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The National eHealth Information Strategy
National context, state of implementation and best practices

NEW NATIONAL
HEALTH
INFORMATION
SYSTEM (NSIS)

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1   The National eHealth Information Strategy

The socio-demographic evolution of the population, together with the need to balance available resources and quality of care provided to population, are a stimulus to develop new ways of delivering healthcare that allow, first of all, to track patient care pathways since the first interaction with the healthcare services. This is possible through the implementation of a system of integrated healthcare services network that enables, in real time, monitoring and systematic evaluation of key parameters such as clinical risk, diagnostic and therapeutic procedures with particular reference to their quality, resources allocated, used technologies and level of satisfaction perceived by the citizens.

The implementation of a system of integrated healthcare services network assumes a considerable importance, first of all at this moment, characterized by a profound change and evolution of the National Healthcare System (SSN) characterized by a ever more prevalent proportion of elderly people, and consequently an ever more need of healthcare necessarily more focused on local services rather than on hospital services, to cope with chronic diseases. In this context, the application of new technologies offers an excellent opportunity to establish a better balance between the need for improved quality of healthcare and an appropriate use of available financial resources.

These actions are essential to create the preconditions for the implementation of an eHealth Information Strategy at national level, with an unified governance. The main objective of this strategy is to ensure an harmonic, consistent and sustainable development of information systems in the Country, so that to support patient care and governance of SSN, with increasing levels of interoperability.

The implementation of the eHealth services is proceeding with considerable dynamism, through major projects at central level and initiatives active in almost all Italian Regions. These initiatives are mainly pertinent to the following areas, with significant priority of intervention:

- access to health services: integrated health services booking systems (CUP) that allow citizens to book health care services throughout the Country;
- availability of patient's clinical history: integrated electronic health record systems (FSE) for the management of all episodes of care for every citizen on individual basis;
- innovation in primary care: establishment of networks of general practitioners, digitalization and electronic transmission of prescriptions (ePrescriptions) and sickness certificates (on line transmission of sickness certificates);
- structural and organizational redesign of healthcare services network through telemedicine.

Common to all the eHealth initiatives, and pre-requisite for their implementation is dematerialization of health documents.

For the implementation of eHealth, it is essential the availability of tools that allow a certain and unambiguous identification of patients, through a unique key which link together, in accordance with national laws and regulations regarding privacy, each episode of care arising from the interaction with SSN. This allows to monitor quality and appropriateness of health care provided to each citizen and, at the same time, to improve national healthcare planning capabilities. Starting in 2004, an Health Card has been distributed to all the citizens assisted by SSN. This card contains, on one side, general informations of the citizen and the tax code (acting also as unique identification code within SSN) and, on the other side , informations established in accordance with regulations in force at EU level for the access to health care in the EU area.

The New National Health Information System (NSIS) is the national framework in which are included all the areas with significant priority of intervention envisaged in the eHealth Information Strategy, as shown in Figure 1 – "*The National eHealth Information Strategy framework*". The New National Health Information System is the reference system at national level for quality, efficiency and appropriateness measures concerning SSN. This system is aimed at supporting adequately the Regions and the Ministry of Health itself in carrying out their respective institutional functions and, with particular reference to the Ministry of health, its role of ensuring Essential Level of Assistance (LEA) to all the population, throughout the Country, accordingly to national legislation currently in force.

