

Country Brief: Italy

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October 2010



European Commission,
DG Information Society and Media,
ICT for Health Unit



European Commission
Information Society and Media



About the eHealth Strategies study

The eHealth Strategies study analyses policy development and planning, implementation measures as well as progress achieved with respect to national and regional eHealth solutions in EU and EEA Member States, with emphasis on barriers and enablers beyond technology. The focus is on infrastructure elements and selected solutions emphasised in the European eHealth Action Plan of 2004.

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Acknowledgements

This report was prepared by empirica on behalf of the European Commission, DG Information Society & Media. empirica would like to thank Jos Dumortier, Time.lex CVBA for the review of the section on legal issues, and Professor Denis Protti (University of Victoria) for valuable feedback.

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Bonn / Brussels, September 2010

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Executive summary

In Italy eHealth development is focused on the overall plan of the government to implement the new “National Healthcare Information System” (NSIS). This is an information system and a governance tool to assist, monitor and oversee all primary levels of healthcare services. Apart from the overall plan for the NSIS, the Permanent Working Board for eHealth TSE¹ published other documents: First “A policy for eHealth” in 2005 and then the “Architectural strategy for eHealth” in March 2006. Both documents employ objectives of the European Union from the eHealth Action Plan.

Another relevant document is the “E-Government Plan 2012” from January 2009. It aims at encouraging government innovation and the increase of online services, including in the field of healthcare. The plan consists of 80 digital innovation projects, including an electronic health record and the digitisation of medical prescriptions and certificates.

In order to consider Italy’s position regarding eHealth interoperability objectives the following eHealth applications have been examined: patient summaries and electronic health records, ePrescription, standards and telemedicine. In overview Italy’s situation is as follows:

At a regional level many patient summary pilots are running and are highly developed. Some have already fully deployed a patient summary that includes administrative data and medical history. At a national level there are also several patient summary pilots which are strongly linked to the “E-Government Plan 2012”.

Italy is also involved in the European epSOS project where the Italian initiative, IPSE, focuses on the trans-regional transfer of medical data and the establishment of a patient summary as well as ePrescription.

Regional pilots for ePrescription have run in Italy since 2002. In the Emilia-Romagna region the programme “SOLE – Online Healthcare”² aims to develop an integrated telematic network for the interoperation of hospitals and healthcare professionals and in this is included electronic management of prescriptions.

Regarding international standards Italy is a HL7 affiliate. At a national level it employs the “bricks” programme to establish a semantic toolkit in order to classify and codify concepts and find a uniform approach. Other areas such as the development of clinical coding for the patient record and performance measures are handled at a regional level.

Italy’s background in telemedicine includes the €50 million (TELEMED) initiative in 1991 that for 10 years represented a focal point for several applications. Many telemedicine pilots and projects are currently ongoing in Italy including the “Renewing Health” Project, which started at the beginning of 2010, and aims to implement large-scale real-life test beds for evaluation and validation purposes.

¹ Tavolo di lavoro Permanente per la Sanità Elettronica

² emilia-romagne digitale

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1 Introduction to the report

1.1 Motivation of the eHealth Strategies study

Following the *Communication* of the European Commission (EC) on “eHealth – making healthcare better for European citizens: An action plan for a European eHealth Area”³ Member States of the European Union (EU) have committed themselves to develop and issue national roadmaps – national strategies and plans for the deployment of eHealth applications addressing policy actions identified in the European eHealth Action Plan.

The *2004 eHealth Action Plan* required the Commission to *regularly monitor* the state of the art in deployment of eHealth, the progress made in agreeing on and updating national eHealth Roadmaps, and to facilitate the exchange of good practices. Furthermore, in December 2006 the EU Competitiveness Council agreed to launch the *Lead Market Initiative*⁴ as a new policy approach aiming at the creation of markets with high economic and social value, in which European companies could develop a globally leading role. Following this impetus, the Roadmap for implementation of the “eHealth Task Force Lead Market Initiative” also identified better coordination and exchange of good practices in eHealth as a way to reduce market fragmentation and lack of interoperability.⁵

On the more specific aspects of electronic health record (EHR) systems, the recent *EC Recommendation on cross-border interoperability of electronic health record systems*⁶ notes under “Monitoring and Evaluation”, that “in order to ensure monitoring and evaluation of cross-border interoperability of electronic health record systems, Member States should: consider the possibilities for setting up a monitoring observatory for interoperability of electronic health record systems in the Community to monitor, benchmark and assess progress on technical and semantic interoperability for successful implementation of electronic health record systems.” The present study certainly is a contribution to monitoring the progress made in establishing national/regional EHR systems in Member States. It also provides analytical information and support to current efforts by the European Large Scale Pilot (LSP) on cross-border Patient Summary and ePrescription services, the epSOS - European patients Smart Open Services - project.⁷ With the involvement of almost all Member States, its goal is to define and implement a European wide standard for such applications at the interface between national health systems.

Earlier, in line with the requirement to “regularly monitor the state of the art in deployment of eHealth”, the EC already funded a first project to map national eHealth strategies – the eHealth ERA “Towards the establishment of a European eHealth Research Area” (FP6 Coordination Action)⁸ - and a project on “Good eHealth: Study on the exchange of good

³ European Commission 2004

⁴ European Commission 2007

⁵ European Communities 2007

⁶ European Commission 2008

⁷ European Patients Smart and Open Services (epSOS)

⁸ eHealth Priorities and Strategies in European Countries 2007

practices in eHealth⁹ mapping good practices in Europe - both of which provided valuable input to the present *eHealth Strategies* work and its reports. Member States' representatives and eHealth stakeholders, e.g. in the context of the *i2010 Subgroup on eHealth* and the annual European High Level eHealth Conferences have underlined the importance of this work and the need to maintain it updated to continue to benefit from it.

This country report on Italy summarises main findings and an assessment of progress made towards realising key objectives of the eHealth Action Plan. It presents lessons learned from the national eHealth programme, planning and implementation efforts and provides an outlook on future developments.

1.2 Survey methodology

After developing an overall conceptual approach and establishing a comprehensive analytical framework, national level information was collected through a long-standing Europe-wide network of national correspondents commanding an impressive experience in such work. In addition, a handbook containing definitions of key concepts was distributed among the correspondents to guarantee a certain consistency in reporting. For the report on Italy, Elena Tamburini provided information on policy contexts and situations, policies and initiatives and examples for specific applications. At the moment she is working as a marketing strategy and sales director at I+ srl, which provides integrated telecare solutions and assisted living services for clinical monitoring. Thereby, she is involved in activities on best practices and strategies studies in the eHealth domain.

The key tool to collect this information from the correspondents was an online survey template containing six main sections:

- A. National eHealth Strategy
- B. eHealth Implementations
- C. Legal and Regulatory Facilitators
- D. Administrative and Process Support
- E. Financing and Reimbursement Issues
- F. Evaluation

Under each section, specific questions were formulated and combined with free text fields and drop-down menus. The drop-down menus were designed to capture dates and stages of development (planning/implementation/routine operation). In addition, drop-down menus were designed to limit the number of possible answering options, for example with regard to specific telemedicine services or issues included in a strategy document. The overall purpose was to assure as much consistency as reasonably possible when comparing developments in different countries, in spite of the well-known disparity of European national and regional health system structures and services.

Under Section B on eHealth implementation, questions regarding the following applications were formulated: existence and deployment of patient and healthcare

⁹ European Commission; Information Society and Media Directorate-General 2009

provider identifiers, eCards, patient summary, ePrescription, standards as well as telemonitoring and telecare.

The data and information gathering followed a multi-stage approach. In order to create a *baseline* for the progress assessment, the empirica team filled in those parts of the respective questions dealing with the state of affairs about 3 to 4 years ago, thereby drawing on data from earlier eHealth ERA reports, case studies, etc. to the extent meaningfully possible. In the next step, national correspondents respectively partners from the study team filled in the template on recent developments in the healthcare sector of the corresponding country. These results were checked, further improved and validated by independent experts whenever possible.

Progress of eHealth in Italy is described in chapter 3 of this report in the respective thematic subsections. The graphical illustrations presented there deliberately focus on key items on the progress timeline and cannot reflect all activities undertaken.

