

Electronic Health Records and the challenge to Master the Patients' Pathways. Proposals around a comparative analysis (France / Spain).

Biedma José Maria
Business Organization Department
University of Cadix
Cadix, Spain
e-mail: josemaria.biedma@uca.es

Bourret Christian
DICEN IDF Research Team
University of Paris East
Marne-la-Vallée, France
e-mail: bourret@u-pem.fr

Abstract - Issues about patients' pathways and interoperability of Information Systems are at the heart of the challenges faced by Healthcare Systems to control costs and also to improve quality of care. We propose a comparative analysis of the issue of computerized patients' records in France and Spain highlighting requirements, similarities and differences and new possibilities of actions. Most of the challenges faced by the Healthcare Systems converge on this issue. After an analysis of the broader context of Healthcare Systems in these two countries, which have different designs, but have also similar problems, we'll examine the issue of the Healthcare record ownership, then the access to its data and its handling of doctors' personal notes. We'll also discuss ethics' issues and especially that of medical confidentiality. We'll then consider the central topic of interoperability linked to different approaches: national in France and at the level of the Autonomous Communities in Spain. The changes are only at their beginning. The use of these new socio-digital tools necessarily meets the European dimension, the issue of using open data and that of digital territories in Healthcare.

Keywords - *Electronic Health Records ; Healthcare ; patients' pathways ; access ; interoperability.*

I. INTRODUCTION

All the Healthcare Systems in developed countries, particularly in the European Union, are in crisis, facing many problems, both to control costs and to improve quality of care. The development of socio-technical devices within the broad context of Information and Communication Technologies (ICT) induces deep changes and provides new opportunities. The solutions are sought through the patient's pathway, i.e., traceability issues with information and communication challenges. Shared Electronic Health Records can be considered as "hologrammatic" (when a part contains the same properties as the whole system cf. E. Morin and J.-L. Le Moigne ideas on Intelligence of the complexity [1]) of the whole Healthcare Systems' challenges. If the problems are the same everywhere, the national or regional approaches may vary. In this paper, which is a joint work between two researchers (Spanish and French), we propose the outlines of a comparative analysis of the requirements, the challenges faced in the two countries

with proposals for improvement and opportunities for future research studies.

After an introduction, we will show that the two Healthcare systems have the same requirements but in different contexts. Then we will analyze some specific aspects of the Electronic Health Records in the two countries: ownership, access, the collection of data with the issue of physician's personal notes. Afterwards, we will discuss the question of the interoperability, ethics' aspects and especially medical confidentiality. After regarding towards a European record and the question of open data, as a conclusion, we will outline that we are only at the beginning of profound changes.

II. SIMILAR REQUIREMENTS IN DIFFERENT CONTEXTS

Spain and France have a different approach of Healthcare issues. In France, the governance of the Healthcare System is traditionally centralized, but with a distribution of roles. The State controls the system (regulation) and the supervision of the Healthcare Organizations. Since 1945, the different Health Insurance Offices: *Caisse Nationale d'Assurance Maladie des Travailleurs Salariés* (CNAMTS), MSA (*Mutualité Sociale Agricole*) and RSI (*Régime Social des Indépendants*), are supervised on a parity way by the social partners (both employers and trade unions representatives). They manage the funds on the basis of contributions coming both from employees and employers. It is a so-called Bismarck's system [2] (from the name of the German Chancellor who created this type of Social Insurance System in 1875). In France, since the 1980s, we also get an important part of resources coming from taxation: General Social Contribution (CSG). Since the mid-1990s, the system has a more regionalized management, with the recent creation of the Regional Health Agencies (ARS) in 2010, but managed at the regional level by State officers (*déconcentration*) and not by Autonomous Regions (*décentralisation*). In Spain, the Autonomous Communities appeared with the Status of Autonomy (1978). They have gradually gained the control of the management of their citizens' Health. They

have developed specific policies. This was particularly the case for Catalonia (1981), for the Basque Country (1982) and Andalusia (1984). These Regional Healthcare Systems are financed through taxation: Beveridge's systems [2] (from the name of the designer of the British Health National System in 1946, mainly the NHS or National Health Service).

