Strategic Intelligence Monitor on Personal Health Systems, Phase 2

Country Study: Italy

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2013
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1. THE ITALIAN HEALTHCARE SYSTEMS AND IPHS DEVELOPMENT

1.1 The Italian Healthcare System

From an organization perspective, the Italian healthcare system is a regionally based national health service (Servizio Sanitario Nazionale (SSN)). Under the Italian Constitution, responsibility for health care is shared by the central government and the 20 regions. The law decree framework presented last October 2010 \(^1\) envisages a further enhancement of regional organizational autonomy and a benchmark-based financing system. This is the last in a series of reforms aimed at the progressive strengthening of regional powers to deliver and finance health care and also at a parallel delegation of managerial authority to hospitals and ASLs started during the 90ies.

The national level is responsible for ensuring the general objectives and fundamental principles of the system. The Ministry of Health guarantees SSN fairness by monitoring the “Livelli Essenziali di Assistenza” – LEA which is the catalogue of SSN benefits and services guaranteed by each region as appropriate for specific clinical conditions and healthcare settings. Through its departments and services, the Ministry of Health is responsible for the following functions: healthcare planning, healthcare financing, framework regulation, monitoring and general governance of the National Institutes for Scientific Research (Istituto di Ricovero e Cura a Carattere Scientifico –IRCCS) that are research-oriented hospitals operating at the local level with competences in research and treatment of particular diseases.

Regional governments, through the initiatives of regional health departments and regional councils, are responsible for ensuring the delivery of a benefits package through a network of population-based health management organizations (Azienda Sanitaria Locale, “local health enterprise” (ASL)) and public (AO) and private accredited hospitals. Healthcare spending represents the main regional budget entry. The process of devolving political power and fiscal authority to regions provided the regional health departments with responsibility for legislative and administrative functions, for planning health care activities, for organizing supply in relation to population needs and for monitoring the quality, appropriateness and efficiency of the services provided.

At the local level, ASLs are organizations responsible for evaluating health needs and providing comprehensive care for a geographically defined population. The reforms during the 90’s reduced their number, widened their population base, increased their autonomy and profoundly reshaped their organizational structure and management system. Regions became responsible for determining the size and organization of ASLs and monitoring their operation. ASLs provide direct care through their own facilities or through services supplied by AOs, research hospitals and accredited private providers (acute and long-term hospitals, diagnostic laboratories, nursing homes, outpatient specialists and GPs – General Practitioners). ASLs are financed through a global budget, with a weighted capitation mechanism adjusted according to historical spending and yearly negotiated compensations with the regional department of health. Hospital providers under ASL control are paid through DRGs for inpatient activities services’ fees and through various mechanisms for outpatient and other specific health care services.

Aziende Ospedaliere (AOs), are public hospital enterprises (public agencies with a high degree of independency). AOs provide highly specialized secondary/ tertiary care (inpatient and outpatient). AOs managers can define hospital's mission and objectives through a three-year strategic plan, consistent with the recommendations of the regional health plan. AOs are mainly funded through a prospective payment system within a global budget negotiated with the regional department of health.

\(^1\) “Schema di Decreto Legislativo in materia di autonomia di entrata delle regioni a statuto ordinario nonché di determinazione dei costi e dei fabbisogni standard nel settore sanitario” (legislative decree framework on regional healthcare financing autonomy and on standard costs and benefits package in the healthcare sector) aimed at actuating law 42/2009: http://www.govemo.it/GovernoInforma/Dossier/federalismo_fiscale_decreto/
health. Figure 1 summarizes the Italian healthcare system highlighting main financial, administrative and care service delivery flows.

**Figure 1: Italian Healthcare System**

![Diagram of the Italian healthcare system]


### 1.2 Challenges and envisaged reorganization of the Italian healthcare system

The Italian healthcare system is facing the same long term sustainability challenges that other Western healthcare systems are encountering in terms of financial sustainability and in terms of changing healthcare services demand.
In terms of financial sustainability, total expenditure on health, as a proportion of gross domestic product (GDP), has risen from 7.9% in 1990 to 9.0% in 2008. Public spending on health accounted for 77.4% of the total in 2008. Italy’s public share of total health care expenditure is in line with other EU member states, although because of the large public deficit public health care expenditure remains an important issue for the government both at the national and the regional levels.

From a demographic perspective: the average life expectancy for men reached 79.2 years and 84.4 years for women in 2010. Citizens over 65 years are 20.3% of the total population. Population aging indicators show a high old age dependency ratio of 31%, which is not expected to easily decrease in the future, as the aging index (the number of persons 60 years old or over per hundred persons under age 15) is 144%. The mortality rate among adults and infants continues to fall. The diseases with the highest mortality rates affecting the population are chronic diseases such as circulatory and heart diseases, tumors, respiratory diseases and endocrinial, nutritional metabolic diseases. Out of every 1000 citizens 131.4 have at least one chronic disease and 138.4 have three or more chronic diseases. Arthrosis, arthritics and hypertension are the three most prevalent chronic diseases within the Italian population (See Tables A, B, C, D E, and F). Smoking and rising obesity levels, particularly among young people, are becoming important risk factors and consequently public health challenges. Individually and in combination, these factors are expected to continue to increase the demand for healthcare services.

1.2.1 Costs of Chronic diseases
Chronic diseases have a strong economic impact. This impact relates to direct healthcare expenditure but also lost GDP because of mortality and invalidating effects of illness. At the time of writing, standardized information of chronic disease costs in Italy are not available. There are different studies addressing various aspects of chronic diseases costs:

- An International Diabetes Federation study estimates the 2010 Italian expenditure for diabetes between €8,314,559 and €15,752,511 ($11,022,611 and $20,883,104 or between 10,129,992. and 19,191,975 in international dollars. According this study, diabetes healthcare expenditure accounts for up to 9% of total healthcare expenditure, while mean health expenditure per person with diabetes is estimated €2117 ($2,807).
- The CODE-2 study has measured the health care costs of people with type 2 diabetes in 8 European countries: Belgium, France, Germany, Italy, the Netherlands, Spain, Sweden and the UK. For these 8 countries the average annual costs per patient with type 2 diabetes were estimated at €2,834 in 1999. The health care costs of diabetes as a percentage of the total healthcare expenditures ranged from 1.6% in the Netherlands to 6.6% in Italy. Hospitalizations accounted for the greatest proportion of costs (55%).

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2 It should be noticed, however, that there has been considerable fluctuation in this figure over time depending on GDP rates and various co-payment measures implemented by different governments, thus changing the private share of health care spending

3 Sources: Istat (estimates 2010)

4 The old-age-dependency ratio is the ratio of the number of elderly people at an age when they are generally economically inactive (i.e. aged 65 and over), compared to the number of people of working age (i.e. 15-64 years old).

5 See Annex A: Statistical Data


• A 2010 international study estimated the epidemiological and economic burden to the health service of metabolic syndrome in patients with hypertension in Germany, Spain and Italy in 2008 and 2020. The economic burden to the health service of metabolic syndrome in patients with hypertension was estimated at €24,427, €1,900 and €4,877 million in Germany, Spain and Italy and forecast to rise by 59%, 179% and 157% respectively by 2020. The largest components of costs included the management of prevalent type 2 diabetes and incident cardiovascular events. Mean annual costs per hypertensive patient were around three times higher in subjects with metabolic syndrome compared to those without and rose incrementally with the additional number of metabolic syndrome components present (see figure 2).

• A 2007 study on Italy estimated the healthcare resource utilization and costs of COPD (Chronic Obstructive Pulmonary Disease) patients, staged by severity. It was a multi-centre observational study conducted in 11 Italian pulmonary departments throughout the country. A total of 268 patients were recruited and followed prospectively for 1 year. The annual average cost per patient was €3040. Hospital admissions and drugs were the largest cost components, accounting together for about two-thirds of the total. The mean total cost rose significantly with severity (€1046.7 for mild, €2319.0 for moderate, €3752.1 for severe and €5033.3 for very severe). When comparing cost components in different patients subgroups (defined by disease severity), through the analysis of variance, it was possible to notice statistically significant differences for all items except for day hospital (e.g. day hospital costs do not vary in a statistical significant way with disease severity).

• Another study published in 2009 showed that in Italy COPD patients cost on average €2,723 (of which €2507 relate to healthcare direct costs and €217 to indirect costs, such as absence from work). The study confirmed that 70% of costs are related to hospitalization, while costs related to diagnostic and other prevention activities are marginal. The study confirmed that costs variation is correlated to severity (from €1,215 to €5,452 for very severe cases) and showed great variation of results when comparing patients from different geographical zones (southern regions have 30% higher costs than central regions).

Moreover, chronic diseases rank high as cause of disability. For example, according to a WHO report, diabetes in Europe accounted for an estimated 2.2 million DALY (Disability Adjusted Life Years) in 2002. Diabetes ranked among the ten leading causes for the loss of healthy life years, expressed in DALYs, in Cyprus, Denmark, Greece, Italy, Malta and Portugal.

As stated on the national Health Plan 2011-2013, these phenomena are putting pressure for a more efficient reorganization of services based on multilayer governance and focused on delivering better care for chronic diseases and fragility conditions. To address the rising incidence of patients with chronic conditions and, most importantly, the imminent public budget issues, Italian healthcare policy makers have embarked on a long term reorganization of the healthcare services delivery model. In particular, during the last decade, the expression organizational "appropriateness" (i.e. promoting the treatment of patients at the lowest level of the health care delivery system that is

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8 Epidemiological and economic burden of metabolic syndrome and its consequences in patients with hypertension in Germany, Spain and Italy; a prevalence-based model; Scholze et al. BMC Public Health 2010 (Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2940918/pdf/1471-2458-10-529.pdf)
10 “La Salute del Respiro”, Dal Negro, Mangiacavallo Viegi, 2009 Collana della Fondazione SmithKline, Franco Angeli
11 The research does not explain how they calculate this figure
12 "European Health report 2005: a public health action for healthier children and population"
appropriate given the severity and complexity of specific clinical conditions) has become an official term in the Italian health care system\textsuperscript{14}.

**Figure 2: Mean annual costs (Euros) per hypertensive patient according to the number of components of MetS; 2008**

Source: Epidemiological and economic burden of metabolic syndrome and its consequences in patients with hypertension in Germany, Spain and Italy; a prevalence-based model; Scholze et al. BMC Public Health 2010\textsuperscript{15}.

Appropriateness has been promoted by creating incentives for health providers to start treating patients in different settings, e.g., day-surgery, day-hospital or, where possible, using outpatient services. This strategy has contributed to increasing inter-regional diversity in the supply mix and reflects differences in regional capacity to design and implement policies to reduce the hospital bed stock and to develop alternative forms of care, including home care and residential care for the elderly. The strategy has been translated in policy decisions aimed at:

- Reducing hospital admissions: through economic incentives such as the selective reduction of DRG rates for ordinary admissions, so as to make the day-surgery and other care settings more appealing such as home hospitalization (Ospedalizzazione a domicilio –OAD).
- Empowering primary care and integrating it with social services: through the reorganization of the primary care by reinforcing group practice\textsuperscript{16}, introducing economic incentives for GPs and promoting integration between primary care physicians and district services such as

\textsuperscript{14} The term “appropriatezza” (appropriateness) was officially introduced with the National Health Plan 1998–2001. (http://www.salute.gov.it/imgs/C_17_publicazioni_947_allegato.pdf.) Moreover, the “Health Pact” signed in March 2005 obliges regions to achieve specific objectives. In particular, heavy emphasis was placed on appropriateness, with the establishment of a National Benefit Package Committee charged with the assessment of the appropriate and efficient delivery of health care services. In addition, regions were requested to adopt all the necessary measures to limit and regulate delivery of services that do not satisfy the principles of organizational appropriateness. These elements have been newly addressed by the current National Health Plan 2010–2012 (http://www.salute.gov.it/imgs/C_17_publicazioni_1252_allegato.pdf)

\textsuperscript{15} Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2940918/pdf/1471-2458-10-529.pdf

\textsuperscript{16} For example the so called “medicina di gruppo” (advanced group practice) initiative where 3 to 8 GPs share the same office and the patient electronic health record system. They can also provide primary care to patients who do not belong to their catchment area.
social care, integrated home care (Assistenza Domiciliare Integrata - ADI\(^{17}\)), prevention, health education and environmental health.

In 2007, for example, the Ministry of Health launched a program to create awareness on home care initiatives and to map projects in the territory: ‘Cure a casa’ (care at home)\(^{18}\). In 2009, the project leaders published \(^{19}\) “Knocking on patient’s door” highlighting eleven actions needed to create successful home care in Italy:

- To enable patient free choice of care
- New LEA (national health service's benefits catalogue) planning to ensure continuity of care
- To create an epidemiologic and economic observatory on home care (in order to profile the home care patient and estimates resources needed)
- To create specific indicators for quality comparison
- To focus on the care-giving in home care (understand and structure the role of caregiver)
- To professionalize informal home care givers (professionalizzazione del badantato)
- To create a governance model for services based on subsidiarity principle
- New role for country hospitals and RSA (Residenze Sanitarie Assistenziali – Health Service Homes)
- Use of ICT and telemedicine
- Transition measures to support stakeholder during change
- Citizen awareness campaigns.

1.2.2 The adoption of Chronic Disease Management and prevention strategies

Public health studies have demonstrated that increasing incidence of chronic diseases and of their complications can be largely prevented or controlled, if appropriate measures like prevention plan and chronic disease management programs are implemented. This has led Italian healthcare authorities since 2000’s to approve national prevention plans. The latest national prevention plan 2010-2012\(^{20}\) is the result of an agreement between the national government and the regions. The government has allocated to the regions €200 million funding for the achievement of the plan’s goals, the development of monitoring tools and the harmonization of initiatives across the country. The harmonization of the various regional prevention plan will be supported by the national center for diseases prevention and control (Centro nazionale per la prevenzione e il controllo delle malattie – Ccm) with the help of the National center for epidemiology, monitoring and promotion of health (Centro nazionale di epidemiologia, sorveglianza e promozione della salute – Cnesps) and of the Higher Institute for Health (Istituto Superiore di Sanità – ISS).

The national prevention plan 2010-2012 has 4 action areas:

\(^{17}\) ADI is a service managed by GPs, in which nurses from the local districts and specialized physicians from hospitals are also involved. Currently almost all regions are proving this service through ASLs. Since 2001 ADI is officially included in LEAs through a government decree (DPCM 29.11.2001) http://www.saluter.it/documentazione/leggi/nazionali/decreti-ministeriali/dpcm-29-11-2001-definizione-dei-livelli-essenziali-di-assistenza

\(^{18}\) http://www.cureacasa.it/index.asp

\(^{19}\) http://www.cureacasa.it/files/sintesi.pdf

\(^{20}\) http://www.comunitappnp.it/file.php/1/Allegato1_PNP_10-12.pdf
• Support and development of predictive medicine to evaluate risk and instituting preventive measures

• Public health prevention programs

• Targeted prevention programs for those segments of population majorly at risk (screening, vaccinations, early detections, risk evaluation)

• Chronic disease management programs aimed at avoiding exacerbations through the design of appropriate care paths. These path should guarantee the continuity of care and be based on a better integration of healthcare and social services in order to better address fragile population like the elderly and disadvantaged people

Given the highly fragmented organization of the Italian NHS, the planning and the implementation of prevention and disease management programs, so far, has been based on independent regional and local projects. With the new prevention plans, regional governments are committed to implement and adapt at local level the actions of the national plans within 2012\textsuperscript{21}. The Ccm will be responsible for evaluating regional prevention plans. In order to increase knowledge sharing and best practices among regions, the Ccm has established different communities of practice. These communities of practice are expected to accelerate the harmonization of prevention programs and disease management initiatives establishing common methodologies and evaluation frameworks.

An initial example of integrated approach to the development of chronic diseases management programs can be found in diabetic patients care. Health for All\textsuperscript{22} statistics indicate that 4.3% of the Italian population is diabetic (approximately 2.6 million people). The spread of the disease increases with age, reaching 17.6% in the age group over 75 years. Diabetes Mellitus mortality rates in Italy have been going up and down, but remain one of the main death causes (mortality rates 3.34 every 10,000 inhabitants in 2010) over the years. Every year more than 70,000 people recur to the hospital for this disease\textsuperscript{23}. Regarding geographical distribution, mortality rates are higher in the southern regions (4.21 per 10,000 inhabitants on average). Southern regions are also those with the highest number of hospital discharges (discharge rate of 28.3 for every 10,000 inhabitants against a national rate of 18.9)\textsuperscript{24}. The number of hospital discharges can be taken as an indicator of the poor “appropriateness” of diabetes’ care organization. Italy was one of the first countries in Europe addressing diabetes management through a law (L. 16 March 1987, n. 115\textsuperscript{25}) aimed at establishing a framework for prevention and care. The law defines diabetes as a “high social interest” disease and establishes, among others, the need for a dedicated and specialized network of care providers and for an integrated approach. In 2004, the ISS\textsuperscript{26} coordinated an epidemiological study on diabetes called QUADRI\textsuperscript{27} (QUalità dell’Assistenza alle persone Diabetiche nelle Regioni Italiane- Quality in care/assistance of diabetic patients in Italian regions) that has demonstrated that the national health system was still far from having achieved high quality standards in diabetes care especially as concern the integration of care providers enabling a patient centered care. In 2006, ISS established the IGEA project (Integrazione, Gestione E Assistenza per la malattia diabetica - integration, management and care for diabetes) for the definition of an overall strategy and coordination of regional projects. Within this project Region Piedmont has developed a specific

\textsuperscript{21} Examples of regional prevention plans are available at http://www.ccm-network.it/Pnp_2010-2012_piani-regionali

\textsuperscript{22} http://www.istat.it/sanita/Health/

\textsuperscript{23} Source: report Osservasalute Rapporto 2010

\textsuperscript{24} Source: Istat, (Health for All database)

\textsuperscript{25} http://www.salute.gov.it/imgs/c_17_normativa_202_allegato.pdf

\textsuperscript{26} Istituto Superiore di Sanità (ISS) is the leading technical and scientific public body of the Italian National Health Service. Its activities include research, control, training and consultation in the interest of public health protection.

\textsuperscript{27} http://www.epicentro.iss.it/igea/pdf/Istisan_Quadri.pdf
regional project for prevention of diabetes and disease management. The approved documentation provides details on the levels of assistance (LEA) guaranteed to diabetic patients in the region, the guidelines for an integrated approach to diabetes management, including a model with the related medical protocol and a series of indicators established in order to evaluate results of different initiatives aimed at preventing and managing diabetes.

It should be noticed, however, that the impact of these coordinated initiatives is still limited, as witnessed by the different regional legislations on diabetic patient management currently in force.

1.3 The role of technology for the continuity of care

1.3.1 HTA in Italy

Among the actions needed for the development of the SSN, the new national health plan continues to stress the centrality of primary care and the importance of the continuity of care integrating health providers on the territory (primary and ambulatory care) with the hospital. The continuity of care should be guaranteed especially for patients in the post acute phase and for chronic patients that need to be more involved and empowered in the care process so as to enable self care. It is therefore necessary to base the care path on an integrated network approach: to this end, the plan recognizes that ICT solutions such as telemedicine/telecare can be beneficial, in helping the communication between institutions, formal and informal caregivers.

Statistics show that the ordinary hospitalization rate has decreased, so from this general perspective the impact of the reorganization of the care system and the implementation of eHealth initiatives supporting it have been positive. The current national health plan, however, highlights that there are wide margins for enhancing appropriateness. Data on hospitalization are not homogenous across the country; moreover, looking more in depth, the high number of day surgery discharge rates for chronic patients suggests a misuse of this institution to the detriment of ambulatory/outpatient care. New technologies enabling new diagnostic services in the ambulatory setting (especially in the imaging branch) are increasingly used; but they do not seem to have an impact on reducing old and obsolete services that they were expected to replace. In the primary care sector, initiatives undertaken are still at a nascent stage and have not yet achieved homogeneity. There is little official data about the outcomes of these new forms of health service delivery. Therefore the new plan encourages a systematic use of:

- The Health Technology Assessment (HTA) approach, applied not only to the device/technology per se, but also to planning, procurement and management.
- The Health Impact Assessment approach for the evaluation of policies and initiatives

Previously the national health plan of 2006-2008 recognized the importance of HTA for the evaluation of innovation in the healthcare system and to support the clinical governance. The budget law of 2007 established that AGENAS (Agenzia Nazionale per i Servizi Sanitari Regionali) established that AGENAS (Agenzia Nazionale per i Servizi Sanitari Regionali) was founded in 1993 with the aim of promoting innovation and quality in the healthcare system and of developing comparative cost and

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28 http://www.epicentro.iss.it/igea/diabete/territorio.asp
29 Analisi della legislazione regionale sul diabete in Italia (Società italiana di Diabetologia, Dr. Alberto Bruno and Dr. Marco Peruffo, 2010) Available at: http://www.siditalia.it/index.php/altri-documenti.html
30 HTA is a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health care technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. As described by the EUnetHTA - European network for Health Technology Assessment (to which Italy belongs through its agency AGENAS), in HTA health care technology is defined broadly as prevention and rehabilitation, vaccines, pharmaceuticals and devices, medical and surgical procedures, and the systems within which health is protected and maintained.
31 AGENAS (National Agency for Regional Healthcare Services) was founded in 1993 with the aim of promoting innovation and quality in the healthcare system and of developing comparative cost and
along with the Commission on medical devices (Commissione Unica sui Dispositivi Medici) plays a coordinating and promoting role for HTA in Italy. In order to ensure its goals, the current national health plan also encourages the government and the regions to pursue the enhancement of the interregional collaboration network for HTA (Rete collaborativa Interregionale per l’HTA or RIHTA). The development of the network is considered essential to the implantation of Evidence Based Medicine.

Looking at ICT application in the Italian system, AGENAS has developed a framework for the assessment of ICT applied in the healthcare service delivery (as described in). Within this framework, AGENAS addresses the potential issues related to or effect of health technologies, dividing them into the 9 domains below as described in the European project EUnetHTA:

1. Health problem and current use of the technology
2. Description and technical characteristics of technology
3. Safety
4. Effectiveness (mortality, morbidity, function, QoL, patient satisfaction)
5. Costs, economic evaluation
6. Ethical aspects
7. Organizational aspects
8. Social aspects
9. Legal aspects

efficiency analysis on public health services. AGENAS provides technical and scientific support to regional health departments; promotes exchanges between regions and supports best practices sharing. AGENAS aims to support the priority setting both at national and regional level by proposing a HTA protocol based on stakeholders involvement, evaluating evidences and disseminating results and by monitoring the efficiency of HTA itself.
AGENAS has not completed any HTA on eHealth technologies or on the use of telemonitoring/telecare systems. So far, the agency delivered a Horizon Scanning with EUROSCAN for emerging technologies, which included telemonitoring systems based on the use of digital TV and wearable devices. Horizon Scanning is a type of analysis that is focused on the identification of new technologies that are still in the development phase. This type of analysis aims to evaluate, often on a prospective/provisional base, the possible impact of a new technology on the NHS (both from a clinical and management perspective).

The Horizon Scanning process is divided in 4 phases:

1. Identification of emerging technologies
2. Prioritization of technologies
3. Evaluation of prioritized technologies
4. Dissemination and systematic review

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32 See Annex B interview 1
33 AGENAS has started an HTA project with consortium Arsenal (http://www.consorzioarsenal.it/) , which groups and provide ICT services to all Veneto region ASLs
34 The International Information Network on New and Emerging Health Technologies (EuroScan) is a collaborative network of member agencies for the exchange of information on important emerging new drugs, devices, procedures, programs, and settings in health care.
35 http://www.agenas.it/innov_sperim_sviluppo/HS_2.pdf

Source: Adapted from an AGENAS presentation held in Siena on the 3rd July 2009 (www.etinnova.it/images/pages/.../14072009152823941_5_cerbo.ppt)
In more advanced systems, Horizon Scanning has a strategic function as it helps decision makers in setting the priorities and it plays a "sentinel role" when identifying the opportunities that new technologies can offer. Since 2008/2009 AGENAS has started different Horizon Scanning exercises for evaluating the potential of technologies that are still under development.

The results of this activity is expected to support NHS decision makers at all levels (central government, regions, ASL, hospitals) while introducing these new technologies. This activity has allowed AGENAS to create an observation center for emerging technologies (Centro per la Osservazione delle Tecnologie Emergenti -COTE).

AGENAS defines as emerging health technologies those technologies that correspond to any of the following definitions:

- Are new for the healthcare market, or in the initial adoption phase, to be used in the clinical environment for a limited time framework, or that are generally just launched in the market.
- Have been just invented, not yet adopted by the NHS (e.g. products that are in the premarketing phase, that are in use only is a very limited number of healthcare organizations)
- Represent a variation in the traditional use of a technology
- Belong to a group of technologies that are still under development in the short term, are not considered disruptive and are expected to deliver small clinical or organizational changes in the short term

AGENAS has launched a survey in order to map all the ongoing projects and initiatives on tele-rehabilitation for post-ictus patients in Italy\(^{36}\). According to the AGENAS representative interviewed, first survey results available together with other research done in the past show a fragmented situation, where initiatives are independent from each other. This, according to the AGENAS representative we interviewed, is due to a general tactical approach to telemedicine. The lack of common objectives and shared strategies are among the main causes of this fragmentation. The lack of specific reimbursement procedures makes these initiatives reliant on national and international R&D funding that usually do not exceed the 5 years time framework. The government along with the regions has started a project aiming at redefining DRGs in order to include telemedicine into the definition of home hospitalization (OAD) and integrated home care (ADI). The current reimbursement model has not evolved in pace with the changes in care delivery models and the financing models in these new care paths are complex.

According to the AGENAS representative, the lack of a common strategy creates a limit for "knowledge translation": generally, even in experiences producing positive results, very few project owners make an impact analysis that will help identifying key success factors and barriers. In most of the cases, the approach to innovation is driven by the technology vendor (devices vendor, software vendor, system integrators), which proposes the experimentation of the solution to the health provider organization. After the end of the experimentation the healthcare organization very rarely has the capability and the resources to generalize the innovation and make it a routine process. When starting a telemedicine/eHealth project, few organizations take care of the evolution of organizational models, running feasibility studies on necessary resources, comparing alternatives, evaluating patient acceptance\(^{37}\), etc. Healthcare organizations rarely adopt for telemedicine (and

\(^{36}\) Results are not available at the time of writing.

\(^{37}\) AGENAS, for example, while analyzing at home dialysis systems projects found out that among the greatest barrier was patient acceptance that wasn't initially addressed while planning the services
more in general for eHealth) the same approach they use for other innovations. Moreover, some technical problems persist, especially with regard to health information exchange because of lack of interoperability and of basic infrastructures. There are also significant variations in the maturity of eHealth adoption across the 20 Italian regions. The decentralized structure of the Italian NHS, centered on the autonomy of regional governments and local health enterprises has encouraged a dynamic environment, where hundreds of projects are in place, which, nevertheless, evolve following centrifugal directions. Regional health departments are now realizing the limit of this fragmentation and opening discussion boards for a shared strategy.

1.3.2 The role of ICT and the opportunities for IPHS in the Italian healthcare system

Beside the national health plans, the national eGov 2012 agenda also considers ICT a key enabler for an efficient healthcare system and for the delivery of health services that are more closely aligned with patient needs. ICT allows the point of care to be moved away from traditional settings and this is one of the key principles of the transformations envisaged in Italian primary and secondary care. At a national level, the Ministry of Healthcare and the Ministry of Public Innovation are promoting initiatives and investments, setting interregional boards aimed at creating coherent guidelines for shared approaches, and infrastructures. There are three main programs influencing the future of eHealth in Italy:

- The New Healthcare Information System (NSIS) a governance tool to support and monitor the LEAs; it will lead to an information system defining a minimum dataset for analytical data to be used for governance needs for health authorities. In particular, in the new national health plan, during the next three years, the Ministry aims to enlarge the current scope of the NSIS including the monitoring of ADI initiatives

- The National Healthcare Service’s “Bricks” (“Mattoni”): establishing a broader semantic toolkit that will ensure comparability and interoperability of regional healthcare services. The program is organized in 15 thematic sub-projects (“mattoni”-bricks), each with a Region as subproject leader. One brick defines the guidelines to develop the EHR led by Lombardy region

- The permanent inter-regional eHealth Board: the institutional setting for technical discussion and consultation, to harmonize the different regional eHealth policies, and to help coordinated implementation of the respective projects. Current projects where collaboration is in place are: the electronic health record (fascicolo sanitario elettronico-FSE), ePrescription, eBooking and the GP and Pediatrician network

The Observatory for the evaluation and monitoring eCare networks

There are several eHealth projects that have been developed or are currently ongoing, as reported in the portal of the National Observatory for the evaluation and the monitoring of eCare networks (Osservatorio Nazionale per la valutazione e il monitoraggio delle reti eCare). The Observatory aims to define a set of indicators (technological, organizational, economical and clinical) necessary for a compared evaluation of eCare networks and for the definition of best practices. In 2008, the

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38 For example, in cancer screening initiatives normally healthcare executives set specific targets on eligible population coverage (e.g. 30% the first year, 60% the second year, 90% the third year); in telemedicine/ eHealth projects, this rarely is the case
40 http://www.onecare.cup2000.it
41 The observatory has divided the analyzed projects into the following categories portals and call center, di e-data – functional to the EHR and EMR – e-booking, eCare/telemedicine and social networks. Each project is analyzed under the light of three environments:
Observatory mapped 562 ICT enabled care networks: 132 of them were focused on tele-support, tele-assistance and telemonitoring; 101 were tele-surveillance projects; and 125 were telemedicine projects. At the end of this mapping initiative, the Observatory eCare executives drew the following observations:

- Strong interest and dynamism around eCare networks
- Difficult evolution of the networks from closed system functional to the single organization (ASL or hospital) to open system that include patients (home care) and citizens
- Public institutions and key decision makers (especially at regional level) are not playing a clear directing role neither are they fostering the stabilization (i.e. making them routine) of the networks
- In current eCare network projects, ICT have a prominent role focusing initiatives more on the technological development of the solution, rather than on changes in social and healthcare services system
- Instability and excessive diversification of architectures and networks governance systems. Continuous duplication of experiences/ projects.

Analyzing more in depth telemedicine projects only, the observatory highlighted that:

- Projects are mainly focused on the clinical aspects and they rarely offer social support services such as tele-assistance. Comparing telemedicine networks with tele-assistance and tele-support networks, it emerged that the "multiservice" nature of the latter is a success and duration factor. Those networks that are able to integrate social and health services, therefore offering more services, last longer
- Telemedicine projects with bigger budgets are often delivered through modules that differentiate the services offering (different specialty areas)
- Huge number of pilots in comparison with fully operational projects
- "High mortality" of projects. Projects often end with pilot phase
- High focus on technology: more and more user friendly for patients while healthcare organizations/ service providers see the complexity supporting the networks rising
- Cardiology and respiratory medicine are the specialties where telemedicine is majorly used in Italy

The Observatory tried to develop a multidimensional evaluation model in order to make projects comparable. The model takes into consideration:

- Economic indicators aiming at quantifying:
  - how eCare networks contribute in reducing the number of hospitalizations, in reducing the number of elderly patients in long term care facilities
  - the overall cost of eCare networks

- Social: networks open to enable the relationship with the patient
- Organizational (type 1) networks open to enable clinical governance
- Organizational (type 2) networks open to enable administrative governance

42 All projects that are basically delivered through call center and a network of care givers (both from health and social services system). They are differentiated by the level of complexity of services.
43 Project where the patient is provided with panic button devices connected to a call center and to ambulance services
44 Projects where patients clinical parameters were monitored through devices
- the overall financial gain following the implementation of eCare networks

- Organizational indicators aiming at evaluating how home care services can be integrated with the more complex network of health and social services. In particular these indicators aim to evaluate the:
  - Organizational model
  - Organizational innovation that impact on access and care delivery
  - Level of communication and collaboration between professionals involved

- Process indicators aiming at identifying common terminology to compare results (semantic indicators)

- Clinical indicators aiming at better understanding medical results
  - By using objective clinical parameters by type of disease
  - By evaluating the level of integration of health and social records that come from eCare networks with those of traditional care settings

- Technological indicators aiming at evaluating
  - Technology adoption
  - Standards adoption
  - Openness and integration and adaptability to a changing environment
  - Adoption of collaborative platforms, open source, 2.0, wikis architectures etc

These indicators are still under development. The Observatory is trying to define thresholds for each indicator, in order to better define good practices. The Observatory uses objective data like reduction of hospitalizations, and, considering the fact that the related scientific literature is still not very rich, it also uses qualitative indicators based on estimates and proxies. This multidimensional model has been initially used during the 2009 research which has been focused on telemedicine networks. The Observatory has analyzed 183 networks, where cardiology confirms to be the elective specialty for telemedicine projects in Italy. The 2009 research highlighted also an interest for telemedicine projects implemented within the integrated home care (ADI) settings. Again, it emerged that telemedicine projects are for the large majority very specialized, with only few of them offering different services for different diseases. Also in the 2009 research, the Observatory noted that in these projects

- The technological aspect is more developed than the organizational one. However, technology is still implemented following traditional “silos approach” with systems that are not meant to be open to other systems

- There is a tendency to think that the real innovation lays in the technology instead of process reorganization and the creation of networks of care.

- There is a need to leave the perpetual pilot stage and enter into roll out and normalization

- Integration between telemedicine and tele-assistance networks is a key success driver

- Data and information collection on telemedicine projects is very difficult. The needed culture of sharing and comparing results is hard to be put into practice.

