This document is a complete translation of the national guidelines for the Electronic Health Record published on Italian Official Gazette n. 50, March 2nd 2011.
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Introduction

In the framework of the modernization of health care, numerous initiatives have been implemented in order to improve the efficiency of the NHS and to simplify the enjoyment of the right of health from patient in every step of the health and social health path through actions such as easing of the documentation produced, the personalization of care, the reduction of human error and developing a patient-centered health care. To this end, a collection as comprehensive as possible and correct of clinical data has an important role in daily medical practice, in the clinical management of the patient, and in the correct procedure such as in the services provided by the health system.

The presence of deficiencies in the transmission and use of clinical data by traditional means has led the Ministry of health to develop innovative tools that, through the use of computer technology, can ensure adequate availability of informations in order to ensure better continuity of care.

The "pillar" on which to base the achievement of this objective is the Electronic Health Record ("EHR"), known as a set of digital data and documents relating to health and social health clinical events generated by present and past, regarding the patient, which is intended to facilitate patient care, provide a service that can facilitate the integration of different skills, provide a consistent information base, contributing to the improvement of all activities and nursing care, in compliance with the regulations for the protection of personal data.

Several Regions have already begun planning activities for the implementation of Electronic Health Record systems at regional level (eg Lombardy, Tuscany, Emilia Romagna, Friuli-Venezia Giulia, Sardinia). For this reason has become so strategic for our country to achieve a synthesis of different instances and promote the sharing of a reference model for the national EHR.

To this end the Minister of health, Professor Ferruccio Fazio, established under the coordination of the Ministry of health an inter-institutional table, involving internal and external experts in addition to the Ministry, representatives of the Regions designated by the Health Commission of the National Conference for relations between the State, the Regions and the Autonomous Provinces of Trento and Bolzano (Lombardy, Emilia-Romagna, Tuscany), the Department for digitalization of public administration and technological innovation of the Presidency of the Council of Ministers, public body for the digitization of Public administration (DigitPa) and the National Authority for the protection of personal data, which participates as an observer.

From the preliminary survey and analysis of current legislation, the Board has identified in the goals of care (and in the related administrative purposes) the scope of the establishment of the EHR. In order to define the scope of development of the reference model of the EHR, they have been focused on specific activities, of which this document represents the final results.
These Guidelines are the national reference for the implementation of EHR systems, they identify reference elements necessary for a consistent design and use of these systems within the NHS and in the wider European context. To this end the guidelines will be updated periodically.

The contents are organized as follows:

- The first chapter recalls the national scenario for the establishment of electronic health records, in the context of the national and local health service
- The second chapter defines the EHR, identifying the purposes and different areas of application, and recognizes its ownership at the regional level. Finally analyzes the legal value of the information contained in the EHR.
- The third chapter identifies the structural components of the HER defining the information contents.
- The fourth chapter analyses the issue of standard coding system used for the description of the information content of EHR.
- The fifth chapter explains the preliminary requirements of legality in the processing of personal data, including the information to the patient for personal data management, and the acquisition of the consent according to National legislative decree n. 196, of June 30th 2003, and the "Guidelines Electronic Health Record (EHR) and the health profile" issued by National Authority for the protection of personal data in July 16th 2009.
- The sixth chapter identifies the users of the EHR describing their roles and responsibilities taking into account the different roles of administrations and operators involved in the National Health Service.
- The seventh chapter describes the aspects of infrastructure and of the technological standards for the implementation of Electronic Health Records.
- The eighth chapter draws attention to the observance of safety measures, which administrations have to respect in order to use the EHR.
- The ninth chapter discusses further developments of the Electronic Health Record, with specific reference to additional purposes than those of health care.

Finally, even if the document is not aimed to inform patient and health and social health professionals who will be involved in the EHR, it’s important to stress about the correct preoccupations of the citizens about the protection of personal data in the context of EHR: attempts of EHR implementation, in Italy and abroad, have shown that a correct and transparent communication to the public on the benefits of adopting an EHR and the guarantees for the protection of data, is an essential element to
increase the confidence of the citizens in the system and, therefore, to encourage a large number of
accessions. Equally important is the communication with health professionals, so that, in the absence of
clear indications of the structures of the NHS, the EHR can see a risk of increased accountability to
patients and an increased exposure to litigation.

1 Reference Scenario

The National Health Service provides a guarantee for the protection of public health and Essential
Levels of Assistance (LEA), under the legislative decree n.502, December 30th 1992, are the
instrument to ensure to all Italian citizens uniform conditions nationwide.

The LEA was intended, in the original spirit of the legislator, regardless of the type of health
organization adopted, to give rise to a national reference and to offer homogeneous health services in
both quantitative and qualitative terms, in relation to predetermined resources.