There is a major difference between Spain and France. In Spain, the Communities are autonomous and develop specific tools and may have specific legislation for Health data, in addition to those of the Spanish State, especially in Catalonia. In France, the main tools, including the Personal Health Record (DMP: *Dossier Médical Personnel*) of the patients, whose construction began in 2004, are implemented from a national perspective. In Spain, they are in a large part developed at the regional level, which immediately raises the question of the transfer of data and systems' interoperability.

As all the other developed countries (United Kingdom, Germany, United States of America, etc.), France and Spain have quite similar requirements to improve different aspects of their Healthcare Systems.

First, they must master the growing costs: 11.7 % of the GDP (Gross Domestic Product) in France and 9.4 % in Spain in 2011. They must also improve the quality of care with a key idea: avoid the breaks in the traceability of care, which is costly and does not improve patients' care. Consequently, the central issue has become that of patients' pathways. Thus, it is imperative to master the use of new tools, especially the Electronic Health Records (EHR).

Other important requirements are both security of managed information and that of interoperability between various technical devices.

If the requirements are roughly similar, the general contexts are different: national in France and rather regional in Spain, as we have outlined above.

The two systems are also different in the way the medical profession is exercised and remunerated in primary care. In Spain, as in the United Kingdom, the General Practitioners (GPs) often work in cooperative organizations and receive a global amount for each registered patient. In France, the GPs' activities is private and still essentially isolated: each GP has his own office. The French GPs are not globally financed but paid for each accomplished medical act by the patients, the patients being reimbursed later by the different Health Insurance Organizations.

In France, the EHR's issue is particularly sore. The GPs fear that new electronic tools may be tools to control their activity and, consequently, their incomes. So, in 2004, the DMP has been named "personal" and not "shared". It has been decided that it will be hosted by private companies.

The question of the ownership of the EHR is essential.

III. THE OWNERSHIP OF THE PERSONAL HEALTH RECORDS

We have already mentioned that in France, the patient's medical record was (Health Insurance Law of August 2004) designed as "personal" and not "shared". For some people, the weight of the medical lobby was very heavy in

Parliament to avoid controlling the activity of Physicians by Health Insurance Companies. The patient owns his personal medical record.

But, since 2004, things have gradually evolved towards a more "shared" DMP. First, medical practice is a little less individual and new cooperative organizations have formed (Healthcare Networks, Homecare, medical centers, etc.).

Then the two public consortia managing the DMP, the GIP- DMP and, after 2008, the ASIP (Agency for Shared Information Systems in Health) have had significant problems. In December 2013, only 500,000 records were opened, compared to 5,000,000 contractually hoped for, and very few are really operational. With this scandal, some people talk to entrust the management of DMP to CNAMTS but then the fear that the DMP then becomes primarily a monitoring tool for rationalization of the activities of the doctors and not only and principally to improve patients' pathways reappears .

As a result of his ownership, the patient may "hide", even destroy some data. Some spoke about a "naked doctor in front of a masked patient." What is the medical value of a non-exhaustive record? The issue is all the more serious since in France the responsibility of the physician remains individual. The DMP is still experimental although originally its generalization was scheduled for 2007.

In Spain, Law 41/ 2002 of November 14 does not tackle this issue which is still debated. We can distinguish four positions. One group believes that the ownership of personal medical records must belong to the health center ([3], [4] and [5]). For the second group ([6] and [7]), the property of the personal medical records must belong to the doctor. This position's basis lies in the notion of the doctor's copyright. This does not mean that the patient doesn't have a right of access its content. A third group, as Gay Montalvo, believes that the ownership of personal medical records must belong to the patient [8]. For other authors [9], the question of the ownership of personal health records is a problem that is irrelevant and of little practical importance. What is really important is to know who gets the right of access.

The debate has rebounded with differences in the various Autonomous Communities. Some (Galicia and Valencia) consider that the property belongs to the government or to a health center if the doctor works for others. If the medical profession is exercised individually, the property belongs to the physician. Other Autonomous Communities have not yet legislated on this subject.

IV. ACCESS TO ELECTRONIC HEALTH RECORDS

The issue of access (consents) is also a key one. As a result of his ownership of the record, in France, the patient gives the access rights (authorizations) to the DMP. He must have access to hospitalizations' data and copies of his hospital records. This follows from the Law of 4 March 2002 on the Rights of Sick People and the Quality of the Health System, confirmed by a law of August 2004 on the evolution of Health Insurance (providing experimentation for DMP) and different decrees in 2006. In case of emergency, when patient's life is engaged, the physician can "force" the access, but the situation is not satisfactory. There are two opposite

camp: the “fundamentalists” of the absolute property of the patient and those who insist that the DMP is not a safe for personal data but simply a tool to improve patients’ care and traceability. Recent developments seem to go to a shared record [10].