The NSIS is aimed at allowing the achievement of governance, service and communication objectives al national, regional and local level of SSN, according to a coherent framework.
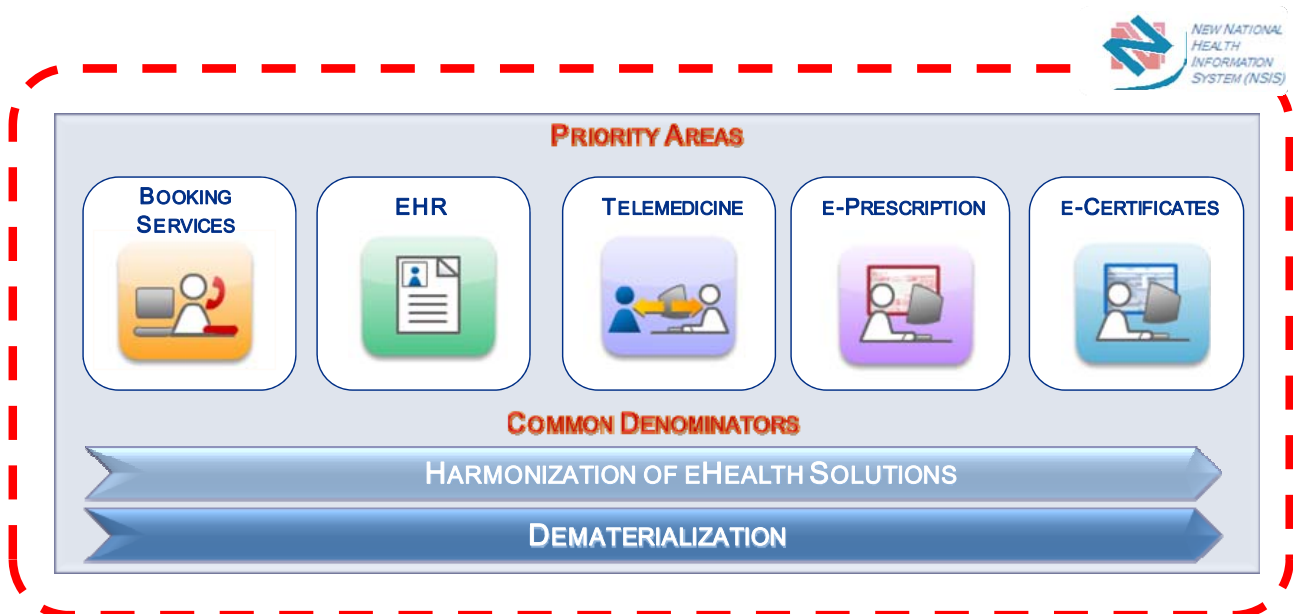

Figure 1 – The National eHealth Information Strategy framework

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1.1   Areas with significant priority of intervention and common denominators

In order to create the preconditions for the implementation of the eHealth Information Strategy described above, the Ministry of health has launched many initiatives, consistent both with the national framework represented by the New National Health Information System, and the areas with significant priority of intervention outlined above.

1.1.1   *Health services booking systems (CUP)*

In order to define a national model, through which to allow a complete and fully integrated representation of healthcare services provided, the Ministry of health has developed, in collaboration with the Regions, specific national Guidelines. These Guidelines are intended to support CUP harmonization and interoperability, through the definition of a set of minimum and uniform requirements.

The Guidelines are mainly focused on the following aspects: organizational models, work processes, information flows, common semantic languages and functional aspects, all preconditions to the effective use of new technologies. The Guidelines illustrate a representation of the possible access channels to booking services, among which are included: computer terminal with dedicated operator, telephone (e.g. call centre), internet, pharmacies. These Guidelines have been endorsed, on April 29th 2010, by the National Permanent Conference for relations between State, Regions and Autonomous Provinces of Trento and Bolzano. The implementation of the national Guidelines will be evaluated periodically at national level and may lead to financial penalties.

The possibility for pharmacies to act as a channel of access to booking services, as considered within the above mentioned Guidelines, has been confirmed by the Italian legislative decree n.153, October 3rd 2009, which outlines a new model of pharmacy: the "pharmacy of services". According to this model, the pharmacy is seen as a place where the citizen, in addition to drugs, can find several additional services with an high health and social value. Among the new services envisaged by the legislative decree outlined above, are included: booking of outpatient care in public or accredited health facilities, payments by the citizen when required, the withdrawal of medical reports.

In order to regulate these services, the Ministry of health has enacted the ministerial decree July 8th 2011, published in the Italian Official Gazette n. 229, October 1st 2011.

1.1.2   Electronic Health Record Systems (FSE)

In order to support the implementation of a unique regulatory framework, propaedeutic for the definition of a national reference model for FSE and, at the same time, exploit the results achieved at all the organizational levels of SSN, the Ministry of health, in the second half of 2008, has established an inter-institutional working group involving: internal and external experts of the Ministry itself, representatives of both the Ministry for the Public Administration and Innovation and the Regions, and a representative of the national Authority for the Protection of Personal Data as an observer. The working group has elaborated, in line with his objectives and accordingly with the needs expressed by the responsible of the national Authority for the Protection of Personal Data, a proposal for legislation governing FSE at national level. This proposal has been included in the bill proposed by the Ministry of health called: "Delegation to the Government for the reorganization of legislations on clinical trials and for the reform of the health professions, as well as rules in the field of health", definitively approved by the Council of Ministers on March 10th 2011, by the Chamber of Deputies on September 28th 2011, and currently under examination by the Senate of the Republic (reference n. AS 2935).