The objective, therefore, to ensure the continuity of care and quality of treatment and care, ensuring the
protection of public health, is then to be contextualized in line with the current division of powers
between the central bodies and local authorities.

The NHS is, in fact, divided in three levels with political and institutional autonomy: national, regional
and local level:

- **The national level** sets the legal framework, within which operational and financial activity
  must take place in order to guarantee the protection of health and to ensure the institutional
  principles of "equal treatment of citizens" and "right to health". The state, in agreement with
  the Regions, defines the LEA, the activation of monitoring systems and identifies the
  resources to implement and provides activities and services that contribute to protection of
  health, as well as the definition of guidelines to ensure consistency in service delivery

- **The regional government** is responsible for the "overall structure of supply" of the regional
  area. Therefore, the provision and maintenance of the LEA also requires definition of the
  role of regional planning (next to the explicit definition and monitoring of the same by the
  State), in the delivery of health services provided. In addition the Regions, with the State-
  Regions agreement of August the 8th 2001 pledged to meet any additional financial needs
  using their own resources to maintain the provision of services included in the LEA.

- **The local level** is responsible for "management of services", that is the implementation of
  the organizational models that allow the combination of inputs to carry out the activities
  from which to obtain health services and protection of health.
2 Implementation of the Electronic Health Record

2.1 Definition

The Electronic Health Record is a set of digital data and documents relating to health and social health generated by present and past clinical events, relating to the patient.

The Electronic Health Record, which has a time horizon that covers the entire life of the patient, is fed continuously by who take care of him under the National Health Service and the regional health and social health services.

2.2 Purposes

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

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

2.3 Areas of application

In the context of support and optimization of operational processes in the health sector, it's possible to identify the following areas of use:

- support to the scenarios and to the processes of care: because it makes the patient's medical history available to all actors involved;
- support for emergency / urgency: because it allows to an health professional to frame an unknown patient during contact in emergency/urgency;
- support for continuity of care: because it allows different health professional who have already assisted a patient to be aware of diagnostic and therapeutic initiatives carried out by colleagues;
- support activities related to management and administrative processes of care: in that it allows operators to share information between administrative (e.g. booking services, prescriptions, etc..) or organizational / auxiliary support networks for patients with chronic diseases and / or in rehabilitation.
2.4 Legal value of the HER and responsibilities of health professionals

The legislative decree n. 82 of March 7th 2005 on the "Digital Administration Code" (CAD), as amended by legislative decree n. 235 of December 30th 2010, defines the electronic document as "the computer representation of acts, facts or legally relevant data" (article 1, paragraph 1, p letter).

The legal value (article 2702 of the Italian Civil Code) of the different types of data and documents potentially present in the EHR is therefore to be found in the provisions of this law and in the technical regulations in force of the national law – DPCM March 30th 2009 – entitled "Technical rules relating to generation, addition and verification of digital signature and validation time of electronic documents ", which can be summarized in the fulfillment of the requirements for qualified electronic signature / digital signature and time stamp.

As an example, but not exhaustive, here are the following cases:

- digital copies of paper documents not signed or not signed electronic documents have the same effectiveness of mechanical reproduction (article 2712 of the Italian Civil Code);
- the electronic documents according to art. 20 and art. 21 of CAD and subsequent amendments have legal value if the conservation respects the requirements of art. 44 of CAD and subsequent amendments and additions;
- data obtained by using automated documents in the EHR have legal value if they have entered according to art. 20 and art. 21 of CAD and subsequent amendments and additions;
- data entered manually by health professionals have a legal value only if signed according to art. 20 and art. 21 of CAD and subsequent amendments and additions, otherwise, if time stamped, they are only acts that have the effectiveness according to art. 2712 of the Italian Civil Code.

As mentioned above it is therefore not significant, given its nature as a "set of data and documents," to speak of legal value of the EHR as a whole immutable, even more because of the dynamic nature of the EHR itself that is fed to the occurrence of various clinical events. In those circumstances it is important to note that the EHR allows to store digital documents, even those which, having the features mentioned above, have a full legal value and whose responsibility pertains the operator analogous to the equivalent paper document (as specified by CAD).

As a result, it’s not possible to configure to health professionals specific responsibilities with respect of the availability and the use of the EHR, compared to those yet existing.

The health professional will continue to make, according to its knowledge and belief, the clinical evaluations, making use of the data contained in the EHR, whose contribution will be to increase as
much as possible but without any pretense of completeness, this wealth of data regarding the variety of patient information and the ability to compare their trends over time.

3 Contents of the Electronic Health Record

3.1 Identification data of registry of the patient

The registry of patient is the core around for all the processes related to health care. The accuracy and updating of personal data for the patient to whom are provided health care services is a prerequisite to the establishment and management of the Electronic Health Record.

Personal data that are not part of the EHR and are managed in separate files, but fed by the registry of patients.