In Spain, Law 41/ 2002 (Article 18) extended the right of access the patient's personal medical records and he is allowed to get copies of the data. Health centers must comply with this patient’s right, exercised directly by them or by a duly accredited representative.

The right of access to medical records is not an absolute right. According to art. 18.3 of Law 41 /2002, the exercise of this right has two limitations: first it cannot be exercised to the detriment of others' right to confidentiality of the information it contains and the therapeutic benefit in relation to the data collected from the patient. It may be exercised at the expense of professionals who have participated in the preparation of this medical story. Yet, there is a limit derived from the rights of the professionals involved in the development of medical records, which may restrict the right of access, excluding its subjective annotations made in the record [11].

Another situation is the access to a record belonging to a dead person, or to a mentally ill person or a minor one. The law allows health centers and individual exercise practitioners to provide access to medical records of patients who died or persons associated with them for family or factual reasons (art.18.4 Ley 41/2002). However, this is denied if the dead people had expressly forbidden it. Some authors point out that the right of access to personal medical records is only for the patients and is not transferable to their heirs. Therefore, in order to get them it is necessary to prove the cause and the legitimate interest of the applicants in the context of a judicial or administrative proceeding [12].

The question of the age of the child to exercise his right of access to personal medical record by himself is also problematic. Law 41 /2002 does not address this issue explicitly. As recalled by Saiz and Larios [13], the doctrine has been applied by analogy to the minimum age (sixteen years, unless emancipation), according to Article 9 of the Act on the Protection of Data for the provision of informed consent without representation. However, for these authors, the entire solution is currently governed by Article 13 of the Regulations of the Organic Law on Data Protection that allows a fourteen years old person to gain access to their personal data "except where the Act requires assistance for holders of parental authority or guardianship." It is therefore necessary to adopt a uniform approach to determine the age when the child can get the right to this access.

V. DATA COLLECTION FOR PATIENTS’ RECORDS: THE ISSUE OF PERSONAL PHYSICIANS’ NOTES

After the questions of the ownership of the patient’s record and of its access, another one is that of the data it contains.

These questions are raised in different ways in France and Spain, according to different specific approaches.

In France, the central issue of the collect of data, patients’ data or not, is a main one. Since 1927, the physician has been

paid directly by the patient for each medical act. The patient is then reimbursed by the various Health Insurance companies. This is the origin of so-called French “liberal system”. Private primary care physicians did not want to be paid directly by the Health Insurance organizations which could thus control their activity. The central issue (often not formulated officially), already outlined, is always the fear of Health Insurance organizations’ control of doctors’ activity and of their incomes. Many blockages around the DMP come from this not formulated but very real fear. So who will fill the DMP? If the data is not validated by the doctor it has no medical value. The doctor did not incur individual responsibility for a medical record that would have been filled by the patient. In times of severe budget pressures, the Health Insurance Organizations do not want that the collection of patients’ data (and also the reconstitution of their personal health history in the past) could become a new and therefore reimbursed medical act. The problem underlines a limit of the doctor’s payment for each medical act [14].

The question can be expressed otherwise: that of the "double collection" of patient’s data by a physician. With the developments in ICT, some optimists believe that a single “click” will switch patients’ personal records with data coming from the personal physician's file concerning the same patient. But then comes the main question of the personal physician’s notes, their ownership and their confidentiality.

The approach is different in Spain. The concept of subjective notes or annotations of the doctor gives way to multiple interpretations. Lorenzo (2006) [15], according to Cantero [5], considers that the notes are personal impressions of the doctor on the attitudes of patients who were tested objectively. For Sanchez-Caro and Abellán [16], subjective notes include comments or personal impressions of the doctor. If they do not have clinical importance, they should not be included in the clinical history. On this issue, the Spanish Justice emphasized that these notes are "assumptions made on prints that do not strictly correspond to the content of the record" (STSJ de Canarias 48904). It is also understood that they are "personal impressions of the patient or his social environment, attitude or behavior of the patient's reactions (STSJ Madrid, 2006/162708). The physician can be attacked on personal notes which were not intended to circulate.

