ANZHSN - RMT of ICD - overview of evidence.pdf</a>

Name	Type	Partners/ Authors	Start & end date	Focus	Outcome	Website
HARTMOTIEF	Clinical trial	Achmea, the department of Cardiology of Erasmus MC and Philips	2006	<p>Randomised trial, intervention group used MOTIVA system and were equipped with automated devices for daily measurements of blood pressure and weight (those who had had heart failure treatment before)</p> <p>Hartmotief study protocol : randomized Control (50%), T1(30%), T2(20%)</p> <ul style="list-style-type: none"> <li>•216 Patients</li> <li>•8 participating hospitals</li> <li>•Ended 31st of December 2006</li> <li>•Principal investigator : dr. AHMM Balk of Erasmus MC Rotterdam</li> </ul>	Presents results in terms of Days in hospital, Mean number of hosp. days per patient Days in study, Days in hospital per day in study, Number of hospital admissions (and range pp), Mean duration of hospitalization (days), Mean number of hospitalizations per patient. Concludes on positive impact of the system on educating patients in their disease management and on care improvement	
Review of published evidence-based applications of telemonitoring for the surveillance of cardiac rhythm management devices	Study	Eucomed / Christian, Elsner, Centre for Health care Management	Aug-08	Present the current evidence pertaining to the clinical and cost-effectiveness of remote surveillance of CRM devices, and highlight the most relevant studies conducted in the broad field of remote monitoring. clinical efficacy and patient safety was examined in 6 studies, including 888 patients	All 10 studies confirmed feasibility and reliability of RMT; clinical effectiveness and patient safety of the remote patient management systems were reported in 7 of the 15 publications; Two studies examined the characteristics of an optimal standard follow-up programme; 6 included financial analyses combined with the clinical study (not comparable). One study underlined the burden imposed on physicians, allied professionals and medical institutions, by the large number of devices that are being implanted. The authors recommend a more intensive use of Internet-based technologies to monitor the devices, and new means of patient data management and sharing. They recommend the recognition of the importance of device follow up, and urge the development of appropriate reimbursement	<a href="..\SIMPHS data collection\Evaluation and assessment studies\2008 - EUCOMED - CRM_Telemonitoring - lit survey remote device checks - final.ppt">..\SIMPHS data collection\Evaluation and assessment studies\2008 - EUCOMED - CRM_Telemonitoring - lit survey remote device checks - final.ppt</a>

Name	Type	Partners/ Authors	Start & end date	Focus	Outcome	Website
Remote Physiological Monitoring	US Report	New England Health care Institute	? 2008	Cost-effectiveness analysis using the expanding evidence base for RPM, status of barriers to adoption, also looks at coverage and reimbursement options.	Shows a 60 percent reduction in hospital readmissions compared to standard care and a 50 percent reduction in hospital readmissions compared to disease management programs without remote monitoring. • Remote patient monitoring has the potential to prevent between 460,000 and 627,000 heart failure-related hospital readmissions each year. • Based on this reduction in hospital readmissions, NEHI estimates an annual national cost savings of up to \$6.4 billion dollars. • Based on this reduction in hospital readmissions, NEHI estimates an annual national cost savings of up to \$6.4 billion dollars. Also highlights three main barriers (reimbursement, lack of user awareness and providers' concerns)	
Einfluss einer telemedizinischen Lanzeitbetreuung auf Hospitalisation und Krankenhausverweildauer bei chronischer Herzinsuffizienz - eine Fall-Kontroll-Studie	Cost benefit analysis	- Authors: Zucca et al - Commissioned by Taunus BKK and PHTS Telemizin	Published April 2009	The objective of the study was to determine whether a telemedicine monitoring of an unselected and wide group of insured patients would lead to a decrease in morbidity.	A group of 650 insured patients from the Taunus BKK who had at least one previous hospital stay because of heart failure were given telemedicine monitoring on top of their medical treatment which included transmission of weight, heart frequency and blood pressure data. A control group followed the traditional medical treatment. The patients groups were comparable in terms of age, sex and underlying condition. After a 12 month period, rehospitalisation, hospital stay length and hospital costs decreased significantly.	<a href="http://www.phts.de">www.phts.de</a>

Name	Type	Partners/ Authors	Start & end date	Focus	Outcome	Website
HTA Report - Monitoring heart functions using telemetry	Cost benefit analysis	Tatjana Heinen-Kammerer, Waldemar Wiosna, Sandra Nelles, Reinhard Rychlik - Institut für Empirische Gesundheitsökonomie, Burscheid, Deutschland	2006	<p>The following research questions are addressed in this HTA report:</p> <ul style="list-style-type: none"> <li>• What is the efficacy of Telemonitoring for monitoring heart functions?</li> <li>• Is it possible to prevent cardiac events with Telemonitoring?</li> <li>• Could Telemetry be useful in secondary prevention of myocardial infarction?</li> <li>• What are the pros and cons of Telemonitoring for the patients regarding diagnosis, prevention of cardiac events, treatment, and quality of life?</li> <li>• Does Telemonitoring have an impact on the treatment strategy of physicians? Is it possible that in certain cases less medication could be necessary.</li> <li>• Do patients accept Telemonitoring?</li> <li>• Where does the implementation of Telemonitoring make more sense: primary or secondary prevention, or treatment?</li> <li>• Does Telemedicine have an impact on the treatment strategy, medical therapy and compliance of the patients?</li> <li>• Is Telemonitoring more cost-effective in comparison to conventional treatment?</li> </ul>	<p>Telemedicine is well accepted by the patients. It has been indicated that the implementation of telemedicine reduces both the number of hospitalisations and the duration of hospitalisation. Treatment costs are accordingly reduced. With an early diagnosis, the therapy can be optimised precociously. Considering acute medical care, a diagnosis prior to hospitalisation can lead to a reduction in the time interval between admittance and the start of therapy. Considering preventive medical care, the continuous surveillance enables a timely diagnosis. The quality of life of the patient is hereby significantly enhanced.</p> <p><b>Conclusion</b></p> <p>Telemetric monitoring can be applied in many areas of health care and be of positive assistance, within the single therapeutic strategies, to patients with acute and chronic cardiac illnesses. The integration of information- and communication systems available for the health sector can significantly support patient orientated medical care. This has been indicated in numerous studies/trials. Telemedicine supports the renunciation of a centralised medical care system, where the patient has to seek for consultancy, towards a patient orientated system, where expert advice (by means of caretaking networks) is transferred to the patient.</p>	<a href="..\SIMPHS data collection\Evaluation and assessment studies\21 IFEG HTA Bericht 2006 Kurzfassung.pdf">..\SIMPHS data collection\Evaluation and assessment studies\21 IFEG HTA Bericht 2006 Kurzfassung.pdf</a>

Name	Type	Partners/ Authors	Start & end date	Focus	Outcome	Website
Remote monitoring of implantable cardiac devices	Briefing / Review of effectiveness of four cardiac implant devices – Medtronic St Jude, Biotronik and Guidant	National Horizon Scanning Centre - University of Birmingham	2006	Results of the first European multi-centre trial have been presented in abstract2. 124 patients with a pacemaker had an implanted transmission chip that was set up to automatically send daily messages. They were followed up for three months. Patients were classified as 'not successfully monitored' if more than three contacts to the patient were necessary to maintain home monitoring or if the longest interval without a message was six days. Six patients were excluded from the study because home monitoring could not be successfully established, and a further 21 patients were not successfully monitored. In the remaining 95 patients, successful transmission occurred for 92% of the messages. Additional abstracts have focused on the use of home monitoring for effects of medication3 and on detecting atrial tachyarrhythmia4.	The potential advantages of remote monitoring of implantable devices could include timely monitoring of clinical events and symptoms, a reduction in routine patient follow-up, closer monitoring of device longevity that may extend usage, and reduced patient transport costs.  Staff time may also be saved, in both primary and secondary care, with electronic transmission of data improving data quality. This may lead to greater patient throughput in specialist clinics. However, there are few studies published with sufficient detail for a full evaluation of the systems' potential impact on NHS services, NHS costs, patient outcomes and quality of life.	<a href="..\SIMPHS data collection\Evaluation and assessment studies\2006 - NHSC-UK - RemoteMonitoring of ICD - overview of evidence.pdf">..\SIMPHS data collection\Evaluation and assessment studies\2006 - NHSC-UK - RemoteMonitoring of ICD - overview of evidence.pdf</a>
Telemonitoring or structured telephone support programmes for patients with chronic heart failure: systematic review and meta-analysis	Meta Analyse	Clark, R.A. and Inglis, S.C. and McAlister, F.A. and Cleland, J.G.F. and Stewart, S.	2007	To determine whether remote monitoring (structured telephone support or telemonitoring) without regular clinic or home visits improves outcomes for patients with chronic heart failure. 15 electronic databases, hand searches of previous studies, and contact with authors and experts.	Programmes for chronic heart failure that include remote monitoring have a positive effect on clinical outcomes in community dwelling patients with chronic heart failure.	<a href="http://eprints.gla.ac.uk/26124/">http://eprints.gla.ac.uk/26124/</a>