As witnessed by the 2009 research, the lively proliferation of these networks and projects has certainly enlarged the potential for integrated personal health system (IPHS) and the awareness of healthcare organizations on their benefits. However, this has also led to a considerable, unevenly distributed number of pilots and experiences which, despite initial positive results, struggle to be

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45 Projects records are available at http://www.onecare.cup2000.it/schedalight_elenco/recenti/all. Responsible for the project is Carla Fiori of CUP 2000 also interviewed for Emilia Romagna case study.
The main challenges for the deployment and implementation of IPHS innovation in Italy are therefore the following:

- A fragmented organization of healthcare.
- General budget pressures leading to underfunding the existing services and lack of investment for innovations.
- Concerning IPHS specifically, lack of funding models, poor regulation about new forms of care, uncertainty about the related deontological issues represent major barriers against widespread adoption.
- Concerning supply, the lack of common technological standards is aggravated by a fragmentation of the supply side of the market parallel and similar to the fragmentation of the demand side.

These main barriers tend to predestine many of Italy's IPHS projects to remain in a constant 'pilot state'.
2. SELECTED IPHS CASE STUDIES IN ITALY

2.1 Case studies in Piedmont region

Piedmont is an Italian region located in the northwestern part of the country. It has a population of 4,446,230 inhabitants. Life expectancy at birth is 78.9 years for males, and 84.2 years for females. Piedmont is one of the regions with the highest values for aging population indicators:

- Population average age is 45 (against a nationwide value of 43)
- People over 65 years is 22.8% of the total population (against a national value of 20.3%)
- Old age index (ratio between population over 65 years and 0-14 year population) is 177.7% (while at national level it is 144.5%)46

The diseases with the highest mortality rates affecting the Piedmont population are circulatory diseases, tumors, respiratory system diseases, digestive system diseases, nervous system diseases, endocrinal, nutritional, metabolic diseases47. Piedmont has 7 hospital enterprises and 13 local health organizations (ASL). Since 2002, the number of ASL has decreased after a regional reform aimed at rationalizing resources and increasing the patients’ catchment area of each local health organization48.

Piedmont health provider organizations have started different telemonitoring services. According to the most recent Regional Health Plan (2006/2010)49, the region aims to integrate these services within the standard regional catalogue of healthcare benefits. In the plan, the role of ICT is considered key to the reorganization of primary care and the integration of different care/assistance levels, especially in non-urban and mountains areas (43% of the total territory).

For the purpose of the research we identified two projects involving two different care settings:

- A telemonitoring project about home based hospitalized or just discharged elderly patients implemented by the geriatric department of AOU (Azienda Ospedaliero-Universitaria, University Hospital) San Giovanni Battista Molinette hospital in Turin;
- A telemonitoring project for chronic patients implemented by ASL Verbanio Cusio Ossola (VCO)

2.1.1 MyDoctor®home at AOU San Giovanni Battista Molinette50

The Background

AO San Giovanni Battista Molinette is a university teaching hospital (integrated with the University of Turin) that offers diagnostic and care services to inpatients and out-patients. It employs 5,957 people (of which 2,856 are nurses and physicians). The hospital can offer 1,270 beds (207 for day hospital activity). It includes four facilities: le Molinette, San Lazzaro, San Giovanni Antica Sede and, outside Turin, San Vito hospital. It is the third largest hospital in Italy and it is the leading center for the oncologic network in Piedmont and Valle d’Aosta regions.

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46 See Istat: http://www.istat.it/salastampa/comunicati/in_calendario/inddemo/20110124_00/testointegrale20110124.pdf
47 Istat (Health for All)
48 Osserva Salute 2010 report
49 http://www.regione.piemonte.it/pssr/
50 See Annex B interviews 2, 3, and 4
Through the geriatrics and bone metabolic diseases’ unit of the hospital rehabilitation department, the hospital has launched a telemonitoring project called “Mydoctor@home” for elderly patients treated in the home based hospitalization (OAD) setting or just discharged. AOU San Giovanni Battista Molinette hospital and, in particular the geriatrics unit, are since long involved in projects to improve the home based hospitalization and after discharge activities. In this context the objectives of the project are:

- Improving patients’ quality of life (moving information instead of these fragile elderly patients)
- Making relevant patient data easily accessible for physicians
- Supporting integrated home care and the caregiver-patient relationship
- Reducing costs: anticipating patient discharge and proactively changing therapy and treatment thanks to real time monitoring (so decreasing the number of re-hospitalization)

The pilot
The Mydoctor@home project started on the premise of results of the project Dream-Adamo developed by the Istituto Superiore Mario Boella research institute. In the “DREAM-Adamo” project elder patients with chronic diseases were given a wearable device monitoring basic vital signs and environmental parameters (i.e. temperature, light). These signals were automatically transmitted via wireless connection to a hub, which was connected to a central tele-monitoring centre. The hub automatically processed data, and signal to the tele-monitoring centre only alarms, that were evaluated by qualified operators.

In 2008, based also on the findings of the “DREAM-Adamo” project, the regional health department and the AOU San Giovanni Battista Molinette, with the scientific collaboration of Istituto Superiore Mario Boella and in partnership with Telecom Italia (through the totally owned company TILab), launched the MyDoctor@home project. The initial objectives of the project were to innovate in the home based hospitalization activity and to reduce the workload of health staff (especially for nurses that are the most active resources in the OAD). The OAD regime has been in place at AOU San Giovanni Battista Molinette since 1985. The OAD service is active every day, normally, involving 13 professional nurses, 1 nurse coordinator, 1 social worker, 3 physiotherapists and 1 counselor. The aim of OAD is to transpose hospital service at the patients’ home. For emergency outside service hours patients rely on emergency services (118 or 112), with which the hospital has special agreement for these patients. Besides routine visits, during working hours the health staff of OAD is also able to answer patient calls and be at his/her home within 20 or 30 minutes. There are different and complex services that can be delivered at the patient’s home such as ECG, small surgeries treating bedsores, central intravenous catheters management, positioning naso-gastric tubes, ultrasounds, blood drawing etc. Normally the service is activated by the family GP (instead of sending patient to A&E), by hospital physicians (protected early discharge) or directly by the emergency department. The hospital estimated an average daily cost of €160 for patients in OAD (including health and administrative staff, ambulance service, drugs and treatments). In March 2010 the region has regulated more precisely the OAD, specifying better organization and reimbursement (DGR 85-13580 of 16th march 2010).

52 From 8.00 AM to 20.00 PM
53 With significant financial gains when compared to hospital stay. For example a 2007 perspective study “Healthcare costs of COPD in Italian referral centres” (authors: Daniela Kolevaa, Nicola Motterlinia, Paolo Banfib, Livio Garattinia) estimated that the average cost of a day of stay for COPD patients in Italy is €268.2
Before starting the telemonitoring pilot:

- OAD staff was trained through a series of meeting explaining objectives, workflows and equipment usage
- A small 2 months experiment on 5 patients was run to consolidate the model
- An indirect evaluation of usability of the system was carried out through questionnaires and staff feedback. All stakeholders involved (patients and staff) have been surveyed with a questionnaire aimed at establishing the degree of acceptance and usability of the telemedicine solution

The experimentation started on November 2008 involving 40 elderly (75-101 years) patients (cardiovascular disease and COPD) hospitalized in OAD regime. During the pilot phase 7/8 hospital professionals were specifically involved. They were divided into 2 randomized groups: 20 provided with telemonitoring and a control group without telemonitoring. The two groups were demographically and clinically similar groups. Both groups were evaluated on several clinical indicators at the beginning of the hospitalization in OAD and at the discharge. Patients provided with telemonitoring devices had different sets of devices based on their diseases. Nurses trained patients on how to use the solution. Measurements were taken daily by the patient his/herself or by the care giver (informal career, relative), however for more complex measurements, such as spirometer and ECG, measurements were done by a nurse during a scheduled home visit. When nurses were at a patient’s home for specific measurement such as ECG it was possible to connect with the physician in order to have a real time analysis with related care indications. After discharge from OAD regime, patients continued their telemonitoring for 15 days. During the whole period physicians were able to access patient data through a web interface accessible through a login and password system. The web portal offers some analytical capabilities that allow a visualization of data and their evolution. Contacts with stable patients were limited to a phone call to encourage the patient in going forward with the initiative. If sent parameters weren’t within established range or were abnormal, according the situation, the clinical staff could call the patient or the care giver to get more information, change prescription dosage, send a nurse to the patient's home or do a full medical visit.

Comparing the two randomized groups, the group with telemonitoring services showed a reduction of medical visits (but not statistically relevant). Mood swings improved more significantly in patients with the telemonitoring service, i.e. those who initially had the worst baseline values. The emotional tension (measured through RSS –Relative Stress Scale) of informal caregivers (e.g. patient relatives) was lower only for the group with telemonitoring solutions.

The pilot has showed how telemonitoring services made geriatric patients more attentive toward parameters that they normally ignore such as weight variation (which it is important to keep under control for patients with skeletal and heart failure problems). In fragile patients affected by several diseases care success is conditioned not only by the complexity of the clinical conditions, but also by cognitive, functional and social aspects. The telemedicine platform helped clinical staff in timely noticing variations in these parameters preventing the worsening of the patient status, obtaining a safer management of the patient, while containing the time spent on each single patient. The quality of the assistance improved and the stress level of the care giver was eased without deteriorating clinical conditions and survival rates. Usability indicators were more positive than expected, controverting the initial skepticism. The clinical study is still ongoing, and continuing throughout the roll out.

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54 The questionnaire was developed by Mario Boella Institute.
The general roll out
Starting from March 2011, based on the pilot phase experience, the project has entered the roll-out phase. No major variations from the pilot phase on the organizational aspects of the project have been made. The projects will be extended also to those patients with chronic conditions that are not treated within the OAD regime. The plan is to reach 5,000 patients in three years (by increments of 400). The enrollment process of the first group of 416 patients has already started. Within the AOU San Giovanni Battista Molinette hospital, the Cardiology, Medicine and Pneumatology departments will adopt the solution, while other hospitals in Piedmont are also entering into discussions with Aress and Telecom Italia to adopt it.

Technology
The project aims to support both patients living quite independently and patients that need constant follow up and physical visits by health staff.

- Those with a higher degree of autonomy or with adequate support from the family are supplied with a specific medical device, a mobile phone with a special M2M SIM card configured to collect data from the devices.
- For less independent patients, health staff going to the patient home is provided with a phone that is able to collect data from an established number of devices (of assigned patients).

In both cases health staff intervention is need for the use of more sophisticated devices such as ECG and spirometer. For the roll out phase, the hospital confirmed the choice, made during the pilot phase, to give each patient a single device (even if in certain cases an additional digital scale is also included in the service). Each medical device is associated with a mobile phone and each phone is configured for one or an established number of devices (when it is used by health staff or when the patient also uses the scale) in order to guarantee an unambiguous data collection and security. Devices and phones are connected and configured through a procedure called "pairing" (a process of mutual recognition used when connecting two or more devices via Bluetooth: it is a process based on the exchange and verification of an ID code that authorizes information exchange). Patients are trained by the clinical staff on taking measurements correctly; and during the service they are supported through a series of SMS reminders to take measurements according to the agreed schedule. Once collected, data are transmitted to a server. In order to ensure privacy data are anonymized during transmission. Then authorized health staff at the hospital can access data and patient profile through a web application. For technical problems (related to the functioning of devices and of phones) patients and physicians can directly call the help desk service (available from Monday to Friday from 10.00 to 19.00). TiLab, in agreement with the hospital, chose a single supplier for medical devices in order to facilitate the organization of the help desk service. It should be noticed that MyDoctor@Home represents a solution of the Telecom Italia eHealth offering portfolio. The company is still investing in the solution development and offers it to other healthcare organizations in Italy; this should guarantee the AOU San Giovanni Battista- Molinette technological support and development through the years. It consists of a technology platform based on a cloud computing model (Platform-as-a-Service). The hospital staff accesses the telemedicine platform service paying a "single user" fee without having to buy any infrastructure support other than the kits (devices and relative consumables) to be provided to patients for remote control. The cloud model limited the hospital investments in technology, allowing hospital stakeholders to focus on clinical and organizational aspects. Moreover this platform delivery model is expected to mitigate the "lock in" problems that eHealth projects usually face in the long term.

55 Later than planned according the initial schedule because of a delay in medical devices delivery
The platform as a service allows the hospital to migrate easily toward new technologies, when available, because there will be no particular legacy problems.

**Personalization of care**

The service “manager” is the physician with the credentials (each department that is involved in the project has to ensure there is at least one responsible physician and a nurse). The patient and the caregivers supporting him/her are trained by the health staff to take measurements. An SMS reminder service can be activated to support the regular collection of data. According to national guidelines in use and to the standard category to which the patient belongs, the physician personalizes the service establishing the alert thresholds: when values transmitted exceed the attention/ alert thresholds, an SMS is automatically sent to health staff (each hospital unit has a dedicated cell phone for alerts) and to the patient (asking him/ her to take action such as taking medications or call a doctor). However, a personal path and procedure based medical protocols and guideline is established for each patient. Therefore beside the standard SMS, when patient data are not conform to the established thresholds, there are different procedures that have to be followed (as witnessed by the use of the service within the geriatrics unit of San Giovanni Battista Molinette hospital): get in contact with the patient, call to the GPs (even if his/ her contribution is not structured within the organization of the service), or call for an ambulatory visit. It important to explain to the patient and to his/her informal caregivers that this is not a 118- emergency service, because it does not provide the adequate assurance of service continuity and safety. The system is not integrated into the electronic medical record or in the hospital information system, but it would be possible since the solution is HL7 based\(^57\). Patients can see their transmitted data on TV (land-based digital cable TV) by digitizing a PIN code\(^58\). Patients received the initiative well and they were feeling at ease with the technology\(^59\). From a user experience perspective, limited problems were experienced.

**Costs**

The total value of the contract between Telecom Italia and the region for the implementation is €10 million per 5,000 patients for 3 years. The cost of the project is about €2 per patient per day (as in the contract with Telecom Italia); the first envelope of funding for €364,416 for the first next 416 patients has been already allocated by Aress\(^60\) on behalf of the region. According to the contract the hospital will also need to fund expenditure for consumable such as batteries.

The contract does not specify who has the responsibility for the technology delivered to the patient. For instance it is not clear whether it is the hospital or the patient who has to refund or not Telecom Italia in the case the patient mobile phone has been stolen or lost.

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57 TiLab is working on the integration with the 2 EHR currently present in the market but independently from this project.

58 It is also envisaged a more traditional solution with fixed broadband and PC (it is not currently in use, but with the enlargement of the project this option is taken into consideration).

59 For example, a group of Alzheimer patients that were involved in the pilot phase at the end of the experimentation didn’t want to stop the service, since they were feeling safer; another example can be drawn from the experience with patients that are taking medications that might lead to bradycardia: the use of ECG was reassuring them and reducing the number of bradycardia episodes.

60 Aress is the regional agency for health services (http://www.aress.piemonte.it). It financially depends directly from the institutional affairs regional department (that is competent for auditing and transparency in public administration management) and provides technical scientific support to the regional health department. It support ASLs and AO in activities such as: planning health services, economic impact analysis, evaluation of health services quality, promotion and planning of innovative organizational and management programs, technology assessment, evaluation of best practices and knowledge sharing across the regional health service. Aress activity is planned annually and it is based on the indication of the regional health department in accordance with the regional health plan. Detailed description of Aress activity for 2010/2011 is available at http://www.aress.piemonte.it/Contenuti/5/8/dgr_pas_2010.pdf
According to the head physician of the geriatric unit, this is the only cost for the region since the medical staff involved in this project is not exclusively dedicated to this service. It is difficult for the hospital to understand how many man/hour are allocated to the project so the €2 per patient per day estimate is not totally reliable in considering the whole expenditure.

**Generalization of the innovation**

During the next three years the Piedmont region expects to reach 5,000 chronic patients with the service. As written above, other departments of the San Giovanni Battista-Molinette hospital and other hospital are already considering the solution. It is planned to also introduce and integrate devices for monitoring diabetic patients.

Given the positive results of the pilot phase the general roll out will continue on the model used so far. For personnel training as during the pilot phase TiLab (Telecom Italia) staff along with physicians supervising the project will train a small group of hospital staff that will further train their colleagues. In turn hospital staff that will work in the field will train patients and their caregivers. This peer to peer system has allowed spreading the knowledge across the involved staff very quickly.

From an organizational perspective key to the success of the pilot was the experience of the hospital department personnel with the OAD regime. The preexisting organizational conditions make OAD well suited for remote patient monitoring in general, and for the project in particular. Organizational (resources such as staff, cars and procedures) and administrative (including reimbursement models) arrangements were already in place before the use of the telemonitoring technology. In a sense the technology was perceived as a kind of natural extension of the OAD. For this first phase, the solution has proved to be very flexible and has allowed a good integration with the department workflow and according to all stakeholders interviewed; this characteristic will continue to be important as the solution will be implemented in different settings.

From a management point of view key to the success of the pilot phase was the high interest and support from the direction of the geriatrics unit and from the Aress commissioner\(^61\). Again this will continue to be essential as, apart from the support from Aress, the position of other healthcare decision makers on the topic is not clear. In October 2010, Aress took the decision to formalize the project and the related allocation of funds with an official document. Besides the administrative aspects (that in highly regulated environment as healthcare are however important) this document has helped in raising the awareness and the interest of other hospitals that are now adhering to the initiative.