The achievement of this objective is also an important contribution to the minimization of errors in the identification of patient in the occasions of contact with health and social health care providers, because the misidentification has implications concerning the handling of personal data, in addition to those related to the overall quality of service to patients, with a probability of problem higher as is the number of patients for whom the EHR is managed.

Among the personal data is essential, in particular, the Tax Code that represents the unique key of identification of the patient. The Tax Code is given only by the National Tax Agency.

Therefore, the Tax Code in the registry of patients are those resulting from the alignment with the National Health Card system.

According to what is said above, is important to indicate, in the registry of each patient, the indication of the "owner" of personal data and its time of validity. "Owner" means the entity that is responsible for managing the personal data for the patient (i.e. insert, modify and delete data).

Where it is necessary to maintain a secondary database, data will be valid if it is possible to verify, through a special process, the correctness of the data base of the Owner, through a request to the Owner itself.
### Identificative data - Description

<table>
<thead>
<tr>
<th>Data Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tax Code</td>
</tr>
<tr>
<td>Surname (at birth)</td>
</tr>
<tr>
<td>Name</td>
</tr>
<tr>
<td>Sex</td>
</tr>
<tr>
<td>Date of Birth</td>
</tr>
<tr>
<td>Place of Birth</td>
</tr>
<tr>
<td>Province of Birth</td>
</tr>
<tr>
<td>Address of legal residence</td>
</tr>
<tr>
<td>Address of physical residence</td>
</tr>
<tr>
<td>Date of death (date of closure of the record)</td>
</tr>
</tbody>
</table>

### Supplementary data - Description

<table>
<thead>
<tr>
<th>Data Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Health Authority of Residence (ASL)</td>
</tr>
<tr>
<td>Start date of assistance c/o Local Health Authority (ASL)</td>
</tr>
<tr>
<td>End date of assistance c/o Local Health Authority (ASL) (to indicate only if present)</td>
</tr>
<tr>
<td>Tax code of the physician</td>
</tr>
<tr>
<td>Surname of the physician</td>
</tr>
<tr>
<td>Name of the physician</td>
</tr>
<tr>
<td>Start date of assistance by the physician</td>
</tr>
<tr>
<td>End date of assistance by the physician (to indicate only if present)</td>
</tr>
<tr>
<td>Type of Assistance (general practitioners / pediatricians, etc)</td>
</tr>
<tr>
<td>Contacts of physician (address, telephone number, etc.)</td>
</tr>
<tr>
<td>Other information</td>
</tr>
<tr>
<td>Exemptions and relative expiry date</td>
</tr>
</tbody>
</table>

### 3.2 Administrative data concerning the health care

The administrative data on health care consist of administrative information regarding the positioning of patients in the National Health Service, with reference to the network of providers offered by the NHS and to other information, including the organization of health care assistance in the Region.
3.3 Health and Social Health documents

The Electronic Health Record of each assisted is automatically updated, taking into account the information content already available, with health and social health documents "certified", that is issued by National Health Service providers (e.g. laboratory reports, radiology and specialist outpatient) stored electronically in dedicated repositories.

The EHR will also contain informations and / or medical records relating to events prior to its constitution, but only if the patient gives specific consent.

In particular, the EHR is composed of a minimum core of essential documents that must be made available by the system and additional documents that allow to expand the scope of use of the EHR in support of the different pathways activated in order to ensure continuity of care. While the minimum core of data should be made available at regional level in order to guarantee freedom of choice of the patient to exercise the right to treatment even in case of change of residence from one Region to another, the other documents may become part of ad additional section of EHR based on the regional choices determined by the maturity level of digitalization processes and regional policies.

3.3.1 Minimum data set

<table>
<thead>
<tr>
<th>Minimum data set</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical reports</td>
</tr>
<tr>
<td>First Aid Reports</td>
</tr>
<tr>
<td>Document of hospital discharge</td>
</tr>
<tr>
<td>Synthetic Health Profile</td>
</tr>
</tbody>
</table>

3.3.2 Other documents

<table>
<thead>
<tr>
<th>Other documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescriptions (ambulatory care, pharmaceutical care, etc..)</td>
</tr>
<tr>
<td>Hospital care records (ordinary and day hospital)</td>
</tr>
<tr>
<td>Health status</td>
</tr>
<tr>
<td>Home Care</td>
</tr>
<tr>
<td>Therapeutical plans</td>
</tr>
<tr>
<td>Residential and semi-residential care: multi-dimensional evaluation report</td>
</tr>
<tr>
<td>Dispensing of drugs</td>
</tr>
<tr>
<td>Certificates</td>
</tr>
</tbody>
</table>
3.4 Patient Summary or Synthetic Health Profile

The individual health record is the information content of the software application of medical records of general practitioners and pediatricians from which to extract the data comprising the Patient Summary or Synthetic Health Profile. The Patient Health Summary or Synthetic Health Profile is the electronic document summarizing the patient's medical history and his current health situation. This document is created and updated by the general practitioner and pediatrician whenever there are changes which they consider relevant to the patient's medical history and, in particular, contains a predefined set of clinical data useful in emergency.

