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# Shaping the Future of Health Law: Challenges for Public Law

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# The digitalization of the healthcare sector in Italy: the Electronic Health Record

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During my presentation, I will focus in particular on the Electronic Health Record.

I decided to focus on the EHR, because it is one of the main Italian e-health tools.

E-health, as we know, is a generic term that indicates the use of information and communication technologies to support the health system; so, it includes a multiplicity of tools and actions. Among these tools, the electronic health record occupies a central place in the Italian legal system.

The EHR was introduced in 2012 and it can be defined as a collection of medical data and documents relating to a patient's medical history.

This tool can be considered as a health digital archive, a google of the patients' health; we can say that it is an example of the dematerialization process of health documentation.

It aims to create an organic information data base; a data base that promotes the improvement of the diagnosis, treatment and rehabilitation of the patients.

Every Italian citizen can decide to activate this personal tool; and when it is activated, new information of patients' clinical history are added. So, it is the main factor that assures the creation of an e-health system based on the centrality of the patient.

However, it also acts as a support for the scientific research and for the health planning, because it gives to the institutions the possibility to check the quality of the health cares.

The EHR must have some minimum elements decided by law. In particular, I would like to talk about the patient summary and the pharmaceutical dossier.

The patient summary is a synthetic overview of the patient's medical profile; it is drawn up by the family doctor and it is very useful especially in emergency situations, because in that case usually there is no time to study the patient's clinical situation before intervening. The pharmaceutical dossier, instead, is an updated section edited by the pharmacists and it is useful, too: it allows to monitor the adequacy of dispensing medicines, for example.

So, we can say that the EHR is enriched, in particular, by the pharmacists and the medical professionals who take care of the patient; however, it can also be integrated by the patient himself: the health record



can in fact consist of an additional element called “personal notebook”: this is a specific area in which the patient can enter personal data and documents relating to his/her own health condition.

The EHR ensures many advantages.

For example, it ensures that social and health care takes place in a shorter time, because it eliminates many bureaucratic steps that would otherwise be necessary.

Certainly, it also ensures a lightening of the documentary burden (and, therefore, it implies a significant saving of time and costs).

Then, it ensures an improvement in the citizen's social and health assistance service: for example, it avoids unnecessary prescriptions for diagnostic tests already carried out; and it can potentially reduce the number of medical errors, because it gives to the professionals the possibility to know in detail the patient's previous medical history.

Therefore, it has a positive impact on the costs that we normally face in Italy due to the lawsuits brought by the patients against doctors and health facilities.

When we talk about the EHR, we have to consider that Italian regions play a very important role in its functioning.

In fact, the EHR is introduced by every Italian Region; so, every region rules the relative methods of its activation.

It means that the ways to activate the EHR are different from region to region and there are various differences between regions.

In 2018, in order to guarantee the full operation of the EHR in the whole country, Italian institutions created a national access portal; this website is not active yet, but it will allow users to access their EHRs from a single national access point. So, in the future, it will ensure equity and it will solve all the problems that we now have in Italy, for example when moving from one region to another.

Currently, almost all regions have reached a state of implementation of the instrument over 85%; it means that they have generally equipped all the EHRs with the needed elements.

However, only few regions have already reached the so called stage of services, a stage in which the EHR stops to be just a global data container and it becomes a control room that gives the patient the possibility to do so many things using internet (for example, patients in Emilia Romagna can book their medical check ups by using the EHR ).

Now: the EHR works well if the regions set up an efficient IT system; this IT system has to be able to manage not only the relationship between the region and other facilities and health professionals, but also between one region and the others.



This is the so-called interoperability, which is an essential condition for the creation of a horizontal paradigm that facilitates the exchange of public data; let's imagine the case of a health service provided in Lombardy to a Calabrian citizen: in Italy interregional mobility is highly developed; interoperability therefore is essential for the right functioning of the tool.

This is the reason why our law-maker created a national facility to assure interoperability between regional EHRs that guarantees the exchange of data between regions.

Recently, in the period of the pandemic, our law maker revised the rules of the electronic health record; this activity confirmed that the EHR is a strategic tool for the digitalization of the Italian health system. In particular, the law extended the database of the dossier: it now also includes information relating to services provided by private health facilities.

The law also provided that the implementation of the EHR takes place automatically; in this way, health professionals don't need the patient's consent to include new data in the digital collection.

In any case, the consent of the patient remains compulsory for the medical staff to consult the file.

Obviously, the health professionals who treat the patient can use the health file, but they are able to see and check the file only if the patient agrees.

I want to underline then that the patient may decide to ask for the data to be hidden; so these data cannot be seen neither by those who are authorized to access the file.

At the end of this short presentation, we can say that the EHR has been and it still is an ambitious and challenging project for Italy, because our country is characterized by a significant delay in digital growth. When I say digital delay, I refer to the data spread by the Digital Economy and Society Index: it represents that Italy is in the fourth lowest place, followed by Romania, Greece and Bulgaria.

In fact, the percentage of citizens who already activated the EHR is still very low, compared to the total number of the Italian patients; and we also have to consider that not all people who activated it, are actually using it.

It depends in particular on the fact that in our country the Italian institutions didn't promote the use of the tool; but it also depends on the fact that Italian citizens do not have good digital skills: they therefore quit to use the health digital services.

It is then necessary to implement the action of raising awareness of the use of the tool; however, it is also necessary to invest in the creation and in the improvement of the citizens' digital skills.

This action will be able to solve the problems created by the *digital gap* that we have to face in our country. Indeed, investing in the training of citizens is not enough: it is also necessary to invest in the training of health professionals, who are those that actually have to use the tool. In fact, the number of health



professionals who use the EHR is very low, now: in the first quarter of 2021, only doctors of 8 regions used the EHR; and only doctors of 3 regions implemented it.

We also have to consider that the PNRR (the Italian plan of recovery and resilience) paid attention to the EHR. In particular, the plan aims to improve, harmonize and disseminate the EHR; it defines the electronic health record as a cornerstone for the provision of digital health services and also for the enhancement of clinical data.

So, in the end, we can say that we have to see what it's going to happen in the next years; and we have to hope that it will start to work efficiently and that in the future all the related existing regional differences will be eliminated.