Electronic Health Record (EHR): implementation in Italy

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The implementation of the Electronic Health Record:

Significantly increases the level of appropriateness of the responses to the health needs of the citizen and therefore also to pursue the sustainability of the health service

Provides assistance according to structured clinical care pathways that can be adapted in a flexible and customized way to the health needs of the citizen
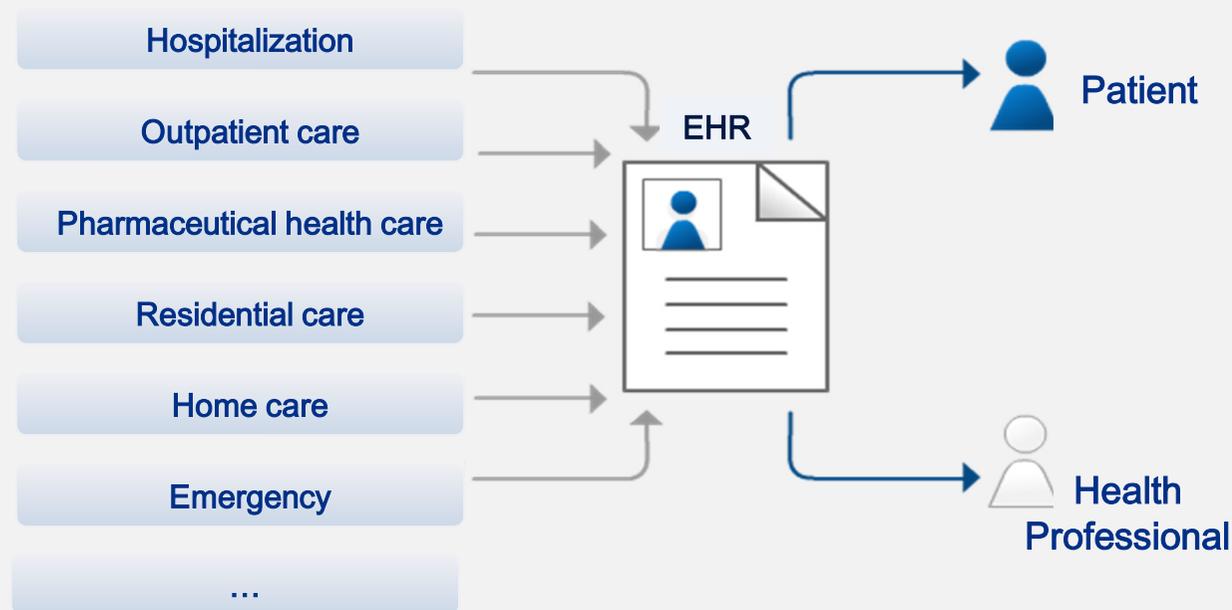
Improves the quality of life of citizens, especially with regard to the elderly and people suffering from various types of fragility and / or disability

EHR

Electronic Health Record

Electronic health record (EHR) is a set of digital data and documents relating to health and social health related to the patient and generated from present and past clinical events. (*)