Name	Type	Partners/ Authors	Start & end date	Focus	Outcome	Website
Home telemonitoring for congestive heart failure: a systematic review and meta-analysis	Literature review	Julie Polisena, Khai Tran, Karen Cimon, Brian Hutton, Sarah McGill, Krisan Palmer and Richard E Scott	2010	An electronic literature search was conducted to identify studies of home telemonitoring use in congestive heart failure (CHF) patients. Twenty-one original studies on home telemonitoring for patients with CHF were included (3082 patients).	Several studies suggested that home telemonitoring also helped to lower the number of hospitalizations and the use of other health services. Patient quality of life and satisfaction with home telemonitoring were similar or better than with usual care. More studies of higher methodological quality are required to give more precise information about the potential clinical effectiveness of home telehealth interventions.	<a href="http://jtt.rsmjournals.com/cgi/content/abstract/16/2/68">http://jtt.rsmjournals.com/cgi/content/abstract/16/2/68</a>
Home telemonitoring in heart failure patients: the HHH study (Home or Hospital in Heart Failure).	Multi-national, randomized controlled clinical trial	Mortara A, Finna GD, Johnson P, Maestri R, Capomolla S, La Rovere MT, Ponikowski P, Tavazzi L, Sleight P.	2009	The Home or Hospital in Heart failure (HHH) study was a European Community-funded, multinational, randomized controlled clinical trial, conducted in the UK, Poland, and Italy, to assess the feasibility of a new system of home telemonitoring (HT). The HT system was used to monitor clinical and physiological parameters, and its effectiveness (compared with usual care) in reducing cardiac events in heart failure (HF) patients was evaluated	Home or Hospital in Heart failure indicates that self-managed HT of clinical and physiological parameters is feasible in HF patients, with surprisingly high compliance. Whether HT contributes to a reduction of cardiac events requires further investigation.	<a href="http://www.ncbi.nlm.nih.gov/pubmed/19228800">http://www.ncbi.nlm.nih.gov/pubmed/19228800</a>

#### **9.4 Scientific evidence on RMT for Diabetes**

The following tables present a summary of the scientific evidence found on the impact of RMT used for patients suffering from diabetes, providing details on the type of study, the authors or sponsors of the study, the start and end date, the focus of the study e.g. cost/benefit analysis, clinical trial etc., the outcomes and a link to the website of the research organisation or to the study itself.

**Table 24 – Scientific Evidence on RMT for Diabetes**

Name	Type	Partners/ Authors	Start & end date	Focus	Objectives	Outcome	
Telemedicine for monitoring chronic diseases (Diabetes)	Review	Spanish Ministry of Health	2006	Diabetes Mellitus, metabolic control, literature review of experiments (40 studies selected)	Efficiency, efficacy, and user satisfaction of telemedicine in metabolic control, through literature review	Better control of glycemic levels, improved self management, improved education	<a href="#">..\SIMPHS data collection\Evaluation and assessment studies\2008 - AETSA 2006-20 Telediabetes.pdf</a>
Evaluation of a mobile phone telemonitoring system for glycaemic control in patients with diabetes	RCT study	Robert SH Istepanian et al, Kingston University London and St George Hospital NHS Trust, London	Trial done in 2006-2007, published 2009	Type 2 diabetes patients. Evaluation of mHealth impact on HbA1c levels	RCT using mobile health technology, 137 patients 72 in intervention group, 65 in control group, over 9 months in 2006-2007, impact on HbA1c levels	Higher default rate in intervention group (32/70 completed the trial) due to technical problems. No difference in HbA1c levels in telemonitoring vs control group. Conclusion is that beneficial effect of telemonitoring on long term diabetes control is likely to be small. Lack of human contact may be weakness of the study as other qualitative studies show that using telemedicine requires supportive interactions with health care providers.	<a href="#">..\SIMPHS data collection\Evaluation and assessment studies\2009 - JTT RCT Evaluation mobile telemonitoring diabetes.pdf</a>

Name	Type	Partners/ Authors	Start & end date	Focus	Objectives	Outcome	
The effect of telemedicine on outcome and quality of life in pregnant women with diabetes	RCT study	Maria Grazia Dalfra * , Antonio Nicolucci , Annunziata Lapolla * and on behalf of the TISG	Published 2009	Type 1 diabetes, pregnant women. To evaluate the effect of a telemedicine system on maternal and fetal outcome in women with diabetes. Evaluation of depression, health-related quality of life (QoL), Stress and Distress for the impact of diabetes.	276 pregnant women with gestational diabetes were enrolled in the study and sequentially assigned to a telemedicine or a control group, 88 in the telemedicine group and 115 in the control group; there were 17 women with type 1 diabetes in the telemedicine group and 15 in the control group.	Women in telemedicine groups were asked to submit their blood glucose data every week, and had a medical examination at the diabetes clinic once a month. Women in the control groups had a medical examination every two weeks. Subjective outcomes were investigated using the following questionnaires: CES-D for depression, SF-36 for health-related quality of life (QoL), Stress and Distress for the impact of diabetes. Clinical variables and pregnancy outcomes were no different between the two telemedicine groups, whereas women with gestational diabetes in the telemedicine group had a better metabolic control in the 3rd trimester and a lower rate of caesarean sections and macrosomia. As for QoL, women in the telemedicine groups showed lower levels of frustration and concerns about their diabetes, and a better acceptance of their diabetic condition. A questionnaire on the use of the telemedicine system showed a high degree of acceptance (85%). Both telemedicine groups had fewer check-ups at the diabetes clinics. The use of a telemedicine system for glucose monitoring improved pregnancy outcome in women with gestational diabetes and improved QoL in all diabetic pregnancies.	