Other authors have objected to the exclusion of subjective notes. For Galán [17], if these possibilities of entries are deleted, they eliminate 90% of the clinical history of the patient. The author argues that these terms should be maintained, because deleting them would act against the fundamental right of patients to access to a document. This would have a negative effect in terms of an investigation or assistance. Other authors believe that the support for this limitation is in accordance with the right to privacy [13].

Regional laws that have tackled the issue of subjective annotations are rare. We can give the example of Article 32 of Law 3/2005 of 8 July (Health Information and patient autonomy) in Extremadura. This article examines the subjective annotations that are considered as "impressions of

health care based on the unique perspective of people, and that in any case are not relevant to the true knowledge and update status patient's health, but cannot be considered a diagnosis." Note also Article 19 of law 3/ 2001 of 28 May the Government of Galicia, which concerns informed consent and medical history of patients. According to Troncoso [18], the right of access to personal medical records cannot affect the rights of health care professionals. Therefore, they may refuse to provide access to their subjective annotations.

Saiz and Larios [13] point out that, in theory, the patient has the right to know and obtain copies of all reports and documents listed in Article 15 of Law 41 /2002. However, in practice, it is not uncommon to find some medical institutions whose internal rules only allow specific delivery of data and diagnostic reports. This is also the case in France where patients do not get the copies of their documents as easily as the law requires it.

A solution would be the standardization of sizes and types of documents that must be provided to patients and to establish greater control of this aspect of the patients' rights to information in health organizations, in order to avoid situations like those listed. In this perspective raises another question: it is not the same thing to write notes for yourself or to be read by others (question of semantic interoperability)?

VI. THE CENTRAL ISSUE OF INTEROPERABILITY

Interoperability is not considered in the same way in France and Spain due to different approaches: national (France) and regional (Spain).

In Spain, the lack of standardization of Personal Electronic Health Records creates problems when the patient moves from one Autonomous Community to another one, with a loss of a chance of survival in case of disease or accident. The launch of the Online Health is a progress. Its purpose is the exchange of clinical information between Autonomous Communities with the "Digital Health Record" project of the Spanish National Health Service. The second phase of the implementation will be completed in 2014. On 20 September 2013, the Council of Ministers has approved the establishment of a National Health Card in the next five years to replace all other cards [19].

For Criado [20], the project is not yet achieved due to the difficulties to reach an agreement between all the actors of the system, despite the fact that the majority of semantic, technical, organizational and even interoperability problems have been resolved. There are 16.7 million electronic medical records existing, but four autonomous communities have not yet joined the project [21].

The Spanish Health System is moving towards a shared and interoperable computerized clinical history. As in France, it concerns three types of professionals: computer scientists, healthcare professionals, clinical documentation workers. To improve the interoperability of the Electronic Health Record, it is necessary to incorporate reference models that also allow to correctly identify the contents [22].

A very effective element to support this interoperability effort is the use of EN / UNE 13606 (Health informatics -

Electronic health record communication) standard [23]. But, in addition to the use of a reference model (standard), Spain must gradually develop archetypes, a decisive technical artefact to incorporate clinical knowledge in existing electronic documents from the design phase of the implementation of the system. Since the project "*Historia Clínica Digital del Sistema Nacional de Salud (HCDSNS)*", significant progress has taken place in the construction and dissemination of archetypes in a large scale, they give support to the requirements of the National Health System projects.

According to the Study of Information Technology and Applied Communication for Health and Inclusion, carried out in 2011 [24], a fundamental challenge for Health Information Systems is interoperability. This means exchanging clinical information so that patients can have their clinical data available in any place. As this study demonstrates, from a technological point of view, interoperability needs Enterprise Application Integration (EAI), Enterprise Service Bus (ESB) or Service Oriented Architecture (SOA) platforms.

Benson [25] considers that the development of interoperability in the health field needs the use of standards. These include:

- SPL HL7 (Structured Product Labeling): electronic labeling standard for drugs.
- HL7 [26] Medical Records: for the management of medical records.
- HL7 Clinical Genomics: This standard facilitates the exchange of customized clinical data between multiple agents: assistance providers, laboratories and centers for biomedical research.
- DICOM [27] (Digital Imaging and Communication in Medicine). It is a worldwide recognized standard for handling, storing, printing and transmitting medical images between different information systems.