Hospitalization

Outpatient care

Pharmaceutical health care

Residential care

Home care
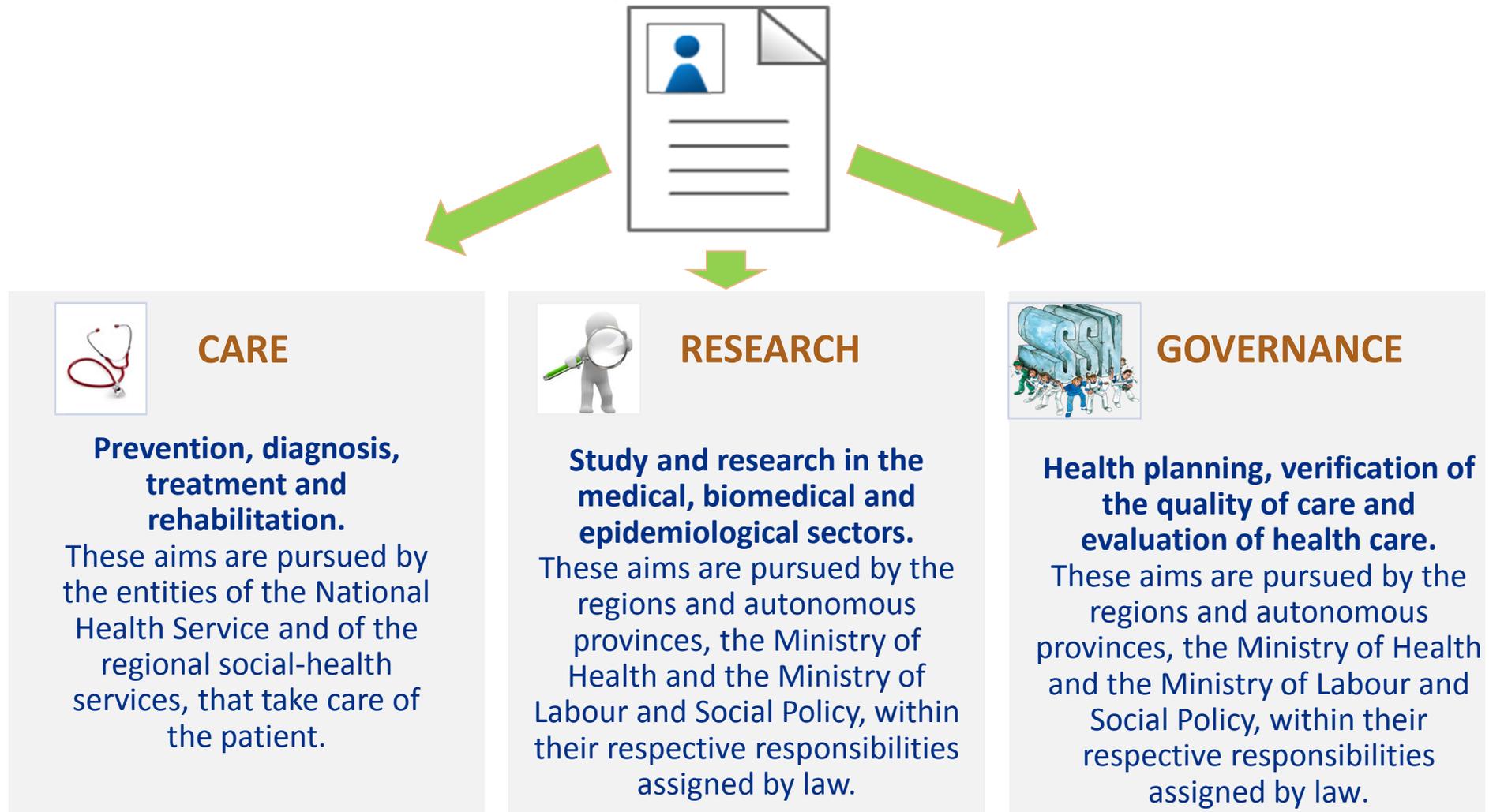
Emergency

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EHR

Patient

Health Professional

Electronic Health Record is a key element towards an integrated model of care, effectively respondent to the citizens' health needs

LAW	Principles of Law n. 221/2012

- The FSE is made, with the consent of the patient, by the Regions and Autonomous Provinces for purposes of prevention, diagnosis, treatment and rehabilitation.

- These aims are pursued by the health professionals of the National Health Service and regional health and social health services that take care of the patient.

- Consultation of data and documents in the Electronic Health Record, for the purposes of care, can be achieved only with the consent of the patient, except in cases of medical emergency in a manner determined by regulation. The lack of consent does not affect the rights of health service delivery.

- It is expected to adopt a regulation for the definition of the contents of the FSE, safeguards and security measures to be taken in the processing of personal data, the methods and different levels of access to the FSE

The EHR's purposes according to the article 12 of Law n. 221/**2012**

CARE

Prevention, diagnosis, treatment and rehabilitation.
These aims are pursued by the entities of the National Health Service and of the regional social-health services, that take care of the patient.

RESEARCH

Study and research in the medical, biomedical and epidemiological sectors.
These aims are pursued by the regions and autonomous provinces, the Ministry of Health and the Ministry of Labour and Social Policy, within their respective responsibilities assigned by law.

GOVERNANCE

Health planning, verification of the quality of care and evaluation of health care.
These aims are pursued by the regions and autonomous provinces, the Ministry of Health and the Ministry of Labour and Social Policy, within their respective responsibilities assigned by law.