Name	Type	Partners/ Authors	Start & end date	Focus	Objectives	Outcome	
Telemedicina en el seguimiento de enfermedades crónicas: Diabetes Mellitus Revisión Sistemática de Literatura y Evaluación Económica Telemedicine for monitoring of chronic diseases: Diabetes mellitus Executive abstract	Review study	Márquez Peláez, Sergio y Canto Neguillo, Rafael - Agencia de Evaluación de Tecnologías Sanitarias de Andalucía; Madrid: Ministerio de Sanidad y Consumo, 2008	2008	Diabetes Mellitus	The main objective of the review is to know whether the use of ITC in Medicine can improve effectiveness, efficiency and satisfaction aspects in DM patients' metabolic control. Moreover, two specific aims have been included: one of them concerns educational aspects, and the other one deals with the possibility to early detect diabetic retinopathy through teleophthalmology techniques both of them due to the importance they get in this pathology.	<p>Conclusions:</p> <ol style="list-style-type: none"> <li>Concerning the effectiveness and combining all the measure groups, there can be said that telemedicine applied to monitoring diabetic patients is effective with an evidence of high quality.</li> <li>With a level of evidence from high to mid, we can state that telemedicine is efficient for glycemic control of patients.</li> <li>With high quality evidence, there can be said that telemedicine systems for metabolic control reach high satisfaction level for users.</li> <li>Considering sensitivity, specificity aspects, there can be affirmed that telemedicine techniques get results very similar to those from traditional techniques with high level of evidence. Taking into account other aspects such as the number of adjustable images, satisfaction, transmission time and costs, we can say that telemedicine is appropriate for the early diagnosis of RD with a low level of evidence.</li> <li>From the economic assessment carried out in a parallel way to the present review, there can be enhanced the conclusion, which deals with the decrease in the cost of detection tests of diabetic retinopathy using telemedicine. However, the effectiveness is slightly lower to that of traditional system.</li> </ol>	

Name	Type	Partners/ Authors	Start & end date	Focus	Objectives	Outcome	
A Ubiquitous Chronic Disease Care system using cellular phones and the internet	Randomized, controlled clinical trial over 3 months that included 123 patients at a university hospital and a community public health centre in Korea	Yoo, H. J.; Park, M. S.1; Kim, T. N.; Yang, S. J.; Cho, G. J.2; Hwang, T. G.2; Baik, S. H.; Choi, D. S.; Park, G. H.3; Choi, K. M.	Published June 2009	Diabetes Type 2 and Hypertension	To improve the quality and efficiency of chronic disease care, the authors investigated the effectiveness and applicability of the Ubiquitous Chronic Disease Care (UCDC) system using cellular phones and the internet for overweight patients with both Type 2 diabetes and hypertension. Patients were given a modular blood glucose measuring device, strips, lancets and an automatic blood pressure measuring device. Patients received advice and feedback depending on measurements sent.	After 12 weeks, there were significant improvements in HbA1c in the intervention group ( $7.6 \pm 0.9\%$ to $7.1 \pm 0.8\%$ , $P < 0.001$ ) compared with the control group ( $7.4 \pm 0.9\%$ to $7.6 \pm 1.0\%$ , $P = 0.03$ ). Furthermore, a significant reduction in systolic and diastolic blood pressure was observed, as well as improvements in total cholesterol, low-density lipoprotein-cholesterol and triglyceride levels in the intervention group. Furthermore, there was a significant increase in adiponectin levels in the intervention group compared with the control group, although high-sensitivity C-reactive protein and interleukin-6 levels did not change in either group. Conclusions: the novel UCDC system presented in this paper improved multiple metabolic parameters simultaneously in overweight patients with both Type 2 diabetes and hypertension.	<a href="..\SIMPHS data collection\Evaluation and assessment studies\2009 - Diabetes ubiquitous care system.TIF">..\SIMPHS data collection\Evaluation and assessment studies\2009 - Diabetes ubiquitous care system.TIF</a>

Name	Type	Partners/ Authors	Start & end date	Focus	Objectives	Outcome	
Home telemonitoring of patients with diabetes: a systematic assessment of observed effects	Review	Mirou Jaana and Guy Paré Post Doc and Chairholder in Information Technology in Health Care, Chemin de la Côte-Ste-Catherine, Montreal QC, Canada	2006	A comprehensive literature review was conducted on Medline and Cochrane Library. The objective of the study is provide a systematic and comprehensive review of all aspects of diabetes 'home telemonitoring' and its effect at the informational, clinical, behavioural, structural and economical level	Close management of diabetic patients through telemonitoring showed significant reduction in HbA 1c and complications, good receptiveness by patients and patient empowerment and education. Yet, the magnitude of its effects remains debatable, especially with the variation in patients' characteristics (e.g. background, ability for self-management, medical condition), samples selection and approach for treatment of control groups.	Close management of diabetic patients through telemonitoring showed significant reduction in HbA 1c and complications, good receptiveness by patients and patient empowerment and education. Yet, the magnitude of its effects remains debatable, especially with the variation in patients' characteristics (e.g. background, ability for self-management, medical condition), samples selection and approach for treatment of control groups	

## **9.5 Scientific evidence on RMT for COPD**

The following table presents a summary of the scientific evidence found on the impact of RMT used for patients suffering of COPD, providing details on the type of study, the authors or sponsors of the study, the start and end date, the focus of the study e.g. cost/benefit analysis, clinical trial etc., the outcomes and a link to the website of the research organisation or to the study itself.

**Table 25 – Scientific evidence on RMT for COPD**

Name	Type	Partners/ Authors	Start & end date	Focus	Outcome	Website
Telemedicine / Telemonitoring in Respiratory Medicine & COPD - COPD and (Tele) Rehabilitation	Review study / Evidence	Scottish Centre for Telemedicine TeleRespiratory_CO PD	15-Sep-08	Review of a 19 COPD telemonitoring trials or studies	Summary of results for each study	<a href="http://www.sct.scot.nhs.uk/documents/TeleRespiratory_COPD.doc">www.sct.scot.nhs.uk/documents/TeleRespiratory_COPD.doc</a>
Home Telemonitoring for Respiratory Conditions: A Systematic Review	Review	Mirou Jaana and Guy Paré Post Doc and Chairholder in Information Technology in Health Care, Chemin de la Côte-Ste-Catherine, Montreal QC, Canada	2009	A comprehensive literature review was conducted on Medline to provide a systematic review of home telemonitoring for respiratory conditions and to present evidence on its effects in relation to data quality, patient medical condition, utilization of health services, feasibility and use, and economic viability.	Home telemonitoring of respiratory conditions results in early identification of deteriorations in patient condition and symptom control. Positive patient attitude and receptiveness of this approach are promising. However, evidence on the magnitude of clinical and structural effects remains preliminary, with variations in study approaches and an absence of robust study designs and formal evaluations	<a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2244878/">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2244878/</a>
Systematic Review of Home Telemonitoring for Chronic Diseases: The Evidence Base	Review	Guy Paré, Mirou Jaana, Claude Sicotte	1990- 2006	A systematic review of the nature and magnitude of outcomes associated with telemonitoring chronic illnesses: including pulmonary conditions, diabetes,.	Telemonitoring effects on clinical effectiveness outcomes (e.g., decrease in the emergency visits, hospital admissions, average hospital length of stay) are more consistent in pulmonary and cardiac studies than diabetes and hypertension. Lastly, economic viability of telemonitoring was observed in very few studies and, in most cases, no in-depth cost-minimization analyses were performed	<a href="http://www.ncbi.nlm.nih.gov/pubmed/17329725">http://www.ncbi.nlm.nih.gov/pubmed/17329725</a>

Tele-assistance in chronic respiratory failure patients: a randomised clinical trial	Randomised trail	M. Vitacca, L. Bianchi, A. Guerra, C. Fracchia, A. Spanevello, B. Balbi and S. Scalvini	2008	The aim of the present study was to primarily evaluate reduction in hospitalisations and, secondly, exacerbations, general practitioner (GP) calls and related cost-effectiveness of tele-assistance (TA) for these patients. A total of 240 patients (101 with chronic obstructive pulmonary disease (COPD)) were randomised to two groups: an intervention group entered a 1-yr TA programme while controls received traditional care.	In chronic respiratory failure patients on oxygen or home mechanical ventilation, a nurse-centred tele-assistance prevents hospitalisations while it is cost-effective. The chronic obstructive pulmonary disease group seems to have a greater advantage from tele-assistance.	<a href="http://erj.ersjournals.com/cgi/content/abstract/33/2/411">http://erj.ersjournals.com/cgi/content/abstract/33/2/411</a>
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## **9.6 Scientific Evidence on RMT for Multi-disease Conditions**

The following tables present a summary of the scientific evidence found on the impact of RMT used for patients with multiple chronic conditions, providing details on the type of study, the authors or sponsors of the study, the start and end date, the focus of the study e.g. cost/benefit analysis, clinical trial etc., the outcomes and a link to the website of the research organisation or to the study itself.

