

eHealth strategy and implementation activities in Italy

Report in the framework of the eHealth ERA project

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1 Executive summary

In building an inclusive European health information space for all citizens, there is complexity and diversity in approaches. Each country's approach is different, reflecting the diversity of national health systems and the Union. The challenge is not only to ensure interoperability among local and regional eHealth systems, but also among Member States and beyond.

The scenario in which the Italian eHealth strategy is being developed is marked by a radical change in the roles and responsibilities of the State and the Regions.

The constitutional reform of 2001 (Constitutional Law no. 3 of 18 October 2001) gave the Regions a legislative authority over health protection, within the context of the essential principles determined by the State. In the new scenario, the Health Minister guarantees the System's fairness by monitoring the Fundamental Levels of Healthcare Services (*LEA; Livelli Essenziali di Assistenza*), i.e. the services guaranteed by each Regional Healthcare Service as appropriate for specific clinical conditions and healthcare settings.

The Italian strategy is thus organized into three interconnected programmes – in the national, semantic, and territorial areas – aimed at common objectives: to improve the efficiency and effectiveness of the healthcare system as a whole, to assure the Fundamental Levels of Healthcare Services throughout the territory, and to speed up the processes of technological innovation of citizen/patient-centred social and healthcare services.

1. National area: the New Healthcare Information System (NSIS)

In February 2001, the Permanent Committee for political issues between central and regional authorities (*Conferenza Stato-Regioni*) endorsed an agreement to develop the New National Healthcare Information System (NSIS) – a common tool to achieve governance objectives, overseeing and monitoring the Fundamental Levels of Healthcare Services.

The strategic framework of NSIS defines the general lines and the progressive stages of development of the system's various components. The patient and the care delivery structure are identified as central information entities. Therefore, the main objectives call for the development, at national level, of:

- an integrated system of individual healthcare information, making homogeneous information available for the individual healthcare events, and making it possible to ascribe each event to the citizen that has interacted with the Regional Healthcare Services, to the prescribing physician, and to the facility that has delivered the service;

- an information system that makes information available on the facilities operating at all healthcare levels, the services delivered, the resources used, and the related costs.

The programme's governance is entrusted to an inter-institutional body referred to as the "Production Room" (*Cabina di Regia*), in which the regional and central Authorities are equally represented.

The interventions provided for in this programme are in an advanced phase of development.

2. Semantic area: the National Healthcare Service's "Bricks" (Mattoni)

This second programme responds to the need of assuring that the information systems, autonomously developed by the Regions and by the local healthcare Administrations, share a common language that makes it possible to:

- classify and codify the concepts in a uniform manner (services, facilities, etc.)
- adopt shared methodologies for measuring quality, efficiency, and appropriateness of the Regional Healthcare Services (waiting times, appropriateness of services, etc.)
- adopt a uniform approach in the generation of the information when organizing, managing, and governing the Fundamental Levels of Healthcare Services.

These common elements have been named "Bricks" (*Mattoni*) of the Healthcare System.

The *Mattoni* programme thus responds to the need to ensure semantic interoperability among the regional information systems, and between them and the national information system.

The *Mattoni* programme started in 2004 and is organized into 15 thematic sub-projects, with a Region responsible for managing each sub-project.

One of the sub-projects is dedicated to define the guidelines that will make it possible to plan a uniform development of the Electronic Patient File at the regional and national level.

The "*Cabina di Regia*" is responsible for governing the programme as a whole.

3. Territorial area: the eHealth Board

At the initiative of *Ministry of Innovation and Technologies* and the *Ministry of Health*, a permanent “eHealth Board” (*Tavolo di lavoro permanente per la Sanità Elettronica*) has been active since 2004, as the official setting for discussion and consultation among the Regions and the two proposing ministries, for the harmonization of the e-health policies and for the implementation of the national and regional action plans (including financial planning, as well as actions on education, change management, communication, and the related governance).

The first result of the eHealth Board is the document “Shared policy for eHealth” (*Politica condivisa per la Sanità Elettronica*) which adopts the European Union’s strategic objectives contained in the 2004 e-Health Action Plan, and sets out the main lines of development for accelerating the processes of technological innovation of social and healthcare services, and identifies the intervention settings for defining a regulatory framework of technical rules.

In March 2006, TSE published the document “Architectural strategy for e-Health” ¹ (*Strategia architetturale per la Sanità Elettronica*), whose aim is to outline a reference architectural strategy for the national system of e-Health.

The document constitutes a first high level guideline addressing the design of the national architecture for e-Health (IBSE - Basic Infrastructure for e-Health²), shared within TSE.

The architectural vision has been tackled with by considering some necessary requirements:

- it must guarantee that the clinical information of the patient is available anytime, anywhere
- it must respect the federated architecture of the Italian Healthcare System
- it must guarantee a high level of security and be able to respect the Italian legislation on privacy
- it must have a high level of Reliability/Availability (24x7)
- it must have a modular structure that allows a progressive implementation across the nation, that it is able to cope with obsolescence
- it must be as less invasive as possible with respect to the existing systems so as to safeguard the already made investments

¹ The document (in Italian) is available at:

http://www.sanitaelettronica.gov.it/xoops/modules/docmanager/view_file.php?curent_file=361&curent_dir=39

The English version of the document will soon be available on the same web site.

² Infrastruttura di Base per la Sanità Elettronica

- it must use open standards

In particular, the interventions deal with:

- The pilot development of IBSE is planned by a set of coherent programs in several Regional Authorities in Southern Italy;
- Standards to represent the collaborative processes, i.e. defining models of healthcare processes which are the topic for digital innovation;
- The data formats, i.e. the set of electronic documents exchanged in the healthcare system;
- The levels of service of information technology services in the healthcare sector;
- The levels of service of a supply.

The eHealth Board has launch important eHealth pilot like as:

- GPs network for e-Health services (54 M€ - 13500 GPs in 9 Southern Regions)
- e-Booking (9.9M€ – 5 regions)
- e-Signature for operators (18.9M€ - 200.000 smart cards in 16 regions)
- Telemedicine and Teleeducation (29M€)
- Oncology Excellence Centers Network
- Proactive prevention (Disease management) (15M€)

In the following table, the services deployed under the umbrella of the eHealth Board through this Program are marked as " GP network", together with the services deployed under other projects, marked by a "+".

Region	prescriptions	diagnostic reports	EHR infrastr.	security
Abruzzo	MIR	MIR	MIR	MIR
Molise				
Campania	MIR	MIR	MIR	MIR
Basilicata	+	+	MIR	MIR
Lazio	+	+		MIR

Puglia	MIR	MIR	MIR	MIR
Calabria	MIR	MIR	MIR	MIR
Sardegna	MIR	MIR	MIR	MIR

Region	provider ID	patient ID	choice of GP	booking
Abruzzo	+	+	+	MIR
Molise	+	+		
Campania	MIR	MIR	MIR	+
Basilicata	+	+	+	+
Lazio	+	+	MIR	+
Puglia	+	+	MIR	
Calabria	MIR	MIR	MIR	MIR
Sardegna	MIR	+	MIR	MIR

The Ministry, supported by the Federation of GPs (FIMMG), the vendors of GP applications and CNR, adopted a National Dataset for Patient Summary in General Practice.