The decree of the President of the Council of Ministers n. 178/2015 (EHR Regulation) implements the following provision:

- *article 12, paragraph 7, of the law 17 december 2012, n. 221*

"**With one or more decrees** of the Minister of Health and Deputy Minister for technological innovation, in consultation with the Minister for Public Administration and Simplification and the Minister of Economy and Finance, after consultation with the Standing Conference for relations between the State, regions and autonomous provinces, having consulted the Authority for the protection of personal data, pursuant to the article 154, paragraph 4, of the Privacy Code, **are established**: **EHR contents** and the **pharmaceutical dossier** and the limits of liability and the duties of those who contribute to its implementation, **data encryption systems**, **safeguards and security measures in the processing of personal data in respecting the rights of the patient**, the ways and the levels of access to the EHR by the persons referred to in paragraphs 4, 5 and 6, **the definition and the method of allocation of a unique identification code** of the bearer that does not allow the data subject 'direct identification', **the criteria for Regional, National and European interoperability of EHR**, according to the technical rules of the public connectivity system".

It regulates the main aspects concerning the implementation of the EHR, in order to enable a coherent deployment in all Italian Regions

EHR Regulation   The dPCM n. 178/2015 has defined in a systematic way

- The **documents that are part of the EHR**, with a minimum dataset and the other documents

- The content of the "**patient summary**" and the content of the **lab report** (the first documents to be activated, with technical details defined as well in the decree)

- The **provisions for the protection of the privacy of the patients** (information, consent, security measures)

- The data collection process and the parties responsible of it, the rules and limitations to access the data for care purposes

- The rules and limitations to access the data for governance purposes, coordinating the provisions with the NSIS interconnection procedures for all national health datasets

- The rules and limitations to access the data for research purposes

- The data encoding systems for the documents

- The services for interoperability among the EHRs of the Regions

- The governance system for the implementation, monitoring and evolution of the EHR

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Minimum Dataset	Other Documents	
a) identificative and administrative data of the patient; b) Medical reports; c) Emergency reports; d) discharge letters; e) patient summary; f) pharmaceutical dossier; g) choice regarding the donation of organs and tissues.	a) prescriptions; b) reservations; c) medical records; d) health checks; e) home care; f) diagnosis and treatment plans; g) semi-residential care; h) dispensing medications; i) vaccinations; l) outpatient care; m) Emergency care; n) hospital care; or) medical certificates; p) patient's personal notebook	q) Continuity of care r) autocertification; s) participating in clinical trials; t) exemptions; u) prosthetic assistance; v) data to support the activities of telemonitoring; z) data to support the activities of the integrated management of diagnostic and therapeutic; aa) other relevant documents

The EHR regulation provides some general and some specific provisions related with the different purposes.

Purposes of *Care*

- the patient can allow access to the subjects of the SSN and the regional social-health services that take care of the patient (Article 14, paragraph 1) ;
- the access to information is allowed only if following conditions are satisfied (Article 14, paragraph 2):
    - the patient gived his consent to the access;
    - the information to be processed are only those relevant to the care process;
    - the persons who access information fall into the categories entitled to the EHR consultation and are actually involved in the care process.

Purposes of *Research*

- the data contained in the EHR, may be processed as long as deprived of direct identification data (Article 17, paragraph 1);
- the data must be processed in accordance with the principles of proportionality, necessity, indispensability, relevant and limited manner and in accordance with Articles 39, 104 and 110 of the Privacy Code and its A4 Annex (Code of ethics and good conduct for the processing of data personal for statistical and scientific purposes - Article 18, paragraph 1);

Purposes of *Governance*

- the data contained in the EHR, may be processed as long as deprived of direct identification data (articolo 20, comma 1);
- the Regions process EHR data referred to in Article 20, in the way provided from the card 12 Annex A of the "Privacy Regulation" (Article 21, paragraph 1);
- the Ministry for Health processes EHR data referred to in Article 20, using the NSIS, accordingly with the "interconnection Regulation" (Article 21, paragraph 2).

According to the Research of the Health Digital Innovation of the School of Management of the Politecnico of Milan, almost all of the Italian Regions have adopted initiatives for the implementation of the EHR. At present, however, the Regions have quite different solutions in terms of ICT infrastructure, application architecture, mode of computerization of the EHR and of the documents made available to the citizens.