The purpose of the Synthetic Health Profile is to promote continuity of care by enabling rapid classification of patients at a no predetermined contact such as in emergency situations and first aid.

Through the Synthetic Health Profile, the general practitioners and pediatricians provide a fast and universal patient presentation summarizing all and only the information they consider relevant and make them available for consultation to all authorized health professionals.

The Synthetic Health Profile is, therefore, a document:

- **synthetic**: it shows only the essential information;
- **with a single author**: it is created, updated and maintained only by the general practitioner or pediatrician, it cannot be created automatically from the EHR, it is always the result of a professional review and frequency of updates are at the discretion of the general practitioners and pediatricians, provided that adequate;
- **non-clinically specialized**: the content must be such as to contribute to the continuity of care regardless of the usage scenario (Emergency, continuity of care, etc.)
- **it has not a default user**;
- **unique**: within the domain of the EHR must exist only one Synthetic Health Profile "valid" for the patient.

In this scenario, has been defined the following header in the Synthetic Health Profile:

- **personal data of patient**;
- **personal data of physician (general practitioner/ pediatrician)**;
- **any contact person**.
The document is divided into the following components:

<table>
<thead>
<tr>
<th>Header</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient data</strong></td>
</tr>
<tr>
<td><strong>Physician data</strong></td>
</tr>
<tr>
<td><strong>Any contact name</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Essential data (if available)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Allergies, adverse reactions to drugs or contrast agents or other substances, allergies, and immune risks</strong></td>
</tr>
<tr>
<td><strong>Significant health problems and diagnoses</strong></td>
</tr>
<tr>
<td><strong>Therapies in progress</strong></td>
</tr>
<tr>
<td><strong>State of health of the patient</strong></td>
</tr>
<tr>
<td><strong>Treatments and therapeutic, surgical and diagnostic procedures</strong></td>
</tr>
<tr>
<td><strong>Risk Factors</strong></td>
</tr>
<tr>
<td><strong>Vaccinations</strong></td>
</tr>
<tr>
<td><strong>Missing organs / transplants / explants</strong></td>
</tr>
<tr>
<td><strong>Prosthesis, implants, assistive</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other information about the patient</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Monitoring parameters</strong></td>
</tr>
<tr>
<td><strong>Active care plan</strong></td>
</tr>
<tr>
<td><strong>Blood Group</strong></td>
</tr>
<tr>
<td><strong>Other diseases of recent onset</strong></td>
</tr>
<tr>
<td><strong>Pregnancy and childbirth</strong></td>
</tr>
<tr>
<td><strong>Agreement / disagreement to the donation of organs</strong></td>
</tr>
</tbody>
</table>
General Practitioner / Pediatrician evaluates which of the above elements, even if available, are not to be included in the Synthetic Health Profile.

Finally, there are other data that, if available, can optionally be entered by the General Practitioner / Pediatrician:

- **findings**: are the results of investigations during the past two years on the problems (pathologies) selected by the General Practitioner / Pediatrician with an emphasis on the branch of cardiology and the results of laboratory investigations (3 most recent results)
- **visits performed by the family doctor**
- **no chronic diseases**

In the Synthetic Health Profile the information must have a precise meaning in order to avoid for example that the mode of presentation of data can bring out doubts between in blank fields and missing information.

### 3.5 Citizen's personal notebook

Within the EHR it’s possible to provide a section reserved for the patient to offer the possibility to enter data and personal information (e.g. data of the family, data on sports, etc..) files, medical records (e.g. reports of examinations carried out in not affiliated facilities, medical reports stored at home), a diary of significant events (visits, diagnostic tests, measures of monitoring parameters), reminders for regular medical checks. This allows to enrich the EHR with additional information in order to complete the description of the state of health, but such additional information and / or documents will be "not certified".

### 3.6 Statement of intent to donate organs and tissues (self-certification)

The EHR shall provide the patient also features that allow him directly or through his doctor, to express his/her wishes regarding organ donation, ensuring clear and specific appropriate information, ensuring the right to change decisions at any time as well as recording the timing of every act of will.

The declaration of intent with respect to the donation of organs is regulated by Italian law n.91 of April 1st 1999 and by ministerial decree of April 8th 2000 (as amended by ministerial decree of March 11th 2008).

In particular, among the various conditions laid down, the statement can be expressed by patients through:

- the recording of his / her own will by the family doctor (article 23, paragraph 3 of Italian law n. 91/1999);
– a written note containing name, surname, date of birth, declaration of intent (positive or negative), date and signature (article 1, paragraph 2, of the ministerial decree April 8th 2000).