A weekly bulletin on eHealth ("Sanità Elettronica") is produced and distributed by email and web (<http://www.sanita.forumpa.it/newsletter/home.php>), in collaboration with the Ministry of Health and the Ministry of Innovation, with the support of the National Research Council.

2 Healthcare System Overview

In Italy the reform of the Constitution (Constitutional Law number 3 of October 18th, 2001) has radically modified the roles and responsibilities of the State and the Regions. The Regions hold the legislative power on health protection, in the framework of fundamental principles defined by the State.

The main decisions are agreed within the "State-Regions Conference", i.e. a committee made of National (federal) Ministries and Regional Authorities.

All regional Authorities have some power to approve regional legislation and allocate freely the funding received from the central government, in particular for healthcare delivery. However, special regions enjoy wider autonomy in this respect and also receive a higher than average share of government funding.

In addition, their self-government rights extend to an additional number of policy areas, such as primary and secondary education, culture and arts and subsidies to industry, commerce and agriculture. Regions, as well as provinces and municipalities, are granted some limited fiscal autonomy within the limits determined by national laws. In addition, they complement their own revenue with state transfers sufficient to carry out their ordinary functions. Besides that, the regions own some health care centres (assigned by law) that are allowed to borrow to finance investment.

Primary care is provided by general practitioners, paediatricians and selfemployed 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.

General practitioners and paediatricians initially assess the patient and are expected to provide most primary care. They act as gatekeepers for access to secondary services. They write pharmaceutical prescriptions and certifications and visit patients at home if necessary. People may choose any physician they prefer; in 1998, each general practitioner averaged 1030 patients, each paediatrician averaged 721 children.

The 1999 reform introduced significant changes in primary health care services by reinforcing group practice, introducing economic incentives for general practitioners and promoting integration between primary care physicians and district services such as social care, home care, health education and environmental health-

Currently, hospital care is delivered mainly by public structures (842 hospitals, corresponding to 61% of the total), which provide both outpatient and inpatient services. Nevertheless, local health units also contract out services to 539 private hospitals (39% of the total), especially not-for-profit institutions.

In 1998, Italy had 276 000 beds: 91% were dedicated to ordinary admissions, 8% to day hospital activities and 1% to private health care. Of about 250 000 beds for ordinary admissions in 1998, 81.5% were public (versus 83% in 1993) and 18.5% were private but accredited by the NHS.

Italy's health care system has experienced profound transformation during the 1980s and 1990s. The transition to the NHS model initiated in 1978 covered an additional 7% of the population, ultimately guaranteeing all Italian citizens access to a wide range of services, irrespective of their social and economic conditions.

This signalled a strong commitment to equity, as a significant effort to increase public expenditure had to be made in a very unfavourable context characterized by considerable political turmoil and a severe economic downturn. In addition, according to available international research, in 1990 Italy compared well with other European countries in equity, ranking high in both the aggregate progressivity of health care financing and the equality of access and utilization levels across income groups.

Some of the critical aims of the 1978 reforms, however, had not been accomplished in the early 1990s.

In particular, access was only free at the point of use for inpatient and primary health care, whereas specialist visits, diagnostic services and pharmaceuticals had relatively high co-payments.

In addition, the envisaged shift to tax-based financing had only been achieved in part, with payroll taxes still financing about two thirds of total public expenditure for health care in the mid-1990s.

A similar implementation gap applied to the expansion of public services, which constitutes a central pillar of the NHS model, as private providers serving both public and private patients received more than 40% of public health care funds in the early 1990s.

Most seriously, deficits in public health care resources were still more prevalent in the less developed southern regions, thereby perpetuating a worrying pattern of geographical inequality.

Moreover, some of the most enduring problems of the NHS remained unsolved in the early 1990s. In particular, the balance in macroeconomic efficiency was mixed. Although aggregate expenditure was slightly under average, the results obtained in health status (as measured by perinatal mortality) were considerably under the average OECD levels. In addition, citizen satisfaction was markedly under average in Italy in 1992, with more than two thirds of the population perceiving the quality of the health care system as being poor and 82% agreeing with the statement that “health services available to the average citizen are inefficient and patients are not treated as well as they should be”.

Similarly, research results obtained for the microeconomic efficiency of Italy’s NHS indicate below-average productivity levels in the hospital sector and high pharmaceutical consumption.

Some of these persistent problems have been adequately addressed and significantly alleviated during the 1990s.

The significant efforts at containing costs initiated during the 1980s and further developed during the early 1990s yielded positive results: the upward trend in expenditure was reversed, with total health care expenditure as a percentage of GDP actually dropping during the mid-1990s, pharmaceutical consumption declining by 15% and public deficit levels also decreasing rapidly.

In addition, public satisfaction with the NHS more than doubled during the same period.

Some of these good results can be safely attributed to the measures launched by the 1992–1993 reform, which initiated a deep process of political and financial devolution to the regions and aimed at introducing managed competition within the NHS.

The reforms further promoted microeconomic efficiency by delegating considerable managerial autonomy to local health units and hospital trusts, changing resource allocation systems to motivate productivity and enforcing innovative monitoring systems aimed at improving the perceived quality of services and implementing patients’ rights.

Similar to the 1978 reform, some of the changes introduced during the early 1990s either were not implemented or produced unintended negative side effects in some domains. First and foremost, the fact that in 1997 most of the complaints to Italy’s health care ombudsman were related to perceived problems of access to health services and drugs (60% of them put forward by elderly patients) constituted the first worrying warning. In addition, strict cost-containment policies ended up promoting increased levels of dual coverage. In fact, the share of private expenditure at the end of the 1990s was more than 30% (one of the highest

percentages in Europe), and private insurance coverage increased from 5–10% of the population in the early 1990s to about 30% in the late 1990s.

The example of co-payments for specialist care, which were 100% subject to a ceiling of €52 from the mid-1990s, illustrates the incentives in place to opt either for direct payment for purely private care or for buying private insurance policies.

Other radical measures proposed during the period, such as deductibles for higher incomes or the opting-out clause included within the 1992 reform legislation, touched the very heart of the NHS and provoked strong popular dissent. Finally, the fee-for-service system designed to promote competition among specialist providers and, ultimately, increase productivity, also generated an upward trend in hospital expenditure, which already consumed an above-average share of total public expenditure on health care compared with other EU countries.

Moreover, the purchaser–provider split envisaged within the 1992–1993 reform package was only partly guaranteed, as under the initial institutional design, most hospitals remained under the direct management of local health units, which were also in charge of purchasing. In addition, central regulation did not foresee contractual agreements between purchasers and providers and therefore did not issue the required guidelines to help regions choose their preferred providers.

This raised complaints from the Italian Competition Authority, which in 1998 compelled the government to address these issues to guarantee true competition in health care. In addition, important interregional differences developed throughout the implementation of the internal market reforms, which advanced little in some of the southern regions mainly because of the lack of managerial skills and technical support to operate the innovative, private sector-like organizational structures and managerial systems prescribed by central legislation.

The period 1997–2000, in turn, witnessed a series of radical and innovative changes in state institutions and health care regulation. First, political devolution of health care powers to the regions was promoted, and the transition towards fiscal federalism started within the context of a profound transformation of Italy towards a federal state.

The fiscal federalism reform undoubtedly represents a step forward in financing health care. The potential advantages and some possible drawbacks have been summarized as follows.

On the positive side, the new regional taxes designed to replace payroll contributions are neutral with respect to factor mix and financing structure and therefore unbiased against employment. Further, the tax base is widened, as it is paid by all businesses, whereas it was previously restricted to income earners.

On the negative side, as the tax base is unevenly distributed across Italy, substantial equalization transfers will be needed, which might reduce the effective political autonomy of different regions unevenly. In addition, poorer regions will have less room for manoeuvre to increase health care expenditure: in fact, recent International Monetary Fund calculations estimated that high-income regions can increase revenue by up to 23.5%, whereas low-income regions can only increase them by 8%.

An even more serious drawback is that, to obtain an equivalent cash increase, lower-income regions will have to raise tax rates more than higher income regions, which will introduce negative incentives for business location and might, accordingly, hinder economic development prospects in the more disadvantaged regions. Moreover, the higher reliance on indirect taxes envisaged in current legislation will make overall health care financing more regressive.

Second, in 1998 the parliament asked the central government to launch new reform legislation to accommodate the new federalist framework and further regulate the health care sector. As a result, the third reform of the NHS was approved in 1999, which represents one of the more ambitious attempts in Europe to produce a detailed regulatory framework that could guarantee adequate levels of health care quality, efficiency and equity without curtailing the political and managerial autonomy transferred to local actors.

Three components of the 1999 reform merit special mention: the first steps towards defining a core benefit package that all regions should guarantee as well as the system designed to monitor implementation at the regional level; the regulation of the steps to be followed by regions and local health units to guarantee institutional accreditation to their preferred public and private providers; and the exhaustive provisions aimed at promoting and monitoring the quality of care.

Finally, the 1999 reform also envisaged eventually abolishing most co-payments from 2001 onwards and a set of parallel measures to guarantee fair competition between publicly funded providers and private ones.

Given how recent these reform measures are, however, there still is a great deal of uncertainty surrounding the actual likelihood and feasibility of the subsequent implementation process. So far, a positive list of benefits has only been detailed for outpatient specialist care and pharmaceuticals. In all other areas, and especially regarding hospital health care, diverging views still exist on how the list should be drawn up and whether this should be negative or positive.

In this sense, current regulations only suggest a set of criteria: ineffective, inappropriate or inefficient procedures should be excluded as well as those that do not satisfy basic health care needs.

Some uncertainty also exists on how detailed the list should be: broad guidelines within which physicians could choose the most appropriate treatment or a more detailed list of mandatory condition–treatment pairs. In addition, the monitoring system aimed at guaranteeing implementation of the benefit package and fulfilling quality standards at the local level still needs to be defined, a task that can prove difficult to achieve until the services to be included in the essential benefit package are clearly specified. In addition, it is still unclear which authority will be responsible for verifying the working of the monitoring system and the degree to which the set parameters have been respected.

The main perceived difficulties within institutional accreditation, selection and monitoring of providers are related to the potential interregional inequality that might develop. In this respect, existing evidence indicates that the organizational arrangements established by regions to control local health units and providers, as well as the intensity and effectiveness of control mechanisms, vary considerably from region to region.

This is in accordance with the more general, marked differences in government performance across regions found by previous research.

In sum, both the 1992–1993 and the 1999 reforms involved a profound process of decentralization of the NHS, both by devolving political and financial authority to the regions and by delegating considerable managerial autonomy to lower-level purchasing and providing organizations. This creates the need for a new regulatory framework that radically transforms the institutional rules

In the new institutional context, the Ministry of Health, the State Department of Innovation and Technologies and the Regions have decreed to operate jointly for carrying out the e-health national strategies and particularly for EHR diffusion, through State-Regions coordinating bodies.

In order to coordinate and audit the building phases of the New National Healthcare Information System, a “Cabina di Regia” (Production Room) has been instituted in 2001, coordinated by the Ministry of Health, and composed of representatives of central government and of Regions. That body also coordinates the implementation of an extensive program activated by Regions and Ministry of Health to develop the semantic interoperability between different regional health information systems and between these and the National

Healthcare Information System. Within this program, a specific project (so-called "Patient File") has two main goals:

- 1) re-engineering some processes (e.g. on registries for patients and healthcare professionals; on the workflow for death certificates);
- 2) definition of a framework for EHR development at regional and national levels.

In 2004 the Minister of Innovation and Technologies and the Minister of Health have activated a permanent Working Board on e-health (Tavolo permanente della Sanità Elettronica, TSE) with the Regions.

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

The e-health Working Board has the further goal to take into account the strategic objectives of European Union contained in the e-Health Action Plan 2004 and to define, consistently with the national strategic context, the national and regional Roadmaps for e-health.

number of GPs	55.000
GPs with EPR system	50 % ?
GPs exchanging electronic data with other stakeholders	14 % ?
number of hospitals	1200 +
hospitals with EPR system	3 % ?
hospitals exchanging electronic data with GPs	3 % ?
hospitals allowing GPs to access patient information	3 % ?

3 Overview of the initiatives in the eHealth sector

3.1 *The three major Regional programmes on eHealth*

The most relevant programmes on eHealth are being deployed by 3 regional authorities: Veneto, Lombardia, Emilia Romagna.

3.1.1 Regione Veneto

Programme: IESS - Integration for Health Services delivery (Integrazione per l'erogazione di Servizi in Sanità)

Objectives:

- Allowing direct approach of citizen to medical facilities (as well as services, booking offices, GP practices, chemists, emergency) by telematic tools;
- Set up of Electronic Health Record (FSP: Fascicolo Sanitario Personale) with electronic data about services received by patients, to which both medical staff and patients can gain access, in order to guarantee the continuity of treatment process;
- Set up of 105.000 smart card for the authentication on line for the citizen of two Health Local Unit in Bassano del Grappa e Mirano/Dolo
- Set up of 200 professional card for the digital sign for the medical staff of the 2 Local Units
- Set up of a interoperability network system, based on the "domain gate" and "e-gov envelope", for all the health local unit of the region for the electronic booking and the EHR
- Agreement with the Ministry for Innovation and Technologies for development and test of a interoperability and cooperation prototype named IBSE (Infrastruttura di Base per la Sanità Elettronica – Basic infrastructure for eHealth)

phase 1: Start: Sep 2003 - Finish: Jan 2006

phase 2: ongoing

Budget: 5.495.000 Euros (78% from regional funds and 22% from national e-government plan)

3.1.2 Regione Lombardia

Regional Services Card - Health and Social care Information System (CRS-SISS)

Objectives:

- The core of the project is an 'Healthcare Extranet' (SISS), which links operators, social services, organizations and citizens, tracking all the events which occur in the patient treatment (from prescription to administration) and providing value added services (the project ends in 2009)
- - The project is based on smart card technologies, granting access to the Network to both citizens and operators by their personal smart cards.
- - The first step of this project is the Regional Health Services Card (CRS): the personal smart card which allows every citizen to access public administration services.
- - At the same time is working the SISS ("Health Care Information System"): the first extranet connecting all healthcare and social operators (professionals and Companies) in Lombardia.
- improvement of the services for the citizen; continuing care process; information sharing and exchange; easy and secure access to the Healthcare System; better planning at Regional level; Simplification of administrative processes.

Phase I, Prototyping: the first phase has begun in December 1999 until March 2002;

- 96-98: definition of the functional aspects
- 1999: financing plan and first contract with Lombardia Informatica
- 2000: Tender for partners for phase one
- Second contract with Lombardia Informatica and tender for partners selection for phase two

Phase II, Extension: this phase has begun in March 2002 and is still working till September 2009, end of the project.

- 03-2005 Extension of the project all over the Region

- 06 2009 Consolidation and maintenance of the project

Budget: The project financing plan is valued as follows: € 400 Mln divided in 9 years and 9 months; furthermore, funds for € 50 Mln are allocated by the Regione Lombardia for the reorganization of the Hospitals informative systems.

3.1.3 Regione Emilia Romagna

Programme: SOLE - Online Healthcare

Objectives:

- development of an integrated telematic network for the interoperation of hospitals and healthcare professionals to provide value added services to citizens
- This is done by: 1) electronic management of prescription - refertation life cycle, and therefore, of continuity of care; 2) a regional registry that indexes clinical events stored into healthcare structures; 3) electronic management of farmaceutical prescription life cycle.

Start: Mar 2002 (ongoing)

Budget: 7,9 Mln euro

3.2 eHealth in Italy – current situation

3.2.1 eHealth portals for the public/patients

In Italy there is a portal named Italia.gov.it which is meant as a central service for Italian citizens where information is provided for whatever life cycle events or needs. The portal includes a section on health "**Vivere in Salute**" which offers the most complete overview of e-health services. It contains information about or access to general health issues (such as vaccination, food, disease and illness, prevention and care) and health services provided in Italy and abroad for Italian citizens.

One section of the portal has the heading "Consulting the doctor" and gives access to information on:

- the Local Health Authority (ASL, Azienda Sanitaria Locale): links to the Health Ministry and to Regional portals help finding ASL and services provided;
- health services provided by family doctors;
- services provided in case of emergency and where these can be requested;
- services provided in each Italian region, featuring links to **Regional Health Portals**;
- regions and municipalities that provide the opportunity to book health services online (at the moment, this option is available only in the case of one Region, Lazio).

The portal provides information about health care abroad both for tourists or for Italian citizens living abroad. Also featured are links to those regions which provide downloadable forms for request of health assistance abroad.

According to the Observatory of the Information Society only 4.4% of hospitals offer online reservation services for visits (november 2004, data IDC), while 90% offer reservation services via telephone call centres.

3.2.2 Online health information services

Because the national health service is managed by regional governments but is funded by the Central Government (specifically by the Health Ministry), the regional level is of most importance for the actual delivery of health care services. This means that the level and quality of online health information services differs a lot between regions, in spite of some common features determined by the national health system and policy-making at national level.

The government portal Italia.gov.it as well as the **Regional Health Portals** all provide health information online (see previous issue).

The **Centre for the Prevention and Control of Diseases** has been set up by the Health Ministry (Law 138, 2004). The Centre is a network of competencies involving a number of Italian institutions working in the field. Its goals are the risk analysis, coordination with regions, diffusion of information. The issues are the following: contagious and infectious diseases, promotion of healthy life style, vaccination, environment and health, accidents prevention, bio terrorism. Apart from the web and the opportunity to write to the e-mail address, there is a phone-in service (N. 15000) that supplies advice to health operators but also to citizens.

The **Health Ministry website** has a section dedicated to health campaigns dealing with issues such as smoking, food and nourishment, cardiovascular risks, vaccinations for

children, alcohol, and AIDS. Services include applications for calculation of the individual risk score of heart diseases, and links to the Istituto Superiore della Sanità (**Institute For Health Research**).

3.2.3 online information about available health services

Online information about health services are available on the regions' websites (21 in total) as these are responsible for the provision of health services to citizens. Content of these websites differs from region to region.

Regions that are well advanced in e-government implementation include **Emilia Romagna**, **Lombardy** and **Tuscany**. Their websites provide wide and in-depth online information about available health services. In Emilia Romagna, an advanced Regional Health Portal called **SALUTER** provide information about prevention and healthcare, and about the organisation and provision of public health services. The Regional Health Portal from Tuscany also features a list of all family doctors including their office hours and services provided.

An example of a region which is much less developed regarding the online availability of health information is Calabria. Its website contains only very little information on health services, apart from the possibility to download the regional healthcare plan for the period 2004-2006.

In summary, all Italian regions provide on their website some information about health services, but the degree of interaction and the quality/quantity of information differ a lot. Moreover, findability and visibility are very variable. It seems that regions where e-government is more developed have also succeeded to reach a high visibility of healthcare services on the web.

3.2.4 Health-related administrative transactions

Health services provision is organised at the regional level and as a consequence administrative transactions are carried out at that level as well.

The Italia.gov.it website provides a list of 13 downloadable forms for health-related administrative transactions; they are:

- Declaration of willingness to donate organs;
- Request of cancellation from general practitioners or children doctors' lists;
- Request for health assistance during a journey in another EU country;
- Request of certification for ability of work in another EU country;

- Request for the maternity vacation in another EU country;
- Request for the tax reduction pharmaceutical products;
- Application for the national health assistance;
- Request for invalidity pension for minors;
- Request for invalidity pension for people who are of age;
- Forms for complaint;
- Forms for certification and applications regarding pet health

3.2.5 Online pharmacies

Italian pharmacies have a joint website (www.farmacie.it) but this does not give the opportunity to purchase medications online.

However, a number of traditional pharmacies with an online sales channel, as well as online-only pharmacies do exist. Online sales are allowed only for non prescription medicines.

3.2.6 Websites of gps/public health clinics and specialists

Services provided by family doctors and general practitioners are known and classified as LEA (Livelli essenziali di assistenza, meaning basic assistance services). These services are provided by the ASL via the general practitioners or directly by the ASL. The family doctors/general practitioners do not have websites, but information about the doctors services are in some cases provided by the ASL. In Tuscany and Lazio, for example, regional government portals contain lists of general practitioners as well as specialists.

Specialists are also represented online through their associations. For example, ANMCO is the non profit professional medical association of the Italian National Health Service's Cardiologists. Its website can be found at www.anmco.it .

3.2.7 Online interaction with one's own doctor

This kind of service is not available in the country.

3.2.8 Availability of online diagnosis

This kind of service appears to be available only on commercial websites that provide healthcare related information in a popularized way, where people can write and ask for the opinion of a specialist.

Another important case is **Salute e Medicina Internet** where citizens can obtain a second opinion about the diagnosis given by their doctor. Practitioners and specialists have the opportunity to contribute to the website. Once registered, they can access incoming requests for second opinions, and send replies to the questions in their field of expertise.

Replies will be made available online.

3.2.9 Telephone consultation

Consultation with one's own GP/family doctor/primary local health care clinic: Each doctor can decide on her or his own whether they want to offer telephone consultation with patients or not. Some doctors are available for telephone conversations during certain hours of the day. No general rule applies.

Outside of office hours, there is a public service "Guardia medica" (medical guard), accessible through the same phone number from all parts of the country (118). After the phone request, and some information about the patient, a doctor may be sent to the patient domicile.

Other telephone services are provided for emergencies such as the request of an ambulance the request of an advice/help to the "Centro veleni" (Poison Centre).

3.2.10 Overall supply-demand match regarding eHealth services

Potential demand for eHealth services is still low in Italy.