In order to overcome the differences in the implementation of the EHR is required an integrated strategy on different areas of intervention

Technology
Organization
Economics
Law

FSE

In order to accelerate the implementation of the interoperability services among the Regional EHRs, and to speed-up deployment of EHR for Regions behind schedule, the law n.232/2016 modified the provisions regarding the National Infrastructure for Interoperability – "INI"

This infrastructure will provide also a complete EHR solution, to be used by those Regions where the local implementation is late or too slow, hence enabling a timely roll-out of the EHR.

The INI has been designed by Digital Italy Agency (AgID), in cooperation with Ministry of Health and the Ministry of Economy and Finance, and will be implemented and managed by the Ministry of Economy and Finance, within the technological framework of the Tessera Sanitaria System.

According to article 26, paragraph 1, of the EHR Regulation, a Technical Working Group for monitoring and addressing the EHR development has been set up. This "article 26 Technical Working Group" acts as an advisor to the NSIS Steering Committee.

The Working Group's targets are:

- Verifies the status of the implementation and use of the EHR and informs the NSIS Steering Committee

- Proposes to the NSIS Steering Committee the annual targets for the implementation and use of the EHR

- Defines and proposes to the NSIS Steering Committee the evolution of:

  - the contents, format and standards used by the EHR

  - the coding systems and classification systems used for the interoperability of regional EHRs

  - the interoperability services

Composed by members of Public Administration, Regions and Autonomous Provinces, selected on the basis of their competence on the matter

Six Thematic Groups (TG) were activated as subgroups of the article 26 Technical Working Group. The results achieved by the Thematic Groups will be carried forward to the NSIS Steering Committee by the Technical Working Group.

	THEMATIC GROUPS	COORDINATION
	GT EHR ACCESS	AGID
	GT CONSENT MANAGEMENT	MINISTRY OF HEALTH
	GT TECHNICAL REQUIREMENTS FOR THE XML DOCUMENTS DIGITAL SIGNING AND MANAGEMENT OF NATIONAL BASED STYLE SHEETS	AGID
	GT COMMUNICATION	MINISTRY OF HEALTH
	GT CODING SYSTEMS MANAGEMENT	MINISTRY OF HEALTH
	GT EHR INTEROPERABILITY	AGID

Many regions having adhered to the thematic groups

In TG groups are also represented the Ministry of Economy and Finance, the Data Protection Authority and the CNR

Focus

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THEMATIC GROUP	AIMS
EHR access	To identify, define and formalize the ways of access to the EHR for patients and operators
GT consent management	To define the consent management ways with particular focus on inheritance from one region to another (interoperability)

THEMATIC GROUP	AIMS
technical requirements for the XML documents digital signing and for managing national based style sheets	To identify and define at national level the necessary elements and technical methods for XML documents digital signing and for managing national based style sheets
Communication	To promote communication and dissemination of EHR-related activities. The components of the working group will define the most suitable mode for the achievement of these objectives, defining suitable tools

THEMATIC GROUP	AIMS
coding systems management	To coordinate, support and provide guidelines for the standardized and integrated management of codes to ensure semantic interoperability of documents and clinical data within the EHR. It will be divided into two sub-groups: 1. SG dedicated to encodings 2. SG dedicated to technical encodings
EHR interoperability	To define and formalize the technical specifications and standards for the interoperability of the EHR through the production, testing, and publishing shared documents supporting the final design of the interventions that will give the necessary time and define the shared guidelines at national level, considering the possible functional evolutions.

Based on the survey carried out among all Regions, the 'article 26 Technical Working Group' organized the activity of the groups working in parallel, each one defining one or more contents and the structure of the related documents.

The priority contents have been identified following this criteria:

❑ belonging to the 'minimum dataset', or

❑ indicated by the provisions of art. 12, paragraph 15 *septies*, of the law 221/2012, as introduced by the 2017 Stability Law, or

❑ emerged in the context of the work table

Through the working groups, 'article 26 Technical Working Group' aims to technically define, at national level, the new contents to be introduced in the EHR with new decrees wich will be adopted in accordance with the article 12, paragraph 7, of Law n. 221/2012. In detail the priority contents are:

Minimum Dataset

- medical reports;
- emergency reports;
- discharge letters;
- pharmaceutical dossier;
- choice regarding the donation of organs and tissues;

Other Documents

- prescriptions;
- Dispensing medications
- outpatient care;
- health checks;
- vaccinations;
- medical certificates;
- patient's personal notebook
- exemptions;
- prosthetic assistance;
- prescription reminder

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THANK YOU

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