This report was subjected to both an internal and an external quality review process. Nevertheless, the document may not fully reflect the real situation and the analysis may not be exhaustive due to focusing on European policy priorities as well as due to limited study resources, and the consequent need for preferentially describing certain activities over others. Also, the views of those who helped to collect, interpret and validate contents may have had an impact.

1.3 Outline

At the outset and as an introduction, the report provides in chapter 2 general background information on the Italian healthcare system. It is concerned with the overall system setting, such as decision making bodies, healthcare service providers and health indicator data.

Chapter 3 presents the current situation of selected key eHealth developments based on detailed analyses of available documents and other information by national correspondents and data gathered by them through a well-structured online questionnaire. It touches on issues and challenges around eHealth policy activities, administrative and organisational structure, the deployment of selected eHealth applications, technical aspects of their implementation, legal and regulatory facilitators, financing and reimbursement issues, and finally evaluation results, plans, and activities

The report finishes with a short outlook.

2 Healthcare system setting

2.1 Country introduction¹⁰

Italy is a parliamentary republic. The country consists of 20 regions, 105 provinces and 8.100 municipalities. The Italian state is undergoing a profound transformation process towards a federalist structure, which has transferred exclusive legislative and executive powers to the regions in several fields, including healthcare, environment, education and training, local security, and others. Local and national administrations are working together, as regions and ministries attempt to define the new boundaries in the shifting balance of power.

Thereby, regional authorities are central players in the evolution of the Italian government structure toward a federal form. Collaboration among public administrations has been identified as a key success factor of the government initiative for Italian eGovernment. In fact regions have the responsibility to develop telecommunication infrastructure and services to enable the interoperability of local administrations.

Italy's healthcare system is also regionally based and provides universal coverage free of charge at the point of service. The system is organised at three levels: national, regional and local. The national level is responsible for ensuring the general objectives and fundamental principles of the national healthcare system. Regional governments, through the regional health departments, are responsible for ensuring the delivery of a benefit package through a network of population-based health management organisations (local health units) and public and private accredited hospitals.

The figure below summarises key facts on the Italian healthcare system:

Key facts about the Italian healthcare system:11

Life expectancy at birth: 81.6 years

Healthcare Expenditure as % of GDP: 8.7% (OECD 2007)

WHO Ranking of Healthcare systems: rank 2

Public sector healthcare expenditure as % of total healthcare expenditure:
76.5% (OECD 2007)

¹⁰ eUser 2005

¹¹ Data from World Health Organization 2000; World Health Organization 2009

2.2 Healthcare governance¹²

Decision making bodies, responsibilities, sharing of power

The main institutions in the Italian healthcare system are the Ministry of Health and its Department of Health Care Planning, which is responsible for defining the NHS health targets through the National Health Plan. The Ministry of Health manages the National Health Fund and allocates resources to regions. Consistent with the emerging federal political system, its role in financing will be restricted to allocating the resources from the global national budget and targeted towards ensuring uniform availability of resources in the regions. The regions will finance the remaining healthcare expenditure from their own sources. The Ministry of Health operates in close collaboration with two public bodies: the National Health Council providing technical and scientific advice to the Ministry and the National Health Institute, responsible for scientific and technical research.

In accordance with the decentralisation process occurring in the NHS since 1992, the administrative control performed by the personnel of the Ministry of Health regarding the functioning, effectiveness and efficiency of public hospitals and local health units is becoming less relevant. These activities have increasingly been devolved to the regional health departments and to local health units.

Regional governments, through their departments of health, are responsible for pursuing the leading national objectives posed by the National Health Plan at regional level. Regional health departments are required to guarantee the benefit package to be delivered to the population through a network of population-based healthcare organisations (local health units) and public and private accredited hospitals. They are responsible for legislative and administrative functions, for planning healthcare activities, for organising supply in relation to population needs and for monitoring the quality, appropriateness and efficiency of the services provided.

Healthcare service providers

Primary care is provided by general practitioners, paediatricians and self-employed and independent physicians working alone under a government contract who are paid a capitation fee based on the number of people (adults or children) on their list. Although primary care physicians are given financial incentives to share clinic premises with their colleagues, they usually work in single practices.

The local health unit is primarily concerned with protecting and promoting public health and responsible for achieving the health objectives and targets established by national and regional planning.

Specialised ambulatory services, including visits and diagnostic and curative activities are provided either by local health units or by accredited public and private facilities. I+D ties with which local health units have agreements and contracts. People are allowed to access specialist care only after approval by their general practitioner, who is responsible for the referral. Once the general practitioner has authorised the visit or the procedure, people are free to choose their provider among those accredited by the NHS.

¹² Donatini, Rico et al. 2001

Figure 1: Important features of primary healthcare organisation in Italy

Political/administrative unit responsible for primary healthcare	Mainly local district responsibility and local health units; big hospitals with financial autonomy.
Consumer Choice	Free choice of GP within a list patient system.
Financing	Mainly tax-based.
Public or private providers	GPs working alone under a government contract are paid a capitation fee based on the number of people on their list.
Gatekeeping function of the GP	GP gatekeeping function for access to secondary care. GPs write pharmaceutical prescriptions and certifications and visit patients at home if necessary.
Integrating health: initiatives for coordination	The regions hold the legislative power on health protection, in the framework of fundamental principles defined by the State. But the reform of the Constitution (Constitutional Law number 3 of October 18th, 2001) has radically changed the roles and responsibilities of the State and Regions. The main decisions are agreed within the "State-Regions Conference", i.e. a committee made of National (federal) Ministries and Regional Authorities.

2.3 Recent reforms and priorities of health system/public health

Currently ongoing reforms in the health and social care systems¹³

The reforms of the past seven years in Italy have effected the transformation of the small local health authorities (USL). They have received far greater powers, budgets, and budgetary discretion – the so-called process of “aziendalisation”. At the same time, many USLs have been merged to form larger health authorities, with greater market purchasing power and procurement expertise. The government intends that all USLs will eventually be merged to form larger units.

An important reform was applied in 2001¹⁴, when the Italian Constitution was changed such that the national government now sets the “essential levels of care” regions must meet, but regional governments still control their own autonomous budgets and distribute resources to the local level¹⁵.

¹³ Tanner 2008; eHealth Europe 2009

¹⁴ Law no 3, 18 October 2001.

¹⁵ Also known as LEA – Livelli Essenziali di Assistenza.

In theory, under the “fiscal federalist” provisions of this reform, discretionary central transfers should have dropped sharply, local tax bases and tax sharing should have increased, and “equalising” transfers should have been standardised and linked to objectives for controlling costs and increasing quality. However, poorer regions and powerful special interests have strongly resisted these changes. The reform therefore remains incomplete, and financial transfers from the central government are still based on historical spending patterns.

In general, the Italian health service, the Sistema Sanitario Nazionale (SSN), is undergoing major structural reforms, which the national healthcare information programme is designed to support.

2.4 ICT use among general practitioners

This section provides a brief overview of relevant ICT related infrastructure and services data. It draws on earlier studies commissioned by the EC, notably the Indicators eHealth Study . Although the results of this study date from 2007 and may therefore not reflect latest changes, a more recent pan-European survey is not available¹⁶.

86% of the Italian GP practices use a computer; a figure which puts the country on a par with its European neighbours. Currently 71% of the Italian practices are connected to the Internet and broadband connections can be found in almost half of the practices (49%).

With regard to the use of eHealth applications, the best results are achieved for the storage of administrative data and the use of a computer for consultation purposes.

The storage of electronic patient data is comparatively common in Italy. At least one type of individual medical data is stored in 83% of the GP practices.

A computer is available in the consultation room in 84% of the Italian GP practices. Nearly all of these GPs actually use the computer for consultation purposes with the patients (81%).