At the moment the working group is elaborating the implementation framework for the proposal for legislation governing FSE outlined above whose, after the entry into force of the bill in which has been included, will regulate the different aspects concerning the implementation and the use of FSE, among which: administrative and clinical contents, guarantees and security measures to be taken into account in the processing of personal data with respect to privacy regulations, rules, user profiling for patient data access, and so on.

The working group has also defined specific Guidelines aimed at supporting the implementation of FSE under a unique regulatory framework. The Guidelines identify the characteristics of FSE and patient summary, the infrastructural and technological specifications and several security and data protection issues according to national privacy regulation currently in force. These Guidelines have been endorsed, on February 10th 2011, by the the National Permanent Conference for relations between State, Regions and Autonomous Provinces of Trento and Bolzano and published on Italian Official Gazette n. 50, March 2nd 2011. The implementation of the national Guidelines will be evaluated periodically at national level and may lead to financial penalties.

1.1.3   On line transmission of sickness certificates

The on line transmission of sickness certificates is aimed at fully automate the whole process that starts with the production of sickness certificates and sickness certificates without clinical diagnosis (for working use due to privacy constraints) by SSN general practitioners and ends with the transmission, by the workers, of both sickness certificates to the National Social Security Institute (INPS) and sickness certificates without clinical diagnosis to their respective employers.

The technical procedures for the electronic transmission of sickness certificates have been defined by the ministerial decree February 26th 2010, published in the Italian Official Gazette n. 65, March 19th, 2010. Through this new service the workers may receive a paper copy of their sickness certificates and sickness certificates without clinical diagnosis produced by their general practitioner, or an electronic copy of those documents via e-mail (either certified e-mail or not). In case of unavailability of those certificates, the workers may request, to their general practitioner, the transmission of an SMS containing the essential data of sickness certificates without clinical diagnosis (i.e. request id, issue date, prognosis duration, worker's name and surname, general practictioner's name and surname).

The workers must promptly notify to their respective employers their absence and the place of residence, if different form official residence, for possible inspections by INPS and/or employers.

In order to monitor the implementation of this service and to identify appropriate solutions for specific local contexts and care settings, with particular reference to hospitals level, have been established at Ministry of health three working groups jointly involving national administrations and the Regions, with the objective of analyze regulatory, organizational, medical and legal issues concerning electronic transmission, technical aspects and administrative implications arising from electronic transmission of both sickness certificates and sickness certificates without clinical diagnosis.

1.1.4   ePrescription

The transformation from paper prescriptions to electronic prescriptions allows easier access to treatments, better monitoring and control of therapies, less clinical errors and lower social costs. This transformation becomes therefore a fundamental step in the automation of communication processes both within the same health facility (especially within complex organizations like hospitals), and between health facilities and general practitioners/pediatricians. The adoption of digital formats makes it possible to efficiently exchange informations between operators and, ultimately, to automate the whole medical prescriptions management process.

The Italian law (DPCM March 26th 2008) established rules and modes for electronic transmission of data concerning prescriptions by general practitioners. In addition, Italian decree n.78/2010, called:

"Urgent measures for financial stabilization and economic competitiveness" converted, with amendments, into the Italian law n. 122, July 30th 2010, establishes , in article 11, paragraph 16, the following points:

- in order to transmit electronically the prescriptions, in accordance with the article 50, paragraph 4, 5 and 5-bis of the Italian decree n. 269/03 converted, with amendments, into the Italian law n. 326, November 24th 2003, is to be used the same technological platform implemented for electronic transmission of sickness certificates;
- the electronic transmission of data concerning prescriptions has the same legal validity of paper prescriptions.

Following the testing of electronic transmission of data concerning prescriptions in some Regions, according with respective implementation plans, has been emerged the need of regulatory requirements aimed at creating the conditions for the actual implementation of ePrescription. At present, ePrescription is expected to be fully operating in 11 Regions out of 21 by 2011.

1.1.5   Dematerialization

Among the several activities carried out in this field, the Ministry of health has prepared the document named: "Guidelines for dematerialization of clinical documents in diagnostic imaging". The document has been elaborated by a working group in which have been involved experts from Ministry of health and other central administrations, as well as representatives of associations and scientific societies operating in the healthcare sector. The document is aimed at giving to Directors General, Medical Directors, Chief Information Officers, Directors of medical departments and organizational units of diagnostic imaging, radiology and nuclear medicine, the guidelines for the management of textual and iconographic clinical documentation in digital format, in compliance with current national regulations, and also at giving practical guidelines and feasibility insights intended for the full dematerialization of medical reports and diagnostic images.