**Table 26 – Scientific Evidence on RMT for Multi-disease Conditions**

Name	Type	Partners/ Authors	Start & end date	Focus	Outcome	Website
Remote Monitoring Review	Study/Review, Diabetes, Heart, COPD	Dr Margaret O'Brien, GP Clinical Adviser, ECCH, Northern Ireland	Jun-08	Review to ascertain if the current evidence base supports the use of remote tele-monitoring in the management of diabetes mellitus, chronic heart failure and chronic obstructive pulmonary disease. 21 systematic reviews summarised.	Evidence strongest for use of home tele-monitoring in management of chronic disease, in particular monitoring of vital signs. Lack of studies of large size and the relatively short duration of a number of the interventions. To date insufficient economic appraisal of telemedicine interventions. RMT acceptable to patients and HC professionals, no adverse events, improved quality of life, reduced hospital admissions, reduction in mortality, empowerment of patients and altered patient attitudes towards their condition.	
Stratego Consortium	Conference report	Diane Whitehouse and Salvatore Virtuoso		Conference aimed to highlight good practice and use cases in telemedicine in Europe, but also to identify the various, possible barriers to the broad deployment of telemedicine initiatives. Content includes: Background to telemedicine (including challenges, problems, and weaknesses); Definition(s); Telemedicine examples with a particular focus on tele-radiology; The organisational context; Legal, regulatory, and professional issues; Issues relating to professional conduct	Examples of projects and pilots and country initiatives already known to us	
Implementation of Care Coordination /Home Telehealth in US	US Review of RMT implementation with ageing	VHA	2008 report on 2002-2007 period	Implementation of RMT for ageing patients for diabetes mellitus (DM), congestive heart failure (CHF), hypertension (HTN), posttraumatic stress disorder (PTSD), chronic obstructive pulmonary disease (COPD), and depression.	Describes implementation process, issues encountered, how the HC was organised and assesses benefits. 40000+ patients. Reports on benefits (reduced hospital stays etc.). Also highlight important issues like educating the patient, need for clinical process re-engineering etc.	

Name	Type	Partners/ Authors	Start & end date	Focus	Outcome	Website
Virtually healthy: Chronic disease management in the home	Article in Disease Management, June 2002, vol. 5, no 2, 87-94	Marlis Meyer, Rita Kobb, Patricia Ryan	2000-2002	From April 2000 and over 2 years, five of eight clinical demonstration projects were funded within the Sunshine Networks of the Veterans Health Administration (VHA) to test disease management principles, the role of the care coordinator and the effective use of technology to maintain veterans in their homes, focusing on CDM (CHF, COPD, Diabetes and Hypertension and combinations). 791 out of 8.704 veterans were enrolled (identified as high risk, high costs, high use patients). A control group of 772 patients was set up to enable cross comparisons, with clinically similar but non-enrolled veterans. The motivation of the projects was to improve health status, increase program efficiency, and decrease resource utilization.	Evaluation after the first year showed: - 40% reduction in emergency room visits - 63% reduction in hospital admissions - 60% reduction in hospital bed days of care, 64% reduction in VHA nursing home admission, and 88% reduction in nursing home bed days of care. Only clinic visits went up, but showed a sharp decline at the fourth quartile. In the control group most parameters went down as well (except for nurse home admission which showed a steep rise), but less sharply. All indicators measuring quality of life and functional ability improved as well. These were measured using the SV 36V questionnaire, a standardized, scientifically validated questionnaire, which is generally regarded as a reliable measure of quality of life and functional ability. Significant improvements were recorded in Role Physical ( $p<0.003$ ), Bodily Pain ( $p<0.000$ ), Social Functioning ( $p<0.004$ ), Role Emotional ( $p<0.000$ ) and Mental Composite ( $p<0.011$ ).	
Supporting Self Care a practical option	UK review report	UK Department of Health		Review of Diagnostic, Monitoring and Assistive Tools, Devices, Technologies and Equipment to Support Self Care (includes list of devices)	Best benefit to cost ratio for devices will result from deployment of the most appropriate solution for individual needs. Rather than 'technology-driven', all solutions must be 'needs-led'. Scope for improved health outcomes at modest investment (cheap devices, mobile technology). Devices that require central monitoring services entail more complexity and hidden costs to implement. Lack of inter-operability and standards across devices. Continuous monitoring devices appear promising, but further research needed to assess effectiveness. Research evidence for the effectiveness of self care devices is not yet available for all the various devices currently in use. Often small scale pilot research studies have been conducted.	

Name	Type	Partners/ Authors	Start & end date	Focus	Outcome	Website
Systematic Review: Impact of Health Information Technology on Quality, Efficiency, and Costs of Medical Care.	Literature review	Chaudhry B, Wang J, Wu S, Maglione M, Mojica W, Roth E, Morton SC, Shekelle PG	2006	A systematically review evidence on the effect of health information technology on quality, efficiency, and costs of health care.	Four benchmark institutions have demonstrated the efficacy of health information technologies in improving quality and efficiency. Whether and how other institutions can achieve similar benefits, and at what costs, are unclear.	<a href="http://www.rand.org/cgi-bin/health/showab.cgi?key=2006_114">http://www.rand.org/cgi-bin/health/showab.cgi?key=2006_114</a>
EU: eHealth is Worth it	Case study	K A. Stroetmann: T J A Dobrev V B Stroetmann	2006	A study shows across a wide range of eHealth applications to show evidence on the benefits of information and communication technology in routine healthcare settings	The benefits range from improvements in quality and better access of all citizens to care, to avoidance of unnecessary cost to the public purse.	

Name	Type	Partners/ Authors	Start & end date	Focus	Outcome	Website
The socio-economic impact of telehealth: a systematic review	review	Jennett, P A; L Affleck Hall; R E Scott Health Telematics Unit, Faculty of Medicine, University of Calgary, Calgary, Alberta; D Haile; A Ohinmaa {Department of Public Health Sciences, University of Alberta, Edmonton, Alberta C Anderson; C A Consulting, Wetaskiwin, Alberta;R Thomas University of Calgary, Calgary, Alberta;B Young, McGill University, Montreal, Quebec;D Lorenzetti; Institute of Health Economics/Centre for Health and Policy Studies, University of Calgary, Alberta, Canada	2003	Literature search on telehealth and socio economic indicators	Telehealth studies till the year 2003 have not used socioeconomic indicators consistently. However, specific telehealth applications have been shown to offer significant socio-economic benefit, to patients and families, health-care providers and the health-care system. The main benefits identified were: increased access to health services, cost-effectiveness, enhanced educational opportunities, improved health outcomes, better quality of care, better quality of life and enhanced social support.	

Name	Type	Partners/ Authors	Start & end date	Focus	Outcome	Website
Telehomecare and Remote Monitoring: An Outcomes Overview	US Review	- Authors: Max E. Stachura et al - Commissioned by AdvaMed - Advanced Medical Technology Association	2007	Focus on diabetes mellitus (DM), congestive heart failure (CHF), and chronic obstructive pulmonary disease (COPD). Review of outcomes in terms of : - Improvements in clinical care - Costs, cost benefits and avoidance - Potential for growth Includes three case studies	The results of studies to date are promising and show clear value in remote monitoring and telehomecare. But they also point to technology, infrastructure, access and reimbursement issues that must be addressed for maximal care quality improvement and cost savings. These are multi-faceted issues that will require careful and coordinated evaluation by payors (Medicare, Medicaid and private insurers), government (federal, state and local), care providers (physicians and nurses, hospitals, home health agencies, and nursing facilities), and employers, as well as an assessment of technology needs (medical technology, infrastructure, and telecommunications). While most published studies are small, some are contradictory, and the need for large well-controlled trials remains, evidence supporting the value and the potential of telehomecare is clear and growing.	
Care Coordination /Home Telehealth: the systematic implementation of health informatics, home telehealth, and disease management to support the care of veteran patients with chronic conditions.	Case report	Darkins A, Ryan P, Kobb R, Foster L, Edmonson E, Wakefield B, Lancaster AE.	2003 - 2007	Between July 2003 and December 2007, the Veterans Health Administration (VHA) introduced a national home telehealth program, Care Coordination/Home Telehealth (CCHT). Its purpose was to coordinate the care of veteran patients with chronic conditions and avoid their unnecessary admission to long-term institutional care.	Routine analysis of data obtained for quality and performance purposes from a cohort of 17,025 CCHT patients shows the benefits of a 25% reduction in numbers of bed days of care, 19% reduction in numbers of hospital admissions, and mean satisfaction score rating of 86% after enrolment into the program. The cost of CCHT is \$1,600 per patient per annum, substantially less than other NIC programs and nursing home care. VHA's experience is that an enterprise-wide home telehealth implementation is an appropriate and cost-effective way of managing chronic care patients in both urban and rural settings.	<a href="http://www.liebertonline.com/doi/abs/10.1089/tmj.2008.0021">http://www.liebertonline.com/doi/abs/10.1089/tmj.2008.0021</a>