Other resources are devoted to the development of projects for the security of information systems and the implementation of technological platforms for the integration of systems that enable interoperability of Electronic Health Records in each region.

In France, a major issue is that of the divisions (*cloisonnements*): between the Ministry of Health and the various Health Insurance organizations, between primary care and hospital sector, between public and private sectors, between doctors and other healthcare professionals, between care sector and the social one, etc.

The question of boundaries may also be involved in the great number of various patients' medical records. In France, the highlighted DMP is nevertheless far from unique [28, 29]. Patients may have different records: DMP, DCC (Communicating Record for Cancer), Drug History (*dossier pharmaceutique*), records of patients in different care or medical-social organizations, and also records of different interface structures (Networked Organizations, Health centers, hospitalization at home, etc.).

Would not all these personal patients' records, expected to help to break down barriers in the Health sector, create new ones finally? A great change is necessary because their multiplication is the source of not essential expenses and of confusing problems. But there are also many competing interests.

The authorities seem to be aware of the problem. During the presentation of the National Health Strategy on 23rd September, the Minister of Health announced the "progressive construction of a Public Information Service in Health" and a wider opening of health data [30]. Initially, it should be designed to validate sites offering health information and ultimately to coordinate all institutions providing and managing health data. The unfortunate experience of DMP still at the experimental level and the financial situation may contribute to temper the initial enthusiasm.

It is also necessary to overpass an initial confusion. The DMP has become a computerized patient record among others. We need a coordination tool for interoperability at national level: the DMP or another device [31].

The issue of interoperability does not have only a technical aspect for cooperation between different socio-technical systems but also a semantic aspect, in terms of vocabulary between different professions (engineers and professionals of care), concepts and national cultures [32]. So if in Spain and France national starting points are different, the problems converge around the notion of interoperability and the need for a tool for national coordination.

VII. ETHICS' ASPECTS AND MEDICAL CONFIDENTIALITY

In the health field, the use of the technologies of information and communication (ICT), is now irreversible and has undeniable advantages, such as traceability of actions (care pathways), but, at the same time, may raise fears. Some, like Romeo and Castellano [3] fear an increased risk of violations of privacy and other individual interests. Therefore the French DMP arises ethics' issues. Three different points emerge very quickly: the issue of the chosen security devices, the use of personal data in relation to the specificity of the health data: their medical confidentiality.

The security issue is primarily that of the systems used. Many examples are discussed showing loss of data, errors in transmission of electronic documents or in data anonymization. Cañas and Santander [33] stress the risk of intentional attacks (malicious) or that of employees' error, which may affect the confidentiality of information transmitted or manipulated.

But we must not exaggerate. The digital data are more largely protected than the paper patient records lying around on tables or in cabinets in medical offices or in hospitals.

Then comes the question of personal data. Nowadays, each country has its own approach resulting from various collective mentalities.

Anglo-Saxon countries do not have the same approach as the Latin countries. The United Kingdom, always very concerned by the civil liberties, is repugnant to the development of national cards, like identity or health cards. In the United States, freedom of use of personal data is much more important, and so the risks of skidding are higher. The Congress instructed the Health and Human Services Department (HHS) to protect the patients' privacy by integrating its aspects into the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (Office for Civil Liberties). Each federate State can add specific aspects. In Quebec (Canada), the Commission of Access to Information has a specific role.

Spain has an agency for data protection (*Agencia Española de Protección de Datos*). Under the Statute of Autonomy of 1978, some autonomous communities have established their own organizations to protect the rights of their citizens. In Catalonia, an *Agència Catalana de Protecció de Dades* (APDCAT) was established by the Organic Law 15/1999 on Data Protection. They also have an *Administració Oberta de Catalunya* which aims at developing a "digital citizenship". We can find too an *Agencia Vasca de Protección de Datos* (AVPD). The *Agencia de Protección de Datos* of the Madrid's Community was closed in 2013.

