eHealth in Europe as well as in Greece and the protection of health data

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Abstract: This study presents the development of eHealth in Europe and Greece, since it is a rapidly growing sector, which during the following years will play an even more important role in states’ economies. Simultaneously, it presents the current legislation on the protection of health data in Europe and Greece, thus making possible the comparison between the two, in order to ascertain where there is a need to supplement the related legislation in order to increase the level of protection of the health data of millions of people who are involved, willingly or not, with eHealth.

Key words: eHealth, data protection, ePrescription, health records, legislation, patient, doctor, pharmacist

1. Introduction
eHealth is a rapidly growing sector worldwide. Following the United States of America, where several years ago they realized for the first time the value of eHealth, important steps have taken place the latest years in Europe and in Greece, where the economic crisis has made necessary the savings in the health area, which can be achieved through the development of eHealth. However, the rapid growth of eHealth, beyond its significant advantages, such as the reduce of the cost of health services which are provided by the states, the faster and more direct service for the patients, the increased transparency at every level, it is accompanied by significant risks too, such as the illegal processing of health data of millions of patients, especially for profit.
This study presents eHealth in Europe as well as in Greece and the legislative framework for the protection of personal data in eHealth sector.

2. Defining the meaning and the scope of e-health
«eHealth» is the overarching term for a range of tools based on information and communication technologies used to assist and enhance the: prevention, diagnosis, treatment, monitoring and management of health services. According to the World Health Organization eHealth is “The combined use of electronic communication and information technology in the health sector”.
The scope of eHealth includes: 1) Clinical information systems, such as specialised tools for health professionals within care institutions and tools for primary care and/or for outside the care institutions, 2) Telemedicine systems and services, 3) Regional/national health information networks, including electronic health record systems and associated services and, finally, 4) Secondary usage/non-clinical systems, such as systems for medical education, research, public health, health education and health promotion of patients/citizens.

3. Health data
In European and Greek legislation it does not exist a definition of the term “health data”, but it is accepted that it includes any information that can characterize the biological or mental status of a person [1]. Thus, it includes data on medical diagnosis, surgeries, laboratory tests and medication, without the need of the existence of a disease. Even the ascertainmnet of the good health of a person is a “health data”, since the disclosure of the negative result of a medical examination may cause harm to him, because it reveals that he visited a doctor, so he had concerns about the existence of an illness. Also genetic data are included to the term health data.
Apart from these, the term “health data” includes all other information contained in the medical record of the patient and any evidence relating to the
management of health services, such as data pertaining to the date importation and the time of hospitalization, the identification number of the patient, even the address or contact information, since these data may suggest that someone seeks medical care, possibly the type of the care, and thus to draw conclusions about the state of his health.

4. eHealth in Europe
The European Union, as mentioned above, during the last years has made important progress in eHealth section [2]. The European eHealth area includes mainly the electronic health record architecture, online health services, teleconsultation, ePrescribing, eReferral and eReimbursement. The European Commission’s basic objectives are:
1) Enabling EU citizens to lead healthy, active and independent lives until old age
2) Improving the sustainability and efficiency of social and health care systems
3) Developing and deploying innovative solutions, thus fostering competitiveness and market growth
Although the legal challenges in the field of the E.U. are still numerous [3], the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross border healthcare is important [4]. Article 14 provides that the E.U. shall support and facilitate cooperation and the exchange of information among Member States working within a voluntary network connecting national authorities responsible for eHealth designated by the Member States. Also the Commission’s Recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems includes eHealth at the i2010 initiative which promotes the building of European information society and encourages provision of better public services [5]. Finally, the European Commission has established the eHealth Action Plan 2012-2020 under the title “Innovative healthcare for the 21st century”, which describes all the actions that need to take place within the E.U.[6].
In this context, the epSOS project took place [7], which provides for cross-border services that support safe, secure and efficient medical treatment for citizens when they are travelling across Europe, medication ePrescription and medication eDispensation, it focuses on services close to the patient and it builds on existing National eHealth Projects.

5. Health data protection in Europe
Primary concern of the European legislator, along with the spread of eHealth, should be to address all data protection issues that may arise [8], as the security of health data of the European citizens is a prerequisite to achieve eHealth in Europe, as noted in the Working Document on the processing of personal data relating to health and in electronic health records [9]. The legislative framework for the protection of health data in eHealth is based on the general legal framework for the protection of personal data.
Health data are considered sensitive personal data as provided in Article 8 (1) of the Directive 95/46 of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [10]. Prerequisite for lawful processing of health data is that the data subject has given his explicit consent to the processing of those data, as it is provided in paragraph 3 of Article 8 of the Directive 95/46. Under this condition, the consent should be given freely, it should be specific and should be preceded by the provision of related information.
In addition to that, according to Article 8 (3) of Directive 95/46/EU the processing of sensitive personal data is allowed when three cumulative conditions are satisfied:
1) the processing of sensitive personal data must be “required”
2) the processing takes place “for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health – care services”
3) the personal data in question “are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy”
Besides, the relevant E.U. legislation for eHealth, as mentioned above, expressly refers to the provisions of Directive 95/46/EU for data protection. Thus, both Article 14 of the Directive 2011/24/EU and par.10 of the Commission’s Recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems provide that all the relevant settings should be in conformity with the European Union’s provisions on the protection of personal data and in particular with the Directive 95/46/EU.
In the context of the process of amending the European legislation on personal data protection, Article 81 of the proposed General Data Protection Regulation [11] provides more specific and detailed
conditions for the lawful processing of health data, requiring, inter alia, that the processing of personal data concerning health should follow European Union’s law or a Member State’s law, which shall provide for suitable and specific measures to safeguard the data subject's legitimate interests, and which shall require that the processing is necessary for the purposes of preventive or occupational medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and where these data are processed by a health professional subject to the obligation of professional secrecy or another person also subject to an equivalent obligation of confidentiality under Member State law or rules established by national competent bodies. Finally, the ECHR, interpreting the current law, ruled in case 1 v. Finland of 17-7-2008, thoughts 41, 44, that hospitals should provide for strict controls regarding access to health records by permitting access only to health professionals directly involved in the applicant’s treatment or by maintaining a log of all persons who had accessed the applicant’s medical file, so that the person who suffered some damage will be able to prove illegal access to his medical record by the staff of the hospital.