3.2.11 Existing policies to encourage eHealth services for the public/ patients

Any national policy or initiative to encourage the provision and usage of e-health services. In any case this kind of policy and initiatives are under the responsibility of the regions. As a consequence, the picture may be very different depending on the region and on the local administration.

3.2.12 Role of user orientation in national eHealth strategies

An evaluation at the national level is not possible since healthcare is managed and provided by the regional and local level public administration. As a consequence, the user orientation of eHealth can only be analysed at regional and local level.

3.2.13 Existing specific policies/regulations for online or telephone-based consultations

There are no specific policies or regulations about this issue. We can say that, generally speaking, consultation by phone or e-mail are not in any way encouraged in Italy. Even most of the family doctors are not available for telephone consultation.

By and large, telephone consultation is limited to some urgent intervention in order to assess what type of relief is needed, as in the case of the poison centre hotline.

3.2.14 Country-specific barriers to implementation and uptake of eHealth services

eHealth is not developed uniformly across the country.

An assessment of the e-health services available in Italian regions municipalities shows that where e-government is already at an advanced stage, eHealth services are available and tend to be well visible and accessible. On the other hand, however, where e-government is still at a starting point, eHealth services are not widely developed. As a consequence, a low development of e-government is for sure one of the most important barriers to the development of supply and demand for eHealth.

3.2.15 Country-specific facilitators which encourage implementation/uptake of eHealth

An important driving force is the recent initiative to simplify the administrative procedures for providing and acquiring health services in the public domain.

3.2.16 Characteristics of national health care system which affect usage of eHealth

Health services in Italy are managed by regional governments but funding comes from the Central Government (Health Ministry). Health care services are directly delivered by the regions.

The Italian health public system is known as being complicated and characterised by long waiting lists. Application procedures are complex and often include a number of application forms. The use of the Internet can potentially help streamline these procedures.

3.3 eHealth user orientation profile for Italy

3.3.1 eHealth service availability

The main point of access for eHealth is the official government portal *Italia.gov.it*. Legislation in Italy currently prohibits the sale of medication on the internet so online transactions are limited to non-medical products, provision of information on health issues and diet and downloadable forms. Online consultations are not encouraged in Italy, thus emergency situations are usually the only circumstances dealt with by doctors over the telephone. Second opinions can be sought via the internet by citizens who have already been diagnosed and want to confirm their prognosis.

3.3.2 eHealth user orientation / quality

User orientation can only be analysed in Italy at a local or regional level since the services vary so dramatically from one region to another. Studies suggest that this is a result of varying degrees of technological advancement between regions. Regions that are electronically advanced have more visible and accessible eHealth services. Every region has some degree of information on health services on the regional websites but the quality of these services varies greatly.

3.3.3 National context

The Italians' perception of the national healthcare system is not at all positive; in fact they are one of the most dissatisfied people among citizens of the old EU member states.

The main access point for eHealth in Italy is part of the official government portal *Italia.gov.it*. This has a dedicated section on health, "*Vivere in Salute*", that can be regarded as the most widely known eHealth gateway for citizens in Italy. It provides access to information and services on general health issues under eight thematic areas. The portal also provides information about healthcare for tourists and Italian citizens living abroad, and features links to regions that provide downloadable forms for request of health assistance abroad. Other areas of interest include vaccination, healthy diet, disease prevention and treatment, recommendation on the use of drugs, relevant health institutions for a given condition, and help on how to quit smoking.

3.3.4 eHealth services and user issues

Access / availability: Both the government portal, which would be the main access point, and the Regional Health Portals provide health information online. There are 21 regional

portals with differing information from region to region. The centre for Prevention and Control of Diseases, set up by the Health Ministry in 2004, is a source of information for citizens on issues surrounding contagious and infectious diseases, promotion of healthy life style, vaccination, environment and health, accident prevention, and bio terrorism. In addition, the website of the Health Ministry contains a section dedicated to health campaigns dealing with issues such as food and diet, vaccinations for children, cardiovascular risks, smoking, alcohol, and AIDS. Services include applications for calculation of the individual risk score for heart disease, and links to the Institute For Health Research.

A list of health-related administrative transactions can be found in the Italia.gov.it portal. The list includes 13 administrative transactions that citizens can perform online, almost all of which are forms for online applications, such as change of the family doctor or request for health assistance in another EU country. Italian pharmacies have a varying presence online including search facilities for pharmacies in a citizens region, information and news on health. Some traditional pharmacies use the internet as an online sales channel through advertisements, but generally the purchasing of medication online is non-existent for legislative reasons. There are online-only pharmacies but these generally sell cosmetics, baby care and natural products.

General practitioners do not have websites nor do they offer online interaction tools. Lists of doctors and specialists are available online in some regions, for example in Tuscany and Lazio. Specialists are also represented online by their associations, for example ANMCO, a non-profit professional medical cardiologists' association. Citizens can also obtain a second opinion online about the diagnosis given by their doctor at www.doctor33.it. GPs and specialists can also contribute to the website after a registration process. When registered successfully, they can offer second opinions. Telephone consultations are at the GPs discretion depending on the particular patient and their circumstances, but it is not generally encouraged in Italy. Often such consultations are in emergency situations where immediate advice is required about treatments.

Findability: User awareness of available services is variable. It seems that regions with more developed eGovernment have succeeded in reaching a high degree of visibility of healthcare services on the web. Apart from web-based information services and email contact, a call centre that gives advice to health operators as well as to citizens is available when dialling 15000.

Quality: The quality of eHealth services varies between regions. In Emilia Romagna, an advanced Regional Health Portal called *SALUTER* provides information about prevention and healthcare and about the organisation and provision of public health services. The

Regional Health Portal from Tuscany also features a list of all family doctors including their office hours and services provided. On the other hand, an example of a region that is much less developed regarding the online availability of health information is Calabria. Its website contains very little information on health services, apart from the possibility to download the regional healthcare plan for the period 2004-2006. In summary, all Italian regions provide some information about health services on their websites, but the degree of interaction, the quality and quantity of information differ between them.

4 Strategic eHealth Plans/Policy Measures

4.1 *Strategic perspective*

The Italian eHealth strategy is strongly influenced by the radical change in the relative roles and responsibilities of the State and the Regions embodied in the constitutional reform of 2001 (Constitutional Law no. 3 of 18 October 2001).

Since then, the Italian strategy comprises three interconnected programmes addressing national, semantic, and territorial needs in order to achieve the following key objectives:

- to improve the efficiency and effectiveness of the healthcare system as a whole,
- to assure the Fundamental Levels of Healthcare Services throughout the territory, to speed up the technological innovation in citizen/patient-centred social and health care services.

The governance of the first and second areas of the programme is entrusted to an inter-institutional body referred to as the “Production Room” (Cantina di Regia), coordinated by the Ministry of Health, and composed of representatives of central government and of Regions.

4.1.1 Privacy and confidentiality

The principles about protection of clinical data are included, in Italy, within the Law on the protection of personal data (Decreto Legislativo nr. 196/2003).

For the assessment of appropriateness of services provided by the NHS, the Regional Authorities and the Ministry of Health need to process the data about the individuals, even if in an anonymous way.

For the support of the care processes, instead, the full identity of the citizen must be taken into account. The different goals in the usage of individual health information allow to define specific levels and measures on security and thus the appropriate technical solutions. In particular, in designing and realizing the EHR and its enabling infrastructure (IBSE), the following architectural choice has been made: each healthcare structure stores and has responsibility of all (and only) the clinical data it produces. Additionally, the solution applied for the management of clinical data for governance purposes within the NHS is based on infrastructural services with pseudo-anonymization and anonymization integrated within the security architecture.

Within the project on "Patient File" (see §2.4), the activity about the definition of a framework on the EHR development envisages the modelling of the process for the management of the EHR

through the telematic network in a secure way. In that context, it will be necessary to make citizens aware of the qualitative potential intrinsic in the availability of their clinical data, with respect to the effectiveness of care provision.

4.1.2 The role of eHealth standards

Within the joint State-Regions project on "Patient File", a task force is active to define the specific infrastructures to support the health information systems of the care-provision level. The task force includes also national organizations involved in the standardization milieu, such as HL7 Italia and IHE Italia.

The interoperability among information systems and the cooperation of healthcare professionals within integrated care processes can be obtained through different action lines, related to the levels of dependency from detailed clinical aspects.

In the last decade, the most stereotypical situations (e.g. the administrative processes or the requests for laboratory tests) were the object of an intense standardization activity, based on the definition of detailed data structures and of enumerated lists of the related compatible coded values (see in particular the messaging standards produced by HL7, ISO, DICOM, CEN and the implementation guidelines produced by IHE). These data structures are able to "transport" clinical data (e.g. the results of diagnostic tests), but in most cases they do not suggest which particular clinical data should be transported in a particular clinical situation (as characterized by a health issue, a care setting, a clinical pathway, etc).

When the care context is less predictable, a suitable cooperation among professionals can be only supported by clinically-oriented provisions. It is a matter of collection, validation and maintenance of a large body of clinical information and knowledge regarding care processes, clinical terminologies (e.g. SNOMED CT), data dictionaries (e.g. LOINC), clinical data sets, authoritative clinical knowledge and pragmatical information. Of course, this is facilitated by the adoption of open standards. From here, the strong need to make SNOMED CT open.

Moreover, there is a urgent need to define the internal structure of the different typologies of clinical documents (e.g. prescriptions, reports, discharge letters, clinical letters, etc), based for example on the standard ANSI-HL7 CDA (Clinical Document Architecture).

4.2 The main strategic areas of intervention

Here is a short description of the main areas for strategic intervention in the medium-long term period.

4.2.1 Online booking.

The goals are the design and the realization of online booking systems at territorial level (metropolitan, provincial, regional), interoperable nationwide.

The benefits expected by the project are: making easier citizen's access to healthcare facilities; improving the transparency in the "offer" of services; the control and reduction of waiting times; the offer rationalization and demand estimation of the health services.

The project plan, during the period between 2004 and 2006, will make provision for the start-up of pilot-projects in some territorial areas and their subsequent extension to a national level.

4.2.2 The development of Telemedicine

It represents a strategic factor in the new National HealthCare Plan. Work is underway in: testing online consultation / monitoring in remote areas (smallest islands and mountains); connecting clinic centres of medical excellence through a network infrastructure; testing of a common application platform for medical and diagnostic cooperation and research; setting up an international cooperation network aiming to sharing knowledge among Italian hospitals worldwide and medical centres of excellence.

4.2.3 Health cards.

A further area of investment concerns planning the card distribution and organizing health services in order to allow the full application of the new procedures related to the introduction of the European Health Insurance Card.

Furthermore, central public investments are dedicated to implement health professionals electronic cards and related services at regional levels.

4.2.4 Network of general practitioners.

This project aims at developing a cooperative information system for all general practitioners, Local Primary Healthcare Units and Hospitals, in Southern Italy, in order to bring better quality services to the public.

The same network also supports services for the monitoring of pharmaceuticals, e-learning activities for physicians, the communication of information to citizens and prescription monitoring.

4.2.5 Design and realization of EHR and of its enabling infrastructure.

This is the key project enabling the overall e-health vision. The goal is to design the technological architecture for an e-Healthcare system and standardize and regulate the exchange of information among the involved entities.

This is achieved by:

- 1) designing the infrastructure for the interoperation of the Italian e-Healthcare Systems, by defining the technical requirements and the communication standards;
- 2) realizing the catalogue of cooperative processes involving the different entities participating to the e-Healthcare System, and the exchanged messages.

4.2.6 Active Prevention.

The goal is to realize integrated informative tools to support active prevention about specific pathologies and categories: diabetes complications, vaccinations, oncologic screening, cardiovascular risk.

The system will allow different subjects (GPs, Territorial Units of Primary Assistance, hospitals) to perform an active role in the prevention, in order to reduce the incidence of these pathologies and the related costs.

The project's milestones within the space of 2004-2006 are the realization of pilot-projects in some regional areas and their subsequent extension to a national level.

5 eHealth deployment status

5.1 Implementation perspective

The National strategy for EHR deployment envisages three strands:

- 1) Implementation of an integrated system of individual health information, at national level. This system aims at tracing analitically all the health and social care events related to each citizen within the National Health Service since each event is linked to the citizen, the author of the event, the care facility, the waiting times. The integrated national system of individual health information is finalized to monitor the suitable application of uniform levels of care provision across Italian Regions. The deployment of this information system is already mature enough to perform an effective analysis of the data collected. In particular, they were used by the Regions and the Ministry of Health as a major statistical source to allocate the funds of the National Health Service for the fiscal year 2005.
- 2) Implementation of IBSE (Infrastruttura di Base per la Sanità Elettronica - Basic Infrastructuer for e-Health), a federated system for the interoperation and cooperation of healthcare professionals spread on the Italian territory, which share individual health information (see § 6.3 for details).
- 3) Semantic interoperability. The actions started in 2004 and are moving along multiple lines:
 - a) adoption of standards for the representation of cooperative workflows, of data formats, of clinical documents, and of use profiles for particular care workflows
 - b) production of guidelines to realize a substrate for interoperability across health organizations (registry of citizens, professionals and facilities; registry of web services available in the different operational domains of the NHS), guaranteeing the security of the EHR
 - c) systematization of clinical terminologies to support the interoperability in the continuity of care

5.1.1 National area: the new healthcare information system (NSIS)

The New National Healthcare Information System (NSIS) was proposed in February 2001 by the Permanent Committee for political issues between central and regional authorities (Conferenza Stato-Regioni) as a governance tool to support, oversee and monitor the Fundamental Levels of Healthcare Services (LEA; Livelli Essenziali di Assistenza). These are the healthcare service levels

guaranteed by the National Healthcare Service as appropriate to particular clinical conditions and care contexts.

The NSIS strategic framework has two primary development objectives:

- build an integrated system of homogeneous individual healthcare information records, where the patient information and the care delivery structure are the central information entities. The goal is to make information available on: the operating facilities at all healthcare levels, the services delivered, the resources used, and the related costs.
- contribute significantly to Public Health Authorities' governance principles and capabilities by ensuring the required analytical data on individual citizen healthcare is available, and using pseudo-anonymisation of patient identifiers to preserve privacy, while grouping all healthcare events for each patient.

The result is an information system defining a minimum dataset for analytical data to be used for governance needs for health authorities.