## **10 Annex V: Patent analysis**

### **10.1 Introduction**

Companies use patents to protect information they consider vital to their businesses. To get this protection they need to publish crucial information concerning the invention they have made, which is an interesting source for researchers who study innovation dynamics. Over the years patent statistics has developed as a field of research which enables the analysis of behaviour of companies, of emerging fields, and of developments over time. Although exploring patent statistics is full with methodological problems, it is generally accepted as a sensible approach to improve understanding of emerging and on-going technological developments on the basis of quantitative data.

A patent analysis was carried out, aiming at uncovering dynamic patterns of innovation in the field of PHS/RMT. Standardised procedures to arrive at an overview of patents available in this specific domain were followed but did not produce reliable results. We therefore developed a method based on a less structured approach, in our case a query of free text keywords. We tried several queries and used the one which produced the best results for our purposes. The results reported in this section should only be considered as a first exploration of the field.

### **10.2 Methodology**

Patent offices gather and make available data on individual patent applications, presenting the information in a systematic manner. Such data includes the names of the inventor, the company, the invention, earlier patents, and classifiers (used to organise patents in classes). One way to search patent databases is by using the classification criteria to check which patents are within a specific class, thus finding about developments within this specific class. Another approach is searching for all patents filed by specific companies, thus discovering developments about companies and their competitive edges. A third approach is using queries of keywords relating to the invention to study the development of a specific invention. Each approach should be precise (relevant patents should be found) and specific (no patents outside the scope should be found) which is a challenge.

We opted for using the WIPO database and the PATSTAT databases, but the latter did not deliver any reliable results. We therefore concentrated on the patents filed at WIPO (60% of the European patents filed at EPO originate from WIPO). It should be noted however that many inventions do not get patented at all, and that registering with WIPO is costly, a potential deterrent for SMEs, which may opt for national patent procedures instead and may therefore be sub-represented in the WIPO results.

We searched the WIPO database, via its PatentScope interface, with a number of keywords (e.g. chronic disease, telemedicine, remote monitoring, and telehomecare) in a kind of trial and error process, until we concluded that the best search string was:

**Table 27 – Search string for RMT-systems in WIPO database**

"remote patient monitoring" AND (COPD OR CHF OR diabetes OR "chronic heart failure") OR "remote monitoring" AND patient AND (COPD OR CHF OR diabetes OR "chronic heart failure") OR "home monitoring" AND (COPD OR CHF OR diabetes OR "chronic heart failure").
--

The results were a total of 357 patents, out of which 48 were not relevant (i.e. 13.4% "recall" rate). One unknown factor is the number of patents we have not found but which exists, thus making it impossible to define the degree of precision of our results.

## **10.3 Patent analysis – main findings**

The results delivered by Patent@Scope enabled the analysis of a number of trends and distributions. It also enabled a more qualitative analysis on the basis of the abstracts provided.

### **10.3.1 Main trends**

#### **Evolution over time**

Since 2000 the number of RMT patents filed yearly at WIPO exceeds 10, to reach 70 patents in 2008 showing a steady increase, with the exception of the period 2004-2005 (which may be due to the internet bubble). There are many more patents dealing with technologies than with services.<sup>264</sup> Since 2005, the number of patents filed per year has grown considerably, which might indicate a rising interest in RMT, although this may be countered by the 2008-2009 economic and financial crisis.

#### **Geographical distribution**

The US lead in terms of numbers of patents filed over the years, with 80% of all patent applications, Europe representing only 15%, with UK and Germany leading (resp. 4% and 3% of worldwide patents). Europe is therefore apparently lagging behind in terms of high-value patents filed through WIPO since Europe.

#### **Distribution over firms**

The table below shows companies with more than 5 RMT patents:

**Table 28 – Distribution of application by firms (> 5 hits)**

<b>First applicant/assignee</b>	<b>International applications</b>
Medtronic, Inc	46
Cardiac Pacemakers, Inc	18
Dexcom, Inc	11
Roche Diagnostics GmbH	10
Health Hero Networks, Inc	9
St. Jude Medical AB	6
Medapps, Inc	6
Cardiocom, LLC	6

*Source: WIPO-Patent@scope, 2009*

Three out of the above eight companies deal with cardiac devices (Medtronic, Cardiac Pacemakers, St Jude Medical) which appears to be a high value domain while there is no company dealing with devices monitoring vital signs (blood glucose meters, spirometers and even ECG monitors) in this list. The list shows that high value patents are part of high value, established markets (cardiac implants, biomedical diagnostics). Companies on the high value segment own about 30% of all patents, the remaining 70% being distributed over a myriad of firms with only one or a few patents. Our method shows some limitation though, as companies like Philips do not appear here while they do when searching "remote patient monitoring" only.

#### **Distribution over IPC keywords**

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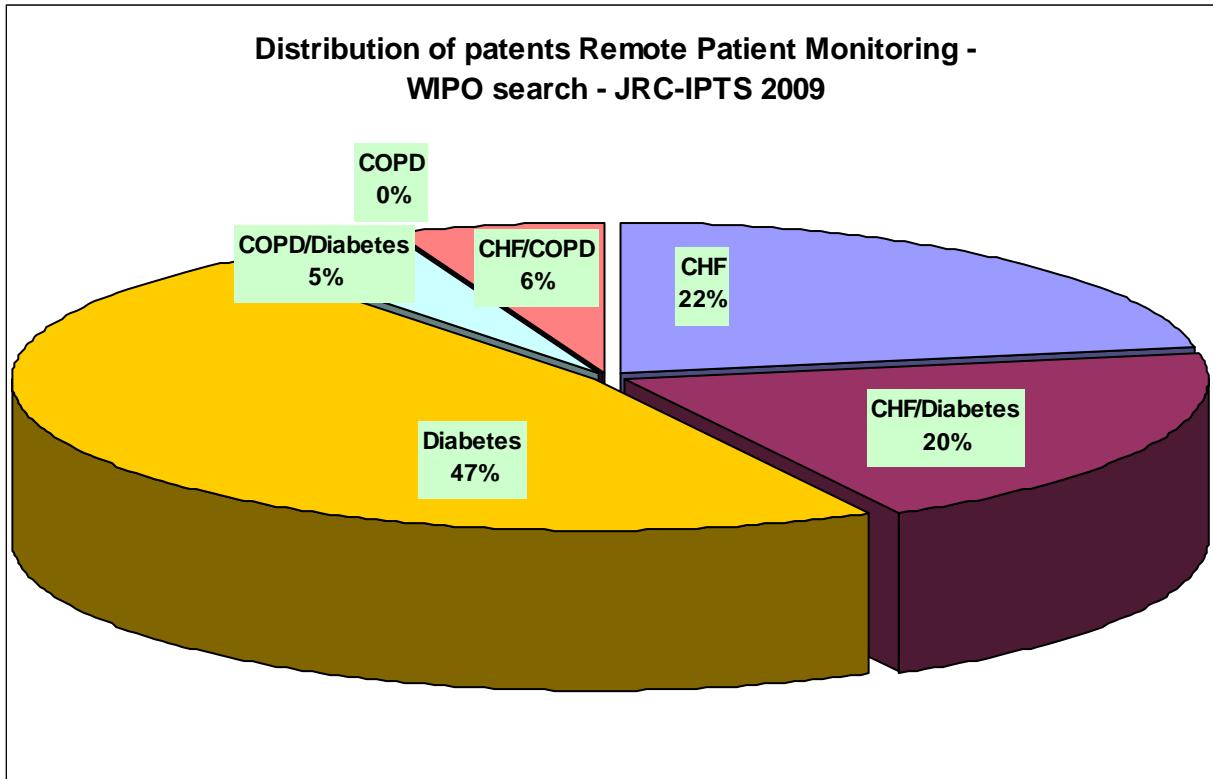
<sup>264</sup> Also in services the patent itself usually relates to some kind of technological element, such as a software programme, an algorithm, a decision support system, or the development of educational content.