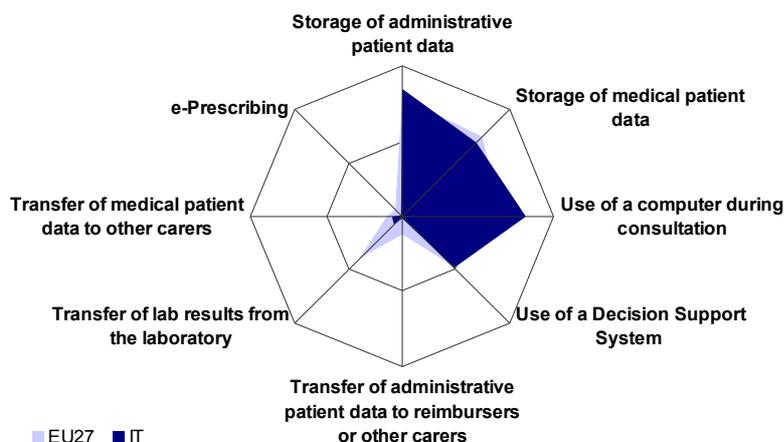
69% of the Italian GP practices use of a Decision Support System.

In Italy the exchange of electronic patient data is not yet well established. 3% of Italian GPs exchange administrative data with other care providers. With 1% of GP practices exchanging administrative data with reimbursers.

8% of the GP practices receive results from laboratories. 7% of the Italian GP practices exchange medical patient data with other carers.

Electronic exchange of prescriptions, commonly referred to as ePrescribing, is practiced by 1% of GP practices in Italy.

¹⁶ ICT and eHealth use among General Practitioners in Europe 2007

Figure 2¹⁷: eHealth use by GPs in Italy

Indicators: Compound indicators of eHealth use (cf. annex for more information), % values. Source: empirica, Pilot on eHealth Indicators, 2007.

3 eHealth Strategies survey results

The following sections present the results of the eHealth Strategies country survey. In a first section, the eHealth policy actions undertaken in Italy are presented. This is followed by a presentation of administrative and organisational measures taken. Section 3.3 presents results on key eHealth applications. Section 3.5 focuses on the technical side of eHealth, namely the role of patient and healthcare provider identifiers and the role of eCards. Legal and regulatory facilitators as well as financing and reimbursement issues are presented in the following chapters, 3.6 and 3.7. The report concludes with evaluation activities (3.8) in the country and an outlook (4.).

3.1 eHealth policy action

The eHealth strategies of EU and EEA countries are not always classified as strategies by the countries themselves. Some countries may indeed publish a policy document which refers to the ICT strategy in the healthcare sector. Other countries such as France and Germany have enshrined the central eHealth activities in legislation that governs the healthcare sector. In Germany, the relevant law is the law on the modernisation of healthcare; in France the introduction of an electronic medical record is included in a law concerning social security.

Sometimes documents from domains such as eGovernment strategies or Information Society strategies may contain provisions which concern eHealth. In cases where the

¹⁷ The notion of „compound indicator“ designates an indicator build from a set of other indicators/survey questions regarding the same topic. The compound indicator reflects an average calculated from different values. (see Annex) The final results of the study on eHealth Indicators is available at www.ehealth-indicators.eu.

healthcare system is decentralised, i.e. where power is delegated to the regional level, regional authorities may even publish strategy documents regarding eHealth.

3.1.1 Current strategy/roadmap¹⁸

In Italy, the landmark decision for eHealth development is not connected to a concrete strategy or roadmap, but rather to the overall plan of the government to implement the new “National Healthcare Information System” (NSIS). This is an information system and a governance tool to support, monitor and oversee the fundamental levels of healthcare services, in short LEA¹⁹.

In 2001, the Ministry of Health and the Conference of Regions “Conferenza Stato Regioni” agreed upon the joint development and operation of a new health information system. The objective of the NSIS is to provide organisations within the healthcare administration and service with core electronic applications and to ensure that they conform to nationally agreed standards and are interoperable.

Another central goal of the initiative has also been to provide regions with reporting structures and data collection systems that would allow them to manage the planning and provision of health services more efficiently. The system was also designed to provide a central reporting system for the collection of accurate outcomes and cost data from healthcare providers.

As a core element of the NSIS, the national clinical coding programme was launched in 2003, the Mattoni SSN. The focus of the Mattoni system is on national secondary uses data rather than regional or local clinical uses. It is designed to form a semantic interface between regional healthcare networks and the national NSIS infrastructure.

In order to address the 20 different regional healthcare systems while implementing the NSIS, a legal act from 2001 rules that the state has the role of coordinating different regional systems and of defining the “Minimum Assistance Levels” that must be guaranteed by all regions.

Beside the overall plan for the NSIS, the Permanent Working Board for eHealth TSE²⁰ published different documents: First “A policy for eHealth” in 2005 and then the “Architectural strategy for eHealth” in March 2006.

Both documents adopt objectives of the European Union contained in the eHealth Action Plan. The first one addresses architectural guidelines and technical specifications that are the basis for the development and spread of the digital innovation throughout the socio-sanitary process. Thereby the policy paper constitutes a first guideline for the design of the national architecture for eHealth. The “Architectural strategy for eHealth” defines further goals in relation to the implementation of a healthcare information system, such as:

- greater participation and awareness of citizens
- construction of a national infrastructure for eHealth
- use of integrated technologies in the treatment process

¹⁸ eHealth Europe

¹⁹ Livelli Essenziali di Assistenza

²⁰ Tavolo di lavoro Permanente per la Sanità Elettronica

Overall plan to build a new “National Healthcare Information System” NSIS

“A policy for eHealth” (2005) and “Architectural strategy for eHealth” (2006)

- collect, in real time, reliable information on system performance and compliance
- address privacy issues of citizens

In sum, the overall idea of the implementation of the NSIS is supported by legal action and the development of actions plans and pilot projects by TSE.

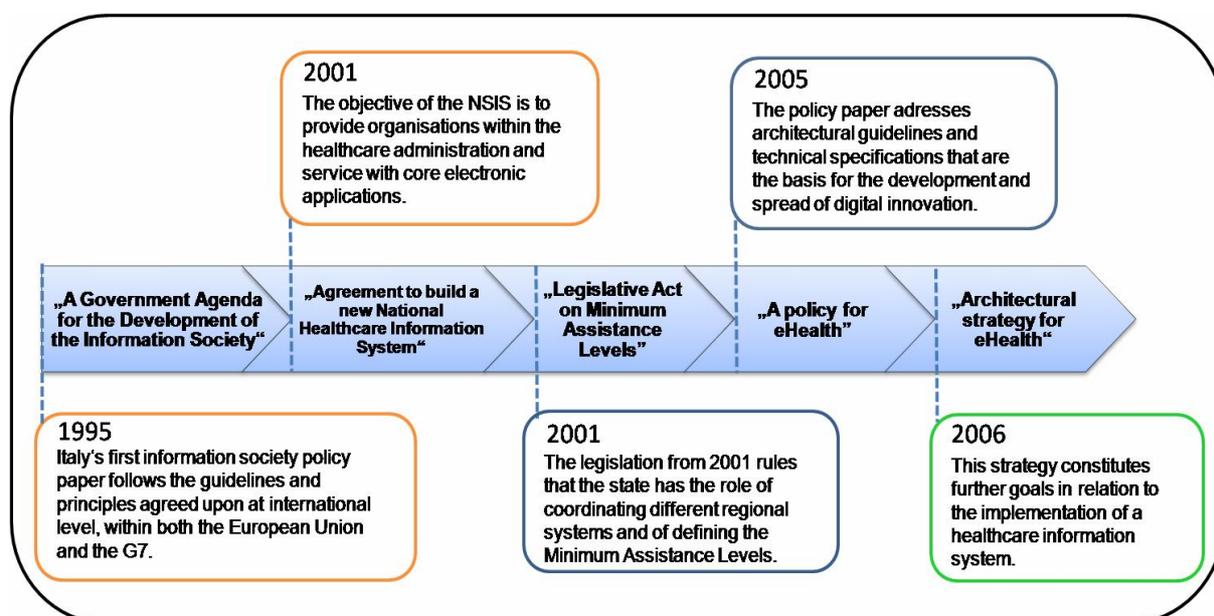
Important documents from other domains include Italians first Information Society policy paper from 1995 and the “E-Government Plan 2012” Italy’s Information Society policy paper is called ‘A Government Agenda for the Development of the Information Society’ and follows guidelines and principles agreed at international level, within both the European Union and the G7.