5.1.2 Semantic area: the national healthcare service's "bricks" (mattoni)

This "Bricks" programme, started in 2004, establishes the semantic toolkit required to ensure a common language to classify and codify the concepts in a uniform manner (e.g. services, facilities), to share methodologies for measuring quality, efficiency, and appropriateness of the Regional Healthcare Services (e.g. waiting times, appropriateness of services) and to achieve a uniform approach in the generation of the information when organising, managing, and governing the Fundamental Levels of Healthcare Services. The toolkit also helps to ensure that the information systems autonomously developed by the Regions, and by the local healthcare Administrations, will all interoperate.

The common elements, named "Bricks" (Mattoni) of the Healthcare System, have been organised into 15 thematic sub-projects, with a Region responsible for managing each sub-project. One particular "brick" defines the guidelines to develop the Electronic Patient File.

5.1.3 Territorial area: the ehealth board (TSE)

On the initiative of the Ministry of Health and of the Department of Innovation and Technologies of the Ministry of Reforms and Innovations in Public Administration, a permanent "eHealth Board" (TSE; Tavolo di lavoro permanente per la Sanità Elettronica) was established in 2004. This is the setting for technical discussion and consultation in order to harmonise the national and regional eHealth policies and to help coordinated implementation of the respective action plans.

TSE's first result is the document "Shared policy for eHealth" (Politica condivisa per la Sanità Elettronica) which adopts the European Union's strategic objectives contained in the 2004 eHealth Action Plan in the Italian context. In March 2006, TSE published the document "Architectural strategy for eHealth" (IBSE; Strategia architetturale per la Sanità Elettronica). The document constitutes a first high level guideline addressing the design of the national architecture for eHealth. The architectural vision considers as essential the following requirements:

- all clinical information of the patient is available anytime and anywhere,
- the system respects of the federated architecture of the Italian Healthcare System,
- the system has a high level of security and respects the Italian legislation on privacy,
- the system has a high level of reliability and availability,
- the system has a modular structure which enables a progressive implementation nationwide,
- the system safeguards existing investments and takes into account the interactions required with existing legacy systems,
- the system is based on the use of open standards.

5.1.4 Future activities

TSE has also launched other important eHealth pilots, such as:

- general practitioners' network for eHealth services (13500 GPs in nine Southern Regions),
- eBooking (five regions),
- eSignature for operators (200,000 smart cards in 16 regions),
- telemedicine and tele-education,
- Oncology Excellence Centers Network,
- proactive prevention (disease management).

5.2 Basic concept model of the new national healthcare information system (NSIS)

It's all change in Italy as the SSN (Servizio Sanitario Nazionale - National Healthcare Service) races to keep up with the latest political and social developments. Current critical issues include:

- significant devolution of power from the State to the Regions (deriving from the amendments to the V Article of the Italian Constitution, LD 347/2001 and L. 405/2001);
- the 'Fundamental Levels of Healthcare Services' protocol, which establishes strict relationships between 'essential' and 'appropriate' medical care;
- a burgeoning elderly population, highlighting the need to redefine SSN funding policies, in particular those which deal with the allocation of resources to treatments for acute and/or chronic illness.

These issues, amongst others, underline the need for a nation-wide database covering - and accessible by - all the Regions. This database would hold all the information required to establish an appropriate balance between the quality and the cost of healthcare services.

In order to get the ball rolling, the committee which mediates between the affairs of the State, the Regions and the independent Provinces of Trento and Bolzano, signed a framework agreement for the development of a new national healthcare information system, the NSIS.

The framework agreement clearly sets the agenda:

- that the NSIS should encourage local autonomy, while providing appropriate support to all parties - whatever their position in the hierarchy - within the SSN;
- that it should help to bring the SSN players closer together, through the open exchange of information, whether that information be the province of the central administration departments, the regions, or independent provinces and healthcare agencies;
- that it should promote collaboration and integration between diverse IT systems, previously managed independently by each region and local agency;
- that it should be able to focus on detail as well as the big picture, in particular devoting increased attention to issues of acuteness and chronicity;
- that it be citizen/user centric, providing an integrated healthcare information system that targets the individual.

As a result, the 'high concept' of the NSIS is open information access, filling in gaps in the healthcare record by providing seamless access via a framework that's compatible with the computing requirements of every level of the SSN: local, regional and central.

Another fundamental principle guiding the development of the system is focus: breaking down the concept of hospitalization into a much broader range of services (outpatient specialist visits, accident and emergency, pharmaceutical assistance, post-acuteness and chronicity services, services for the elderly).

A comprehensive strategy like this necessarily encompasses a large number of internal dependencies, but the overall concern remains the balance between the cost and the quality of national healthcare services. Quality and cost in healthcare are determined by doctor-patient interaction. Only at this level is it really possible to monitor the economic and qualitative performances of the system as a whole.

Any new healthcare IT system must be capable of capturing this critical, real-time process: the point at which the patient's needs are translated by the physician into services, quality and costs.

The foundation stone of the NSIS is therefore the individual medical information system. This database holds information related to healthcare services on an individual patient basis. It provides the raw data required to evaluate the appropriateness of any requested treatment, its medical consistency, the average time spent by the patient on the waiting list, the expense incurred by the level of service delivered, as well as the initial conditions against which the final outcome can be assessed.

Gathering and processing all the data required by NSIS for the development of an individual medical information system requires:

- Collecting homogenous information related to specific events (hospitalizations, outpatient specialist visits, home care and treatment, etc.);
- Tracing all events to individual citizens interacting with the SSN;
- Accessing additional care-flow information, enabling the identification of diagnostic and treatment routines followed by patients.

Initially, this information will be used by the SSN for management purposes. As the system matures, it should be able to provide diagnostic, treatment and rehabilitation features for individual patients.

It's worth noting that the implementation of a nation-wide individual medical information system also requires:

- Tools enabling citizens throughout the entire territory to be uniquely and 100% reliably identified;
- The gradual development of regional information systems to power the NSIS and in particular the integration of local healthcare and administrative processes, enabling the collection of Electronic Health Records for all welfare beneficiaries

The NSIS would therefore become a "connectivity backbone" between regional IT systems, making SSN management more efficient and also delivering better services to the individual, in particular

by enabling rapid access to medical histories for patients even when they are hospitalized far from home and in a different administrative region.

Comprehensive integration of individual medical information is going to take place in several distinct stages, each more challenging than the last. In the first stage, information will be leveraged mainly for the achievement of SSN management objectives. The following stages will be aimed at gradually providing access to information to improve the level of treatment and services delivered to individuals.

In its final stage, the system will allow the creation of comprehensive files for each patient, containing their entire medical history and including the results of treatments, actual and even suspected diagnoses.

The NSIS isn't just going to be looking after the patients, however. It's also intended to provide a valuable tool for monitoring the healthcare infrastructure. It will facilitate the assessment of hospitals and other centres charged with delivering healthcare and welfare services. Current infrastructure monitoring is mainly based on a hospital-centric model; it has become apparent, however, that decentralization and the increased emphasis placed on the treatment of chronic disease (due to increased life expectancy) has changed the healthcare landscape. In particular:

- Regional authorities have maneuvered hospitals into modifying the range of services they offer, as well as changing their organizational structure;
- New and existing local healthcare centres delivering welfare services are becoming increasingly important within the SSN.