4 The methods of encoding the information content of the EHR and the structuring of documents.

The creation of an Electronic Health Record System faces with the need, common to all information systems, to choose and adopt common coding systems, even for semantic interoperability in different operational contexts.

All "levels" of information can benefit greatly from the adoption of standards ("de jure" or "de facto") approved and adopted at international level and, in fact, the guidelines of the main countries are converging on well-defined coding systems that have the following characteristics:

– completeness: every object must be put into a class;
– economy: a relatively small number of codes used represents a larger number of information content;
– orientation to an end: the criteria for the establishment of classes are arbitrary and depend, for each classification, to the purposes of the same classification;
– mutual exclusivity: each object must be uniquely classified into one class.

The coding system used is crucial for the proper sharing and interpretation of information content of clinical events represented in the EHR, so that it is necessary to define ways of representing information which are consistent and interpretable by the systems involved with the use of information encoded by use of classifications defined and shared nationally.

If it is necessary to further define specifics for the definition of clinical contents and method of filling in clinical documents, these all will enclosed in subsequent specific documents issued by Ministry of health.

With regard to complex information structures (e.g. e-Prescription and Patient Summary), the orientation is now directed to the adoption of the HL7 standard (Health Level 7), and in particular to the progressive use of CDA Release 2 (Clinical Document Architecture).

In any case, the choice of a coding system in place of another must be made taking into account factors such as the spread in the healthcare context, adaptability (also for other than the original criteria for which the encoding was designed) and maintainability (the effort to adapt to changes in the phenomenon that you want to analyse).
5 Requirements for the lawful processing of personal data contained in the EHR

5.1 Compliance to the citizen

5.1.1 Information

The data holders must provide appropriate information to citizens in advance, containing all the elements required by article 13 of legislative decree n. 196, June 30th 2003, which is a requirement of lawfulness.

In particular, it must be highlighted the intention to establish an EHR that containing the medical history of the patient in order to improve health care process (by collecting a larger amount of information possible), clarifying that the data stored in the EHR are relative to its previous and / or current state of health.

In addition, the information to citizen:

- must explain in a simply way the opportunities that EHR offers in terms of improved procedures to ensure the right to health but, at the same time, the broad spectrum of knowledge that it may offer;
- must inform the citizen that his denial has no effect on his right to the provision of health care required;
- must give sufficient information about the way of operation of the new digital instrument;
- shall specify the operators who, in taking care of the patient, can access the EHR, as well as the related ability to accept that only some of these individuals have access to EHR;
- must inform also the citizen that the EHR could be consulted, even without his consent, but in respect of the general authorization of the National Authority for the protection of personal data, if this is essential to safeguard the health of a third party or the collectivity (article 76 of the legislative decree n. 196, June 30th 2003);
- must highlight the fact that the consent to the consultation for a particular operator (e.g. the general practitioner or the doctor of the medical department where the hospitalization occurred) may also be related to his deputy;
- shall provide to the citizen the identity of the controller of personal data processed by the EHR;
- must inform the citizen that he/she can exercise at any time the rights under art. 7 et seq. of the Italian Civil Code (see paragraph 5.1.3).

5.1.2 Informed consent to data processing

Activities related to the creation of the Electronic Health Record give rise to a way of further and distinct processing of personal data than all treatments resulting from disbursement of the assisted
medical care in relation to which the data have been acquired or produced.

The distinction and diversity consist in the activity of collection of all information relating to medical history of the citizen, produced by different controller of personal data involved, and in pertaining information sharing by health providers and doctors authorized to access anytime and from anywhere.

The processing of personal data in EHR must fully respect the rules governing the protection of personal data and must therefore submit to the free will of the citizen, who with his/her consent has the right to allow or not allow the establishment of its EHR, to archive in it any data pertaining his/her previous and/or current health status and to exercise control on who can access the proper EHR and to which groups of information. His/her choices can be changed at any time by himself/herself.

The consensus, therefore, constitutes the first condition for the lawfulness of such treatment and is valid only if it is given freely, and specifically to treatments clearly identified and for which the citizen has been clearly informed in advance.

The consent to the creation of Electronic Health Record by the patient must be explicit and clearly expressed.

In case of denial by the patient it should not be any effect on his/her ability to avail of the healthcare provided by NHS.

Therefore, the expression of the will of the patient for modular access to his/her EHR is manifested through:
- a general consensus, necessary and preliminary element for the establishment of the Electronic Health Record;
- specific consent on both the information to make visible and the NHS operators providing care to the citizen (e.s. general practitioners, pediatricians, pharmacists) to enable for the access to data contained in the EHR.

The architectural solution, therefore, must be such as to ensure that access to information from the EHR will only be permitted if the following conditions occur:
- the citizen has given explicit consent to the establishment of his/her EHR;
- the information to be treated are essential for the specific care of the citizen;
- the information to archive into the EHR have not been subject to obscuration by the citizen;
- the citizen has given explicit consent to access to authorized information;
- the citizen has indicated the categories of health professionals who can consult, provided that the qualified medical personnel involved in the care of a patient can see only the clinical data of the patient associated with the disease being treated.

Each type of consent given by the patient may be revoked or modified at any time. The denial of consent determines that the EHR is no longer integrated with new data and restricts the availability of the data contained in it exclusively to health professionals or the medical institutions that have prepared
them and therefore are the owner of those data (GPs, Pediatricians, Local Health Authorities, etc.) and to the patient, thus denying access to EHR to those allowed to access only in case of consent of the citizen.

In any case, changing the level of access authorization shall not affect the traceability of the EHR consultation made by operators authorized till the time of its withdraw.

The consent in the case of a minor of 18 or person subject to social protection can be expressed by a parent or a tutor with a valid identity document. When minor reach 18 they must explicitly express their consent, not being valid a confirmation by parents of the consent previously expressed by themselves.

In addition, the patient has the right to impede the visibility of certain health information related to individual clinical events that could be archived in the EHR to other operators than those who produced the data (“obscuration”), without the latter being automatically aware of the fact that the patient has done so. This choice is reversible at any time. The operators caring the patient can access the clinical data archived in the EHR except for those data subjected to obscuration.

Data holders, in developing the EHR and identifying the type of information that there may also be archived later, have to comply with regulations to protect the anonymity of the person including victims of sexual violence or pedophilia, people with HIV, people who make use of drugs, psychotrophic substances and alcohol, women with voluntary interruption of pregnancy or who decide to give birth anonymously, and with reference to family counseling services. These data types are "confidential" by default ("obscured" by law) and can be made visible only by specific and explicit consent of the citizen, in accordance with the provisions of the "Guidelines on the subject of electronic health records (EHR) and the health profile "approved by the National Authority for the protection of personal data of July 16th 2009.

Health information related to clinical events preceding the establishment of the EHR (e.g. previous medical reports related to medical services) can be archived in it only if explicitly authorized by the citizen, which anyway has the right to “obscure” some of the those data. However, in view of objectives pursued through the EHR, the patient should be informed about the utility to set up and make available the fullest possible complete picture of the health information concerning him/her, in order to offer better support for care. A thorough knowledge of clinical data relating to the past too can contribute to more effective detection of the elements useful for the evaluation of the case.

5.1.3 Exercise of rights by the patient

The citizen must be guaranteed the possibility to exercise, at any time, the rights under art. 7 of the Italian Civil Code with respect to personal data processed by the EHR.

These rights, including access to data concerning him/her and to have them in a comprehensive form, as well as the integration, updating or correction, may be asserted directly against the data holder.
The citizen must also be guaranteed easy access to his/her FSE, and the possibility to make copies in order to make them available to third parties.

6 **Definition of roles, profiles, and access modes**

Given the different nature of the information managed, it is necessary to determine the most appropriate level of visibility for each healthcare category.

This profiling activity can be facilitated through the use of a modular provisioning management system that, basing on a prior classification of data, attributes the rights of access and authorizations limited to only a subset of them.

In addition, the modular organization of the EHR must be such to guarantee not only the correct and differentiated profile articulation based on the classification of types of health information necessary for the care of the client, but also on different levels of authorization for operators authorized to access as well.

It is necessary to foresee the management of access policies to allow a user to identify himself, and therefore to authenticate, using weak and/or strong authentication mechanisms. It is therefore necessary to define in detail each profile (e.g. general practitioner, pharmacist, citizen, citizen) foreseen by the system. Each Region can define different access policies to be federated with the operators of other involved systems in order to enable federated identity.

In order to ensure the traceability of the operations performed on the system and those who have carried out them so as to enable auditing and certification capabilities on the activities carried out for the different purposes, all transactions shall be recorded, both those that were successful and those terminated.

6.1 **Identification of the enabled sources to feed the EHR data**

The general practitioners and the pediatrician, the providers, the services for drug addiction, home care teams, the continuity of care doctors, the specialists related to the different network for pathologies, pharmacies and doctors who work in facilities that provide residential care, supply clinical documents and information that are important for diagnosis and treatment of the citizen.

6.2 **Identification of subjects and their access profiles**

Below are the main categories for identifying the information needed to specify the rules of access for authorized operators:
The demographic information will not be inserted directly into the EHR, but retrieved from the registers of the citizens, which guarantee the correctness and updating.

<table>
<thead>
<tr>
<th>Role</th>
<th>Enabled functions</th>
<th>Data type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacist</td>
<td>Read</td>
<td>Patient registry</td>
</tr>
<tr>
<td>Health care professional of</td>
<td>Write</td>
<td>Prescriptions</td>
</tr>
<tr>
<td>the pharmacy enabled to</td>
<td></td>
<td>Consent</td>
</tr>
<tr>
<td>the profession.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Administrative operator in</td>
<td>Read</td>
<td>Patient registry</td>
</tr>
<tr>
<td>health and social-health</td>
<td>Write</td>
<td>Administrative</td>
</tr>
<tr>
<td>facilities (e.g. Hospital,</td>
<td></td>
<td>Prescriptions</td>
</tr>
<tr>
<td>Local Health Authority, GP...)</td>
<td></td>
<td>Consent</td>
</tr>
<tr>
<td>Medical Director</td>
<td>Read</td>
<td>Patient registry</td>
</tr>
<tr>
<td>Doctor who carries out</td>
<td>Write</td>
<td>Administrative</td>
</tr>
<tr>
<td>managerial activities</td>
<td></td>
<td>Clinics</td>
</tr>
<tr>
<td>within a Health Department</td>
<td></td>
<td>Consent</td>
</tr>
<tr>
<td>in health and social-health</td>
<td></td>
<td></td>
</tr>
<tr>
<td>facilities.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>General Practitioner/Paediatrician</td>
<td>Read</td>
<td>Patient registry</td>
</tr>
<tr>
<td>Physician contracted with a</td>
<td>Write</td>
<td>Administrative</td>
</tr>
<tr>
<td>Local Health Authority to</td>
<td></td>
<td>Prescriptions</td>
</tr>
<tr>
<td>perform as a General</td>
<td></td>
<td>Clinics</td>
</tr>
<tr>
<td>Practitioner /Paediatrician</td>
<td></td>
<td>Consent</td>
</tr>
<tr>
<td>Administrative Director</td>
<td>Read</td>
<td>Patient registry</td>
</tr>
<tr>
<td>Person who carries out</td>
<td></td>
<td>Administrative</td>
</tr>
<tr>
<td>managerial activities</td>
<td></td>
<td>Clinics</td>
</tr>
<tr>
<td>within an Administrative</td>
<td></td>
<td>Consent</td>
</tr>
<tr>
<td>Office in health and social-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>health facilities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician</td>
<td>Read</td>
<td>Patient registry</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Administrative</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Role</th>
<th>Enabled functions</th>
<th>Data type</th>
</tr>
</thead>
</table>
| Doctor who works within health and social-health facilities | Write | Prescriptions  
Clinics  
Consent |
| Physician in nursing homes for residential and semi-residential care  
Doctor who works in a health facility that provides residential care | Read | Patient registry  
Administrative  
Prescriptions  
Clinics  
Consent  
Write | Prescriptions  
Clinics  
Consent |
| Nurse  
Non-medical operator that operates within health and social-health facilities. | Read | Patient registry  
Administrative  
Prescriptions  
Consent  
Write | Clinics  
Consent |
| Medico belonging to a pathology network | Read | Patient registry  
Administrative  
Prescriptions  
Clinics  
Consent  
Write | Prescriptions  
Clinics  
Consent |
| Citizen | Read | All data in the EHR  
Write | All data specified in the previous paragraph 3.5 “Citizen's personal notebook” |

In the definition of authorized persons should be taken into account what is specified by the "Guidelines on the subject of electronic health records (EHR) and the health profile" of the National Authority for the protection of personal data July 16th 2009, in terms of identification of individuals who may manage EHR data (section 4 of the above mentioned Guidelines) and access to personal data contained in Electronic Health Records and Health Profile (section 5 of the above mentioned Guidelines).
6.3 Methods for access and profiling management

With reference to the access mode, it’s necessary to recall the provisions of art 64 of CAD, and subsequent amendments and additions, which provides, in paragraph 1, the use of Electronic Identity Card (CIE) and the National Services Card (CNS) as tools for accessing network services provided by the public administrations for which electronic authentication is required and also with reference to the provisions of art 11, paragraph 15 of the Italian decree n. 78 May 31st 2010. However, as provided by paragraph 2 of the aforementioned art 64 of CAD, and subsequent amendments and additions, access may also be allowed by means of strong authentication towards the use of smart cards issued by accredited certifiers, or weak, using userid and password, or other solutions provided they meet the minimum security measures in compliance with legislative decree n. 196, June 30th 2003.

7 Technological infrastructure

Objective of this chapter is a description of the architectural model of the technological infrastructure of the Electronic Health Record, both in terms of mechanisms for the collection of documents and medical data in digital format, and in terms of support services to medical processes.

The architectural model must allow all the authorized stakeholders of the National Health Service to access the pertinent health documents, wherever they are located, and to manage the evolution of health processes over time. The infrastructure proposed has, among its objectives, the compatibility with the regional architecture solutions already developed in a vision oriented to a federated infrastructure model, shared at national level and aligned to open technologies and international standards as a key aspect. In addition, the proposed model incorporates the infrastructure requirements necessary to achieve functional and semantic interoperability, which is the goal of several national and european projects.