The “E-Government Plan 2012” from January 2009 aims at promoting government innovation and spreading online services, including in the field of healthcare. Thereby, the plan consists of 80 digital innovation projects, including an electronic health record and the digitisation of the medical prescriptions and certificates.

Italian project on patient summary and ePrescribing “IPSe”

In synchronisation with current efforts at European level in the framework of the epSOS Project, there is a parallel implementation of an Italian project focused on ‘patient summary’ and ‘ePrescribing’, called IPSe (“Sperimentazione di un sistema per l’Interoperabilità europea e nazionale delle soluzioni di fascicolo sanitario elettronico: Componenti Patient Summary e ePrescription”²¹). The main IPSe objective is to develop an ‘electronic health records’ (FSE), a real folder digital hospital will be able to make compatible the different regional health systems, both Italian and European, and also the requirements for computerisation of therapies (see section 3.3.1 below for further information on the IPSe project).

Figure 3: Italian policy documents related to eHealth



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²¹ emilia-romagne digitale, http://www.regionedigitale.net/progetti-piter/servizi-per-la-sanita/sole-sanita-on-line?set_language=en&cl=en

3.2 Administrative and organisational structure²²

Permanent Working Board for eHealth: TSE

There are different important actors in Italy, which are responsible for strategic and organisational aspects of the NSIS development, as well as for procurement and implementation management. These are the Ministry of Health and the Ministry for Public Administration and Innovation. Together they created the Permanent Working Board for eHealth, TSE. Overall, the regions also play a major role in developing diagnostic and clinical networks, such as cancer screening and electronic patient records.

More precisely, the TSE aims at accelerating the technological innovation of healthcare services and at defining a framework which is both normative and technical. In practice, it is designing the infrastructure of the federated system for the nationwide sharing of healthcare information based on EHR, called IBSE (Infrastruttura di Base per la Sanità Elettronica - Basic Infrastructure for eHealth).

To meet the requirements of a smooth interplay of national and regional agencies and developments, the steering committee “Cabina di Regia” brings together Italian regions and the responsible national agencies since 2002.

The financing of this structure is regulated as followed: The State annually shares out the National Healthcare Fund among the regions, according to the rules agreed in the State-Regions Conference²³. The Regions decide how much to allocate for eHealth activities.

Stakeholders are integrated into the process mainly through conference sessions. Some stakeholders (predominantly doctors and pharmacists) are represented in official decision making bodies – not including caregivers, nurses or patients. Also payers aren't seen as eHealth stakeholders in Italy.

As a supporting actor of the administrative and organisational structure, the Italian National Agency for Digital Administration (CNIPA) makes proposals to the Central Government, administrations and communities of ICT professionals in the innovative use of ICT. CNIPA issues technical frameworks such as guidelines and recommendations for the implementation and management of administrative information systems as well as security, interoperability and service delivery. Furthermore, the Agency supports the administrations in the definition of technical rules in specific sectors, such as healthcare or justice.

3.3 Deployment of eHealth applications

3.3.1 Patient summary and electronic health record (EHR)²⁴

In this study, the epSOS project's definition²⁵ of a patient summary was used as a general guideline. There a patient summary is defined as a minimum set of a patient's data which would provide a health professional with essential information needed in case of

²² Mercurio, Mori et al. 2007; ePractice.eu 2009,

²³ State-Regions Conference is a committee made of National (federal) Ministries and Regional Authorities.

²⁴ ePractice.eu 2009

²⁵ European Patients Smart and Open Services (epSOS)

unexpected or unscheduled care (e.g. emergency, accident), but also in case of planned care (e.g. after a relocation, cross-organisational care path).

Lacking a standard definition, a patient's electronic health record (EHR) is here understood as an integrated or also interlinked (virtual) record of ALL his/her health-related data independent of when, where and by whom the data were recorded. In other words, it is an account of his diverse encounters with the health system as recorded in patient or medical records (EPR or EMR) maintained by various providers like GP, specialists, hospitals, laboratories, pharmacies etc. Such records may contain a patient summary as a subset. As of yet, fully-fledged EHR systems rarely exist, e.g. in regional health systems like Andalusia in Spain or Kronoberg in Sweden, or in HMOs (health maintenance organisations) like Kaiser Permanente in the USA.

It should be noted that in most policy documents reference is made simply to an "EHR" without any explanation of what is meant by it, thereby in reality even a single, basic electronic clinical record of a few recent health data may qualify. As a consequence, this section can only report on national activities connected to this wide variety of health-related records without being able to clearly pinpoint what (final) development stage is actually aimed for or has been reached so far.

Regional and national pilots for patient summaries

For the progress assessment of the Italian patient summary deployment it has to be differentiated between the regional and the national level. At regional level, many pilots have been started since 2002 and most of them are highly developed as the status of planning and deployment is – on average – at about 70%. Some have already fully deployed a patient summary, such as the Basilicata Region. Here, the patient summary includes information on administrative data and a medical history.

The national situation shows that also here different projects are ongoing. The following box summarises the most important ones:

Patient summary projects at national level in Italy:

"Technological infrastructure of patient summaries" (Infrastruttura tecnologica del FSE): Involved in this project are the Ministry for Public Administration and Innovation and the National Centre for Research.

Status: Stipulate protocol: 100%; Status of activating project: 100%; Status working in progress: 40%.

"National interoperability project of patient summaries" (Interoperabilità nazionale del FSE): Involved are the Ministries of Labour, Health and Social Policy. Furthermore, the regions Lombardy, Friuli-Venezia Giulia, Veneto, Emilia-Romagna, Tuscany, Umbria, Marche, Sardinia, Abruzzo, Molise.

Status of stipulate interregional agreement and executive project: 100%.

"Pre-disposition guidelines of patient summaries" (Tavolo tecnico MLSPS - DDI-DigitPA- Garante Privacy - Regions)

Status: 90%.

These projects are closely linked to the "E-Government Plan 2012", which was developed by the President of the Council (Prime Minister) together with the Minister for Public Administration and Innovation. The plan aims at promoting government innovation,

IPSe project – parallel to European epSOS initiative

spreading online services and reinforcing the accessibility and transparency of the Public Administration, so as to bring it closer to the needs of citizens and businesses. On eHealth it states that by 2012, digitised primary services (prescriptions and sickness certificates digital booking systems) will be simplified and that the infrastructure for disbursement of health services nearer to people needs (electronic medical file and innovation of healthcare) will be created.

Within the framework of the European epSOS project, an Italian initiative focuses on patient summaries and ePrescription – it is called IPSe (“Sperimentazione di un sistema per l'Interoperabilità europea e nazionale delle soluzioni di fascicolo sanitario elettronico: Componenti Patient Summary e ePrescription”²⁶). The goal is develop an 'electronic health records' (FSE) for compatible regional health systems, both Italian and European, and also to fulfill the requirements of computerisation of therapies. In addition to Lombardia, which will finance the project with 210,000€, other 9 regions will be involved (Friuli, Veneto, provincial autonoma diTrento, Emilia Romagna, Toscana, Umbria, Abruzzo, Molise and Sardegna), with contribution from the Department Innovation and Technology (DIT) of Ministry of Health.

IPSE will last 36 months and will be developed in parallel to the European 'Smart Open Services' (epSOS).

The main achievement is to create a trans-regional secure network, based on Internet technology and able to connect all partners is useful for authentication of citizens, for the transfer of medical data and support the establishment of a structured document, called "Patient Summary" that allows the clinician to classify in the macroscopic (but safe, accurate and legally relevant) that is overseeing the clinical case. In additional a set of medical documents which are also structured to enable electronic health records (FSE) collected in an even drug prescriptions and specialist of General Practitioners and the Pediatrician and supplies of products and services to them connected.

The technical solution is based on a repository distributed, decentralised and federated understood as a peer-to-peer which includes healthcare providers and ensures the possibility of collecting health data of citizens to make them available on demand throughout Italy, and potentially in Europe.