Citizens' attitudes towards personal data (privacy) may vary. A survey conducted in the United States on adults by Harris Interactive in March 2003 [34] distinguish the "privacy fundamentalists" (26%), the "privacy pragmatists" (64% compared to 54 % in 1994) and the "privacy unconcerned" (10 % compared to 22% in 1994). Nearly 70 % of surveyed adults agreed with the statement that "consumers have lost all control on information collected and used by companies" and the majority are relatively pessimistic about the impact of legislation, 53% do not agree on the fact that "existing laws and organizational practices provide a reasonable level of protection for the consumer today".

There exists fears with the development of Big Data (large and unstructured data that invade networks and storage systems of all kinds) uses and, above all, about the risk of sales of patients' data to organizations for commercial purposes, for example of patient's personal data to pharmaceutical companies, without patients' consent.

The European Directive of October 1995 extended the protection of individual rights, introducing the concept of personal data, understood as any data that allows the identification of an individual. The United Kingdom adapted its legislation with EU Directive in October 1998. France will put a lot more time. Begun in 2002, the legislative process has been only finalized by the Act of 6th August 2004.

On 21th October 2013, the European Parliament voted a major revision of the 1995 Directive to strengthen citizens' control over their personal data. In the following years, a

new EU regulation is going to replace the various national regulations. If it succeeds, in Europe, national approaches should be progressively erased.

Health data are personal and sensitive data but with strong specificities especially regarding medical confidentiality.

The concept of medical confidentiality is very old. It goes back to the famous Hippocratic Oath (from the name of the famous Greek physician of Antiquity), taken by all physicians who specifies that, "admitted in the privacy of people, I will not reveal the secrets that will be entrusted to me" [35].

For Dr. P. Cressard: "Medical confidentiality is the sum of the exchanges collected in a context of trust between a doctor and a patient" [36].

In France, the concept of breaking medical confidentiality appeared in 1810 under the First Empire. It has been extended to other professions in 1992.

The Law of 4th March 2002 on "Sick people's rights and the quality of the Health System [37] introduces major changes: medical confidentiality has become a right of the patient and not just an ethics' obligation of the physician. It placed the patients at the center of all decisions that affect them, introducing the concept of "health democracy." This law has been adapted to the hospital sector in particular with the 2nd March 2006 circular on the "Charter of the hospitalized person and the rights of users."

For Pr Anne Laude, the current state of the law reflects the partitioning (divisions) of the French Healthcare system: it would be preferable that a single text should bring together all the citizen's rights, whatever the nature of the medical act to simplify the work and the responsibility of physicians [36].

Thus, in France, but it can be generalized, the concept of medical confidentiality is going to evolve: with the impact of the new technologies of information and communication (ICT) at the heart of this article, but also because of the evolution of the practices of medicine. The medical practice is less isolated. Interface Organizations between isolated primary care and hospital have developed: Healthcare Networks, Homecare Organizations (in French: *Hospitalisation à Domicile* - HAD), medical houses, etc. Many actors are involved in the patients' care. But the responsibility of the physician and of medical confidentiality remains individual. What information is the doctor permitted to share?

The term of trust is often used in the relationship between doctor and patient or in the use of socio-technical devices (ICT). The "digital trust" is an essential issue. For Kaplan and Francou [38], we may invent new tools to rebuild the relationship between organizations and individuals and new creative spaces to develop trust. In France, perhaps the new interface organizations in Healthcare can play this role.

VIII. PROSPECTS: TOWARDS A EUROPEAN HEALTH RECORD AND THE CHALLENGE OF OPEN DATA

Today, in the European Union, health issues are always managed by the different national States. But we have seen that for personal data, national legislations had to adapt to the European Directive of 1995 and that they should gradually give way to a single European regulation. Moreover, since 2002 we have got a European Health Insurance Card, which permits medical or hospital care be obtained in a foreign country without advance payment. This is particularly important in the tourism sector or for people who move a lot [39].

Various projects have been developed in the European area to improve interoperability in the Health sector. This is for example the Calliope (European thematic Network for eHealth Interoperability) [40] project, HITCH (Healthcare Interoperability Testing and Conformance Harmonisation) [41], and especially, the epSOS or European patients Smart Open Services project [42]. It is the largest project in the European e-Health sector which emphasizes interoperability. The epSOS project is of great interest to facilitate the evolution of the national personal records to a European record.

Its main goal is to improve the health monitoring of citizens when they are outside their origin country, allowing health professionals of any country participating to the epSOS' project access to his medical data. To achieve this, providers of health services participating to the project cooperate by sharing their data to test this new service. For the first time, European people can use these cross-border services when they need health services in all countries participating in epSOS as a tourist, businessmen, students, travelers or tourists. This project is still in progress. In Spain, are associated the Ministry of Health, Social Services and Equality and five Autonomous Communities are associated: Andalusia, Castilla la Mancha, Catalonia, the Balearic Islands and Valencia.

In France, the project is managed by the ASIP [Agency for Shared Information System in Health] and is especially tested in the Ile-de-France region.

For Criado [20], the role of the European Union in this area is primarily for general guidance and incentives. We have shown important first steps for interoperability of data, imperative for data exchange in all the European Union territory.

Beyond the national projects, a more ambitious project would be the creation of a European personal medical record for each European citizen, which would allow access to his record from any country of the European Union. Of course the Health's sector is still a national competence, but the European Union is trying to facilitate cooperation to converge to a European health policy. There is already a European Health Insurance Card. It is only an administrative card and must be renewed each year. But it could be an entry for the access of the patient's data, including first emergency data. It would be an important step to a European e-Health.

Another point to outline is the use of digital data to improve care at a local level. In France, at the end of 2013, a

new specific project was launched around areas of digital health or territories of digital care (in French, TSN: *territoires de soins numériques*) to develop the uses of digital data to improve the patient's care on specific territories. In an other manner, couldn't we also consider the creation of a specific new digital territory at the level of each patient representing a specific and personal digital care territory around its own personal medical record? This issue is very connected with telemedicine. Its development depends on specific national regulations (in France, 19th October 2010 decree).

Another important point is the challenge of the Open Data. In France, the CNIL, already mentioned, organized a seminar about this issue last July [43]. Participants stressed the idea that the open data is primarily a tool for modernizing public action and of general interest for democracy which needs the best opacity and privacy for citizens and transparency of the State, while it is often the opposite that happens. Open Data is an essential component of transparency. Personal data is not *a priori* the first concerned by the Open Data. Open Data have no personal nature, they concern mainly State data (maps, raw data, general indicators).

But we have entered a period of "revolution of the data." "Putting the world in data" lead us to redefine the way we act, and to create knowledge infrastructure of a new kind. The boundaries between the different categories of data, personal or public, anonymous or indirectly identifiable, are not always clear. "To build an Open Data legitimate and sustainable, it is essential to examine ethically the role of personal data, anonymisation, consent, etc."

IX. CONCLUSION: ONLY THE BEGINNING OF PROFOUND CHANGES

Privacy, ethics, consent, and also the concepts of access, interoperability, ownership; we find all the essential points of this article on the issues surrounding the Electronic Health Records and the challenge to master the patients' pathways through proposals around a comparative analysis in France and Spain.

The question of the implementation of electronic medical records is at the heart of the challenge of mastering the patients' pathways, both in France and Spain. We are only at the beginning of great changes caused by the rapid development of e-Health. In the future, the EHR that nowadays concern national or regional levels, will also be effective at local level and European level.

According to E. Morin's idea, it is also largely "hologrammatic" (representing a summary of various problematics) and at different levels.

Firstly, the EHR is "hologrammatic" for the challenges tackled by the two Healthcare Systems, and more largely those of all developed countries, facing the double problem of controlling costs and improving quality of care, in a particularly hard financial situation.

New ICT tools can help. The issue of electronic patient data is at the heart of our evolving health systems with the

central issues of traceability of patients' pathways in care. Patients become involved in their health and co-producers of new services concerning themselves, data and experiential knowledge such as tools, interoperability and the development of new uses and care practices. This is one aspect of the concept of "health democracy" (*démocratie sanitaire*) proclaimed by the Act of March 4th, 2002 which also insists on the idea of patients' responsibility, the Anglo-Saxon speaking of "empowerment".

But, secondly, it is also "hologrammatic" in a wide perspective around the "data revolution" with the definition of different data (public, personal, sensitive ...), the questions of personal data and open data. So it is a global societal subject.

The newspaper *La Tribune.fr* (January 10th 2014) points out that "France is struggling to bring its Health System in the Digital Age". For the authors of the article, with the affirmation of the patient 2.0, the DMP reviewed, essential for the coordination of care, "may be the passport to the world of e-health" [44].

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