The architectural model of the infrastructure of the EHR must be compliant to specific design requirements, among which the most important are:

- enable the localization and availability of health information
- support adequately health processes
- support the federated nature of the NHS
- allow easy integration with already existing systems and infrastructures so as to make them interoperable
- based on open standards
- be scalable and modular, allowing an incremental and distributed development
- provide reliability features, so that the infrastructure has any single-point-of-failure
- provide adequate performance in terms of accessibility to documents and medical data
- ensure a high level of security
- be integrated with the Italian Public Connectivity System (SPC)
- be compliant to the specifications of the National Authority for the protection of personal data in terms of security, confidentiality and access to data contained in the EHR.

7.1 Architectural model of the infrastructure

The infrastructure of the EHR should ensure consultation of documents archived and the management of the temporal evolution of the same.

The technological infrastructure of the EHR must be able to integrate all the facilities that in various ways contribute to the generation (and/or consultation) of clinical events concerning interactions of the individual citizen with the NHS.

The infrastructure should be based on a multi-level service-oriented SOA (Service Oriented Architecture) distributed architecture, in which are included the points of service delivery called "nodes", both of first and second level. The first level nodes (regional nodes) made of the national infrastructure, while the second level nodes (local nodes) make available their services and information through a first level reference node. The presence of second level nodes is optional.

The regional nodes through the EHR infrastructure components that meet the requirements listed should be able to provide all the functionalities needed for the retrieval and for the information management. The local nodes may be functionally equivalent to the regional nodes (full local nodes) or provide only some of the infrastructural components (local nodes incomplete).

The localization of the information in the EHR will be through a federation of index registers each of which will be part of the software components of each regional node. As regards the notification of events of interest to authorized users, it must be done with publish-subscribe mechanisms.

The architectural model envisages the integration in the Italian Public Connectivity System for communication between the various infrastructure components. Consequently, for each regional node the connection is provided through a Domain Gate (PDD), while a local node make available his services and information through the regional node.

8 Safety measures

The treatment of personal and health data of citizens needed to feed and use the Electronic Health Record are considered sensitive data processing carried out by electronic tools: so the solutions needed to ensure confidentiality, integrity and availability of data must in any case be taken in accordance with the security measures expressly provided for in legislative decree n. 196/2003 and in its technical
specification (Annex B), further explained in the specifications "Guidelines on the subject of electronic health records (EHR) and the health profile" of the National Authority for the protection of personal data of July 16th 2009.

Particularly important, given the multiplicity of actors involved, is the analysis and the design of healthcare processes, so that to make possible to define in detail the tasks and functions to be allocated in line with current legislation, and identify suitable organizational and technological solutions through which to maintain accountability and availability of information only at actors who are entitled to use them.

9 Further developments of the EHR

Within the NHS, the Ministry of Health has the role of guarantor for the right to health and for the respect of LEA throughout the country: it is therefore necessary to have data and information in order to monitor and ensure the quality of assistance given. Similarly, within its territory, each Region needs the information necessary to ensure the governance of the Regional Health Service.

The implementation and diffusion of an Electronic Health Record that integrates information produced by the different regional systems, could help achieve institutional purposes, ensuring consistency, timeliness and overall quality and accuracy: for example the extraction of information organized according to selected clinical pathways can allow to evaluate the appropriateness of the resources compared to the peculiarities of single patients.

It therefore follows that the EHR in addition to pursuing the prevention, diagnosis, treatment and rehabilitation, may facilitate also the construction of monitoring systems to support the planning, management, monitoring and evaluation of health care, and support studies and scientific researches in the medical, biomedical and epidemiological fields too.

Consistently with the principles of pertinence and proportionality of art. 11 of legislative decree n. 196, June 30th 2003, such systems should be organized so as to use by default only data that are not directly identifiable of the citizens, applying the appropriate security measures, providing the use of directly identifiable data only in cases where it is strictly necessary.

With respect to the traditional split between information directly supporting the care and information for planning and evaluation of assistance the introduction and development of the Electronic Health Record, could allow to realize monitoring systems available in systematic fashion for the government purposes.

However, to concretely reach such objective, it is necessary a legislative intervention at national level that, further to providing a unified and coherent structure at national level for the Electronic Health Record for the purposes of care, creates the preconditions for the treatment of data for these additional
purposes, both in regional contexts and within the New Health Information System at the central level. To this aim, the inter-institutional working group established at the Ministry of health has prepared a proposal for legislation governing the EHR at national level. This proposal has been included in the bill proposed by the Ministry of health called: "Clinical trials and other provisions relating to health."\(^1\)

\(^1\) Subsequently 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"