As a result, people need to access information that gives a clear picture of all the resources available, at every level of the healthcare system and regardless of where they are. What's more, this information has to be expressed in a standardised format so that regional diversity can be fairly monitored.

All this is central to the NSIS implementation: a clear understanding of the SSN healthcare providers - the supply - and an equally clear understanding of the patients - the demand. In the NSIS Concept Model the patient, the treatment, and the service provider are all building blocks for the entire system and the source of all information. Linking these three elements makes it possible to monitor and manage both individual medical information at one end of the scale and the entire healthcare infrastructure at the other.

This degree of scope makes it possible for the NSIS to underpin all other strategic objectives - monitoring the Fundamental Levels of Healthcare Service, appropriateness, costs, waiting lists, drug life cycles, public investments and mental health.

5.2.1 Monitoring FLHS (LEA) and appropriateness

Means keeping track of services delivered at different healthcare levels and evaluating the balance between how desirable and effective they are, and how much they cost. This doesn't require the implementation of an independent IT system; what it needs is a means of interpreting the data made available to the NSIS - and the individual patient data in particular.

In the normal hospital environment, evaluating appropriateness tends to mean:

- Being limited to the assessment of specific operations or other events, since anonymous global data (such as area of residence, age, service delivered, service provider etc.) is not available to help determine appropriateness criteria;
- Being frustrated in any attempt to determine appropriateness criteria for care-flow as a whole, as opposed to specific procedure or treatment categories, because such an attempt would require a system which collates all medical events for each patient and links them with diagnoses (actual or suspect).

It's clear, therefore, that the development of best practice in monitoring appropriateness is inextricably bound up with the development of an individual medical information integration system. To answer this problem, the Monitoring and FLHS (LEA) systems will be completed gradually in two main stages: the first will address a generic appropriateness level for healthcare services, while the second will focus specifically on the appropriateness of care-flow.

5.2.2 Monitoring costs

Means identifying costs at both ends of the healthcare market: the service-provision end and the consumer end. In strategic terms, the manner in which healthcare costs are monitored has been redesigned by integrating:

- Agency accounts;
- Cost aggregates by service provider;
- Cost aggregates by levels of service.

Monitoring costs will enable cost analyses by category, making it clear how and where costs arise and where the money is going. Either a supplier or a service can be treated as a cost-centre and analysed accordingly, enabling the user to assign an accurate cost to a single treatment.

5.2.3 Monitoring waiting lists

Can be done either globally to highlight trends with reference to particular services or suppliers (average wait time for a hip operation, for example) but can also be focused down to the actual time individual patients have to wait.

Waiting lists are a very complex issue - and they're also top priority. The complexity arises because there are so many issues to consider on both sides: the service provider (supplier) side and the consumer (demand) side.

The demand side delays are influenced by:

- Increasing demand for healthcare services due to population aging
- Lack of demand management causing inappropriate delivery of services

The supplier is influenced by:

- Availability or lack of human, technical and physical resources
- Organization and efficiency of delivery methods
- Competitive pressure

Monitoring the average wait-time in relation to patients, services and suppliers will allow us to see both sides of the equation. From a demand perspective this will mean monitoring the average wait time for each individual and/or related category (e.g. area of residence), while on the supply side it will imply monitoring individual service- providers and/or related categories (e.g. location).

5.2.4 Monitoring and protecting mental health

Involves integrating information related to suppliers, services and patients.

Following the approval by the State-Region Conference of new policies regarding the National Mental Health IT System (October 2001), the development of the NSIS will be developed in line with all other related development environments, particularly the Individual Medical Information Integration System and the Healthcare Monitoring System.

Monitoring drug life cycle and use of medication involves linking patient data to information about drug life cycles and monitoring the use of medication.

5.2.5 Monitoring drug life cycles and the use of medication

Implies, on the one hand, keeping track of all stages of the drug life cycle - from the very early stages of research and discovery to clinical trials leading finally to marketing approval, release to

the general public and finally elimination due to lack of efficacy or side effects. On the other hand, you need to link drug usage information to individual patients and also to the various distribution channels.

Observatory for public healthcare investments: the information system enables the planning, assessment and monitoring of investment projects.

Where government funding is earmarked for healthcare, very close attention has to be paid to planning and monitoring how that money is invested. A detailed policy setting out how public healthcare funds can be used, in line with SSN objectives and requirements, has been drawn up.

Where particular objectives have been publicly set, it is essential to ensure a link with the “Monitoring the Healthcare Infrastructure” programme in order to:

- Enable tracking through to completion of specific projects and identification of the funding sources used;
- Enable prior and post evaluation of project investment opportunities based on a comprehensive break-down of all information relating to the project;
- Enable benchmarking analyses in order to assess the potential of single investment opportunities.

NSIS shows how quality planning accompanied by intelligent strategic thinking can create new national healthcare information system in Italy. It should be clear from the above that the next steps of the NSIS are going to be wholly dependent on the two foundation stones of the project: monitoring the healthcare infrastructure from a global perspective and building an integrated medical database based around the individual.

Healthcare systems cannot change overnight. The development of the NSIS has to take place within the context of gradual change, but a phased approach ensures that at least some tangible objectives can be achieved as soon as possible. The hard work and thoughtful collaboration of services and understanding of the importance integrating citizen centric services have been crucial importance. To make sure we get there in the end, there's also a longer-term vision for each of the strategic objectives involved, with intermediate milestones along the way. With everyone working towards the same goal, we can all have confidence in Italy's new and comprehensive health information system.

6 Web resources

National and regional institutions

- Ministry of Health: <http://www.sanita.it/sanita>
- National Institute of Health: <http://www.iss.it/laboratori/index.htm>
- Agency for Regional Health Care Services: <http://www.assr.it>
- Abruzzo region: <http://www.regione.abruzzo.it/sanita/servizi.htm>
- Basilicata region: http://www.regione.basilicata.it/Regione_informa
- Calabria region: <http://www.regione.calabria.it/regione/regione1.html>
- Campania region: <http://www.regione.campania.it>
- Emilia-Romagna region: <http://www.regione.emilia-romagna.it>
- Friuli-Venezia Giulia region: <http://www.regione.fvg.it>
- Lazio region: <http://www.regione.lazio.it/internet/index.htm>
- Liguria region: http://www.regione.liguria.it/menu/0901_fr.htm
- Lombardy region: <http://www.sanita.regione.lombardia.it>
- Marche region: <http://www.regione.marche.it/index.asp>
- Molise region: <http://www.molisedati.it/homepage.htm>
- Piedmont region: <http://www.regione.piemonte.it>
- Puglia region: <http://www.regione.puglia.it>
- Sardinia region: <http://www.regione.sardegna.it/ital/sanita/sanita.htm>
- Sicily region: <http://www.regione.sicilia.it/sanita/index.htm>
- Tuscany region: <http://www.rete.toscana.it/index.htm>
- Umbria region: <http://www.regione.umbria.it/sanita>
- Valle d'Aosta region: <http://www.aostavalley.com/REGIONE/index.html>

- Veneto region: <http://www.regione.veneto.it/home/sanita.htm>
- Autonomous province of Bolzano:
http://www.provinz.bz.it/sanita_servizisociali.htm
- Autonomous province of Trento: <http://www.provincia.trento.it/menu.htm>