The data involved in the project are either administrative nature, for the identification of citizens, that of health nature, including Patient Summary (understood as the dataset contains essential information in case of unexpected or unscheduled assistance), the ePrescription (understood as electronic documents that contain drugs and specialist services required or provided).

Dataset for electronic health records

The entire dataset must be handled, shared and transferred in full compliance with the law National Privacy: particular attention should be paid to the level of security, confidentiality and consent of the citizen.

This security infrastructure and application cooperation must follow the specifications of the "Sistema Pubblico di Cooperazione" and gained experience at regional level on these topics in particular should use the" Carta Operatore" as security system.

²⁶ emilia-romagne digitale

Semantic interoperability will be ensured, taking into particular account the information needs of the NSIS and Health Card System, the achievements of the future NHS needs Brick Project of evolution in the meaning and expectations of the Patient Clinical Summary and the need to ensure a transnational interoperability and, therefore, needs its easy translation into other languages.

The pursuit of this objective will be achieved taking into account:

- achievements already implemented or in an advanced state of development at the regional level, while respecting national legislation on access, operation and protection of personal data;
- the planning and determinations made within the control room of the NSIS, with particular reference to the draft NHS Bricks and provisions relating to information content to feed the NSIS itself;
- developments and results obtained from the European project "SOS-Smart Open Services" on the subject of European interoperability;
- Public Connectivity System (SPC);
- Guidelines issued by the permanent table for eHealth;
- The results of the project "Bricks of the NHS" the Ministry of Health.

The operational objectives of the Project are the following

Operational objectives of IPSe:

Share a common definition of patient summary and ePrescription services of that enable solutions to ensure compatibility with measures already existing or under development (infrastructure, security infrastructure, protection of privacy, siding with the hospital information systems, liaison with the medical records of GPs);

Define technical specifications and a system architecture in terms of semantic interoperability, security systems and identification of citizens and health professionals;

Develop, implement and test a system of inter-regional interoperability for patient summaries and ePrescription (compatible with what is being tested at the European level);

Realise pilot sites in test areas to define implementation strategies, pre-service (including relationships with GPs and hospitals) and to create a central system (creating installation and testing of the Web Site, contact the National node and the provision of central services), as well as local systems (creation of local computer components and installation of all computer components, including the regional gateway, and laboratory tests of all components) up to functional testing and commissioning of production pilot sites;

Evaluate all project phases from needs analysis to define the technical specifications to implement pilot sites;

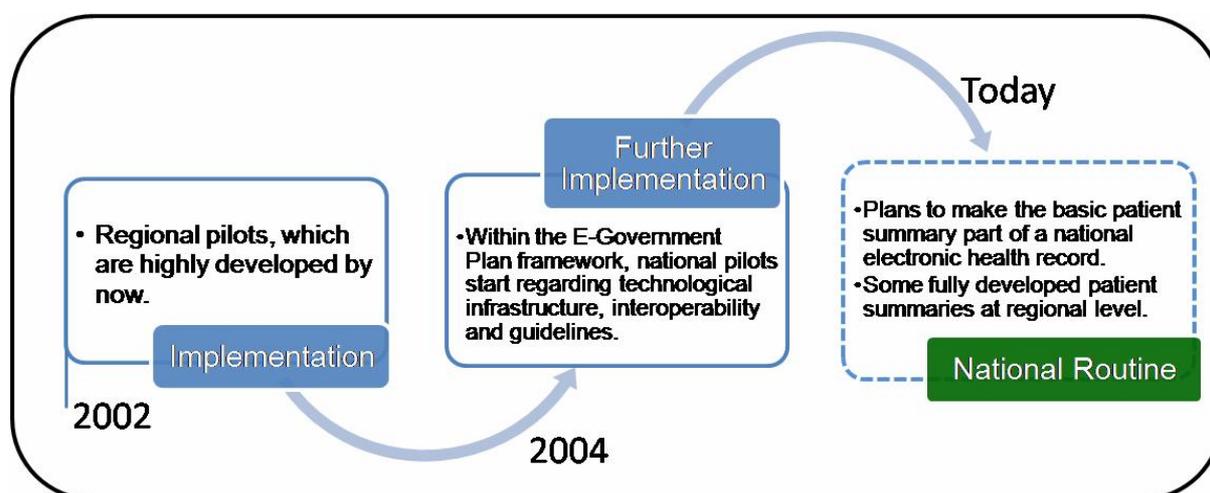
Insure, at all stages of project development at national level, the organisational coordination and synchronisation of activities with epSOS from a technical point of view, methods of evaluation / testing / monitoring of pilot sites, of industrial achievements of administrative support for project activities, of the report by the eHealth Strategy and of computerisation of healthcare and fitting with the objectives of NSIS, promotion and dissemination of results.

The expected results of the project can be summarised in the following benefits:

- for the Italian citizens: increased of the inter-regional mobility and improving of the continuity of the care and of the patient safety;
- for the national health system: strengthening of the cooperation and of the efficiency between the regional health and regional socio-health systems, and between these and the NSIS in the context of the national e-health strategy;
- for Italy in Europe: development of a harmonised solution in the Italian contest, that is an advantage for Italy, which has united and ready to seize the opportunities within the European e-health turned to promote the interoperability at European level to reduce the current difficulties of cooperation between health information systems of the Member States.

Up to this point, this basic patient summary is not part of a national electronic health record, but this process is at a planning stage. Here, it is foreseen to include data such as administrative, demographics, GP record and a medical history in the EHR.

Figure 4: Patient summary in Italy



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3.3.2 ePrescription

In the framework of this study and following work in epSOS²⁷, ePrescription is understood as the process of the electronic transfer of a prescription by a healthcare provider to a pharmacy for retrieval of the drug by the patient. In this strict sense, only few European countries can claim to have implemented a fully operational ePrescription service.

Regional pilots for ePrescription in Lombardy and Emilia-Romagna

Since 2002, pilots for the regional use of ePrescription are ongoing in Lombardy and Emilia-Romagna. In Lombardy the core of the project is an 'Healthcare Extranet' (SISS), which links operators, social services, organisations and citizens, tracking all the events which occur in the patient treatment (from prescription to administration) and providing value added services (the project ended in 2009).

²⁷ European Patients Smart and Open Services (epSOS)

In the Italian region Emilia-Romagna the programme is called “SOLE – Online Healthcare”²⁸. This project is aiming to develop an integrated telematic network for the interoperability of hospitals and healthcare professionals to provide value added services to citizens. This is done by: 1) electronic management of prescription – referring to life cycles, and therefore, of continuity of care; 2) a regional registry that indexes clinical events stored into healthcare structures; 3) electronic management of the pharmaceutical prescription life cycle. It is still ongoing.

Overall, the relative share of ePrescriptions compared to paper-based prescription is less than 20%. Thereby, some regions have a higher share, as the number is an average value at national level.

Challenges, which are faced in Italy in relation to ePrescription, are the acceptance of the electronic transmission of prescription to pharmacies and the inclusion of a medication record. Furthermore, the organisational structural poses an obstacle as regional initiatives can hardly be combined.

3.3.3 Standards

Standards are not only crucial to enable interoperable exchange of meaningful information in the healthcare system; they also ensure secure access to patient records by healthcare providers and citizens. This study aims to identify, among other usage, standards related to the domain of health informatics, such as the SNOMED Clinical Terms or the LOINC terminology.

Ministry of Health and eHealth Board TSE are responsible for standards

In Italy, generally the Ministry of Health is responsible for the development and deployment of standards. Furthermore, the established eHealth Board TSE poses a setting for technical discussion and consultation in order to harmonise the national and regional eHealth policies and to help coordinate the implementation of the respective action plans in accordance to standards.

At a national level, the “bricks” programme has been developed. It establishes the semantic toolkit required to ensure a common language to classify and codify the concepts in a uniform manner to share methodologies for measuring quality, efficiency, and appropriateness of the regional healthcare services and to achieve a uniform approach in the generation of the information when organising, managing, and governing the fundamental levels of healthcare services. Up to this point Italy is a HL7 affiliate.

This programme addresses one of the main challenges regarding the deployment of standards, as it has proven to be difficult to agree on a common terminology among different health specialists and in different regional contexts. Other obstacles are related to organisational and cultural issues.

Other coding and performance measurements are being managed by the regions: Tuscany and Sicily are handling the development of clinical coding for the patient record; Lombardy and Molise are developing outpatient performance measures; primary care and home care performance measures are being developed by Puglia and Lombardy.

²⁸ emilia-romagne digitale

3.4 Telemedicine²⁹

The use of telemedicine applications is recognised as beneficial to enable access to care from a distance and to reduce the number of GP visits or even inpatient admissions. Commission services define telemedicine as “the delivery of healthcare services through the use of Information and Communication Technologies (ICT) in a situation where the actors are not at the same location”³⁰. In its recent communication on telemedicine for the benefit of patients, healthcare systems and society, the Commission re-emphasises the value of this technology for health system efficiency and the improvement of healthcare delivery³¹.

In the field of telemedicine, different projects and pilots are ongoing in Italy. Two of these are 1) the IBM project for teleassistance at home (2009) and 2) the participation in a home monitoring system project by the Spanish research and development firm “Telefónica”³².

Different telemedicine services available in Italy, e.g. home telemonitoring

The latter is a monitoring system, which collects five different vital signs, detects falls and transmits data to a caretaker centre to be assessed by doctors. The solution was developed with partners from Italy, Germany, Ireland, the UK and Portugal.

The ongoing IBM project started in late 2009 with a duration of one year. It involves 30 patients who are in their 80s, and who will be remotely monitored with in-home sensing gear. They are provided teleassistance as needed during daily activities, as well as guidance on exercises for mental agility and tutored physical training. The system is based on a net of integrated sensors that send data about the assisted person to a control room run by the municipality, where the data is analysed. If data indicates that an elderly person has fallen, for instance, a medical team is immediately alerted to assist.

Other telemedicine applications available in Italy are the following:

Telemedicine services in Italy:

Home telemonitoring services concern chronic diseases (diabetes, COPD, Congestive Heart Failure).

Teleconsultation (doctor-to-patient) service is not much common, mainly used in relation to telephone consulting about chronic diseases.

Teleconsultation or videoconferences between health professionals mainly concern second opinion about image processing (radiology, neuroradiology).

Already in the 70s and 80s different projects and products were developed in the field of telemedicine³³. In 1991, the Ministry of Research financed a €50 million initiative (TELEMED) that for 10 years represented a focal point for several applications in e.g.

²⁹ Bruce 2009; McGee 2009

³⁰ Europe's Information Society 2009

³¹ European Commission 2008

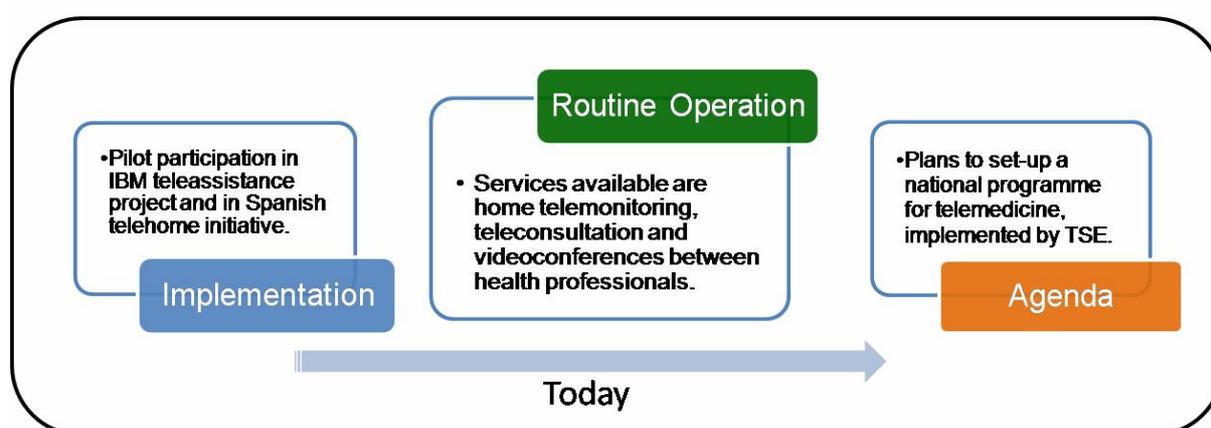
³² Telefónica I+D

³³ Finalised Programs of National Council of Research on Parallel Computing and Expert Systems and Epidemiological Disease Risk Factors

radiological teleconsulting, telecardiology, network of excellence hospitals or teletraining in medicine. The main results of the TELEMED project were to initiate prototypal platforms in radiological, cardiological and oncological fields and in the implementation of some Hospital information system networks.³⁴

The main challenges are related to organisational and cultural issues. Education and training activities concerning not only "how" to use a system but "why" to use are ongoing, but not enough economic and organisational efforts are devoted to these activities. In general, it is planned to set up a national programme for the field of telemedicine, which would then be coordinated and implemented by the eHealth working board TSE.

Figure 5: Telemedicine services in Italy



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Another important telemedicine project ongoing in Italy since the beginning of 2010 is the "Renewing Health" Project:

"RENEWING HEALTH aims at implementing large-scale real-life test beds for the validation and subsequent evaluation of innovative telemedicine services using a patient-centred approach and a common rigorous assessment methodology. In 9 of the most advanced regions in the implementation of health-related ICT services, belonging to 9 different Member States or Associated Countries, service solutions are already operational at local level for the telemonitoring and the treatment of chronic patients suffering from diabetes, COPD or CVD diseases. The services are designed to give patients a central role in the management of their diseases, fine-tuning the choice and dosage of medications, promoting compliance to treatment, and helping healthcare professionals to detect early signs of worsening. These services will be scaled up, integrated with mainstream Health Information Systems, grouped into a limited number of clusters bringing together services showing similar features, trialled and assessed with a rigorous and common assessment methodology, and using a common set of primary indicators for pilots belonging to a same cluster."³⁵

³⁴ Sicurello, "Health Informatics and TeleCare in Italy"

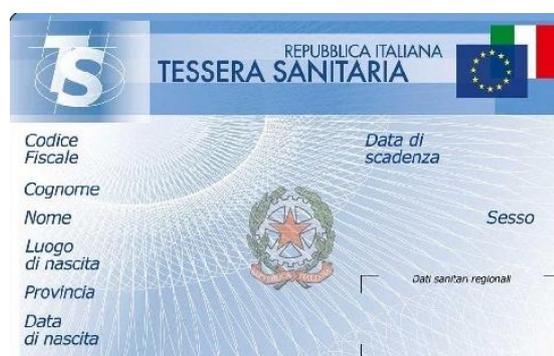
³⁵ ICT Policy Support Programme 2010

3.5 Technical aspects of implementation

A key prerequisite for the establishment of an eHealth infrastructure is the ability to uniquely identify citizens/patients and healthcare professionals. This part of the survey deals with identifiers and how they are stored. This section does not deal with the tokens through which identification can or will take place. One such possibility would be via an eCard. This topic is dealt with in the following section. The current section focuses solely on whether or not unique identifiers are in place in Italy and for which purpose.

3.5.1 Unique identification of patients

In Italy, the tool to identify a patient at national level is the “Health Card” (Tessera Sanitaria, TS). The Health Card is a personal card that replaces the plastic card for tax codes and provides access to National Health Service (NHS). The card, which was introduced in 2004, not only contains data and assistance (including tax code) that is stored on the magnetic stripe (barcode), it is also valid throughout Europe, as it is compatible with the paper model E111.



The Health Card has been sent to all Italian citizens and foreigners residing in Italy. The card can be used to access benefits of health service, such as: to obtain drugs, clinical and healthcare. If for example a prescription is issued by an Italian doctor, he/she will need the tax code, which is provided on the back of the card. Furthermore, the card has been developed by the Ministry of Economy and Finance to monitor the public health expenditure and to prevent any waste and fraud that harms the interests of the community. The card is laminated and has the size of a credit or cash card. Against the blue background, the social security number, expiration date and personal information are stamped, including: name, last name, date, place of birth, an open area where they may be signs of regional health data. On the back, the tax code, a barcode, a magnetic stripe and the words of the assisted European health insurance can be found.