**Challenges ahead: the governance in the extended environment**

Clinical stakeholders expect that during the roll out phase the main challenge will be posed by the unclear administrative status of patients who will be included in the project but will be not treated under the OAD regime (in particular patients after discharge). The pilot demonstrated that for patients that have been discharged, especially for geriatrics patients that very frequently have chronic diseases, telemonitoring can be very useful in reducing re-hospitalization. Since 1st October 2010 the region has preliminarily approved a specific DRG including telemedicine but, at operational level, the regulation is not clear. These problems are already emerging in the first steps of the extension of the project to other departments. The protocol is still in definition and has slowed down the roll out kick off. The before mentioned document of Aress has encouraged other organizations that were interested explaining the framework agreement with Telecom Italia. The slowdown experienced between the end of the pilot and the roll out is also due to the fact that the project is involving three big organizations such as the hospital (the biggest in the region), the region (through Aress) and Telecom Italia.

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\(^61\) Dr. Claudio Zanon
According to the geriatrics' unit head this type of project can have a significant impact as long as it does not remain an exception limited to the San Giovanni Battista Molinette hospital and becomes part of a more complex network. Besides OAD telemonitoring can be a useful element in a system of protected discharges. More benefits can be achieved through the involvement of primary care (GPs), but so far there are no incentives for GPs to participate. As other hospitals will adhere and as the system will grow the integration of hospital and primary care and the long term care will be essential. The definition of objectives from the higher regional healthcare executives is not always clear for hospitals' management, which slows down the take up. As the project will move forward to a larger scale the lack of a system organization might create some problems. The related regulatory/ directive framework is still missing. However, according to the geriatrics units head, it is important to understand that these directives should set objectives and incentives, then, at the operational level the initiative should maintain the flexibility that has allowed a smooth integration of the solution into department workflows during the pilot phase.

2.1.2 Telemedicine in ALS VCO

The background

ASL Verbano Cusio Ossola (ALS VCO) is a Piedmont local health enterprise born after grouping 3 former ULS\textsuperscript{63} (local health unit) (Usl55 di Verbania, 56 di Domodossola e 57 di Omegna). ALS VCO has a territory of 2,300 square km, 96% of them in mountain area, including 84 local councils, and a population of 174,036 inhabitants. ALS VCO manages a multisite hospital (Castelli di Verbania hospital and San Biagio di Domodossola hospital) and three health districts: Domodossola, Omegna and Verbania. The ASL VCO has historically put high attention in developing care path/ protocols for chronic and fragile patients. Diabetes (6,617 Patients), hypertension (17,430 patients) and cardiovascular problems (9,691 patients) are the most frequent chronic diseases in the VCO area.

The telemonitoring project of VCO involves patients with different chronic conditions: diabetic, COPD, cancer and chronic heart failure patients. The majority of patients involved in the project are diabetic patients. In the territory served by ASL VCO there are 9638 diabetic patients (9002 type 2- T2DM). ASL VCO has started different innovative projects on diabetes management such as:

- integrated management of Type 2 Diabetes Mellitus patients
- "PTDA Diabete" (Percorsi Diagnostici Terapeutici Assistenziali- Diagnostic, therapeutic care paths for diabetes) which is a disease management tool used to define the best clinical care process based on official guideline and recommendations, adapted to the local context and the available resources. The purpose of PDTA is to promote the integration of healthcare providers, reduce the clinical variability, and promoting evidence-based medicine (EBM)
- When a PDTA describes workflows that integrate hospital and primary care they are also called Integrated Care Profiles (PIC-profili integrati di cura)

Currently 43% of ASL VCO type2 diabetic patients are under the integrated management of T2DM patient projects, involving the support of 95% of GPs of the territory. These projects have helped in defining protocols for the telemedicine project.

The rationales subtending the project are:

- to provide a service whose priority is promotion and continuity of care

\textsuperscript{62} See Annex B Interviews 5 and 6

\textsuperscript{63} USL and USSL were former local health organizations before the health reform of the 90ies. In USL and USSL the municipalities within the health organization catchment area had a significant decision power (especially from an administrative point of view). With the advent of ASL, local health organizations are more independent ( municipalities maintain an orientation function on management designation an on public health policy priorities)
to ensure a follow up for chronic and fragile patients out of traditional care settings

to focus on clinical and organizational aspects while technology should be perceived as a commodity

to preserve the role of the physician through the establishment of a rigorous clinical protocol for telemedicine services

The objectives were to reduce the distance between patient and the healthcare organization, help implementing new diagnostic and therapeutic paths, optimize processes and resources, and reduce A&E access, hospitalization and ambulatory visits.

**Project milestones and organization**

The VCO telemedicine project started at the end of 2008, with the launch of the public competitive tender for a telemedicine services platform set out by CSI Piemonte (on behalf of the ASL), won then by Tesan in partnership with Medic4all.

The first six months of the project were dedicated to the definition of clinical protocols and to tuning services. In June 2009 the services were fully operational. The project is monitored regularly:

- Every three months the supplier (Tesan) provides a project status report
- An annual review based on established indicators is carried out

The requirements described in the tender assigned to the supplier play a key logistic role. The service is delivered through a telemedicine centre managed by the supplier.

The supplier:

- Provides patients with the devices and the related training
- Receives, validates, stores patient data in a repository and makes it available to ASL VCO clinicians through a service centre
- Also offers technical and nursing assistance to patients through the same service centre.

The telemedicine contact centre is available Mon-Friday, 8.00-18.00, while access to repository information is available every day, at any time.

It is important to understand that the role of the supplier has been carefully defined by the tender specification, but the tender itself asked for a continuous evolution (and in particular the evolution of service level agreements - SLA). The possible redefinition of SLAs allows the services to be more flexible to respond to new needs that might emerge with time. Key factors while selecting the supplier were simplicity of the offering, adoption of proved user-friendly devices and openness to an evolving development of the service.

The role of ASL in the project is focused on the clinical side. ASL clinicians:

- identify and enroll patients that can be treated through the service
- establish the monitoring protocol, that prescribes the number and the frequency of the measurements
- get in contact with supplier and the health personnel to ensure the compliance to the protocol and SLAs.

Although not responsible for the patients’ training, ALS VCO has published a specific guide thoroughly explaining the type of services offered, the responsibilities of the caregiver and of the patients, the activation and the suspension of the service, diseases specific information summarizing clinical protocols and a specific disease related glossary. This communication activity that has been concentrated at the beginning of the implementation has helped in setting patients’ expectations on the type of services delivered. In particular patients have been explained that it is...
not an emergency/ lifesaving service as it does not guarantee the level of system business continuity and disaster recovery normally required for emergency services. This has been carefully explained to patients in order to avoid causing harm: so far no misunderstandings or misuse has been experienced.

As operational aspects such as technological platform and contact centre management have been outsourced to the supplier, clinicians can focus on patient clinical aspects reducing at the minimum the time devoted to "technical"/ operational aspects.

CSI Piemonte\textsuperscript{64} plays a connection role in the project. It is the contracting authority. It monitors the service execution and, given its ICT expertise, collaborates with the supplier in problem solving. CSI Piemonte reports to the regional government and to the project permanent committee (composed of representatives of all project stakeholders) on service performance, and helps ASL VCO and the regional government in designing the strategy evolution in technical, organizational and economic terms.

\textbf{Technology and service personalization}

Once the ASL VCO professionals have identified a suitable patient for the service (normally ASL VCO nurses are the ones that identify suitable patients and refer them to the head physician), the supplier's staff (a technician and a nurse) go to the patient's home to verify that the conditions for service functioning (e.g. availability of ADSL) are met and provide the patient with training to start using the device. From a technological point of view it should be noted that local councils in the ASL VCO area have invested heavily on broadband in the last few years.

ASL VCO opted for a single device policy (one patient one device)–excluding the scale– in order not to confuse patients and to simplify measurement processes. Patients collect their data according to an agreed schedule: for example diabetic patients send their data 3 times a week at specific hours. Sending their clinical information through the system, patient has reduced the number of ambulatory visits to 2 times per year (when they need to do a complete blood check) instead of once or in certain cases twice a month.

For each patient, clinicians decide a minimum of parameterization based on patient characteristics and national treatment guidelines. For each patient it is possible to set alarm or alert thresholds. If collected data are not in conformity with these settings, a nurse from the contact centre will call the patient and evaluate the situation. The contact centre is at patient disposal (at office hours) for further clarification and it verifies that each involved patient is correctly following the monitoring protocol. The contact centre is attended by nurses that monitor patient measurement and eventually activate ASL clinicians or contact patients through video-conferencing, send patients' clinical reports to involved GPs and specialists. ASL VCO clinicians have scheduled contacts with patients and can always access patient data.

\textbf{First year results}

During the first year of the project 150 protocols were activated (data at 31/12/ 2010). Patients enrolled have different diseases implying a broad spectrum of data monitored:

- 105 diabetic patients\textsuperscript{65}

\textsuperscript{64} CSI-Piemonte (Consortium for Information Systems) was founded 1977 with the aim of promoting the modernization of local administrations by using the most advanced information and IT-based tools to create information services and systems. CSI Piemonte is a consortium of 89 public administrations that provides ICT services and infrastructures to Piedmont public sector (organizations that adhere to the consortium are also clients of the consortium).

\textsuperscript{65} Two types diabetic patient involved in the project ( March 2011):
- 11 patients with chronic heart failure
- 32 patients with COPD
- 2 patients with cancer

Four patients were monitored for two diseases at the same time. During the first year, 22 protocols were deactivated (14 deaths, 3 opt out, 5 house-moving out of the territory of ASL). As of March 2011 there were 128 patient involved. The large majority (60%) are over 66 years old. The target for the end of 2011 is to reach 250/300 patients.

CSI Piemonte and ASL VCO carried out a customer satisfaction survey. Key results highlighted that:

- Generally the initiative is positively considered: 93% of responses were positive. The remaining 7% was just somewhat negative.
- Patients’ perception of training was positive with no negative opinions.
- Devices were also generally judged easy to manage (75% had no difficulty at all, 22% had sometimes difficulties, 3% said that difficulties were not manageable)
- Support was effective and timely: for 81% of patients the service was always effective and timely, for 15% nearly always, and for 4% only sometimes.
- Patients generally think they are better followed (48% of them think they are treated in a much better way, while none of them think that care has deteriorated in quality) and a large share of them states that the service has helped improve their lifestyle and change habits in a significant way (37%), while only 16% of them noticed no (6%) or few (10%) changes towards a healthier lifestyle.

CSI is running a first analysis to extract some efficiency indicators (based on previous history of involved patients). The study is based on data for a total number of 35,000 follow up days delivered in 2010. Data will be available only after internal review. The analysis will be focused on measuring benefits in order to estimate the impact of a generalization of the service to the whole Piedmont territory. Initial results available show that:

- Considering to have avoided at least one travel per month from the patient home to the closest ASL ambulatory, the project should have saved to patients and their relatives car travel for about 25000 Km.
- Considering patients interactions with the ASL VCO between July 2008 and 30 June 2010 there has been: 124 access to A&E; 92 hospitalizations; 1554 ambulatory visits. Comparing the history of the same patients before being involved in the telemedicine project, CSI recorded a decrease in
  - A&E accesses (-80%)
  - Number of hospitalizations (-56%)
  - Ambulatory visits (-63%)

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30 A type patients (T1DM) following insulin therapy (4 injection per day), with brittle diabetes (type of insulin-dependent diabetes characterized by dramatic and recurrent swings in glucose levels, often occurring for no apparent reason)

85 B type patients (T2DM) Most of them are elderly patients, with more than one chronic disease, experiencing difficulties in accessing ambulatory care. They are supported by a parent or caregiver (some of them are in long term care homes --RSA Residenze Sanitarie Assistenziali-- RSA Orta San Giulio)

Those were the only exceptions to the single device policy

April deadline has been postponed as internal review is taking longer. In parallel a proper clinical study has also been launched.
From a clinical point of view results for diabetic patients are already available. After one year, large percentages of involved patients have experienced reduction of average values for key clinical parameters:

- Reduction of glycosylated haemoglobin (HbA1) average values in 76% of patients. Most importantly, especially for type A patients, there is a reduction in the number of peaks and hypoglycemia episodes.
- HbA1 average variance from a value of 8.5 went down to 7.2
- Hypoglycemia episode rate per months went from 10 to 5 for type A patients and from 4 to 3 in B type patients
- Reduction of cholesterol count in 54.4% of patients
- Reduction of triglycerides in 53.9% of patients

It is important to note that these reductions are homogeneous in all three districts of ASL VCO.

Costs
The ASL VCO tender was attributed to Tesan in partnership with Medi4All for about €1,817,000. The contract started officially in March 2009 and it will expire in December 2011. Contractually the supplier is expected to provide service for 300 patients. On top of that, CSI Piemonte costs about 2% of total costs. The region is paying the costs related to the supplier and the start up costs, as included in contract specifications, and it is using internal and already available resources (CSI Piemonte staff for example). As infrastructures, such as technological platform and contact centre management have been outsourced to the supplier, the ASL VCO, and consequently the region, have been able to minimize capital investments, focusing on operational expenditure of the project.

Looking at the reimbursement model, so far the adoption of a specific DRG was not necessary because the project is officially considered an experiment. Once the services will be extended to other ASLs there will be some marginal costs to be added, however CSI executives interviewed expect those not to be significant because the project was already conceived with the goal to expand (so no further or only limited infrastructure costs needed and most importantly no need for going through another procurement process). The price setting, considering also the current 150 patients, is still for a 'prototype'. However, before contract expiration, when the project will serve a sufficient number of patients and it will be possible to prove economies of scale, CSI will open tariffs renegotiations.

Each new active patient represents a new cost that according to CSI Piemonte executives is balanced by savings and benefits for health care providers. The study which CSI Piemonte is going to publish will provide some ROI analysis, in order to demonstrate savings and to ask for additional funding to further expand and improve the service.

The generalization of the project: potential success factors
According to CSI executives interviewed what differentiates this project from other initiatives and is making it a sustainable reality are the organizational and governance aspects.

Instead of focusing on the ICT aspects, adopting the so called technological approach for this project, the ASL along with CSI Piemonte was more interested from the beginning in creating new care models through a service built around specific needs. Technology has been considered a

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70 *Cost of these resources was not available: costs for CSI Piemonte resources are within the above mentioned 2%, while ASL VCO staff cost were not available*
commodity. Feasibility studies done before starting the implementation have analyzed the investment in ICT in the same way as other types of investment. Hypothetically, if it had emerged that this project would achieve better results without ICT, CSI Piemonte and ASL VCO would have chosen that option.

The choice made was for an approach more focused on process, organization and governance. For all stakeholders interviewed, defining precisely protocols has been fundamental: where they were less precise in defining protocols (for example with cancer patients) results were worse. This approach has initially led to delays (especially in the first phases of the project: in January 2009 protocols were still in definitions so the project started being operational only in June 2009) which, however, have been recovered in the following months.

From a development point of view, the whole system has been set up to be in a constant process of fine tuning. For instance, at the beginning of the implementation, video conferencing with diabetic patients was perceived as important by ASL and CSI project managers. Once in the field, it emerged that many patients consider videoconferencing quite intrusive and not always necessary. Therefore videoconferencing sessions have now been reduced to specific circumstances and with specific scheduling. Moreover, thanks to the tuning process it was acknowledged that the service was not suitable for cancer patients (who needed another type of service, more live human interaction based), while it was possible to start thinking at expanding the service to gestosis patients. Even if gestosis is not a chronic disease and it ends with the end of pregnancy, the similarities with diabetes, the incidence of the phenomenon in the ASL area and the positive attitude of candidate patients are making possible the extension of the service.

An extension of the service to a much broader geography was envisaged since the beginning with the procurement process. As required by the tender specification, the current infrastructure is conceived for managing more patients than the current 128. The ASL VCO and CSI Piemonte management preferred to adopt a step by step approach rather than a big bang one.

In a few months time ASL of Biella will be able to join the initiative and start treating its diabetic patients through the ASL VCO system. The aim is to achieve the 50 patients’ threshold within one year. In this case clinicians are following the defined protocols used by VCO albeit maintaining a margin for tuning and personalization that should allow a better integration of the service within ASL Biella organization.

**Barriers to the generalization of the service**

According to CSI executives the human factor can be a barrier to the adoption and to the success of the initiative. Looking at the extension of the program to other ASLs, once having carefully addressed the organizational/logistic aspects, finding motivated and supportive clinicians can be difficult. CSI is therefore participating in and organizing several conferences to create awareness around this project. Especially at the beginning the support of the general direction of the ASL is the key to the success of the initiative, but the real success is given only when all stakeholders fully understand the value of the initiative. A good definition of processes is also important in order to understand roles, workloads, responsibilities and setting expectations correctly. According to the clinician interviewed it is important to understand that telemedicine does not replace primary care / ambulatory care but integrates them. Clinicians can analyze and share patient data with his/ her colleagues before the videoconference with the patient, so visit time can be optimized by concentrating on key aspects.

The system also eases patient management from the perspective of the clinician workload. Simple ICT skills are sufficient to access and use data; therefore there is no need for long training sessions.

**2.2 Case Study in Lombardy region**

Lombardy (Lombardia) is an Italian region situated in the central-northern part of the country. Lombardy has a population of 9,826,141 inhabitants. Life expectancy at birth is 78.9 years for males and 84.4 for females. The population over 65 years represents 20% of the regional
Looking at Lombardy's aging population indicators, it is possible to notice that they are in line with overall national values and slightly lower than those of other Northern regions:

- Population average age is 43 (in line with national value, while for northern regions average age is 44)
- Aging index (141%) and old age dependency ratio (30%) are below both national and northern regions

Diseases with highest mortality rates affecting the Lombardy population are circulatory system diseases, cancers and ischemic heart diseases (see tables A to F). Lombardy has 15 ASLs (controlling 9 local hospitals) and 29 AOs. Since 2002 the number of ASLs has not dramatically changed, however the number of local hospitals controlled by ASLs decreased from 11 in 2002 to 9 in 2009. The number of available beds has significantly decreased: this is the result of a progressive inpatient resource rationalization initiative started in early 2000's, aimed at rebalancing healthcare workloads toward primary care.

The regional health plan 2010-2014 and the 2011 Rules book (a document setting out the short term implementation framework for the regional health plan) highlight that for the regional health system key goals are to ensure long term sustainability and patient empowerment. Appropriateness is the key principle governing the whole strategy to offer patient a more integrated and personalized service. ICT is considered an enabler of the strategy. The Lombardy eHealth strategy has been at the forefront at national and international level for a long time. Key projects are: the patient eCard integrated with the regional health information system connecting all healthcare providers (the CRS-SISS project), the ePrescription project, region-wide PACS, and electronic health records. Telemedicine is considered a strategic tool within the development of care networks and patient empowerment. Projects currently implemented can be divided into telemonitoring /tele-support for chronic or fragile patients and second opinion (teleconsultation) systems for physicians. Within these projects, the region is not only testing operational aspects but also administrative/management issues such as service level agreements and reimbursement models.

For the purpose of this research we identified a project for the telemonitoring service for severe and very severe COPD patients, formerly known as Telemaco, and now part of a bigger initiative called Nuove Reti Sanitarie - NRS (New Health Networks) which focuses on enabling new care paths for chronic patients.

### 2.2.1 Telemonitoring service for severe and very severe COPD patients within NRS (formerly Telemaco)

#### Background

Telemaco is the acronym of TELEMedicina Ai piccoli COMuni lombardi (telemedicine to small Lombardy municipalities and councils). The project was conducted from April 2006 to September 2010 and was aimed at supporting the accessibility to specialized healthcare for small municipalities in mountain valleys through the provision of telemedicine services:

- telemonitoring for patients with chronic heart failure (CHF) or chronic obstructive pulmonary disease (COPD) after hospital discharge;
- tele-consultation for GPs from specialists in cardiology, dermatology, diabetology and respiratory medicine;

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71 See Annex A Statistical Data
72 See Annex B interviews 7, 8 and 9.
73 www.telemaco.regione.lombardia.it
- tele-consultation on digital images (Computerized Tomography) between rural hospitals and high specialized hospitals for traumatic brain injury and stroke

Telemaco was initially implemented by 5 AOs and one ASL (AO Chiari, AO Pavia, AO Seriate, ASL of Vallecamonica Sebino, AO of Valtellina and Valchiavenna, AO Varese). At the end of the experimentation in September 2010, Telemaco involved patients in the catchment area of 8 ASLs (organized in 19 health districts with 400,000 inhabitants). Telemaco project was funded by the Ministry of Health (£1.6 million), the Ministry of Innovation and Technology (£0.45 million) and by the Lombardy regional health department (£1.4 million). After this independent phase, the project has been included (without major organizational changes) within Nuove Reti Sanitarie 74 (New Health Networks). NRS is a regional common framework for new experimental initiatives aimed at developing chronic disease management tools for chronic and post acute patients.

All initiatives included in this framework are commonly characterized by:
- a defined care protocol
- an information system for reporting activities
- experimental tariffs
- clinical and organizational evaluation as well as customer satisfaction evaluation

First experimental services within NRS were included in 2006 with
- Telemonitoring service for patients with CHF
- Rehabilitative home hospitalization (OAD) after heart surgery

These two clinical paths were then joined by the oncology palliative care home hospitalization services in 2008, while Telemaco services were integrated 75 in 2010. Specifically:
- Telemonitoring service for severe and very severe COPD patients, also called PTP (Percorso di Telesorveglianza domiciliare sanitaria per pazienti con BPCO grave e molto grave)
- Tele-consultation for GPs from specialists in cardiology, dermatology, diabetology and respiratory medicine, also called TCS (teleconsulto specialistico ai medici di medicina generale)

With the inclusion of Telemaco, NRS currently includes almost all specialists within the regional network of respiratory medicine, cardiology, and palliative care physicians.

**Telemonitoring service for severe and very severe COPD patients (PTP)**

The objectives of the care model enabled by PTP are to improve COPD patient management, in particular the efficacy of oxygen therapy 76 delivered at patient home, and avoid recurring acute episodes as well as to:
- Improve clinical effectiveness and patient quality of life;
- Reduce unnecessary / inappropriate hospital admissions and recourses to A&E
- Improve accessibility to secondary care in rural and mountain areas;
- Improve patient’s satisfaction and disease self management
- Promote telemedicine networks involving governments, ASLs, AOs, small hospitals, GPs and external Service Centers.

75 "percorsi da Telemaco" (Telemaco paths)
76 Also in terms of drugs and oxygen consumptions
The PTP path integrates the activities that the GPs are usual asked to perform when dealing with COPD patients. The service is also meant to provide consulting support to GPs for an integrated management of chronic patients. The service has a strong clinical emphasis, which makes the specialty department a key element in the care path. From a reimbursement point of view, the role of specialists has allowed to assimilate the service to an outpatient activity. Generally speaking, GPs remain responsible for care services delivered at the patient’s home but the operational decisions are made within the hospital department.

**Services and technology**

The service involves:

- A specialized nurse (tutor) which will follow the patient during the service and that will play a major role for counseling and patient education activities
- Electronic transmission of clinical data
- Regular phone contacts between patients and tutor
- A call centre available to patients 24/7 for ad hoc requests
- Management of a shared database which can be accessed by GPs, Nurses and Specialists

Key players in PTP implementation are:

- The respiratory medicine (pneumology) department within the hospital. Normally departments organize a dedicated team / unit for the telemonitoring service composed of:
  - One or two specialists who are the clinical referent for the service, the referent and coordinator for GPs and the service centre eventually involved; and
  - Patients’ tutors (specialized nurses) who are the patient’s main contact point, responsible for the patient’s education as concern adherence to prescriptions, rehabilitation activity and self management
- GPs give their assent for patients to participate in the telemonitoring. The GP is regularly informed on a particular patient condition by the specialists and the tutor
- The service centre provides technological and organizational support for telemonitoring (devices, information systems, such as electronic patient record, and complementary services such as the management of the shared database where information is stored) and call centre functionalities for weekends, holidays and all other moments when the tutor is not working. The service centre is at the same time an application service provider, a web contact centre and a call centre. The service centre is also responsible for collecting all patient data and sending them to Cefriel on a regular basis.
In Telemaco, the service centre provider was selected through a European tendering process. The selection procedure was managed by a temporary group of enterprises led by HTN and consisting of:

- Cefriel in charge of all experimentation management including planning support, evaluation activities and reporting
- Telecom Italia in charge of service integration
- Tesan -Ital TBS in charge of providing back up functionalities in service peak and interruption
- Telbios in charge of providing a web based solution for clinical information exchanges, videoconferencing and repository management.

Within the NRS framework, hospitals and ASL can decide to choose the service provider they prefer. They are not anymore obliged to use the temporary group of enterprises led by HTN, but selected providers need to meet technical and organizational requirements. Requirements to be a qualified service centre provider are almost the same as those described in the Telemaco tender specifications. By using the service centre the hospital is relieved of implementing all the operational infrastructures. However, it is also possible for the hospital to create an internal service centre. A similar approach has also been adopted in the PTS path (for CHF patients) and in this path, hospital Monzino has developed its own service centre.

**Patient enrolment and clinical services**

Patients are enrolled for a period of 6 months (high intensity phase), which is the time estimated to clinically stabilize the patient, and educate him/her and his/ her family on how to manage the disease and adhere to rehabilitation / cure programs. Enrolment criteria are quite strict: for example, the condition of entering patients should be classified as stage 3 or 4 following the GOLD guidelines; the patient should have had recurring acute crisis, been treated with specific antibiotics and oxygen therapy, been hospitalized or have had access to the emergency department during the
last year\textsuperscript{77}. The care protocol developed for Telemaco and used also in PTP was developed in accordance with the national guidelines for COPD and represents a reference framework for all healthcare providers that are joining the initiatives with their respiratory medicine departments. Procedures for service activation can be triggered:

- By the GP, who, after informing the patient, will ask the telemonitoring unit (or the physician dedicated to the service) within the pneumology department to verify patient admissibility. The patient will be admitted (or not) after a specific visit from the specialist in the telemonitoring unit (general conditions, Saint George questionnaire-SGRQ, etc). If the patient condition meets the protocol requirements, the services centre will open a new record and will arrange all organizational aspects.

- By a hospital during the patient discharge phase or by a specialists after an ambulatory visit. In this case the specialist, after informing the patient and having his/her consent, will ask the telemonitoring unit within the department to verify patient admissibility. In the mean time, the specialists will also ask the GP for his/ her assent. If all enrollment conditions are met, and the GP has given the assent, the services centre will open a new record and will set all the organizational aspects.

The patient is provided with a saturometer (oximeter), a very basic device that can be used easily by all patients. In the 6 months period, on a regular basis, the tutor calls the patient through the service centre. During the call, the tutor asks the patient about general physical conditions, adherence to the care path, risk factors/ indicators such as weight variation, lifestyle, symptoms, etc. Unstructured information along with punctual saturometer data are registered in the electronic patient record. Normally saturometer punctual data collection is done over the phone with the patient communicating them to the tutor, but, in certain cases, when the monitoring of oxygen saturation trends is needed, the patient is provided with a device that electronically transmits information. In this case devices have Bluetooth and transmit data to the service center over UMTS network through a connected mobile cell phone. If the need arises, patients can also call the tutor during service time (Monday-Friday 8.00 AM- 16.00 PM) or the service centre, which provides access to a specialist or a specialized nurse anytime. Home visits can also be scheduled if the specialist responsible for the service considers them useful. After the 6 months period, in selected cases and when the specialist considers it appropriate, the service can be extended for another 6 months (low intensity). During this second 6 months period the service will be less structured, offering the patient the opportunity to call the tutor or the service center in case of need, while there will be no longer regular calls from the tutor. Also in this phase all data collected will be registered in the electronic patient record which will also help analyzing and evaluating this phase of the service. Cefriel collects all patient information from the various service centres. Every six months Cefriel elaborates anonymized information, fills agreed dashboards and sends reports describing the overall and institution by institution situation to the regional healthcare department.

**Costs**

Hospitals participating in the PTP receive a funding envelope based on tariff for each patient activated of €720 for the first six months (€120 per month), when high intensity services are provided, and €480 for the next eventual 6 months (€80 per month) with low intensity\textsuperscript{78} services. This funding is expected to cover all costs related to the service center and hospital internal costs (i.e. the allocation of nurses and specialist time to the telemonitoring unit). The service center offering includes devices, call center services and information systems. Currently hospitals...


\textsuperscript{78} The same tariffs and time framework are also used for chronic health failure patients see http://ftp.cefriel.it/nrs/default.htm
participating to the initiative buy services directly from the Temporary Enterprises Group- RTI Raggruppamento Temporaneo d’Imprese that won the framework contract tender. As PTP, as all NRS care paths, is still considered an experimental initiative, this funding is on top of the annual budget of the hospital. In the summer of 2010, when the regional health department decided to continue the Telemaco experience and migrate it into the NRS, the regional government approved a decree (DGR IX/409 del 05/08/2010) for the prolongation of services included in Telemaco and its transition toward NRS. This decree confirmed that in 2010, resources allocated for the continuation of the home telemonitoring path for severe and very severe COPD patients (PTP) covering 300 authorized care paths (of which 150 already authorized within Telemaco) were €216,000. This funding covers hospital reimbursement (therefore covering tariffs for 300 ‘possible’ patients) but do not include all activities such as experimentation management, evaluation and reporting. These activities have been so far covered by Cefriel (leveraging on Telemaco agreements). Before the end of the summer 2011, the region will officially identify the provider of these services. In order to have an idea on the relative weight of this type of expenditure, it can be useful to consider that within the 2010 total budget for the NRS (€6,937,500), including PTS, ODCP and ODP paths (therefore excluding PTP), the sum allocated to experimentation management, evaluation and reporting was € 237,500.

**Governance: from Telemaco to Nuove Reti Sanitarie-NRS**

The regional government with the regional decree d.g.r. n. IX/409 dated 05.08.2010 confirms the continuation of the deployment of TELEMACO services through NRS to ensure the continuity of care in remote areas. The transition to NRS is part of a process that aims making initiatives like Telemaco more integrated with the traditional services offering of the regional health system. The project NRS is still officially considered an experiment on new models for chronic disease management; however it is the result of a long term reconsideration of the services delivery organization. In Lombardy enabling integrated services supporting the continuity of care has been a buzz word for the last 15 years. There is a need to reduce the number of hospitalizations driven by long term sustainability issues, which has been translated into new hospital budget restraints and reimbursement models that makes longer stays economically unsustainable for hospitals.

The region is trying to implement the concept of “appropriateness” explained in the national health plans and also adopted by the regional plan. The latest regional health plan 2010-2014 and the 2011 Rules book (Regole 2011) anticipate a decreasing expenditure for hospital care (or better, a decreasing weight of hospital expenditure compared with the total healthcare expenditure) in favour of primary care. At regional level, the total number of available beds for acute care is actually

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79 Decree available at http://www.telemaco.regione.lombardia.it/download/news/dgr409_05-08-2010.PDF
80 The number of authorized care paths is the maximum number of patients that can be enrolled. This number is based on the estimates of the hospital asking to participate to the PTP path initiative and it is validated during the authorization procedures performed by the regional health department.
81 Telemonitoring for patients with severe chronic heart failure (Telesorveglianza sanitaria domiciliare per pazienti con scompenso cardiaco cronico medio grave).
82 Home hospitalization for cancer palliative care (ospedalizzazione domiciliare per cure palliative oncologiche).
83 Home hospitalization after heart surgery (ospedalizzazione domiciliare post-cardiochirurgica).
84 Services agreement assigned to Cefriel. See also for service specifications DRG VIII/010072 August 2009.
85 Decree available at http://www.telemaco.regione.lombardia.it/download/news/dgr409_05-08-2010.PDF
87 http://www.sanita.regione.lombardia.it/shared/ccurl/956/366/DRGregole_e_allegati.zip; See: “Allegato 1 Indirizzi di programmazione”
“Allegato 2: Il quadro del sistema per l’anno 2011”
“Allegato 4 Piani e programmi di sviluppo”
decreasing. According to regional healthcare executive interviewed, the implementation of the concept of "appropriateness" requires an in depth analysis of the territory’s current offer and demand of healthcare services. Various aspects such as population demographics, the density and the quality of healthcare providers available in a certain district, need to be taken into consideration when implementing initiatives like those in NRS. For example, Telemaco (now called PTP) was born to serve small councils and municipalities in a territory far away from specialty centers. In cities like Milan or Brescia or in their suburbs this is a model that is hardly applicable. Therefore, in the spirit of appropriateness, in the case of Telemaco in the past and today for PTS (as well as for other NRS paths), the region has mainly adopted a bottom up approach in defining project specifications and governance models.

Stakeholders such as the regional network of respiratory medicine specialists, ASL and AOs management, technology and telemedicine services providers have been involved since the beginning of the project. The redefinition and the possible evolution of the service are regularly discussed by stakeholders of the project. In this perspective, the role of Cefriel as connecting hub between all the stakeholders has been very important. Cefriel has both an organizational and research function in the project. Cefriel has helped in organizing the definition of protocols, outlining patient records and facilitating the interaction between the various stakeholders in the planning phase (both during Telemaco and during the transition into NRS). In the long term this type of services will be integrated in the standard service delivery of the regional NHS. The fact that a relatively small project like Telemaco has been integrated into a bigger and more structured one, as the NRS, is coherent with this long term vision. At this stage the experimentation status of the NRS gives the project organization enough flexibility to enable the fine tuning process. Over the next year, the number of patient is expected to grow strongly (from 296 patients in 2010 to 1,013 at the end of 2011) and the opportunity to modify services and protocols is expected to ensure the sustainability of the project.

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88 Source: Osserva Salute 2010 report http://www.osservasalute.it/
89 See Annex B Interview 10
90 http://ftp.cefriel.it/nrs/ptp.htm Even if all stakeholders interviewed are skeptical about the foreseen 1,000 service activations, as figure 5 shows the number of authorized hospitals has grown. It should be noted that up to now the only hospitals with active patients are those coming from the Telemaco initiative.
As mentioned above, from an operational point of view the transition from Telemaco to NRS has not impacted the daily activity of project players. However, when analyzing funding mechanisms, one can note that NRS has introduced an important innovation. Within the NRS it has also been possible to test tariffs based reimbursement models for telemonitoring services. Hospitals, once authorized by the region to participate in the network, have to select their (qualified) telemonitoring services provider and to organize their internal telemonitoring unit with physicians and nurses. In the NRS framework hospital decision makers must respect quality criteria (including technical, organizational requirements and data security), monitor the work of the Service Centers, involve GPs and patients while ensuring the collection of clinical and organizational data. According to a physician interviewed, tariffs are adequate to the resource effort required considering the general case mix of patient and the specification of the protocol for patient enrollment, and all the organizational activities just mentioned. Tariffs are adequate especially for hospitals like Maugeri that thanks to the significant number of patient enrolled have achieved the necessary economies of scale. Hospital Maugeri has also had the opportunity to exploit the know-how and the organization of a previous telemonitoring services experience for chronic heart failure patients. Leveraging on the experience and the infrastructures of the cardiology telemonitoring unit, hospital Maugeri has built a unit also serving COPD patients. This structure is also composed by nurses and physicians coming from respiratory medicine department, but the key players are operators with a solid telemonitoring experience. According to the specialist interviewed, specialization is an important factor, as remote interaction with patients requires specific skills. It is important, however, to ensure a certain degree of “turnover” between operators dealing with the patients through the telemonitoring service, because this is a service that needs a constant evolution.

91 Hospitals indicated with the blue icon are hospitals that participated to Telemaco; hospitals indicated with the yellow icon are those which have joined the PTP initiative. http://ftp.cefriel.it/nrs/mappe.htm?servizio=PTP
92 Or alternatively set up an internal infrastructure to cover that function
93 Ranging from heavy to small health services consumers
Dealing with patient through telemonitoring is different from dealing with them live: operators/nurses need to pay attention to different aspects. Over the long term, there is the risk that operators/nurses, focusing too much on these aspects, might start underestimating or ignoring the traditional ones. Therefore operators/nurses need to alternate times doing telemonitoring with period of live visits and wards in order to maintain a strong connection between the two settings and to have access to continuous specialty care training.

Results
Since the PTP path has only been included in NRS from September 2010 at the time of writing it is too early to have access to new results. During the Telemaco project, however, a continuous, systematic and comprehensive assessment has been conducted, covering effectiveness, costs, access, satisfaction and organizational impact. Between May 2007 and September 2010, the total number of activated Telemaco paths was 393. The number of activation has constantly grown over the 3 years’ period. Patients enrolled were mainly males (73%) with an average age of 72 years presenting comorbidity and other risk factors. When asked about their satisfaction with the service, patients judged the service very positively overall, for the support received in difficult moments, for the communication with the tutor and other health staff and for the ease of use of the device. These satisfaction results are remarkable, since users are stage 3 and 4 COPD patients: in this type of patients, even successful therapy programs improve patient conditions very slowly. Through the Telemaco project, it was possible to dedicate more time to patient education. Patients are more aware of their conditions and can have a more active role in their disease management.

Even though results are not statistically significant because of the small size of the sample, they show that the service has led to fewer hospitals re admissions, fewer accesses to emergency service and disease peaks have been largely addressed at patient home. Hospital readmissions for respiratory disease in Telemaco patients were 11%, while deaths directly caused by COPD were below 1%. These data were also reported in the regional decree D.R.G. IX / 000489 in August 2010 that established the transition of Telemaco to NRS.

Barriers
The transition toward NRS and the extension of the project to more than 30 AOs and ASLs will certainly need to be carefully managed. During the Telemaco planning phase, activities like defining protocols, workflows and rules has been relatively easy, as the number of organizations involved was limited. The extended network of healthcare organizations participating in the initiative today is already expressing some difficulties in applying the established protocol. It will be important therefore to continue with the regular review process. As NRS initiatives continue to be labeled as an experiment, the PTP project has the required flexibility to be adapted to emerging needs. For instance, some hospitals have found the Saint George questionnaire too detailed to be fully completed: at the time of writing, the Maugeri hospital is testing other tools in order to make the enrollment and evaluation phase more straightforward.

The service has been accepted positively among patients and specialists. However, nurses showed a different attitude towards the initiatives. This is mainly due to the fact that they are responsible for the larger part of the workload and very often this work is not economically recognized. The project so far has been successful because the care management level was maintained close to the patient by the tutor role. It will be important to invest in these players, in this “human middleware” between the patient and the specialist, by increasing training and incentives. The service will be successful only if health staff has confidence in potential results, therefore dissemination and awareness

94 See Zanaboni presentation for the seminar closing Telemaco project in November 2010 http://www.telemaco.regione.lombardia.it/download/documenti/convegno_2010-11-12/09-TELEMACO20101112-Zanaboni.pdf
95 http://www.telemaco.regione.lombardia.it/download/news/dgr409_05-08-2010.PDF
campaigns across healthcare organizations need to be increased as well. During the Telemaco review, it has been highlighted that using HTA methodologies for the review process can help increase physicians and nurses trust in the project and can ease training and communication campaigns. Technology and organization have not represented an issue; however with the entry of 32 health organizations in the network, the infrastructure might be a problem.

Looking at the economic analysis done on Telemaco, comparing four hospitals, as showed in table 1, one can notice that costs vary significantly from hospital to hospital. This variation confirms that the problem of reaching economies of scale can be determinant over the long run. Smaller hospitals activating a smaller number of patients might find the services difficult to manage risking to allocate resources that will be underexploited, or to assign extra workload to already busy staff that will be not able to deliver the service. It will be important to encourage shared service models also for the clinical/ nursing part of the project, with a hospital or a third party (e.g. a scientific society such as AIPO – Associazione Italiana Pneumologi Ospedalieri\(^\text{96}\)) providing the services for a group of hospitals. Incentives fostering this type of shared service models, such as establishing a minimum threshold for patients enrolled, to achieve economies of scale will be therefore an element that can ensure sustainability to the project.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Esine hospital</th>
<th>Lumezzane Hospital</th>
<th>Voghera Hospital</th>
<th>Cuasso Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planned Phone calls</td>
<td>€ 114.12</td>
<td>€ 215.62</td>
<td>€ 64.03</td>
<td>€ 98.90</td>
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<td>Unplanned Phone calls</td>
<td>€ 54.28</td>
<td>€ 204.05</td>
<td>€ 29.67</td>
<td>€ 121.58</td>
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<td>Tutor visits at patient home</td>
<td>€ 0.00</td>
<td>€ 0.00</td>
<td>€ 0.00</td>
<td>€ 0.00</td>
</tr>
<tr>
<td>Specialists visits</td>
<td>€ 0.00</td>
<td>€ 0.00</td>
<td>€ 0.00</td>
<td>€ 0.00</td>
</tr>
<tr>
<td>Specialist Consultations</td>
<td>€ 3.83</td>
<td>€ 31.79</td>
<td>€ 1.60</td>
<td>€ 30.40</td>
</tr>
<tr>
<td>Interactions with GP</td>
<td>€ 0.00</td>
<td>€ 0.00</td>
<td>€ 0.00</td>
<td>€ 0.00</td>
</tr>
<tr>
<td>Therapy modifications</td>
<td>€ 0.00</td>
<td>€ 7.90</td>
<td>€ 0.00</td>
<td>€ 0.00</td>
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<tr>
<td>Patient Education and Training</td>
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<td>€ 22.06</td>
<td>€ 0.00</td>
<td>€ 18.40</td>
</tr>
<tr>
<td>Enrollment visits</td>
<td>€ 25.72</td>
<td>€ 25.72</td>
<td>€ 14.71</td>
<td>€ 28.08</td>
</tr>
<tr>
<td>Discharging visits</td>
<td>€ 44.12</td>
<td>€ 44.12</td>
<td>€ 11.64</td>
<td>€ 28.08</td>
</tr>
<tr>
<td>Organization (internal)</td>
<td>€ 15.85</td>
<td>€ 3.05</td>
<td>€ 28.63</td>
<td>€ 21.74</td>
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<tr>
<td>Blood gas analysis</td>
<td>€ 38.00</td>
<td>€ 38.00</td>
<td>€ 38.00</td>
<td>€ 38.00</td>
</tr>
<tr>
<td>Trend Oximetry (with electronic transmission)</td>
<td>€ 9.50</td>
<td>€ 9.50</td>
<td>€ 9.50</td>
<td>€ 9.50</td>
</tr>
<tr>
<td>Spirometry</td>
<td>€ 23.75</td>
<td>€ 23.75</td>
<td>€ 23.75</td>
<td>€ 23.75</td>
</tr>
</tbody>
</table>

Source: Adaptation from Zanaboni presentation for the seminar closing Telemaco project in November 2010

GPs need to be more involved in PTP patient management. Their action is considered key for efficient case management and to support patient self management. The GP can play a much more important and effective role in e.g. prescription adherence, lifestyle changes, education. The

\(^{96}\) The national association of respiratory medicine hospital specialists. http://www.aiponet.it
specialist needs to be obviously involved, but he/she should become more a background actor that intervenes only when there are acute episodes. Currently GPs have little incentives to get involved. Currently a significant part of GPs adopt one of the following attitudes toward the project: either the GP totally gives up his/her case manager role or he/she feels it is something that is duplicating (and invading) his/her work.

The role of the GP as case manager for chronic disease is an issue that goes beyond the NRS project itself. The definition of chronic patient embraces a broad range of conditions that so far in Lombardy have been mainly addressed through specialized care. NRS foundations are laid down into the different specialty focused networks. On the one hand this has allowed to properly address chronic patients needs from a clinical point of view. On the other hand, all aspects related to patient rehabilitation, lifestyle change and disease self management have been subdued. According to regional health executives interviewed, NRS are therefore more suitable to be in charge of more complex chronic patients cases. The region in the “2011 Rules book” acknowledged the fact that primary care lacks the necessary organization, the contractual framework, and the clinical and administrative competences to properly take care of chronic patients outside the specialty service. In other words the role of the case manager has not been clearly defined. The launch of CReG (Chronic Related Groups), which can be defined as a DRG for chronic disease management in primary care, aims at providing a framework for the role of the case manager. Launched in February 2011, this initiative should be considered as part of the effort to better address chronic patients’ needs across the healthcare continuum. CReG are expected to help creating a support organization for chronic disease management in the territory and to give an economic value to the case manager’s work in established diagnostic and therapeutic paths. CReG are based on three pillars:

- A patient database (BDA- Banca Dati Assistito) that will be refined to better segment the chronic patient population. BDA will allow to understand which are the disease management services more suitable for a specific class of patients.
- Diagnostic and therapeutic processes (PDT processi diagnostico terapeutici di cura) and guidelines. These tools help understanding patient care needs. Different PDTs have been already developed at regional level for the key chronic diseases such as diabetes, COPD and Hypertension, while guidelines need to be better developed and updated in order to ensure patient adherence to care paths.
- Reimbursement. The establishment of a tariff is needed to set the right incentives for care managers. Tariffs will include the definition of individual care plan, patient information recording, and verification of copayments duties exemption conditions, infrastructure and services organization. If the case manager is the GP, this tariff will exclude capitation fees, already included in practitioner compensation. Case managers that do not respect the protocols and cause misuse of emergency services and unnecessary hospitalization will see their tariffs reduced by 15–20%.

The CReG will involve specific protocols for chronic patients with COPD, diabetes, hypertension and heart diseases, neuromuscular disabilities, and osteoporosis. Five ASLs (Milano, Milano 2, Bergamo, Como, Lecco) are participating in the initiative, with their GPs, Pediatricians, ASL hospitals and outpatient services. GPs will certainly be good candidates to cover the role of case manager; however, the innovation in the CReG is the fact that it does not establish a priori which category of health professionals will be more suited to cover that role. The CReG simply establishes the requirements that a care manager must fulfill and describes the main services that are expected to be delivered. The CReG system aims to use the resources closer to the patient (which does not

97 http://www.sanita.regione.lombardia.it/shared/ccurl/956/366/DGRregole_e_allegati.zip; See ‘Allegato 14 Cronicità e CReG’
necessarily mean the GP). With the CReG the case manager role can be covered by third parties like doctors association, NGOs, private organizations, small infrastructures such as local hospitals and hospices offering rehabilitation and long term services.

For the time being the CReG and NRS are voluntarily kept separate and in an experimentation status, in order not to create confusion and to allow the needed flexibility to adjust the services to emerging needs. Indicatively the CReG will be applied to patients with higher autonomy and less complicated medical history than those enrolled in NRS. Moreover, before deciding which service is more appropriate for a particular case, elements such as healthcare service offering and health staff demographics will be analyzed and will influence the choice. Misunderstandings are possible, especially for GPs that will operate on both programs. In order not to worsen the situation of GPs, according to some of the stakeholders interviewed, it will be necessary to be clear about the differences between the two programs. Communication campaigns and dissemination activities such as seminars and training are needed to increase awareness, to set the right expectations and to eventually manage conflicts.

**Possible next steps**

With the integration of Telemaco into the NRS, all stakeholders interviewed think that there will be major opportunities to generalize and extend the service. Considering the different conditions that COPD patients might present, a new definition of services, accompanied by increased modularity, is considered essential. Future goals will be to identify other specific paths, targeted for the different types of COPD patients in order to avoid ‘ceiling or floor’ effects, excluding part of the chronic population. This modular approach is expected to allow services being aligned with patients’ needs and expectations. For instance more complex patients, or patients with comorbidities, may have access to more than one single device or have the integration with additional services delivered at home. Another possible evolution will be using the PTP path for patients accessing the emergency services, so that right after the 24/48 hours they spend under observation they can be sent home but monitored through the service. This will require further pilots and discussion among the various stakeholders. Generally speaking, in terms of the evolution of the service the stakeholders interviewed agreed on the need to take into consideration different types of service integration connecting the different types of care providers. As mentioned above, even if the evolution is not clear, the role of nurses and GPs is expected to be enhanced in order to give more importance to prevention and rehabilitation aspects rather than to intensive care ones. However in the short term the key focus will be about managing the activation of PTP for 32 healthcare organizations. The number of patients is expected to grow significantly and all stakeholders expect that when growing the system will need further fine tuning. Tuning mechanisms such as regular meetings and seminars are considered to work well, considering, however, that it is a process built on subsequent approximations and it is in continuous development.

### 2.3 Case study in Emilia Romagna region

Emilia Romagna is an Italian Northern region with a population of 4,395,569 inhabitants. Life expectancy at birth for males (79.6 years) and females (84.7 years) is above national average. The demographic structure shows a current and future population older than the national and Northern regions average:

- People over 65 years represents the 22.2% of the regional population
- Old age dependency ratio is 35 while aging index is 167

Diseases with the highest mortality rates affecting the Emilia Romagna population are circulatory system diseases, cancers, and ischemic heart diseases. Emilia Romagna has 11 ASLs (controlling 21 local hospitals) and 5 AOs. Since 2002 the number of ASLs has decreased from 13 to 11 and

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98 See Annex A Statistical Data
the number of local hospitals controlled by ASLs decreased from 32 in 2002 to 21 in 2007. The population served by a single ASL has increased\(^99\). The number of available beds has significantly decreased. Also for Emilia Romagna, this is the result of a series of reforms aimed at rationalizing inpatient care and developing primary care capabilities in order to ensure long term sustainability and better address healthcare changing demand, more focused on chronic diseases and other effects of an aging population. Emilia Romagna, given the forecasted developments of its population demographic structure, besides a better integration of primary and secondary care, is also focusing on a better integration with social services as started in its regional health prevention plan\(^{100}\) and its regional health plan\(^{101}\). Since 2007 the region has established a specific fund for non self-sufficient people (fondo regionale per la non autosufficienza- DGR 509 / April 2007). It is important to note that Emilia Romagna’s fund is equivalent to that established at national level. According to stakeholders interviewed it is an indicator of how Emilia Romagna is seriously addressing the challenge of independent living. The region has established a specific taxation for this fund that covers all the expenditures for classic health and social services for non self sufficient people for all ASLs, municipalities and since 2006/ 2007 and also for the development of ICT enabled services.

To support this transformation, Emilia Romagna is actually developing a series of eHealth services based on the regional health information system SOLE, which connects all healthcare providers in the region. Besides the development of the regional EHR and of the region wide eBooking system, on the basis of the semantic and technological infrastructure called SOLE, Emilia Romagna is developing different eCare networks for fragile citizens:

- A network for planning and audit of services within the non self-sufficient people fund (fondo regionale per la non autosufficienza) and eGovernment services supporting social care
- Networks to address fragility issues: telesupport, telecounselling, domotics, first aid services (such as eCare, the European commission funded project OLDES, the social service counter, etc)
- Network to support protected discharges (teleassistance, telemonitoring, domotics, teleortogeriatrics)
- Network to support chronic conditions (the European commission funded project Confidence, teleortogeriatrics, cardiac decompensation in Bologna)

In particular in the district of Bologna (and from next year also that of Ferrara) has developed eCare: a telesupport / telecompany initiative, based on an ad hoc call centre offering services for fragile elderly people. Even if the use of medical devices is almost inexistent, given the high maturity that this project has achieved from an organizational point of view, we decided to include a brief analysis of the project.

### 2.3.1 eCare network in Bologna \(^{102}\)

#### Background

The projects were born as a telesupport / telecompany after the summer of 2003, when several deaths of elderly citizens occurred, caused by heat and difficult health and psychological conditions.

\(^{99}\) Rapporto Osserva Salute 2010

\(^{100}\) http://www.saluter.it/documentazione/piani-e-programmi/piano-regionale-della-prevenzione/piano-prevenzione-2010-2012-

\(^{101}\) http://www.saluter.it/documentazione/leggi/regionali/deliber/175-2008

\(^{102}\) See Annex B Interview 10
It was a service activated only during the summer for a limited number of users. Until 2006/2007 the service was funded through small financing and charity (mainly from local banks -casse di risparmio). With the establishment of the fund for non self-sufficient people (fondo regionale per la non autosufficienza) and the inclusion of the service within the activities covered by the fund, the service went through a radical transformation enlarging both the services’ scope and reach.

**Service description**
eCare is a network for tele-assistance, company and support for elderly people with chronic conditions. The project is aimed at enabling citizen empowerment, prevention, social and health service integration, de-hospitalization and home care, as well as personalization of care. The project eCare covers the territory of 50 councils within Bologna district (without the 10 councils of Imola districts that have not adhered). The service is delivered through a specialized call centre. The call centre is provided by CUP 2000: an in-house company owned by the regional government, the municipality of Bologna, the province (district) of Bologna, and by most of Emilia Romagna’s ASLs and AOs.

Citizens (patients) enrolled are over 75 years old, present at least a fragility factor (such as chronic diseases), they have been hospitalized in the last 6 months and are not in a position to rely on strong social and family relationship networks. Selected users are fragile people sometimes with some sensorial handicaps, however to be enrolled, they should have a minimum of self-sufficiency such as the cognitive capacity to make a phone call.

Enrolment is done by the authorities that are participating in the project:

- the AUSL Bologna (that provides epidemiological service with the list of patients by disease), its GPs (even if so far they have not been really active contributors ) and nurses,
- Social services workers and councils/ municipalities
- Non-profit organizations.

Citizens themselves can ask to be included. This channel is increasing as municipalities carry out a lot of awareness campaign for the service.

Before activation, CUP 2000 verifies with municipalities and the district if the citizen already has access to other social support services. The potential user is then contacted by the call centre to verify his/her capabilities. Once all requirements are met, enrolled users will be followed, through the CUP 2000 call center, by specialized and dedicated operators.

The service is very focused on prevention but it also has many proactive aspects. According to an established schedule (also on a daily basis) the operator calls the user and starts going through a series of questions. It is important to notice that these questions are not posed in questionnaire form but through a conversation. This avoids patients giving automatic / standard answers and allows for better evaluation of psychological aspects. The call centre staff of CUP 2000 has been specifically trained for this activity. In 2010 call center operators made 128,000 calls with users.

A large part of the users of the service have chronic diseases mainly COPD diabetes, chronic heart failure, depression and chronic pain. The monitoring information is collected through a questionnaire, which has been defined case by case. Each patient will answer a series of personalized questions based on an established clinical protocol (by type of disease and in line with national disease guidelines) and a series of social parameters. Several levels of alert have been established for each patient. When patient’s indicators exceed these levels, the call centre operator sends a notice to a group of nurses at AUSL Bologna. According to the case, a nurse will call the

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103 The company provides eHealth services and Internet networks for health and social care. In particular is deploying the FSE (EHR) in the region, it is in charge of the eBooking system and it is a major player for the delivery of international eHealth projects on behalf of the region.
patient or visit him/her at home. Alternatively, the call centre can directly call the GP or the ambulance service or the social service workers. In the last 12 months nurses directly intervened on 73 alerts, while social services were alerted 164 times.

eCare network Bologna offers a different set of health services

- Call center 24/7 (inbound and outbound calls): 128,000 calls in 2010
- The health-social record
- Connection to the first aid
- Connection to GPs
- Monitoring of fragile conditions
- eBooking for healthcare services

Besides healthcare specifics services, through a partnership with local NGOs and the collaboration of municipalities, the eCare network offers services like transportation, shopping home delivery, recreation, access to a network of professionals offering services at agreed prices or advisory services for accessing welfare initiatives.

The service is available 24/7, users are free to call the call centre whenever they need however when activating the service it is made clear that this is not an emergency service. Every user has a personal digital record\(^1\) which is based on the OLDES platform, but at the moment, it is not integrated with the regional EHR which in Emilia is based on the SOLE platform. Standardization and integration of the records is currently planned but not underway.

At the moment standard users are not provided with electronic medical devices. There is a group of 150 CHF patients that have direct access to a first aid service and are provided with a panic button connected to the emergency service. This group of patients is enrolled by AUSL Bologna. They follow a specific path, even if they are always integrated in the eCare service.

Considering the fact that this service is targeted at fragile elderly people, CUP 2000 chose to reduce to a minimum the technology to be used at home limiting it to the telephone. Moreover, since CUP 2000 and its stakeholders had opted for a fast implementation schedule aiming to reach a great number of users in different conditions and settings within a short period of time, the selection and the implementation of different devices was seen as an obstacle.

**Organization and governance**

On the one hand the fact the CUP 2000 is a captive company owned by local authorities and hence not obliged to comply with all the complex public authorities regulations has given the eCare project the flexibility needed to evolve rapidly. On the other hand from a governance perspective the decision making process is more structured and complex. As mentioned before, since 2007, the budget is covered by the fund for non self-sufficient people (fondo regionale per la non autosufficienza) and therefore is included also within the social services financial resources of Bologna district, district’s municipalities and AUSL Bologna. Given the high number of organizations involved, a technical committee was established. It has a monitoring, auditing, and strategic coordination role and makes sure that all stakeholders are aligned on key decisions for the development of the service. This committee is supported by specialty boards that are in charge of redefining the services for the different types of users enrolled. For instance, a specific board was recently opened to refine protocols and selection criteria for users with cardiovascular diseases.

The integration of different domains such as healthcare and social service is the real added value of the service, each user report is truly multidisciplinary and it is created by physicians, nurses and

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104 See Annex B Interview 10 for record screenshots
social workers. eCare is a "community health service" in the truer sense of the word. Both clinical and social indicators are taken into consideration. As to social aspect, it is important to highlight that the service includes volunteers of non-profit organizations. eCare currently involves 27 volunteers groups, 225 associations at councils level, 28 social and recreational centres in Bologna city and 65 social and recreational centres across the Bologna district. Non-profit organizations help in identifying individuals that are suited to the service and integrating other services such as shopping delivery at home or socialization activities. For example, non-profit organizations have built a self support group, in which the most active users of the service help other more fragile users keeping up their morale. The interaction between non-profit organizations and users has increased by 300% over the last two years. Moreover services such as support after mourning has been positively judged by AUSL geriatric physicians for their impact on patients health. CUP 2000 has two dedicated people in charge of the relationship with non-profit organizations. Altogether CUP 2000 has allocated a staff of 14 people to the project:

- 14 call centre operators trained for this specific service
- 1 reference manager
- 2 people responsible for the relationship with non-profit associations
- 1 person in charge of the relationship with municipalities and social services.

Costs
The total budget for 2011 is €800,000. CUP 2000 has calculated that the cost per user, after having passed the 3,000 users threshold, is around €1 per patient per day. These estimates include all costs (capital allowances, volunteers' reimbursements, wages etc, phone costs etc).

Barriers
Major project barriers were experienced especially during the first year of the service. This service was strongly supported by the regional government and Bologna district, while other stakeholders were initially prejudiced about the project. Municipalities/councils that are now experiencing cuts in social care are still quite suspicious or have difficulties in understanding the money spent on the project. Moreover the project includes different professionals, normally used to work in silos, and therefore the cooperation is often difficult. It is more than just an organization issue; it is a cultural process that had to be triggered. For this reason a key contribution was given by Walther Orsi of AUSL di Bologna (walther.orsi@ausl.bologna.it) who is an expert in sociology applied to healthcare service. His contribution made it possible to design processes and decision making flows and to better target awareness campaigns and trainings.

Benefits and Results
Between 2007 and 2010 the number of citizens included grew from 800 to 3,327. In 2010 the percentage of users with higher fragility condition grew from 8% to 44%. The overall penetration of the service in the addressable population is 19%. This increased appropriateness is the result of the continuous redefinition of the service.

CUP 2000 has commissioned a survey to understand customer and stakeholders satisfaction. It has emerged that:

- 90% of users are satisfied by the service, 90% have seen improvement to their health status following call center advice, and 70% feel safer.
- Social service workers have judged the service quite positively as it increases awareness on social service offering, the sense of loneliness is relieved and the service has increased the compliance to medical prescriptions.
- GPs were also positive about the service but to a lesser extent since only 21% perceived that the service has reduced misuse of their service
An epidemiological research from AUSL Bologna indicates that the service has reduced hospitalization rates. Analyzing a sample of users and comparing it with a control sample results shows that in 2 years there were fewer hospitalizations (~100). Considering that average costs for inpatient care are €600 per day and that the average length of stay is 10 days, the service has helped save €600,000 in two years.

From the study it has also emerged that 50% of users have reduced their access to the emergency service. Moreover, AUSL Bologna has confirmed that in several cases, the service has allowed an early intervention in cases that would have resulted in a serious exacerbation. This was possible given that through the monitoring it is possible to evaluate parameters that patients normally ignore.

**Next steps**

In order to further increase the appropriateness of the service, the eCare network is further evolving into smaller specialized branches:

- **Tele-orthogeriatrics in Ferrara** for protected de-hospitalization. Patients are followed through the call centre and by specialized nurses and physiotherapists delivering services at home or in local ambulatories.

- **Project dementia** (with Hospital Maggiore in Bologna): services monitoring not only the conditions of patients affected by dementia but also the conditions of their family care givers.

- **Difficult hospital discharges project**: offering telemonitoring and additional home services such as rehabilitation and personal hygiene services to elderly patients in the first 6 months (or longer) after discharge.
3. OBSERVATIONS AND CONCLUSIONS

After having analyzed some examples of chronic disease patients' telemonitoring projects in three Italian regions, the general context of the National Healthcare System and its specific policies addressing the challenges posed by chronic diseases, it is possible to draw some conclusions on the current scenario of IPHS and some consideration of future developments. It is useful to compare the three regional experiences using three axes (diffusion of innovation, governance and HIA) which help understanding some common traits and drawing some general considerations.

3.1 Diffusion of Innovation

3.1.1 Diffusion

Analyzing the passive spread of innovations introduced within the projects it is possible to note some common characteristics regarding:

- Technology solutions. In all projects the number of medical devices introduced is limited. The aim was to reduce to the minimum the difficulties for users that in most of the cases were fragile patients. In the project MyDoctor@home, more complex data collection such as spirometer and ECG, measurements are done by a nurse during a scheduled home visit. In this perspective, it is interesting to note that within the eCare project stakeholders decided to avoid completely devices at patients' home, using in person call center operators to collect patient data through protocol based questionnaires. On the other hand the technology selected for patient information presentation, data management, storage and retrieval are quite advanced in all projects. MyDoctor@home employs a 'platform as a service' model, an off-the-shelf offering of Telecom Italia. VCO and Telemaco/PTP-NRS opted for a more traditional outsourcing contract with a third party service provider selected through a European tender. In both projects, stakeholders were looking not only for technology integration but also for a partial externalization of clinical services. Considering the number of healthcare organizations involved in each project, the shared services solution has allowed to contain and optimize costs, while avoiding putting further pressure on healthcare organizations' departments. Also eCare opted for a shared service model, even if the service provider was 'internally' available. CUP 2000 had already some of the functionalities and skills needed for the project. This has facilitated the roll out. It should be recalled however that the "private-like" legal status of CUP 2000 guarantees flexibility in infrastructure and resources.

- Patients. At the time of writing, the number of patients involved are limited (20 for MyDoctor@home, 130 for VCO, 393 for Telemaco/PTP-NRS). The limited number is due to the experimentation status of all projects (excluding eCare that is a full service and that has crossed the 3000 patients threshold). In most of the projects, selected users are chronic patients with fragile and severe conditions. This choice was done in order to address the needs of patients requiring more expensive care. Patient selection was also driven by the analysis of territory specific health demand. For example, given the high prevalence of diabetes in VCO ASL population, the organization decided to involve a greater number of diabetic patients in the project.

- Health and social services professionals. In almost all experiences, the health projects leaders are specialists. However the bulk of the monitoring activity is the remit of nurses. This is particularly true in MyDoctor@home and in Telemaco/PTP-NRS projects, where nurses are the main references for patients. During the interviews, it has been stressed that this extra effort of nurses is not always recognized from an economic and organization point of view. The role of nurses is considered key in projects' objectives achievement. A need for further investments on nurse training and for a better definition of incentives emerged from the interviews. The GPs role is often limited and marginal. They often
participate in patient enrollment, but they do not play any particular role afterwards. The need to better define the role of GPs as case manager, to ensure a real continuity of care (coordinating patient access to the various services available) is particularly dear to stakeholders interviewed in the Lombardy project. Other health staff included in the services analyzed is the call centre operators (where this service is integrated). These are mainly specialized nurses trained for the specific needs of chronic patients and with distance monitoring skills. The only project that also involves social services and non-profit organizations is eCare. The eCare project actually started as a social service rather than a healthcare one. The project is still not focused on a particular disease but on the multifaceted concept of "fragility" (users are classified as fragile not only from a medical perspective but also from a social one). This has allowed developing a series of complimentary "social services" around the eCare platform that further personalize the offering for users.

3.1.2 Dissemination
In almost all project dissemination activities like education and awareness campaigns are in place, supporting the introduction and the acceptance of the services. Initiatives are addressing:

- **Patients/users.** These activities are considered very important to engage current and prospect patients in VCO (mainly sponsored by CSI Piemonte and ASL VCO) and in eCare project. For Telemaco/PTP-NRS and MyDoctor@home, awareness campaigns are not considered really important as patients are in too delicate conditions, and the information asymmetry between physicians and patients is too high to allow them to decide whether they want to participate in the project. Enrolled patients in all projects are trained by nurses and other specialized staff on the use of devices and services. Moreover they are continuously provided with support services. A clear patient administrative status is also helpful to set patients expectation correctly. For example in the case of MyDoctor@home clinical stakeholders expect that during the roll out phase the main challenge will be posed by the unclear administrative status of patients who will be included in the project but will be not treated under the OAD regime (in particular patients after discharge). The region has preliminarily approved a specific DRG including telemedicine but, at operational level, the regulation is not clear. These problems are already emerging in the first steps of the extension of the project to other departments.

- **Health organization staff.** For instance in MyDoctor@home training for physicians is done by their peers and involved physicians have published articles on scientific reviews in order to show initial project results. In Telemaco/PTP-NRS, Cefriel organizes education sessions showing achievements and results for organizations that are considering joining the project.

3.1.3 Implementation
According to interviewed executives, change management/cultural issues remain one of the key barriers for all projects’ evolution. Healthcare decision makers adopt both strategic and tactical tools to deal with this issue. From a general strategy perspective, all regional health plans address the need to make the health system evolve towards a network of caregivers built around patients’ needs and the concept of patient empowerment (especially in the case of chronic patients). In the projects’ specific contexts, mechanisms that have been established to mainstream innovation are:

- **Specific trainings and education sessions for key project players (as described above).**
- **Intervention by experts e.g. in culture change management to redesign processes and workflows**
- **Managing boards involving all stakeholders supported by technical committees.** These bodies have provided platforms for discussion and problem solving, ensuring that projects
are constantly fine-tuned, avoiding the escalation of issues and smoothing the process for new organizations joining the projects

- Shared infrastructures. All projects opted for a shared services

The strategy underlying project implementation is generally a mix of top down and bottom up approach. VCO, Telemaco/PTP-NRS and eCare have established official boards, scheduled meetings and activities to support the implementation. MyDoctor@home is probably the least structured project in terms of technical and managing organization making more difficult to achieve a general implementation.

After the pilot in AOU San Giovanni-Le Molinette, regional decision makers have decided for a big bang approach with the contract with Telecom Italia. Aress would play a hub role for organizations that are interested to join, but there is no structured process established.

The above shows that a diversity of approaches has been adopted depending on the local context and the stakeholders involved. It is therefore difficult to conclude that one or the other approach is more conducive to success.

### 3.1.4 Sustainability

All projects analyzed have the goal to extend their services to a greater number of organizations and patients and, in the longer term, to introduce telemonitoring services within the standard set of services offered to chronic patients. eCare, Telemaco/PTP-NRS and VCO have established some structured review processes to better understand how the services should evolve and improve. These review processes are based on:

- Patients and health staff satisfaction surveys
- A few established indicators like hospitalization rates, clinical results, costs

For the project MyDoctor@home, the decision to move forward was taken after the preliminary clinical study of AOU San Giovanni Hospital-Molinette: a more structured analysis of the project will be set up during the first months of the generalization phase.

Regional health authorities started setting some legal framework and regulation to support the generalization of the service. All regional health plans mentioned the importance to move toward new models of care delivery enabled by ICT and telemedicine in particular. Almost all projects analyzed rely on the regulatory framework of OAD and ADI as legal foundation. eCare, being focused on prevention and counseling found its foundation on the prevention plan and on the objectives of the fund for non self-sufficient people (fondo regionale per la non autosufficienza). Regional laws and regulated chronic disease management approved programs were also used as preconditions in most of the projects analyzed. For instance, Region Piedmont for the care of diabetic patients in VCO projects referred to the approved documentation detailing the levels of assistance (LEA) in the chronic disease management program for diabetic patients. Specifically for the project My Doctor@home, Piedmont region authorities are setting up but at an operational level, the situation is not very clear.

The financing model is considered important for the project to ensure long term sustainability. For MyDoctor@home the region has established a DRG but it is not clear how it will be operationally adopted by hospitals. So far, the hospital has used tariffs for traditional OAD services. The region has agreed a daily fee for patients with Telecom Italia; however, it is covering just the technological support. The financing model used for VCO is the traditional funding model used for pilot projects: the contract with the service provider is managed by CSI and it covers technological and logistic support provided to the VCO ASL. It is not clear how the work of ASL VCO physicians is accounted for in the costs structure. Lombardy is the region which is mainly focusing its attention on the reimbursement model. With the integration of Telemaco into NRS it is testing the reimbursement model by setting tariffs according to the intensity of the service provided. The hospital is responsible for organizing the service and complying with the requirements specified for the service.
For the moment, since the project is still experimental, the funding for the telemonitoring comes on top of its standard yearly budget. eCare is already at a more advanced stage, with the region allocating part of the fund for non self-sufficient people directly to the initiative. Targets and new investments are decided by the governing committee, which includes all project stakeholders.

The financing model influences how the system of incentives works. At a higher level, key stakeholders understand the process and see the advantages coming from the initiatives, while at a lower and more operational level, there are little or no specific incentives, neither economic nor organizational for important players like nurses and GPs. These financing models address the question of incentives for players involved only at a higher level. Providing incentives to nurses and GPs who are playing (or could play) a bigger role, being closer to patient is a neglected aspect in all projects analyzed. To ensure a long term sustainability of the projects it will be important to invest in these players by increasing training and incentives, as they are the connecting level between the patient and the specialist.

3.2 Governance
All of the items described above, sustainability in particular, are strongly related to the aspect of governance that rules how the supply chain is organized and establishes how decisions are made.

3.2.1 Services’ Supply chain
The organization of the supply chain of services has been simplified through the externalization of complex component like technological and logistic ones. The use of third parties or specialized internal organizations (e.g. CUP 2000 for eCare and partially also in the case CSI for management issues in the VCO project), has allowed physicians and other health staff involved to focus only on patient care. SLAs set the standards that these third parties are expected to meet. Compliance is monitored, however SLAs can be reviewed and modified in order to adapt to the evolution of needs. Emilia Romagna and Lombardy, also due to the fact that their projects have been implemented for a longer time, have better structured this process. Further from a clinical side, care protocols have been initially established involving physicians from all participating hospitals and ASLs. Clinical protocols are regularly fine-tuned, even if they need to be compliant with national and regional guidelines for disease management. The question of patient data security, which might jeopardize the trust relationship with patients, is addressed through the application of the general legal framework surrounding healthcare and privacy, which includes provisions relevant for eHealth implementations. Italy has a tightly regulated privacy framework: consent is an absolute requirement in healthcare scenarios, even when the data exchange is initiated by a public institution. The pilot status of almost all projects analyzed has so far allowed greater flexibility, thus making fine tuning processes relatively manageable. It is not clear however whether this participative approach will be as effective as in this initial phases or whether it will lead to delays and further rethinking of the structure, when the project enters the generalization phase. Regional health authorities will be asked to provide a vision and greater commitment in order to avoid centrifugal forces to jeopardize projects’ advances.

3.2.2 Decision making process
As described above, the decision making process has been shared between the different stakeholders from the initial planning phase. Management boards and technical committees have been established to monitor the service, to make the required changes and to decide upon future evolutions. In this way, the higher management executives are able to share targets and goals, to set their expectations more correctly and to understand the budget allocations. This participative approach has been used less during the roll out phase when players like nurses and GPs are involved. In Telemaco/NRS-PTP, for example, nurses, as patient tutors, are responsible for the greater part of the relationship with the patients. During the review process, however, it emerged that in many cases nurses have a more marginal role in the care path design. They are not provided with specific training for telemonitoring services, which require certain skills (as witnessed by the
eCare project and from the Hospital Maugeri experience with Telemaco). Moreover the monetary and organizational incentives aimed at increasing their commitment to the project are limited. There is the risk for some of them to perceive the project as a job on top of their standard assignments and responsibilities. When the role of GPs is envisaged, it is often limited to the enrollment phase. This can represent a limitation in the future as GPs can play a hub role between all the different services available in the territory; therefore there is a need to better design their tasks and responsibilities. Moreover also for GPs there are no particular incentives for participating in the projects. They also need to be better trained about the services and they need to be conscious and convinced about the potential benefits for the patients. All projects have gone through an internal review process analyzing costs, clinical effectiveness and satisfaction of patients and operators. GPs and nurses need to be more informed on the findings of these analyses. Moreover, as projects become bigger in scale, it will be useful to evaluate them by applying international methodologies such as HTA: resulting evidences on benefits of telemonitoring services will be useful to increase the trust of all health professionals. In the longer term, the marginalization of GPs and nurses in the decision making process and in the incentive system if not properly addressed may represent a barrier for project generalization and its transferability to different tier of care.

3.3 Health Impact Assessment (HIA) / Cost-benefit analysis

All projects analyzed are relatively small and recent. Costs structures are strongly conditioned by the current ‘prototype’ status. In most of the interviews, stakeholders stressed the importance of reaching a certain size to reach some economies of scale and thus, having a sizable impact on the healthcare system.

Financial gains are difficult to estimate as at the time of writing standard costs for chronic patient care were not available. Looking at available literature, it is important to highlight that in chronic patients care hospitalization costs are the heaviest entry, and in all the projects analyzed the hospitalization rates have decreased. Telemonitoring services are widely well accepted by patients and even if results are not always statistically significant, clinical and psychological indicators show improvements. Table 2 summarizes available cost information and key benefits achieved.
<table>
<thead>
<tr>
<th></th>
<th>Total costs</th>
<th>Estimated cost per patient</th>
<th>Benefits</th>
<th>Notes</th>
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<tbody>
<tr>
<td><strong>My Doctor@home</strong></td>
<td>Contract with Telecom Italia: €10 million (per 5,000 patients over 5 years)</td>
<td>€2 per day (just Telecom Italia services) + OAD regime is reimbursed on average €160 per day</td>
<td>Preliminary studies show: better patient responsiveness to treatments, improvement of the mood, and reduced access to specialists. Early detection of deteriorating conditions, allowing timely care and reduced acute episode recurrence rates. Estimated financial gains when compared to hospital stay.</td>
<td>Financial gain estimates in line with results of a 2007 study “Healthcare costs of COPD in Italian referral centres” which estimated that the average cost of a day of stay for COPD patients in Italy is €268.2</td>
</tr>
<tr>
<td><strong>VCO</strong></td>
<td>Contract with Tesan and partners: €1,817,000. (contract covers 300 patients within 3 years time framework) On top of that +2% of contract value covering CSI activities (€36,400)</td>
<td>When the project will enroll 300 patients the estimated costs will be around €6-€6.50 per day per patient. Considering January 2011 results costs were between €14 and €15 per day per patient (Costs per patients are IDC estimates)</td>
<td>Good patients’ acceptance and satisfaction rates. Reduced use of ambulatory care services, access to A&amp;E, and hospitalization rates. Better adherence to prescriptions, reduction of average values for disease key clinical indicators.</td>
<td>Estimates do not include ASL VCO’s specialists time</td>
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<tr>
<td><strong>Telemaco/ NRS</strong></td>
<td>Telemaco was initially funded for €3.45 million. When the project was moved into NRS, funding for 2010 was €21.6000 (300 potential patients)</td>
<td>Tariffs: €720 (120 per month/€4 per day) for 6 months high intensity care // €480 (€80 per month, €2.7 per day) for 6 months low intensity</td>
<td>Good patients’ acceptance and satisfaction rates. Increased role of patients and informal care givers in disease management. Fewer hospital admissions, fewer access to emergency service, acute episodes have been largely addressed at patient home.</td>
<td>Funding is directly managed by hospital. The project addresses patients with severe COPD, which according the available literature are the most expensive</td>
</tr>
<tr>
<td><strong>eCare</strong></td>
<td>2011- the total budget of the project is €800,000. Budget includes all costs (capital allowances, volunteers’ reimbursements, wages etc, phone costs etc).</td>
<td>€1 per day (but new estimates are showing also lower numbers)</td>
<td>High acceptance and satisfaction rates. Reduction of fragility conditions. Reduction of hospitalization rates. Reduction of acute episodes recurrence. More effective integration of social and health resources.</td>
<td>This is the only project integrating health and social services. The project does not entail the use of medical devices.</td>
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3.4 Conclusions

All projects analyzed have delivered interesting results so far, setting the premises for an 'industrialization' of telemonitoring services within the Italian healthcare systems. Projects have proved interesting findings related to giving a more prominent role to the patient in care management, reducing access to hospital resources, and improving patients' clinical and psychological conditions.

These results are expected to drive a greater attention towards the opportunity to extend and make routine this type of services, in a context of increasing prevalence of chronic diseases, more stringent healthcare funding models and greater role of local health authorities.

The analysis of these initiatives has however highlighted some barriers that might put the generalization at risk. These barriers are more related to the need of organizational and cultural changes in the Italian healthcare system than to technology aspects.

Chronic disease management requires a coordinated approach to care. The importance of networking the various care providers has not always been addressed properly. With the only exception of Emilia Romagna, analyzed projects are centered on specific specialty care. GPs have a limited role and the case manager is generally not well defined. The care manger has a delicate coordinative role in the care continuum, but it has remained in the background. The Lombardy region has started a pilot on the definition of case manager (CReG) role but for the moment it will be maintained separate from telemedicine services. This decision is partly due to the fact that the concept of network is more widespread among specialists than among general practitioners who are more used to work in isolation. There is the risk that GPs, which currently play an important role into the referral systems, would develop hostile or passive attitude toward these initiatives. Nurses and other staff are in charge of the larger part of operations, however their work is not always properly recognized and they have limited education around projects' objectives and results. If these issues fail to be properly addressed there is a risk to jeopardize fundamental aspects such as patient education, prevention and rehabilitation that are usually led by these professionals. Future training and education activities need to be focused on the needs of these types of professionals. Moreover to support these dissemination activities, it will be important to base project reviews on internationally recognized methodologies such as HTA: this will help physicians and staff to have better confidence in results and benefits that can be achieved through these systems.

Looking at policy and decision making, to ensure a sustainable growth, regional health authorities in their role as payers and healthcare decision makers need to show greater commitment through regulations and, most importantly, by setting incentives. In the first phases of the projects, key decisions on the evolution of processes and the establishment of protocols were made using a participative approach and involving management from all organizations involved. It will be important in the generalization phase to maintain certain aspects of this approach to ensure the evolution of projects. However, to avoid deadlocks, regional decision makers should play a greater role in guiding the process, communicating targets and objectives and setting financial or non-financial incentives for players involved at all level.
<table>
<thead>
<tr>
<th>Glossary</th>
<th>Description</th>
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<tr>
<td>ADI</td>
<td>Assistenza Domiciliare Integrata - Integrated Home Care</td>
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<tr>
<td>AGENAS</td>
<td>Agenzia Nazionale per i Servizi Sanitari Regionali – The national Agency for the regional health services</td>
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<tr>
<td>AIPO</td>
<td>Associazione Italiana Pneumologi Ospedalieri – The national association of respiratory medicine hospital specialists</td>
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<tr>
<td>AO</td>
<td>Azienda Ospedaliera – Public Hospital Enterprise</td>
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<tr>
<td>AOU</td>
<td>Azienda Ospedaliero-universitaria – University Hospital Enterprise</td>
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<tr>
<td>ASL</td>
<td>Azienda Sanitaria Locale - Local Health Enterprise</td>
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<tr>
<td>AUSL</td>
<td>Azienda Unità Sanitaria Locale – Local Health Enterprise Unit</td>
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<tr>
<td>BDA</td>
<td>Banca Dati Assistito – Patient Database</td>
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<tr>
<td>CCM</td>
<td>Centro nazionale per la prevenzione e il controllo delle malattie – The national center for diseases prevention and control</td>
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<tr>
<td>CHF</td>
<td>Chronic Heart Failure</td>
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<tr>
<td>CNESPS</td>
<td>Centro Nazionale di Epidemiologia, Sorveglianza e Promozione della Salute – The national center for epidemiology, monitoring and promotion of health</td>
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<td>COPD</td>
<td>Chronic Obstructive Pulmonary Disease</td>
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<tr>
<td>COTE</td>
<td>Centro per la Osservazione delle Tecnologie Emergenti – The observation center for emerging technologies</td>
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<tr>
<td>CReG</td>
<td>Chronic Related Group</td>
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<tr>
<td>DALY</td>
<td>Disability Adjusted Life Years</td>
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<td>EBM</td>
<td>Evidence-Based Medicine</td>
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<tr>
<td>EHR</td>
<td>Electronic Health Record</td>
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<tr>
<td>EUnetHTA</td>
<td>European network for Health Technology Assessment</td>
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<tr>
<td>FSE</td>
<td>Fascicolo Sanitario Elettronico – electronic health record in Italy</td>
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<tr>
<td>GP</td>
<td>General Practitioner</td>
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<tr>
<td>HIA</td>
<td>Health Impact Assessment</td>
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<tr>
<td>HTA</td>
<td>Health Technology Assessment</td>
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<tr>
<td>IGEA</td>
<td>Integrazione, Gestione E Assistenza per la malattia diabetica – Integration, Management and Care for diabetes</td>
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<tr>
<td>IPHSS</td>
<td>Integrated Personal Health System</td>
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<tr>
<td>IRCSS</td>
<td>Istituto di Ricovero e Cura a Carattere Scientifico – National Institute for Scientific Research</td>
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<tr>
<td>ISS</td>
<td>Istituto Superiore di Sanità – Higher Institute for Health</td>
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<tr>
<td>LEA</td>
<td>Livelli Essenziali di Assistenza – the national health service’s benefits catalogue</td>
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<td>NHS</td>
<td>National Health Service – Servizio Sanitario Nazionale</td>
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<td>NRS</td>
<td>Nuove Reti Sanitarie – New Health Networks</td>
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<tr>
<td>NSIS</td>
<td>New Healthcare Information System</td>
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<td>OAD</td>
<td>Ospedalizzazione A Domicilio – Home Based Hospitalization</td>
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<td>ODCP</td>
<td>Ospedalizzazione Domiciliare per Cure Pagliiative Oncologiche – Home hospitalization for cancer palliative care</td>
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<tr>
<td>PDT</td>
<td>Processi Diagnostici Terapeutici di cura – Diagnostic and therapeutic processes</td>
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<td>PIC</td>
<td>Profili Integrati di Cura – Integrated Care Profiles</td>
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<tr>
<td>POD</td>
<td>Ospedalizzazione Domiciliare Post-cardiochirurgica – Home hospitalization after heart surgery</td>
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<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>PTDA</td>
<td>Percorsi Diagnostici Terapeutici Assistenziali – Diagnostic, therapeutic care paths for diabetes</td>
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<td>PTP</td>
<td>Percorso di Telesorveglianza domiciliare sanitaria – Telemonitoring service for severe and very severe COPD patients</td>
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<tr>
<td>QUADRI</td>
<td>Qualità dell’Assistenza alle persone Diabetiche nelle Regioni Italiane – Quality in care/assistance of diabetic patients in Italian regions</td>
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<tr>
<td>RSA</td>
<td>Residenze Sanitarie Assistenziali – Health Service Homes</td>
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<tr>
<td>RSS</td>
<td>Relative Stress Scale</td>
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<tr>
<td>RTI</td>
<td>Raggruppamento Temporaneo d’Imprese – Temporary Enterprises Group</td>
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<tr>
<td>SLA</td>
<td>Service Level Agreements</td>
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<tr>
<td>SSN</td>
<td>Servizio Sanitario Nazionale – National Health Service</td>
</tr>
<tr>
<td>TCCS</td>
<td>Teleconsulto Specialistico ai medici di Medicina Generale</td>
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<tr>
<td>USL</td>
<td>Unità Sanitaria Locale – Local health unit</td>
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Abstract
This study presents and discusses the status for integrated personal health systems (IPHS) in Italy. It aims to illustrate through case studies the patient and health monitoring systems that are available, the level of implementation of these systems, the impact they have on the general socio-economic context, as well as their cost-effectiveness where applicable. The analysis presented in this report is based on interviews with key experts and stakeholders from Italy and a substantial secondary data collection.
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Key policy areas include: environment and climate change; energy and transport; agriculture and food security; health and consumer protection; information society and digital agenda; safety and security including nuclear; all supported through a cross-cutting and multi-disciplinary approach.