The WIPO search enables to check the keywords (IPC) most commonly used to describe inventions. The largest part of patents is covered by keywords representing "Diagnosis, surgery and identification", followed by "Electrical data processing", then "Vital Sign Analysis". Unfortunately this is too general to enable drawing any relevant conclusion on the type of invention.

### Distribution of patents over diseases

Patents either relate to one specific disease (CHF, COPD or diabetes), at least two diseases (all combinations possible) or cover all three diseases. As shown in **Figure 35**, the majority of the patents are in the field of diabetes. COPD only accounts for a minor fraction of the patents found, while CHF is more or less on an equal footing with diabetes (almost half of all patents).

Figure 35 – Distribution of patents over chronic diseases



Source: WIPO-Patent@scope, 2009

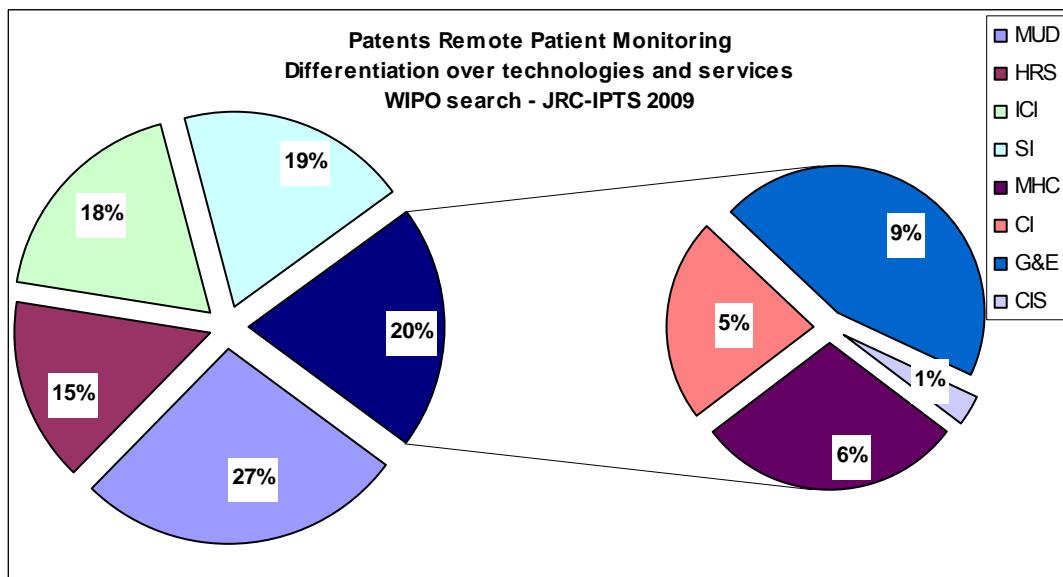
### 10.3.2 Content analysis of the patents

The main technology and service categories we defined for our 50+ company review (See **Section 7**) have been used here to analyse the content of patients, namely:

- Technologies: Medical User Devices (MUD), Information and Communication Infrastructure (ICI), Health Related Software (HRS) and System Integration (SI)
- Services: Monitoring Health Conditions (MHC), Clinical Intervention (CI), Guidance and Education (GE), and Clinical Information Services (CI).

The figure below shows that 80% of all patents relate to technologies while 20% relate to services.

Figure 36 – Distribution of patents over services and technologies



Source: WIPO – Patent@Scope; processing: JRC-IPTS 2009)

As may be clear from the above, patents we categorise under "service" usually have a technology component as well such as a software package. Since patents need to have a technological dimension, the number of patents that are fully service oriented will be (very) limited if not nonexistent.

## Technologies

*Medical user devices (MUD)* are the technology that evokes the most patents, while the *information and communication infrastructure (ICI)* and *system integration (SI)* are each responsible for slightly less than 20% of all patents. Inventions in medical user devices cover a broad array of activities, from implantable devices to sensors to dispensers. They cover all diseases studied and can be very limited (just a sensor measuring a vital sign) or encompassing (a full device including measuring equipment) in scale. The information and communication infrastructure covers inventions such as wireless processing systems and methods for medical device monitoring, or systems and methods for processing and transmittal of medical data. An example of an invention in systems integration is a remote health care diagnostic tool that includes the device, the measurement and the communication system. *Health related software (HRS)* still captures 15% of patents. An example of HRS patents is a web-based integrated information system for sharing patient medical information across an organisation.

## Services

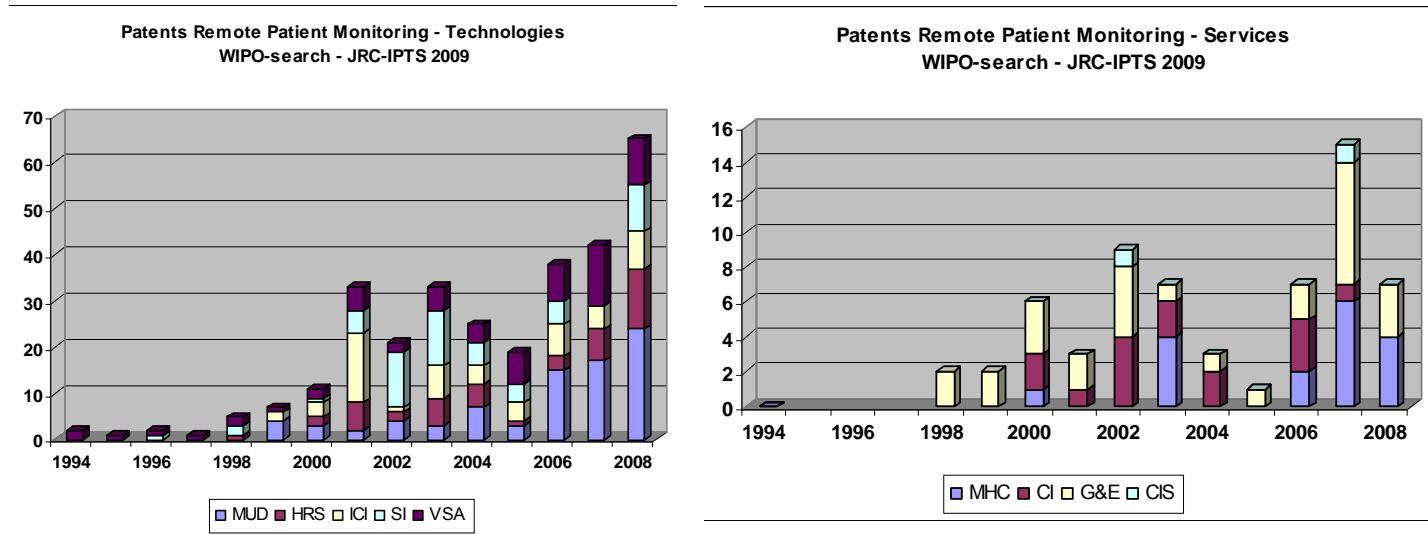
On the service side, patents in the field of *Guidance and Education (GE)* almost cover half of all service-oriented patents. The core of these patents is a software package, steering the interaction with the patient and storing medical data. An example of a patent in the domain of *Monitoring Health Condition (MHC)* is an invention dealing with monitoring physiological signs from a subject to determine the subject's susceptibility for a seizure. This is monitoring which requires some software package to make sense of the monitoring data. An example of a *Clinical Intervention (CI)* service is an application for an enhanced acoustic monitoring and alarm response, which sends an alarm on the basis of monitoring health parameters back via the Internet. Patent applications in the field of Clinical

Information Services (CIS) are almost absent. This is mainly due to the choice of keywords that focused on the remote monitoring part and not on the interconnection with back-end systems.