3.5.2 Unique identification of healthcare professionals

Up to this point, there is no centralised ID for healthcare professionals in Italy. But each professional (e.g. doctors, nurses) is registered in a local specified registry. Furthermore, since 2009, the Italian Government is planning to implement a national electronic registry for healthcare professionals in the framework of the “E-Government Plan 2012”. It is aiming for:

- The creation of a national electronic registry for professionals;
- A digitalisation of the prescription cycle;

- The creation of a national electronic health record.

It is foreseen to develop the health professional registry by the year 2012.

3.5.3 The role of eCards³⁶

In Italy, three regions have so far introduced an eCard for citizens/patients: Lombardy, Tuscany and Friuli Venezia Giulia. These regions started out with pilots based on cards with chips, which store the relevant patient data.

For the Lombardy case, the eCard “Carta Regionale Dei Servizi” (CRS) is a smart card with multiple functions for daily use: It replaces the paper medical card, the European Health Insurance Card, the tax code card as well as the National Service Cards. Generally, the card was created according to international technical standards for smart cards, which allow the user to access online services that require identification.

The CRS is free and was sent home to all citizens enrolled in the local health unit (ASL) of Lombardy. Users can access data stored on the card for different administrative purposes. Generally, the procedure to consent to the use and storage of data and to receive a PIN is as follows: The citizen must sign a “Form of Consent”, which is followed by the distribution of a



personal PIN code. The PIN is needed for safe access to the network and to services which the region is progressively making available. Thereby the card has a microchip which contains a certificate that allows Italian citizens to have an electronic signature and to be identified on the network. Furthermore, CRS can be used as a payment card.

“The Electronic Health Card” in Tuscany is one of six major projects of the Regional Health Plan 2008-2010, which is aiming to better respond to citizens' expectations by providing additional means of guaranteeing the protection of health. The primary objective is in fact to offer the citizen a system to track and store health data. Through the card, every citizen will have access - either directly or through a healthcare professional authorised by him (a general practitioner, paediatrician of free choice, specialist, emergency room physician or nurse) - to all health information.

The stored information, which subject to strict privacy rules, will include the following data:

³⁶ Telecom Italia and Lombardia 2006

Data stored on the Tuscany eCard:

Specialised reports, which can be accessed in emergency cases, for laboratory tests and for radiology.

Personal health plan, including allergies, illnesses, surgeries, hospitalisations.

Medication history, including the consumption of drugs, exemptions, prescriptions and clinical records of the treating physician (patient summary).

Plans and prevention programs, such as vaccination, regular checks and cancer screening.

Thereby the card is aiming to fulfil different purposes and respond to different needs:

- facilitate citizens' access to medical data (main purpose);
- ease, for the citizen, the burden of documentation, while ensuring completeness of information;
- verify the preventive and therapeutic measures, towards the personalisation of care, particularly to chronic patients;
- prevent and reduce health risks, eliminating possible errors of transcription and making – even in emergencies – data and medical history available;
- share information among all health professionals;
- reduce duplication of examinations;
- create a catalogue of benefits for prescription, booking and reporting.

The pilot phase of the eCard project started in January 2009 and foresees the involvement of local health units in Florence, Empoli, Arezzo, Siena, Livorno and the University Hospital of Careggi. For every 'pilot farm' 25 GPs and paediatricians of free choice were involved, which in return involved about 20 patients with chronic diseases (diabetes in adults, asthma for children) in the trial. Overall, the first trial phase encompassed about 3000 patients/citizens, 150 doctors and six healthcare companies. Subsequently, the project will be extended to the entire population of the region and therefore involve all general practitioners and paediatricians of free choice in the future.

Concerning electronic cards for healthcare professionals at national level: All professionals are identified via a smart card or a barcode inside their work place. These cards contain information, such as the role of the healthcare professional, time of work and the name of the local health unit or the related hospital.

Many challenges are related to the creation of health service related identifiers: there are technical issues concerning interoperability requirements among local informative systems, but the most critical factors are related to organisational and cultural issues..

There are cultural resistances to share data with other structures and to put into action integrated organisational models based on interoperability of systems, due to power divisions between different organisational levels and institutions and because of a not clear legal context too.

Moreover, it's a common practice that healthcare provider autonomously manages health information concerning own patients. Healthcare services interoperability, even if are formally promoted by the institutions, are still at pilot phase.

Aside from national use of eCards Italy is also involved with STORK (Secure idenTity acrOss borders linKed):

“The pilot project launched by the Commission aims to achieve the pan-European recognition of electronic IDs. This will be done without imposing one single solution but allowing national systems to work together. The pilot project will test some of the services that are most useful to the many Europeans working and studying in EU countries other than their own. The participating countries will test a set of services using open standards. These include:

- a common service architecture allowing citizens to use their national eIDs to access eGovernment portals across borders,
- a platform for safer online communication using eIDs for children,
- a service facilitating students' mobility across Europe,
- use of eID for cross-border electronic delivery for citizens and businesses,
- and for testing the electronic process of address change for EU citizens that move to other Member States.”³⁷

3.6 Legal and regulatory facilitators³⁸

Specific legislation for EHRs is in the legislative process of enacting

Legal and regulatory issues are among the most challenging aspects of eHealth: privacy and confidentiality, liability and data-protection all need to be addressed in order to make eHealth applications possible. Rarely does a country have a coherent set of laws specifically designed to address eHealth. Instead, the eHealth phenomenon has to be addressed within the existing laws on professional liability, data protection etc.

In Italy, there is legislation regarding health-related data processing in accordance with EU Directives, but specific legal regulation of eHealth and telemedicine is very limited. The broader legal framework surrounding healthcare and privacy does, however, include provisions relevant for eHealth implementations. The Italian Data Protection Authority emphasises the obligation to respect the dignity and privacy of patients and sets a strict set of rules guaranteeing privacy in health data exchange scenarios. Thereby, Italy has one of the most tightly regulated privacy frameworks in Europe. One of the consequences of the tight privacy regulations in Italy is that health data can hardly ever be processed without patient consent. Furthermore it is required under Italian law that any processing of health-related data shall be notified to the Italian Data Protection Authority³⁹.

An important communication of the Italian Data Protection Authority furthermore determines that only anonymous data can be processed in databases in the healthcare sector⁴⁰.

³⁷ European Commission: Information society and Media 2008

³⁸ European Patients

³⁹ Art 76 §1, a) and art. 37 § 1, b) Legislative Decree no. 196/2003 on the protection of personal data.

⁴⁰ Communication of the Data Protection Authority of 28 October 2003.

At the moment specific legislation related to the patient health record system and the exchange of this record is in the legislative process of enacting. Adoption was expected in the course of 2009, but has been delayed⁴¹. Thereby, it is defined that all health related data has to be stored in decentralised repositories. Furthermore, it states that the reference to patient data has to be compatible with technical and organisational scenarios at national level. Some regions are heading towards this approach as they are aiming to be compliant with cooperative application rules (e.g. Tuscany).

3.6.1 Patient rights

The legal framework for patient rights in Italy requires consent in healthcare scenarios as an absolute necessity – even when the data exchange is initiated by a public institution. Explicit consent by the patient is furthermore needed before an electronic patient record can be created (opting in model). Patients also decide which medical data is included in their regional/national record on a case-by-case basis. The main legal sources with regard thereto are article 2, 13 and 32 of the Italian Constitution recognising the fundamental right to self-determination, the liberty to dispose of one's own body and the right to health. The Law of 13 May 1978 furthermore sets forth the principle that medical verifications and treatments shall – as a rule – be on voluntary basis. Finally the Law no 833/78 establishing the National Health Service grants the patient the basic rights to free choice and information.

There is no common procedure for patient representatives to have access to the electronic patient record – the patient needs to agree every time. The patient him or herself has read-only access to the record and he/she can decide if data is further used for example for scientific purposes. However, in order to avoid unnecessary shocks to data subjects, this right can only be executed through a healthcare professional⁴².

Further formal decisions on patient rights will be defined within the E-Government framework until 2012, whereas solutions and legal suggestions will derive from the evaluation of (regional) pilot applications.

Regarding telemedicine services, there are – up to this point – only national political and strategic goals, which are realised in different ways according to regional settings. Generally, telemedicine services are required by healthcare professionals.

3.6.2 ePrescription

Although Italy did not adopt any specific legislation on e-Prescription, the current legal framework is not an obstacle to introduce e-Prescribing. The current framework required the prescription to be written, dated and signed by a physician⁴³. The legislation on “firma digitale” put in place all the necessary rules on time-stamping and electronic signatures with qualified certificate and allows both techniques to be used for evidence purposes⁴⁴.

⁴¹ Divisione La Repubblica 8/7/2008

⁴² Art 84 §1 Legislative Decree no. 196/2003 on the protection of personal data.

⁴³ Royal Decree 1706/38 concerning the regulation on the pharmaceutical service and Legislative Decree no 219 of 24 April 2006 on the community code relating to medicinal products for human use.

⁴⁴ Art. 20 en 21 Presidential Decree no 82/2005 and art 2712 Italian Civil Code.

3.7 Financing and reimbursement issues

At the beginning of the development of the new Italian health information system NSIS in 2004, an initial investment of Euros 44 million seed funding was made by the government in order to get first projects up and running. This was followed by a recurring public budget, which is mainly allocated to pilots. The amount allocated to these pilots varies between 50 and 100 million Euros each year.

Generally, funding is allocated by the central government and complemented with regional and EU funds.

Challenges related to financing and reimbursement issues derive from the current legal framework. Legal issues related both to the patient's data management and role and responsibility of every service chain stakeholder, are currently in definition phase, thanks to the activity of TSE. Until all aspects of privacy and responsibility are not regulated, reimbursement schemes cannot be defined for telemedicine services

3.8 Evaluation results/plans/activities

From a public policy perspective, evaluation is a key activity in the policy-cycle. It provides insights into the success or failure of a policy or project and leads to new policy goals and new methods of implementation. The need for evaluation of eHealth policies and projects has been stressed time and again by the EC, not least in order to further the spread of eHealth in the process of healthcare delivery.

In Italy, since 2005 technology, functionality, as well as acceptance and trust by citizens and professionals is assessed regarding the following eHealth applications:

- eCard (healthcare professional);
- eCard (patient as qualifier);
- Patient summary/ EHR;
- Interplay of various infrastructural components and the overall system.

These evaluations are mostly done by universities and research centres that cooperate with government agencies. These activities are very effective at regional level, but not enough at national level, as in this case continued action in this field is strongly related to political continuity.

Furthermore, the Italian National Agency for Digital Administration (CNIPA) is responsible for evaluation activities⁴⁵ – the agency performs:

- Ex ante evaluation (consistency with national strategies for innovation of the Government)
- Progress evaluation (during the project implementation program)

**Assessment of
different eHealth
applications
since 2005**

⁴⁵ the CNIPA is National Centre for Informatics in Public Administration but the guidelines for FSE (electronic health records) are prepared by a Technical Table consisting of: MLSPS (Ministry of Labour Health and Social Policy), DIT (Department of Innovation and Technology) which is part of the Ministry of Public Administration and Innovation, CNIPA (National Centre for Informatics in Public Administration), Privacy Guarantor, Regions.

- Ex post evaluation (results achieved)

These evaluations apply for eGovernance, eService and eHealth activities done at a regional or national level.

4 Outlook

In Italy, the development of eHealth is mainly led by the implementation of the new National Health Information System NSIS, the E-Government Plan 2012 and the ongoing reform for federalism, which distributes more power to the regions also in healthcare issues.

Throughout this process, it has to be noted that on a regional level, eHealth deployment has progressed continuously and many applications are at a final piloting stage or already in use. These existing systems now have to be brought together regarding different issues: They are aiming for technological interoperability, unified terminology, as well as communication structures between different health units.

Overall, decision-makers at national level try to learn from evaluations of regional pilots in order to create a nation-wide infrastructure in the fields of patient summaries and the inclusion on an EHR, telemedicine and ePrescription. Challenges ahead will include the wide acceptance of new eHealth applications in daily health routine and power divisions between different organisational levels and institutions.

5 List of abbreviations

CNIPA	Italian National Agency for Digital Administration
CRS	Carta Regionale Dei Servizi [eCard]
DRG	Diagnosis Related Group
EC	European Commission
EEA	European Economic Area
EHR	Electronic Health Record
EMR	Electronic Medical Record
EPR	Electronic Patient Record
epSOS	European patients Smart Open Services
ERA	European Research Area
EU	European Union
FSE	Italian Electronic Health Records
GDP	Gross Domestic Product
GP	General Practitioner
HCP	Healthcare Provider
HL7	Health Level Seven International (authority on standards for interoperability)
HMO	Health Maintenance Organisation
HPC	Health Professional Card
IBSE	Infrastruttura di Base per la Sanità Elettronica [Basic Infrastructure for eHealth]
ICT	Information and Communication Technology
ID	Identification (e.g. number, card or code)
IHTSDO	International Health Terminology Standards Development Organisation
IPSE	Sperimentazione di un sistema per l'Interoperabilità europea e nazionale delle soluzioni di fascicolo sanitario elettronico: Componenti Patient Summary e ePrescription
IT	Information Technology
LEA	Livelli Essenziali di Assistenza
LSP	Large Scale Pilot
NSIS	National Healthcare Information System

OECD	Organisation for Economic Co-operation and Development
PHS	Personal Health System
R&D	Research and Development
SNOMED	Systematized Nomenclature of Medicine-Clinical Terms
SSN	Sistema Sanitario Nazionale [Italian health service]
STORK	Secure Identity Across Borders Linked
TS	Tessera Sanitaria [Health Card]
TSE	Tavolo di lavoro Permanente per la Sanità Elettronica [Permanent Working Board for eHealth]
USL	Small location authorities
WHO	World Health Organization

6 Annex

6.1.1 Annex 1: Compound indicators of eHealth use by GPs

Compound indicator name	Component indicators	Computation
Overall eHealth use	<ul style="list-style-type: none"> - Electronic storage of individual medical patient data - Electronic storage of individual administrative patient data - Use of a computer during consultation with the patient - Use of a Decision Support System (DSS) - Transfer of lab results from the laboratory - Transfer of administrative patient data to reimbursers or other care providers - Transfer of medical patient data to other care providers or professionals - ePrescribing (transfer of prescription to pharmacy) 	Average of component indicators
Electronic storage of individual medical patient data	<ul style="list-style-type: none"> - A2a - Symptoms or the reasons for encounter - A2c - Medical history - A2c - Basic medical parameters such as allergies - A2d - Vital signs measurement - A2e - Diagnoses - A2f - Medications - A2g - Laboratory results - A2h - Ordered examinations and results - A2i - Radiological images - A2j - Treatment outcomes 	Average of component indicators
Electronic storage of individual administrative patient data	<ul style="list-style-type: none"> - A1 - electronic storage of individual administrative patient 	A1 value
Use of a computer during consultation with the patient	<ul style="list-style-type: none"> - B2 - Computer use during consultation 	B2 value
Use of a Decision Support System (DSS)	<ul style="list-style-type: none"> - B3a - Availability of DSS for diagnosis - B3b - Availability of DSS for prescribing 	Average of component indicators
Transfer of lab results from the laboratory	<ul style="list-style-type: none"> - D1e - Using electronic networks to transfer prescriptions electronically to dispensing pharmacists? 	D1e value
Transfer of administrative patient data to reimbursers or other care providers	<ul style="list-style-type: none"> - D1a - Using electronic networks to exchange of administrative data with other health care providers - D1b - Using electronic networks to exchange of administrative data with reimbursing organisations 	Average of component indicators
Transfer of medical patient data to other care providers or professionals	<ul style="list-style-type: none"> - D1c - Using electronic networks to exchange medical data with other health care providers and professionals 	D1c value
ePrescribing (transfer of prescription to pharmacy)	<ul style="list-style-type: none"> - D1d - Using electronic networks to transfer prescriptions electronically to dispensing pharmacist 	D1d value

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