According to the law 3892/2010, the process which has to be followed for ePrescribing is as follows [1]:

1) The patient visits the doctor
2) The doctor prescribes medicines online and the prescription is stored in the central system
3) Then the patient visits the pharmacist
4) The pharmacist retrieves the e-prescription from the central system, performs the prescription and informs the system about that
5) Insurance providers and the department which is responsible for the costs on health section have access to data
6) Health care providers have access to patient data produced by themselves

Although there is still much to be done, particularly in the area of electronic health records (EHR) and electronic patient card, since the implementation of the law 3892/2010 significant results have been achieved. Thus, Greece has saved 1 billion euros from 2010 to date, because of e-prescription, but it is estimated that it will also save approximately 800 million euros the next 2 years. Moreover, 92% of the total number of prescriptions are performed each month through e-prescribing system, in which 100% of the total number of pharmacies and 90% of the total number of doctors participate.

6. eHealth in Greece

By 2010 every doctor in Greece devotes 85% of his time to the management of its clientele. As a result the patient has only 3.5 minutes from his time when the European average is 8 minutes and in Sweden is 12 minutes. Moreover, the pharmaceutical expenditure in Greece amounts to 2.7% of GNP, when the EU average is below 1.8%. However, in recent years important steps have taken place in the development of eHealth in Greece. The first attempt took place with law 3235/2004 on “Primary Health Care”, Article 9 of which provides for the establishment of electronic medical records and electronic health card. Nevertheless, eHealth in Greece, at least as regard the ePrescribing, became reality with the law 3892/2010 for “Electronic registration and execution of prescriptions and referral medical examinations”. The implementation of this law has led to the creation of two basic portals, through which now eHealth is applied in Greece: www.e-syntagrafisi.gr και www.e-diagnosis.gr. The authorized institution for retention of the databases of e-syntagrafisi and e-diagnosis is the “Electronic Governance Social Security - IDIKA SA” (www.idika.gr).

7. Health data protection in Greece

As in Europe, also in Greece, in order eHealth to have a success development, a very important factor is the protection of health data of patients, since the health market is one of the most profitable markets. Despite that patients should not be treated primarily as consumers and health data should be strictly protected against unlawful processing [12]. As already mentioned in Greece so far mainly the ePrescribing has been developed, while significant steps have not taken place yet as regards the EHR [13]. For the operation of ePrescribing special permission by the Greek Data Protection Authority has been given [14]. The protection of health data takes place in the light of legislation on medical secrecy and in the light of legislation on the protection of personal data [15]. Thus, firstly, all health data are protected by the Article 14 of the Code of Medical Ethics (law 3418/2005), in which, under the title “observance of medical records”, the requirements for electronic record keeping by doctors, clinics and hospitals are included, while Article 371 of the Greek Penal Code on professional secrecy is also applied. Moreover the provisions of the law 2472/1997 for the data protection are applied, Articles 7 and 7A of
which contain provisions similar to those in Directive 95/46/EU.

As regards the protection of personal data in ePrescribing in particular, there are adequate provisions in the law 3892/2010, under which access to health data kept in the central electronic prescription system is regulated as follows:

1) the insured have access and knowledge of their data, which are registered in the system (Article 6 par. 6)

2) physicians have access to data that they have registered themselves or other doctors, provided that the express and specific consent of the patient has been given (Article 3 par. 8)

3) pharmacists have access to prescriptions performed by themselves (Article 4 par.9)

4) social insurers have access to data only for specific reasons and with the requirement of a specific consent (Article 7 par.1)

5) health service units have access to health referrals which were performed by themselves (Article 5 par.8)

8. Conclusion

Although important steps in the development of eHealth have already taken place, in Europe and Greece, crucial element for further development is the security of health data of patients. Given the fact that eHealth has not in our continent the same growth as it has in the U.S.A., it can be argued that the current legislative framework adequately protects data in the area of eHealth. However, it is also undeniable that the following years the development of eHealth will be rapid. For that reason, both the European and Greek legislator should form the right framework for the protection of health data as soon as possible.

The proposed E.U. Regulation for the protection of personal data, seems to satisfactorily meet the requirements of safety and security of health data. Nevertheless, the general provisions for health data are not sufficient but special arrangements are necessary for eHealth, that will ensure the respect of self determination, the identification and authentication of patients and health care professionals, the use of health data only for specific reasons, special authorization for accessing HER in order to read and write in HER, organizational structure of an eHealth system, transparency, control mechanisms for processing health data and other major issues related to eHealth.

References:


