Strategic Intelligence Monitor on Personal Health Systems

Country Report
Italy
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1 The Italian Health care System

Italy’s health care system is a regionally based National Health Service (Servizio Sanitario Nazionale (SSN)) that provides universal coverage free of charge at the point of service. The national level is responsible for ensuring the general objectives and fundamental principles of the national health care system. Regional governments, through the regional health departments, are responsible for ensuring the delivery of a benefits package through a network of population-based health management organisations and public and private accredited hospitals. There is a considerable north–south divide in the quality of health care facilities and services provided to the population, and there are significant cross-regional patient flows, particularly to receive high-level care in tertiary hospitals. Health care is mainly financed by earmarked central and regional taxes. Each region is free to provide additional health care services if budgets permit, as long as they also deliver the basic package.

The most important state-level reforms from the beginning of the 1990s include: the devolution of health care provision to regional governments and the progressive strengthening of regional powers to deliver and finance health care; a parallel delegation of managerial authority to hospitals and local health enterprises; the establishment of the uniform basic package of health services that should be guaranteed to all citizens; the introduction of a national clinical guidelines programme to enhance the quality of health care; and the development of an electronic patient records system.

The 2006-2008 National Health Plan’s main strategies for the achievement of these objectives are: the promotion of innovation, research and development (e.g. through implementation of health care service and biomedical research, and through HTA); citizen involvement in health care decision-making and health care assessment; training policies directed at personnel in the SSN (National health Service); the improvement of clinical governance and waiting lists; managerialism, management experimentation, pharmaceutical policy and medical technologies.

Future challenges for the devolved Italian health care system include: overcoming the large variability in the quality of health care among regions; providing a national policy for the governance of patient mobility; the reorganisation of primary health care; the integration of health care networks for emergency care, transfusions and transplants; and the integration of health, social care and palliative care[1].

1.1 Organisational structure

The Italian health care system is regionally based and organised at three levels: national, regional and local (as detailed in figure 1). Under the Italian Constitution, responsibility for health care is shared by the state and the 20 regions. The state has exclusive power to set the ‘essential levels of care’ (livelli essenziali di assistenza (LEAs)), or basic package, which must be available to all residents throughout the country, and is responsible for ensuring the general objectives and fundamental principles of the national health care system. Regions have virtually exclusive responsibility for the organisation and administration of publicly financed health care and influence government decisions through the 'State-Regions Conference'. The parliament approves framework legislation, which lays out the general principles for organising, financing and monitoring the SSN.
At national level, the main central institution is the Ministry of Welfare (former Ministry of health) and within it the Department of Health is directly responsible for health care planning, financing, framework regulation, monitoring and general governance of the National Institutes for Scientific Research.

The regions are responsible for ensuring the delivery of a benefit package through a network of population-based ASLs (Azienda Sanitaria Locale or Local Health Unit) and public and private accredited hospitals (OA - Azienda Ospedaliera or Hospitals). 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 organising supply in relation to population needs and for monitoring the quality, appropriateness and efficiency of the services provided. The regional level has legislative functions, executive functions and technical support, as well as evaluation functions.

At local level, Health services are delivered through a network of population-based ASLs and public and private accredited hospitals.

![Figure 1 – Overview of the Italian health care system. Source: IPTS elaboration based on Italy: Health System review (2009)[1], OECD[2], and IPTS field work](image)

### 1.2 Health care expenditure and financing

In Italy, as in most OECD countries, health care expenditure has steadily increased over time, making its containment a major issue for successive governments (details are available in figure 2). In 2007, total health care expenditure represented almost 9% GDP reaching nearly €111 billion (€86 billion in public expenditure and €25 billion in private expenditure). The private share is expected to keep on rising mainly due to budget restrictions and cost controls in public spending (at an average annual. Although Italy has one of the lowest public shares of total health care expenditure among EU countries, the volume of public health care expenditure remains an important issue for the government, both at the national and at the regional levels, mainly because of the existence of a large public deficit. Available research on public health care expenditure shows that differences in regional expenditure are mainly

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explained by socioeconomic factors, such as differences in GDP, and in the supply of health care (see figure 3)

![Health Expenditure over GDP](image)

Figure 2 – Italian health care expenditure over GDP (historical and forecast). Source: Ragioneria Generale dello Stato

Actually, the regional differences in health care debt, budgets resources dedicated to health care and health care expenditure by type of costs show great variety from region to region. When one considers data at the regional level, Lazio, Veneto, Liguria and Campania devote a greater than average amount of resources to hospital care, at 50.7%, 47.4%, 46.1% and 47.1%, respectively. In contrast, primary and community care are highest in Lombardy (48.1%) and Tuscany (48.2%). Lastly, Valle d’Aosta, with 5.5%, and Molise, with 5.2%, stand out for public health spending. Such differences together with changes in size and age composition of the population often represent a source of health inequalities, being the North regions in a more privileged position.
The abolition of social insurance contributions in 1998 transformed the sources of financing; currently the main source of finance for the Italian SSN is a mix of hypothecated taxes applied both at the regional and national levels. Out-of-pocket payments, which include both cost-sharing payments (mainly for pharmaceuticals) and direct payments to private suppliers of health care, represent the second largest source of income (as outlined in figure 2). As a result of the near universal coverage, voluntary health insurance (VHI) does not play a significant role in funding health care in Italy. Inpatient care and primary care are free at the point of use; past attempts to introduce co-payments within these categories failed.

1.3 Health and social care coordination

A variety of attempts since the 1990s aimed at coordinating health and social care services have been implemented at policy level, however, the gaps in operationalising this coordination still exist. The first policy attempt addressed rehabilitation with Law No. 104/1992 establishing a precise health care programme and medical devices for rehabilitation included in the list for reimbursement. Moreover, the law stated that where ASLs were not able to deliver this type of care, agreements with public or private hospitals had to be defined to guarantee service provision. In 1994, the National Health Plan highlighted the importance of rehabilitation and the creation of a regional integrated network (including health and social services), as well as specific activities that had to be carried out at three different levels: (a) activities aimed to maintain patients’ autonomy at the highest possible level, with the ideal setting being home care coordinated by a GP; (b) activities aimed at managing the disabling effects following trauma or disease, in cases of which intensive rehabilitation care could be

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delivered within specific settings, such as hospitals or ambulatory clinics; and (c) activities aimed at managing severe disabling effects following trauma or disease, in cases of which a specialized tertiary hospital would represent the best setting.

In fact, the actual coordination between health and social care services takes place through the Distretto Socio-Sanitario or Socio-Health District. These are intermediate bodies between the ASL level and the territory defining the joint jurisdiction of health and social care, where the latter is usually implemented by municipalities.

It is expected that the recent reform, transforming the former Ministry of health into a Department of Health under the Ministry of Welfare would enhance coordination amongst health and social care services
2 The future development of the market for 'Assistive Technologies'

The future development of the market for 'Assistive Technologies' may be considered in the context of three general themes

2.1 A focus on Informatics

'eGov2012' is the very ambitious eGovernment Action Plan 2009-2012 for innovation and digitalisation developed by the Italian government. The “eGov 2012” is a €1.3 billion plan for innovation, online services deployment, accessibility and transparency of public administration, with a view to bringing it closer to citizens and business in line with the Lisbon Agenda. eHealth is included as a key pillar in the Action Plan. In particular, two eHealth strategic objectives have been set:

- **ePrescription**: “Digitalization of prescriptions and medical certificates cycle” thus providing for the replacement of paper prescriptions and medical certificates with digital documents, in line with the Electronic Health Records’ standards.

- **EHR**: “Electronic Health Records” to build each patient’s medical record in an electronic format, thus improving diagnosis and treatment process.

The DDI - Department of Digitalisation and Innovation within the Italian ministry of Public Administration - is the organisation responsible for delivering the eGov2012 plan. DDI only intervenes for inter-operability and infrastructural issues and as such coordinates a roundtable with the Department of Health at the Ministry of Welfare and with the regions.

A budget of €329 million has been set aside to achieve the eHealth objectives within the eGov2012 plan; the specific allocation of this budget is planned as follows:

- GPs network: €80 m
- EHR: €90 m
- ePrescriptions: €25 m
- Online booking: €44 m
- ASL/AO innovation: €90 m

Hence, 'Assistive technologies' are not directly included in the scope of the eGov2012 plan.

Although ICT expenditure in health care has increased over time in absolute numbers, expenditure as a percentage on overall health care expenditure decreased during the 2003-2008 period as seen in figure 4. Furthermore, ICT expenditure in health care remains low compared to other sectors. As a term of comparison in 2008 Central Public Administration spent 2% of its budget in ICT, and the financial sector 13%.
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Figure 4 – ICT expenditure on Health care. Sources: Ministero Salute, Assinform, Cnipa, ABI.

According to the Pilot on eHealth Indicators carried out by Empirica[3], Italy is among the average eHealth performers in the EU27. This concerns both the availability of ICT infrastructure (computer, Internet) and the use of ICT for different eHealth-related purposes.

Specific data gathered at national level by the Italian Observatory on eHealth (Osservatorio Sanità Elettronica) provides detailed data on eHealth deployment (figures 5 and 6). According to this data 25% of citizens hold an electronic health card, however, how actively the card is used provides lower results. At regional level, use of ICT tools is higher in hospitals than for ASLs. As pointed in figure 3, most Italian regions health budgets are burdened with debt toward the National Health Fund or toward other regions. Not surprisingly the most e-ready of the Italian regions are the richest ones and namely Lombardia, Emilia-Romagna, Toscana, Veneto and Piemonte.
Figure 5 – eReadiness in health care. Source: Osservatorio Sanità Elettronica, Between SpA (courtesy of Marco Mena, Director)

Figure 6 – Availability of online services in Local Health Units (ASL) and Hospitals (AO). Source: Osservatorio Sanità Elettronica, Between SpA (courtesy of Marco Mena, Director)

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Given the high decentralisation of the system, eHealth activities and strategies vary per region. For some of them, eHealth governance is lead by the corresponding Department of Health whilst in others is lead by Information Systems (see figure 7). These and other dimensions provide a full contextual picture of the eHealth landscape in the Italian SSN with clear evidence on regional differentiation.

Figure 7 – eHealth governance lead in Italian regions. Source: Osservatorio Sanità Elettronica, Between SpA (courtesy of Marco Mena, Director)

In sum, strategies and deployment of eHealth is fragmented in Italy and there is wide variation across regions. This picture mirrors the structure of the health care system in general. Even though, there is great variability on eHealth depending on the region, Italy has several pilot projects evaluating the use of information technology[4]. Competences are spread between DDI, Department of Health and regional politics and policy making. DDI steers a roundtable on eHealth inter-operability whose actual functioning is dubious, and the participation of the Department of Health only symbolic and weak. Most of the DDI activities currently in this area focus around the EPSOS CIP large scale pilot. As seen in figure 7 there is a trend towards moving the eHealth competence from the regional Innovation Department into the Health Department. Another priority is the Fascicolo elettronico (EHR) and a few scattered projects funded in Southern Italy. eHealth figures as an important pillar of the new ambitious eGov2012 action plan, but this plan originally foreseeing investments for a total of €1.3 billion, so far has been financed only for €130 million.
2.2 Long-term care and Chronic care management

Long-term care requires a high level of coordination between health and social services (i.e. ASLs and municipalities). In fact, even though several laws – including Law No. 328/2000 and National Health Plan 1998–2000 – clearly state that this collaboration is necessary, efforts thus far have been insufficient to integrate health and social care. In particular, municipalities have traditionally been responsible for organising the delivery of social care, and ASLs have managed health care services and social services relevant to health. The presence of different providers, however, has sometimes hampered unified social and health care services, and in response municipalities sometimes decide to delegate the delivery of social care to local health authorities. This choice often reveals a lack of coordination and partnership, and the level of integration between services is still at its early stages. From a prevention perspective, most initiatives are related to public health programmes (i.e.: vaccination; anti-smoking policies) and little is done on chronic disease management. But again, this varies across regions.

Reliable prevalence data on chronic diseases has not been found. However, when looking at cause of death, chronic diseases represent a relevant cause of deaths when compared to external causes (figure 8), of particular relevance are malignant neoplasms and circulatory diseases.

<table>
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<tr>
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<tbody>
<tr>
<td>Malignant neoplasms</td>
<td>187,0</td>
<td>195,7</td>
<td>193,6</td>
<td>182,1</td>
<td>172,1</td>
<td>172,4</td>
<td>167,3</td>
<td>166,0</td>
<td>157,6</td>
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<tr>
<td>Diseases of the blood</td>
<td></td>
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<td></td>
<td>1,8</td>
<td>2,2</td>
<td>2,5</td>
<td>2,6</td>
<td>2,5</td>
<td>2,2</td>
<td>2,3</td>
<td>2,2</td>
<td>2,2</td>
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<td>Diabetes mellitus</td>
<td>24,9</td>
<td>26,8</td>
<td>24,5</td>
<td>19,9</td>
<td>17,7</td>
<td>17,2</td>
<td>16,4</td>
<td>17,9</td>
<td>16,0</td>
</tr>
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<td>1,3</td>
<td>2,1</td>
<td>6,6</td>
<td>8,4</td>
<td>8,9</td>
<td>8,7</td>
<td>8,3</td>
<td>7,7</td>
<td>6,5</td>
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<td>Diseases nervous system</td>
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<td>13,1</td>
<td>12,9</td>
<td>13,8</td>
<td>14,0</td>
<td>14,2</td>
<td>13,9</td>
<td>18,0</td>
<td>16,4</td>
</tr>
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<td>Diseases circulatory sys.</td>
<td>408,5</td>
<td>357,3</td>
<td>288,8</td>
<td>262,7</td>
<td>224,0</td>
<td>212,1</td>
<td>205,7</td>
<td>205,0</td>
<td>170,5</td>
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<tr>
<td>Diseases respiratory sys.</td>
<td>61,4</td>
<td>53,9</td>
<td>44,2</td>
<td>36,9</td>
<td>35,3</td>
<td>30,4</td>
<td>31,3</td>
<td>34,5</td>
<td>27,6</td>
</tr>
<tr>
<td>Diseases digestive system</td>
<td>51,0</td>
<td>46,9</td>
<td>38,0</td>
<td>32,0</td>
<td>26,6</td>
<td>25,9</td>
<td>24,7</td>
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<td>External causes</td>
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<td>45,2</td>
<td>42,2</td>
<td>38,1</td>
<td>33,2</td>
<td>33,4</td>
<td>33,0</td>
<td>31,3</td>
<td>28,1</td>
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</tbody>
</table>

Figure 8 – Deaths /100000 pop. (sdr) selected causes. Source: OECD 2009

Given the existing north–south economic imbalance, regional differences in demographic and health indicators are also marked. In 2003, the proportion of the population aged 65 years or older ranged from 14.8% (Campania) to 26.27% (Liguria). In addition, fertility rates ranged from 1.17 (Tuscany) to 1.48 (Campania), while birth rates ranged from 7.3 (Liguria) to 11.4

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3 PHS and RMT market: Italy Stakeholder Interviews

As in the case of France, Germany, Sweden and the UK, Italy’s health care system could benefit from large-scale implementation of personal health systems and remote patient monitoring. In the face of similar challenges concerning the ageing population[5], the increasing prevalence of chronic diseases, constant cost pressures and the uneven geographical distribution of health care resources, there will be a clear need for new kinds of services that address these challenges in different ways than currently is possible.

Frost & Sullivan estimated that the total revenues for the Italian RMT market would amount €31.0 million in 2009 with an estimated compounded average growth rate of 10.7% from 2007 to 2014 (see figure 10). The same source also positioned the Italian remote patient monitoring market as the third largest contributor with 17.0 per cent of the total European patient monitoring market revenues, contributing to $29.7 million in 2007, and it is expected to reach $71.4 million by 2014. It is likely to grow at a CAGR of 13.3 per cent from 2007 to 2014. Nevertheless, interviews with stakeholders estimated that if small local initiatives were also accounted for, the size would go up to almost €35-40 million

<table>
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<tr>
<th>Year</th>
<th>Revenue ($ Million)</th>
<th>Revenues Growth Rate (%)</th>
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<tbody>
<tr>
<td>2004</td>
<td>23.0</td>
<td>-</td>
</tr>
<tr>
<td>2005</td>
<td>25.0</td>
<td>7.7</td>
</tr>
<tr>
<td>2006</td>
<td>27.0</td>
<td>8.0</td>
</tr>
<tr>
<td>2007</td>
<td>29.7</td>
<td>10.2</td>
</tr>
<tr>
<td>2008</td>
<td>33.1</td>
<td>11.3</td>
</tr>
<tr>
<td>2009</td>
<td>37.0</td>
<td>11.8</td>
</tr>
<tr>
<td>2010</td>
<td>41.7</td>
<td>12.7</td>
</tr>
<tr>
<td>2011</td>
<td>47.2</td>
<td>13.2</td>
</tr>
<tr>
<td>2012</td>
<td>53.8</td>
<td>14.0</td>
</tr>
<tr>
<td>2013</td>
<td>61.6</td>
<td>14.5</td>
</tr>
<tr>
<td>2014</td>
<td>71.4</td>
<td>15.9</td>
</tr>
</tbody>
</table>

Figure 10 - Remote Patient Monitoring Market: Revenue Forecasts (Italy), 2004-2014.
Source: Frost & Sullivan[5]. (Note: All figures are rounded; the base year is 2007)

The growth of the ‘Assistive Technology’ markets in Italy over the next 5-10 years will be influenced by a number of trends and developments. Some of the developments address specific concerns (such as evidence for economic rationales and clinical efficacy), the enabling infrastructure issues (such as the introduction of Electronic Health Records), and the confidence that will arise from the learning experiences of early adopters. These manageable developments need to be considered in the context of the health care system, government health policy, market education and consumer expectations.

3.1 Market drivers

All the interviewees agreed that there were major driving forces pushing the market forward. The most common cited factors were the perhaps “usual suspects” from the demand side when talking of RMT service adoption and diffusion. Although the market for RMT applications on prevention and wellness was not estimated, demographic changes due to an
ageing population (around 11.6 million people), and the increase of chronic conditions (8.5 million patients) as detailed in figure 11 represented the main drivers from the demand side.

Moreover, interviews with stakeholders also revealed that RMT has significant potential to become a major part of health care delivery in the future, but before this happens there are significant barriers that will have to be overcome. These barriers are built deep into the current structures and attitudes of the health care system and are difficult to overcome without a common vision to which all stakeholders are committed to in the long-run.

The Italian Ministry of Welfare and the regional governments were seen as key stakeholders in driving the RMT market in Italy. It was believed they had the power to “create the rules of the game” concerning RMT. These rules were mainly related to health care system design, reimbursement and incentives systems. Only after these rules had been set would other stakeholders dare to take a more active role. Some examples providing positive experiences represent the source for hope of the RMT and the potential for growth.

3.1.1 Regional Initiatives in Lombardy, Veneto and Piedmont

**Lombardy**

The Lombardy health care system differs from arrangements common to most other Italian region in respect to the role of the ASL (Local Health Unit). The ASL is the basic building block of the Italian SSN. Each Region comprises a number of ASLs depending on its size. Regions finance health care from local taxation and from transfer of funds from the Fondo Sanitario Nazionale (National Health Fund). ASLs receive a budget from the region and are responsible directly for the Aziende Ospedaliere (AO, Hospital), Medici Medicina Generale (MMG, General Practitioners), and specialist laboratories located within its territorial

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jurisdiction. Under this basic model, ASLs can be seen in aggregate both as a managing and production unit (as if AO were its arm’s length agencies). Given that it all goes through public money, there is no real separation between the service purchaser and the provider. Lombardy has introduced a purchaser-provider split by making the AO as the autonomous producing units (provider) and the ASL as the purchaser. Additionally the ASL can buy health care delivery services also from accredited private hospitals. Through DRGs, the ASL purchases a bundle of virtual services that become materialised and are reimbursed as a result of the exercise of free choice on the side of the users/patients (they choose an AO or a private hospital for service X, and the chosen producers gets reimbursement from ASL according to the corresponding DRG X). It is worth noting that, as part of this model, all health care structures being reimbursed are subject to the so called Debito Informativo Telematico (Telematic Informative Debt): they must provide the ASL in digital form and through the regional telematic network detailed information on the utilisation of the resources for the activity being reimbursed, and the ASL in turn must aggregate this information into reporting statistics and transmit them to the Region Health Department. In sum, the purchaser-provider split has lead put the ASL into a monopsony position by which they have established the need to use ICTs for invoicing and reporting purposes to all providers, as a result, the use of ICT in health care has been stimulated.

In parallel, Lombardy has evolved from pilot projects to reimbursement. The experimentation eventually leading to the reimbursed protocols for Telememonitoring for chronic health failure (and also for other technology enabled services) started at the beginning of the decade through a series of research projects and pilots funded by either the Italian Ministry of Health or the European Commission, such as for instance Criteria¹, Piano Urbano², Radici³. Even before these projects and pilots were launched, the Region had set up a group of clinicians to discuss which could be the appropriate targets and type of diseases, the kind of therapeutic paths to be followed (six months versus sine die, versus various other solutions). All these experiences were transformed into a self-standing programme of the Region going under the name of Nuove Reti Sanitarie (New Health care Networks)⁴ in the context of which the protocol for the reimbursement of TLM of patients with chronic heart failure was defined and is currently managed, together with other important initiatives in the field of telemedicine and in other areas of eHealth. In sum, as of 2006, the Lombardy Region proceeded autonomously and as a result of the years of experimentation, it introduced regional protocols (it is not formally a DRG, but it comes close to it⁵) for three services (see below). The three protocols currently reimbursed are: a) Home Telemonitoring protocol for patients with chronic heart failure; b) Post-cardio-chirurgic home based assistance. c) In 2008 a new protocol was launched for Home based palliative assistance (for terminally ill cancer patients). Both the post-chirurgic and palliative assistance are home based as a result of using ICT enabled solutions. The Region, through a number of regional level regulations⁶, has

¹ http://www.cefriel.it/criteria
² http://www.cefriel.it/pianourbano
³ http://www.radici.regione.lombardia.it/
⁴ http://www.cefriel.it/nrs
⁵ The detailed illustration available in the documentation received will be summarised in the Country Profile.

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identified, defined and priced the three protocols, and subsequently authorised the health care structures of the region requesting the reimbursement for the provision of such services to implement them with another set of Regional regulatory acts\(^7\). The reimbursed tariffs have been defined on the basis of a preliminary simulation of costs, but will be steadily adjusted for the protocol mandates that the health care structures receiving reimbursement must provide detailed information on the usage of resources, on the basis of which the tariffs for reimbursement will be adjusted. The flow of information required from the Region to the reimbursed health care is part of the Debito Informativo Telematico, mentioned earlier. Additionally, the protocols foresee a structured evaluation process with the gathering and analysis of data on clinical outcomes, cost-effectiveness and organisational outcomes, patients satisfaction. The supporting regulatory acts explicitly foresee that: "\textit{The protocols are carried out only under the full responsibility of the health care organisations authorised by the Region, but can be implemented with the support of external Centri Servizi (Services Services) for what concerns the technological support}". It is a B2B2C model: hospitals decide to use the services and enrol the appropriate patients, then they pass them for the technological component of the monitoring part to the suppliers, the Region reimburses the hospital, which in turn pays the supplier. Before this, however, the various hospitals must explicitly request to be included by the Region in the list of organisation authorised to implement, and being reimbursed for, the various protocols. Furthermore, once authorised, when the hospitals decide to actually launch the services they must further operationalise the detail of service provision and negotiate with their ASL the conditions of reimbursement.

\textbf{Veneto}

The Veneto region has long standing experience of home care and their activities in telemedicine have recently been acknowledged at European level. This has been the result of the strong leadership and vision at regional level which has led to plenty of initiatives in telemedicine. The most recent example of these initiatives have been the investment through a tender procedure of €200 a year (or €0.6 per day) for each of the 25,000 patients for a 5-year period (not 25,000 every year) that are currently being monitored through telemedicine services. This cost includes exclusively the technology to be used and does not include additional resources – i.e.: health care professionals – accompanying the technology. The device and overall system to be used entails some level of incorporated intelligence: gathered data are steady processed and alert are sent in case of abnormal patterns. The process was described as follows: the region has elaborated a multidimensional fiche (known as SVAMA) where individuals are assessed along three dimensions: economic capabilities, social conditions and health status. Looking at these three dimension a local Committee composed by the ASL, the hospitals, and the GPs will decide which patients should be enrolled in the programme and pass them to the provider, who cannot object to the decision. The service of the provider will gather a number of vital signs (ECG, blood pressures, and others), perform an automatic preliminary analysis and then transmit the output to the Distretto Socio-Sanitario (an intermediate body between the ASL and the hospitals) where a specialist full time employee of the ASL (so not a cost charged by the provider) periodically look at the data and reporting transmitted by the provider. In case of abnormal patterns (but not in case of full blown emergency when the patient is immediately brought to the hospital) the specialist would decide either for a change in the pharmacological therapy by consulting the GP.

\footnote{DGR N. VIII/2471 of 11.05.2006 and with DGR N.VIII/7933 of 06.08.2008 and with the recent DGR N. VIII/10072 of 7.8.2009.}

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responsible for the patient or for a short hospitalisation. According to the Veneto region all of
the service requires a minimal labour input from personnel paid for by the Region.

Piedmont

Given the natural mountainous setting of the Piedmont region surrounded on three sides by
the Alps, first initiatives on telemedicine and telemonitoring in this area have also aimed at
facilitating access. The most recent example have been a tender adjudicated for RMT services
targeting Chronic Heart Failure (CHF) patients population in remote mountainous areas. The
cost per patient depends on their specific health status and three bands have been defined
accordingly:

- CHF € 273 per patient per month (€ 9 per patient per day)
- CHF € 232 per patient per month (€ 7.7 per patient per day)
- CHF € 253 per patient per month (€ 8.4 per patient per day)

The technology and the operationalisation involve added value process following a home-
based telemonitoring (HBT) model. Therefore, the model is fully integrated and as part of it, a
fair deal of work is performed by nurses and highly specialised 24-hour call centres.
Moreover, it occurs in remote and difficult to reach areas, thus an additional constraint when
making clinical decisions. To start with, the project was launched involving 400 patients; the
possibility of rolling it out to a larger scale will depend on the preliminary results of this
experience

3.1.2 Initiatives at National Level

Currently the former Ministry of Health (today the Department of Health within the Ministry
of Welfare), is allegedly developing a state of the art analysis of all existing telemedicine and
telemonitoring experiences in Italy to then possibly proceed with a law on Telemedicine
which according to interviews may take place in 2013-2014.

Additionally, the Department of Health launched a survey to the Regions on telemedicine
practices but the rate of reply was very low, partly due to the fact that Regions are
increasingly independent from the Ministry. Following this first attempt, the central
government recently outsourced a state-of-the-art study to an external organisation, aiming to
gather evidence from the regional experiences. As a result an eCare Observatory
(http://www.onecare.cup2000.it/) was set up as a web platform where initiatives are self-
reported. Currently the platform includes some 700 cases, without a clear organised taxonomy
to search among them with various examples of initiatives. Out of these initiatives, around
11.2% would be within the RMT market and 56% would fall within the broadly defined term
Telecare; the rate of sustained services versus pilots/experimental stages was estimated at 2 in
10.

Beyond these two initiatives, the Department of Health has not come up yet with a concrete
action plan and guidelines on Telemedicine. Four years ago, when it still was the Ministry of
Health, there was a plan to include a set of Telemedicine protocols (DRG with related tariffs
for reimbursement) within the LEA; unfortunately it did not crystallise.

Is social care the alternative for market take up? Indeed, as a result of both National and
Regional level regulation and provisions, social and health care overlap. Home services
(servizi domiciliari) falls within the Dept of Family, but then there are the Piani Socio-
Sanitari (Social-Health Plans) falling under the joint jurisdiction of the Region’s Department of Family and of the Department of Health (for policy making and overseeing) and jointly implemented by ASL and Municipalities social services. Interviewees considered the current developments in the provision of remote home care services as relevant phenomena and as the alternative entry points for the future development of basic and advanced Telemonitoring services. In this respect it is worth reporting that the Regions has already implemented a system that resemble the one designed in the Spanish Ley de Dependencia. The Regional Department of Family provide individuals in need of long term care (or their relative) with an Health Voucher that they can decide to use as they prefer. In addition there are regional level and municipality level services of tele-assistance and surveillance. Yet, most of the services currently being provided as tele-assistance or telecare are simply based on call centres and a very basic button device that the elderly can push in case of emergencies. It is nothing even close to domotics, independent living, AAL and the likes. There are not yet examples of complex network of sensors for monitoring situational and health parameters of elderly who may suffer from multi-chronic pathologies (co-morbidity). These would require complex geriatric approaches supported by sophisticated technologies, of which in the Regions there are only a couple of very experimental pilots.

### 3.2 Market Barriers

Italian stakeholders identified a number barriers hindering RMT market growth. On a general level it should be noted that the majority of stakeholders agreed, that current barriers are not technical. The technology is there, but organisational, financial, social and cultural barriers prevent the large-scale adoption of RMT.⁸

#### 3.2.1 Lack of incentives and reimbursement

The lack of a favourable incentive framework is a key barrier. Until Telemedicine and Telemonitoring are not included into the LEA provided with a reimbursed DRG decided at national level no take up of the market can be expected from hospitals. Additionally, interviewees further elaborated on the GPs as a key bottleneck. Telemedicine and Telemonitoring are part of what is generally referred to in Italy as “medicina extra muros” (beyond wall medicine) or also “medicina territoriale” (territorial medicine), where both expressions refer generally and generically to all the delivery of care occurring outside of the hospitals and of specialist ambulatory. Within the Italian SSN, the key pillar of such territorial delivery of care is (or should be) the GP, who as such should have an important role in the recruitment of patients into home based and technology supported disease management of chronic patients and also contribute to the actual delivery of remote care. Yet, in the Italian system, GPs represent a very peculiar case of a professional category that is paid very well with public money but has the same freedom of any professionals working in the market as a result of their strong lobby being well represented in parliament and high level authorities cannot mandate them anything without negotiations and monetary incentives. Moreover, the penetration of the EMR amongst GPs is not high enough to take this forward. As many hospitals, for reason of bed occupancy scarcity, are now practicing early dismissal of chronic patients it should be the responsibility of the GPs to start the disease management process.

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⁸ Although technical issues were not seen as actual barriers, it was noted that certain technical standards concerning interoperability and access to Electronic Patient Records are requirements for significant RMT market growth.
They should select among their patients with chronic conditions those suited for Telemonitoring and collaborate with Telemonitoring specialist organisations in launching and implementing such services. Under this scenario the likelihood of large scale take up would be higher than under the current situation where the decision lay with the hospitals. Maybe, Italy could learn some lessons from the "Quality Outcome Framework" that England included in their GP payment system.

3.2.2 The need for evidence

Interviewees also stated that in Italy there is not yet a robust counterfactual evidence on the outcomes of Telemonitoring. There are only very small clinical trials not enabling to draw any conclusive assessment of the results of Telemonitoring. The only large and randomised control trials in Italy are those conducted and published by Simonetta Scalvini, one of the founders of the Health Telematic Network. A common sense rule of thumb assessment developed by the Region, though, is that on average Telemonitoring seem to reduce hospital admission (re-admission) by 19%. In sum, additional cost-effectiveness studies would assist in developing the business case.

4 Conclusions and summary

The Italian market for RMT is one of the largest in Europe, yet, for the market to fully develop, there are a series of barriers that need to be overcome. These can be summarised as:

- Develop the appropriate incentives to overcome GPs psychological difficulty to leave old medical traditions often due to the absence of telemedicine dissemination actions and common use of information technology tools in daily health care;
- Stimulate the development of chronic disease management programmes;
- Include telemedicine applications in the DRG list for reimbursement;
- Develop a robust business case for telemedicine applications in order to ensure sustainability;
- Address the current complexity of e-Health systems governance and, also considering the need for a common telemedicine legal framework and the absence of substantial public and private funding to support health institutions and physicians to set up telemedicine services;
- Coordination between central government and regional government;
- Address the sharp separation and lack of joined-up activity between DDI and the Department of Health of the Ministry of Welfare. DDI should ensure coherence in the work toward the digitalisation of public services, but the Department of Health does not accept intromission into its core area. The same kind of “turf war” logic can be found in most Regions among the regional Departments of Health, Innovation & Information Society, and of Budget; and
- The need for additional coordination between health and social care services.

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ITALY RMT MARKET SUMMARY

- The Italian RMT market is the third largest contributor of the total European RMT market in terms of revenues representing 17% of the total European market

- The demand side represents a market driver for the RMT market due to the ageing population and the increase in chronic diseases

- There is a political commitment at central level towards ICT applications in health care, however:
  - RMT are not specifically included within this strategy and
  - the nationals strategy for territorial medicine and supporting ICT enabled services is not clear

- Lombardy, Veneto and Piedmont represent the main regions providing (quasi) successful examples of RMT applications; on the other hand, the regional health inequalities currently identified in the Italian health care system are also reflected in the RMT experiences

- The main barriers for the RMT market to fully develop are lack of incentives to both GPs and hospitals as well as the need for evidence and cost-effectiveness studies on RMT applications

- Potential for RMT in a social care setting but organisational boundaries major barriers for implementation. Need for inter-organisational co-operation:
  - between health and social care services; the newly established Ministry of Welfare (former Ministry of Health) aims to mark a trend towards coordination of these services
  - between central and regional governments

- Future development and emphasis of chronic disease management programme could contribute positively to increase in RMT applications
## Appendix - RMT / PHS RELATED projects that were identified during the interview process in Italy

<table>
<thead>
<tr>
<th>Project</th>
<th>Description</th>
<th>Funding model</th>
<th>Type of innovation</th>
</tr>
</thead>
<tbody>
<tr>
<td>eCare</td>
<td>A web platform for self reporting initiatives</td>
<td>Outsourced by the DoH</td>
<td>Dissemination of best practices</td>
</tr>
<tr>
<td>Non Piu Soli</td>
<td>This project addresses both telecare and teleassistance/telemonitoring services. The telecare service provides people with psychological support, medical assistance and supply of meals and medicines. These services can all be accessed through home speaker-voice devices connected to the telephone, furnished with remote control and placed in the homes of older people. The telemonitoring service uses ICT devices supplied to the user that automatically monitor their health conditions (blood pressure, temperature, etc) and alert emergency services when needed. The ICT devices are part of SILVERNET telemonitoring system: a local peripheral unit is connected with the telephone line directly in the house of the patient and the older person is provided with a body-worn ICT tool, an innovative bracelet similar to a watch that can generate alarms manually or automatically. This telecare service is provided by the Municipality of Rome, where over 4,000 people are using the telecare service and more than 3,000 are using the teleassistance/telemonitoring service.</td>
<td>patients</td>
<td>Process, organisational</td>
</tr>
<tr>
<td>CardioNet</td>
<td>Use of telecardiology systems as part of the CardioNet network on telecardiology of the eldest involving home care centres services and the cooperation of pharmaceutical services assisting in the delivery of the services. The technology allows for heart beat monitoring through an ECG and in case of irregularity a 24-hour call centre with cardiologists is available.</td>
<td>Lombardy region</td>
<td>Process, organisational</td>
</tr>
<tr>
<td><strong>Asclepio</strong></td>
<td>Similar to cardioNet and additional telespirometry systems, both for patients in penitentiary centres</td>
<td>Ministry of Justice</td>
<td>Product, organisational</td>
</tr>
<tr>
<td><strong>Non Piu Soli:</strong></td>
<td>This project addresses both telecare and teleassistance/telemonitoring services. The telecare service provides people with psychological support, medical assistance and supply of meals and medicines. These services can all be accessed through home speaker-voice devices connected to the telephone, furnished with remote control and placed in the homes of older people. The telemonitoring service uses ICT devices supplied to the user that automatically monitor their health conditions (blood pressure, temperature, etc) and alert emergency services when needed. The ICT devices are part of SILVERNET. Non Piu Soli: telemonitoring system: a local peripheral unit is connected with the telephone line directly in the house of the patient and the older person is provided with a body-worn ICT tool, an innovative bracelet similar to a watch that can generate alarms manually or automatically. This telecare service is provided by the Municipality of Rome, where over 4,000 people are using the telecare service and more than 3,000 are using the teleassistance/telemonitoring service</td>
<td>Rome municipality</td>
<td>Product, organisational</td>
</tr>
<tr>
<td><strong>San Ferdinando of Puglia Project:</strong></td>
<td>This is now a mainstreamed service provided by the Municipality of San Ferdinando di Puglia (municipality of approx. 15,000 citizens) which has been conceived to provide constant help to the older people through a telecare network that utilizes new ICTs. The service (through the dedicated operating centre) and ICT tools installed in the older persons’ living environment are supplied by Telbios on behalf of the Municipality</td>
<td>Municipality of San Ferdinando di Puglia</td>
<td>Process, organisational</td>
</tr>
<tr>
<td><strong>CHRONIOUS</strong></td>
<td>The project addresses a smart wearable platform, based on multi-parametric sensor data processing, for monitoring people suffering</td>
<td>EU funding</td>
<td>Product, process,</td>
</tr>
</tbody>
</table>

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from chronic diseases in long-stay setting. It is constantly monitoring their activity using audio observation methods and activity sensors while at the same time tracking their medical condition via vital signs sensors. Any trait of abnormal health status and possible alerting incidents are detected by CHRONIOUS Intelligence. The system generates alerts in case of invalid medical data or if current activity and behaviour lay outside the well established activity patterns and locomotion behaviour. CHRONIOUS proposes an adaptive and ubiquitous chronic disease management system that offers continuous monitoring to patients by using several sensors either in a form of a wearable solution or scattered in the patient’s living environment and a series of “intelligent” services to health care providers and organisations that aid them in the monitoring of their patients. An overarching goal of the proposed system is to underline and emphasize the partnership between technology-centered and human-centered sciences as technologies for sensing, computing and communications become increasingly ubiquitous.

| **MyDoctor@Home** | Telecom Italia, together with Hospital San Giovanni Battista in Turin, started the trial “MyDoctor@Home” service by Telecom Italia, in order to telemonitor all the patients of the service “Home Hospitalisation”, directed by doctor Nicoletta Aimonino Ricauda at the hospital’s geriatric ward. MyDoctor@Home allows the patients to detect their own physiologic parameters at home, through medical portable devices provided with Bluetooth technologies, and to transmit them via cell phone to an operating platform located at Telecom Italia’s data centers, and accessed by the assistance team. Through their computers, doctor enter the platform supporting the service, and check the therapy course remotely; patients can receive automatic text messages, set by the doctor and reminding them to proceed with the surveying or to take their medicines. The clinical study’s aim is to show the benefits of telemonitoring in terms of... | organisational | private | Process, organisational |
of better quality of life for the patients, and of less welfarist burden for the hospital, with a consequent higher level of service accessibility for the citizens.

<table>
<thead>
<tr>
<th>Multispecialist teleconsulting for domiciliary assistance</th>
<th>The project provides home visits by a nursing staff, assisting the patient and gathering clinical data which will later be sent to the hospitals’ specialist doctors. The transmission is performed by a simple portable PC, linked to the hospital’s network through a VPN which operates in connection to a USB key.</th>
<th>Venice local health unit</th>
<th>process, organisational</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRITERIA</td>
<td>Research project experimenting innovation models to offer home services to patients suffering from heart disease of heart failure. Two models were explored: post-surgery home rehabilitation and home telemonitoring</td>
<td>Ministry of Health</td>
<td>Process, organisational</td>
</tr>
<tr>
<td>RADICI</td>
<td>The objectives of RADICI are:</td>
<td>Ministry of Health</td>
<td>Process, organisational</td>
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<tr>
<td></td>
<td>- to develop a model of assistance</td>
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<td></td>
<td>- to evaluate the experience by developing criteria and indicators to be measured uniformly</td>
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<tr>
<td></td>
<td>- to create a networked model for the organisation of the health service based on needs and diagnose</td>
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<tr>
<td></td>
<td>- to populate the model</td>
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<tr>
<td></td>
<td>- to develop a transitory DRG for this treatment</td>
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<tr>
<td>Nuove Reti Sanitarie (NRS)</td>
<td>The project experiments telemonitoring services and home services to post-surgery patients. The target diseases addressed so far are home treatment and monitoring to patients under the following conditions: Home Telemonitoring protocol for patients with chronic heart failure;</td>
<td>Ministry of Health</td>
<td>Process, financial and organisational</td>
</tr>
</tbody>
</table>

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| epSOS-Large Scale Pilot | Smart Open Services for European Patients - epSOS, (previously known as S.O.S. - "Smart Open Services", an Open eHealth initiative for a large scale European pilot of patient summary and electronic prescription) is a Europe-wide project organised by 27 beneficiaries representing twelve EU-member states, including ministries of health, national competence centres and numerous companies. This makes it the first European eHealth project clustering such a large number of countries in practical cooperation. The overarching goal of epSOS is to develop a practical eHealth framework and an Information & Communication Technology (ICT) infrastructure that will enable secure access to patient health information, particularly with respect to basic patient summaries and ePrescriptions between different European health care systems. To achieve this goal, the national entities cooperating within epSOS test both services in pilot applications, which interconnect national solutions. The approach, which is based on advanced and distinct use cases and associated infrastructural components, aims to deliver both a methodological process and durable implementations: building blocks. These building blocks will form the basis for a longer term, pan-European approach to develop interoperable service solutions. | EC - Competitiveness and Innovation Framework Programme (CIP) | Process, organisational |
| Valli d’argento | After a two-years pilot the project has turned into a mainstreamed service. Telecare is supplied free of charge to 150 older people resident in the inland valleys in the Genoa district with the objective to reach 250 users by the end of 2009. Each person is supplied with a small transmitting device to be worn whilst staying in the house. The service involves a monitoring centre operating on a 24 hours basis, | Genoa district | Product, organisational |

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365 days a year.
6 References