One set of patent applications has been neglected in the figure **Figure 36** above. Several patents covered inventions that were difficult to classify under each of the four technology categories (or the service categories). These inventions dealt mainly with bio-medical, bio-chemical and bio-physiological processes, offering analytical tools to measure specific dimensions within these processes. They are disease-related rather than remote monitoring related which is why we have excluded them from the above figure. The number of inventions in this domain (which we may label "Vital Sign Analysis") lies between the numbers found for "Information and Communication Infrastructure" inventions and "medical user devices".

### Evolution over time

Figure 37 – Patent applications in RMT technology and RMT services



Source: Authors' elaboration on WIPO – Patent@Scope; processing

As could be expected, both figures show the same dip in 2001-2002 and 2003-2006. As to technologies, one can notice the growth of "medical user devices" and the decline of "systems integration" over time. Specialisation seems to have become more prominent in the later years. Focus on technological infrastructure (communication protocols and networks) for monitoring solutions is clearly visible in the years 2001-2003 (in combination with systems integration) but declining thereafter. This might indicate that technological issues for communication networks somehow have been settled and are no major area for further investigations. "Health related software" has experienced varying growth figures over the years with a steady increase over the last four years. It is however difficult to indicate a precise focus in HRS as the number of patent applications is limited. The descriptions of patent applications in HRS vary from image normalisation techniques to techniques to monitor progression of heart failure, to systems for remote patient monitoring communication and command execution and a portable programmer for providing patient status information.

The picture of services-related patents is more difficult to interpret as the figures per category are very low (a few per year), as seen earlier. The most prominent category is "Guidance and Education" (GE), which deals with content issues offered through various media (e.g. questionnaires, educational

content). Except for one of the GE patent applications in 1998, all patents in this domain between 1998 and 2000 are from a single company, Health Hero Networks, which developed a strong position through advanced questionnaire and feedback systems to remotely check the health condition of patients.<sup>265</sup>

#### **10.4 Limitations of our approach**

Our pilot study on patents brought to light a number of issues relating to the usefulness of the methodology and to insights patent analysis can deliver about innovation and market dynamics.

##### **10.4.1 Conclusions on content**

The search strategy used delivered a limited set of patents, which is inherent to the database used (WIPO) and companies strategy with patents. The WIPO is a relatively expensive route to patent. This may lead to an overestimation of high value patents and of large firms who are able and willing to pay the high costs. During workshops and interviews representatives of small firms indicated that they opt for national patent databases.

A few companies own many patents, especially in the high-end RMT market segments, i.e. (implantable) cardiac devices and bio-diagnostics, but there is a long tail of companies with one or a few patents only. They cover all segments of the value chain.

The number of RMT patents seems to have taken off over the past few years, as the number of patents per year quadrupled over the last four years. This may be due to low numbers in 2004-2005. It would be interesting to see if this trend will continue and at what pace.

The US are clearly leading, both in terms of high-end companies (with many patents) and lower end companies (with fewer patents). Europe is lagging behind together with the rest of the world.

As to content, most patents relate to technology and within technology to medical user devices. Health related software and patents on information and communication infrastructure are well placed as well. Service related patents are less visible with the notable exception of services on guidance and education. Furthermore, service-related patents have an IT component that is usually software based.

##### **10.4.2 Conclusions on the methodology**

The methodology followed is sensitive to the keywords used. Keywords were chosen based on limited insight in the field. Although we checked the query for robustness, the method is difficult to validate. It would be better to use an automated method based on text analysis, revealing specific keywords or to set up an expert panel to elicit a set of keywords to validate the field under research.

The database used (Patent@Scope of WIPO) has its limitations as it does not offer a full overview of all patents which might relate to RMT/PHS since patents filed at national offices are not included. To get a proper picture of the contribution of SMEs to the knowledge base other sources should be used, although PATSTAT is not an appropriate one. Search in EPO and national patent offices data might offer an alternative.

The content analysis that has been done manually has not been validated and the allocation of patents to the specific categories has been done on the basis of the information provided in patent abstracts.

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<sup>265</sup> See <http://is.jrc.ec.europa.eu/pages/TFS/documents/SIMPHS17AprilWorkshopsummaryfinalrev1.pdf>

The categorisation we used is probably too fine-grained but it is consistent with the different components we identified in the PHS/RMT value chain. There may be suitable alternatives we did not explore.

The same goes for the distinction between products and services. We found very few patents dealing with services, which is explained by the fact that all patents need to have a technological invention. The usefulness of the distinction between services and technologies is therefore questionable.

#### 10.4.3 Next steps

Patent analysis is a useful tool to follow PHS/RMT growth and "discover" new, emerging fields. It can be used as one of the monitoring tools of the SIM as it enables the quantitative analysis of the growth in number of patents, of the distribution of patents per region, per company and per disease.

The approach used in this pilot is just a first attempt. A more sophisticated approach, whose results can be validated more readily, is needed. Three possible strategies can be followed:

- Start with a textual analysis on abstracts to reveal keywords and keyword combinations and extend it to other patents as well (e.g. EPO). Use the set of keywords to search for additional patents in PATSTAT and/or EPO database and/or a subset of national databases. Outsource the activities to an organisation that has the appropriate tools to tackle such databases.
- Start with selecting a number of representative companies and search for their patents. Then perform the analysis as suggested above.
- Repeat the approach of this pilot a year later on the WIPO database to check what has changed.

#### 10.5 Full description of the methodology used for the patent analysis

Patent offices gather data on individual patent applications. They present this information in a systematic manner. Information on the inventor, the firm, and the invention itself is stored, as well as additional information such as the patents which preceded this invention and classifiers which organise the patents in specific classes. The information stored about patents may be used to search for patents that meet specific criteria. One approach is using the classification criteria to check which patents are within a specific class. This will reveal developments within this specific class. Another approach is searching for all patents of a number of specific firms. This might be used to study the development of firms and the competitive edge of these firms. A third approach is using queries of keywords relating to the invention to study the development of a specific invention.

Each approach will have to obey two constraints: it should be precise, and it should be specific. 'Precise' means that all patents that are produced on the field under study will be found. 'Specific' means that no patents are found which are outside the scope of the study. Meeting both criteria at the same time means that one has defined a search strategy that delivers only those patents that are within the scope of the search strategy. This is the basic challenge of each patent search strategy. It is the problem of '*precision*' and '*recall*'. One should strive to high precision, i.e. all patents that are within the scope of what one wants to study are indeed found. And one should simultaneously strive to low recall, i.e. only few patents that are outside the scope are found as well.

In constructing our search strategy, we opted for a start through the user-friendly interface of WIPO (see <http://www.wipo.int/pctdb/en/>) which enables user guided searches on the basis of multiple entries (inventors, firms, IPC,<sup>266</sup> abstract, title, description). This first stage was meant to be

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<sup>266</sup> International Patent Classification, a structured (but not hierarchical) set of keywords used to delineate patents. See <http://www.wipo.int/classifications/ipc/en/> for an overview and an in-depth presentation of the IPC.

exploratory only. The second stage was intended to use the experience of the first stage for performing a more intensive search in the PATSTAT database.<sup>267</sup> We tried the second stage, but it showed that the PATSTAT database is not yet sufficiently well accessible to deliver reliable results. For one, it lacks a user-friendly interface. Search strings have to be created 'by hand'. This was not a problem, since we already had constructed a query that was initially tested in the WIPO database. For another, it only allows for searching in titles and abstracts. The full text of the patents (including the description of the invention) is not yet available for searching purposes. And thirdly, while WIPO returns results 'immediately' (i.e. within a few tens of seconds) the PATSTAT database needs considerable more time to process the requested data (up to several hours and even days). We tried a search on the basis of the query we produced for WIPO. This hardly delivered any results. Key words (such as 'remote patient monitoring') apparently are seldom used in titles or abstracts of patents.