The Guidelines analyze several types of documents, ranging form reports, to diagnostic images and to structured electronic report which includes both of them. For the several types of documents are specified the minimum storage time required and indicated the employees responsible for archiving.

The Guidelines specifies also the technical rules for the authentication and archiving of clinical documents in digital format. The document has been subjected to formal opinion by national organization for public administration digitalization (DigitPA) and national Authority for the Protection of Personal Data.

The document, currently under evaluation by Regions, will be subjected to endorsement by the the National Permanent Conference for relations between State, Regions and Autonomous Provinces of Trento and Bolzano.

The Ministry of health is also preparing, in accordance with the strategic pathway undertaken, and in collaboration with a dedicated working group, a further document aimed at defining guidelines for dematerialization of laboratory clinical documents.

1.1.6 Telemedicine

European Commission attributes particular relevance to telemedicine. In particular, in the EU Communication (COM-2008-689) of November 4th 2008, named "Telemedicine for the benefit of patients, healthcare system and society", are described several actions that involve both European Union and Member States, aimed at promoting a greater integration of telemedicine services in clinical practice, removing major barriers to its full and effective implementation.

In order to analyze in a systematic way home care services provided towards telemedicine, and to widespread the best practices arising from organizational, clinical, care delivery, technological and/or economic point of view, the Ministry of health has stipulated, in 2007, an agreement with the Emilia Romagna Region, subjected to subsequent renewals, for the establishment and execution of the National Observatory for the evaluation and monitoring of eCare services. The following Regions are participating to the Observatory: Tuscany, Liguria, Marche, Campania; in addiction, from 2009, Veneto and Sicily Regions and lastly, from 2011, Lombardy Region.

With the aim of making available a detailed picture of telemedicine services available in the Country, being also able to provide the information required at EU level towards the above mentioned EU Communication, and in agreement with the Coordination of the Health Committee of the Conference of Regions and Autonomous Provinces, the types of telemedicine projects and services investigated towards eCare Observatory have been expanded from homecare to all telemedicine services. The systematic and continuous update of those informations by the Regions within the eCare Observatory allows not only to have detailed informations about the state of implementation of telemedicine in the Country, but also to monitor and measure the results achieved in the different Regions over the time.

The Ministry of health is participating directly in several initiatives in this area.

Within the "Consiglio Superiore di Sanità" (advisory body of the Italian Ministry of health) have been set up, on February 24th 2011, a working group aimed at drafting national Guidelines for supporting the systematic use of telemedicine in SSN. The working group is currently working at defining a strategic framework in which to place telemedicine services, models, processes and pathways for integration of

telemedicine services in clinical practice, taxonomies, common classifications, as well as aspects relating to legal and regulatory profiles as well as economic and sustainability issues concerning telemedicine services.

1.2   Main eHealth initiatives at European Union level

With reference to the initiatives launched at European level, is worth to mention the epSOS (Smart Open Services for European Patients) project – http://www.epsos.eu/home.html – an initiative, activated in July 2008 with a duration of 36 months, aimed at testing at European level patient summary and electronic prescription, in order to ensure the interoperability of the solutions adopted by Member States. This project involves 12 Member States, including Italy.

In addition, the Ministry of health has participated, in 2010, together with a large group of EU Member States, Agencies and Associations related to both ICT and medical sphere, in drafting a project proposal, submitted to the EU Executive Agency for Health and Consumers (EAHC) and the EU Directorate General Information Society and Media (DG INFSO), under the Second Programme of Community action in the field of health. The project, based on two EU financial instruments – Joint Action and Thematic Network – has been positively evaluated. The project, called "eHealth Governance Initiative", aims at creating a governance mechanism through which to coordinate activities in the field of eHealth at UE level, and in particular:

- establish continuous and systematic dialogue mechanisms between institutional, strategic and operational level, at European and national level, whose lack constitutes today an obstacle to the further development of eHealth;
- create a common platform for all Member States within which to identify and jointly address common issues concerning eHealth, support the implementation of EU interoperable eHealth services and solutions in close collaboration with most appropriate stakeholders, starting from end-users and associations representing IT operators.

The project has officially started in February 1st 2011, and will run for 36 months.