We tried to circumvent this problem by checking the IPC codes used in the patents we found in the first WIPO search. This might offer an alternative to be used for PATSTAT as well. This route showed however to be highly problematic. No set of IPC keywords realised any kind of high precision and low recall. Though many RMT patents fall in one specific category (the category of medical diagnostic tools: 'A61B') this category still is much too broad to have any significant meaning in identifying patents on Remote Patient Monitoring. Using much more detailed classifiers (such as 'A61B 05/02' which relates to patents measuring pulse, heart rate, blood pressure or blood flow) did not alleviate the problem. Combinations of IPC keywords (such as 'A61B 05/02' with 'G06F' – electrical digital data processing, see also Table 2) neither did produce better results. The keywords showed to be disjoint; no patents were categorised with both classifiers. The conclusion to be drawn with respect to the usefulness of IPC in identifying patents in the domain of Remote Patient Monitoring unfortunately thus must be that IPC does not offer the proper classification structure to do so.<sup>268</sup> The overall conclusion at this stage was that the PATSTAT database was problematic to use at this stage.

To continue the pilot study we concentrated on the patents that are filed at the WIPO. This implied we would focus on a subset of all patents, namely those that are filed at WIPO. Firms have different options to file a patent. They can use national patent offices, regional ones or the WIPO. Many inventions will not be patented at all (given the figures known, this will probably be at least 50%). The majority of European patents (over 60% of EPO patents<sup>269</sup>) originate however from WIPO. This makes WIPO an interesting starting point. For firms, WIPO has the advantage of introducing a longer lead time before publishing information about the patent; it has the disadvantage that it is more costly. The last aspect may rule out patents by SMEs that are not able to cover the costs associated to the WIPO procedure. They most probably will start with protecting their intellectual property through national patent offices (or regional ones, which in case of European SMEs is the EPO<sup>270</sup>). Patent applications in WIPO will thus be patents of firms who presume to have an economically advantageous invention. For getting a view on the innovation dynamics within a specific sector focusing on this subset, this limitation appears to be reasonable.

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<sup>267</sup> PATSTAT is a database which collects information of all distinct databases of the different European Patent Offices. It is however, yet under construction and not fully operational.

<sup>268</sup> We tested several subsets of IPC keywords. No set delivered any reliable data, neither in terms of precision, nor in terms of recall. The process of attributing classifiers to patents apparently is not done with the aim of retrieval in mind.

<sup>269</sup> OECD, 2009. EPO is the European Patent Office; EPO enables firms to file a patent directly at European level and offers the opportunity to decide later in which specific European countries the patent will be registered.

<sup>270</sup> During the workshops we have held we have asked the participants what patent strategies they used. These were very wide-ranging and interesting. But all in all, whenever small firms file a patent, they will do so at the national office and use a description which is sufficiently large to cover a wide array of possible applications.

From a pragmatic perspective WIPO offers an interesting starting point as well. As indicated above, it offers its database for free through Internet and has produced a user friendly interface which enables searching on various dimensions at once (see extract in **Figure 38**). The various entries present the various information categories that are collected of each patent.

Figure 38 – User interface for patent search at Patentscope

The screenshot shows the WIPO Patentscope search interface. The main header reads "PATENTSCOPE® Search International Patent Applications - Structured Search - Windows Internet Explorer". The left sidebar includes links for "About Patents", "Patent Search", "Content", "Glossary", "National Office Databases", "Terms and Conditions", "Technology Focus", "PCT Resources", "Priority Documents", "Data Services", "Statistics", "Patent Law", "Life Sciences", "Meetings", and "Contact". The right sidebar features a "SHORTCUTS" section with links to "Log in / Create account", "Search Help", "Sequence Listings", "Country/Office Codes [PDF]", "INID Codes [PDF]", "Kind Codes", "Data Formats", and "Feedback". The central search area is titled "PATENTSCOPE® Search International Patent Applications" and includes a search form with fields for "Keywords", "Publication Number", "Application Number", "Publication Date", "English Title", "English Abstract", "Applicant Name", "Int. Class", "Inventor Name", "National Phase Country", "Description", and "Claims". Below the search form is a "Search" button. At the bottom of the page, there is a "PATENTSCOPE® Search Service - News" section with links to various news items. The taskbar at the bottom of the screen shows several open windows, including "Inbox - Microsoft", "Windows Ex...", "Microsoft O...", "Contactperson...", "PATENTSCOPE...", "Adobe Read...", and "11:59".

Source: <http://www.wipo.int/pctdb/en/>

Inserting a specific search string delivers an overview with all patents attached. Next to yielding basic information over each patent (title, WIPO number; date of filing, firm filing and full abstract), the WIPO patent service Patent@Scope provides four different forms of analysis:

1. It delivers a breakdown of patents relative to the keywords used.
2. It delivers a breakdown over the years.
3. It delivers a breakdown over companies involved.
4. It delivers a breakdown per category of the IPC terms involved.

The development of the query to be used was done in a heuristic manner, by trying and improving, meanwhile checking for robustness of results. We did this for a series of keywords, ending up with the following combination of keywords:

**Table 29 – Search string for RMT-systems in WIPO database**

"Remote patient monitoring" AND (COPD OR CHF OR diabetes OR "chronic heart failure") OR "remote monitoring" AND patient AND (COPD OR CHF OR diabetes OR "chronic heart failure") OR "home monitoring" AND (COPD OR CHF OR diabetes OR "chronic heart failure").
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The keywords on chronic diseases restricted the patents in the subclasses found through remote patient monitoring and home monitoring to those patents which indeed dealt with RMT for chronic diseases. Other terms that are frequently used in literature, such as 'telehomecare' and 'chronic disease' showed to deliver few additional – if any – patents on top of those found by the query indicated above.

This query delivered a total of 357 patents of which 48 could not be classified as being relevant for RMT systems (recall of 13.4%). Regarding the degree of precision we have realised, unfortunately this is impossible to determine by this method. We know what we have found, but we do not know what we have not found. We optimised the query heuristically, but patents that do not have a specific combination of keywords in one of their fields will not be found.<sup>271</sup> We relied on the fact that by adding new keywords to the search string (within the limits posed by the WIPO interface, i.e. no more than ten different entries) the sample did not grow, implying that we already had included the most relevant keywords.

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<sup>271</sup> As indicated during the workshops, firms have different strategies in patenting. One of them is to use an open formulation so that the patent can be used in several circumstances.

European Commission

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Title: Strategic Intelligence Monitor on Personal Health Systems (SIMPHS): Market Structure and Innovation Dynamics

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**Abstract**

Personal Health Systems (PHS) and Remote Patient Monitoring and Treatment (RMT) have the potential to alter the way healthcare is provided by increasing the quantity and quality of care. This report explores the current status of PHS and, more specifically, of the RMT market in Europe. It addresses the question of how these technologies can contribute to dealing with some of the challenges facing the European healthcare delivery systems caused by higher pressure of demand through chronic diseases and demographic change, combined with diminishing resources for health care. Uptake and diffusion of these services would potentially reduce death rates, and avoid recurring hospitalisation in a cost-effective manner. However, the report identifies various barriers which hamper the full deployment of RMT in Europe. In the conclusion, the report provides a number of tentative policy options which aim specifically to foster EU-wide deployment of RMT/PHS.

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