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Protection of patients' data in e-Health systems: A concise review for Greece and Europe

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Abstract

E-health is a new reality in healthcare and medicine. It is a field that is starting to find application mainly in developed economies but not only. The complexity of modern systems poses new challenges in the management of information and also requires the development of legislation to safeguard citizens. This article highlights this need in a comparative approach setting Greece as a case study in the European environment. Being an ever-growing sector, it is deemed that this system will play a catalytic role in national economies in the following years. At the same time, this essay provides a presentation of current legislation concerning health data protection in Europe and Greece, presented both individually and comparatively. Finally, it examines if further supplements to the current legislation are needed, aiming for higher health data protection levels concerning millions of people involved, either voluntarily or not, in e-health.

Keywords: e-Health, European Union, Greece, Health Data, Health Data protection

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1. Introduction

The major requirement for the fulfillment of the vision of Information and Communication Technology in healthcare is a patient-centered system (Haux, 2002). Establishing an information society within the healthcare system requires six major issues to be taken into consideration (Kardasiadou, 2011). In detail, 1) issues of organization and culture, 2) the inevitable technological gap between professionals within the healthcare system, 3) legal issues such as privacy policies concerning patient related data within the system, 4) industrial and marketing policies of the newly formed domain of healthcare informatics, 5) the issue of people on managerial and leading positions within the healthcare lacking a vision along with the issue of unwillingness for the whole healthcare process being reengineered to achieve higher levels of efficiency and quality of care delivery and last but not least 6) the issue of persuading the users involved in this information system about its usability and benefits. Thus, taking all six abovementioned issues into consideration and adopting all the appropriate policies, healthcare organizations will be enabled to incorporate ICT effectively and economically concerning organizational expenses (European Commission, n.d.a). It is important to note that non-governmental

organizations have been integral to healthcare projects internationally (Sidiropoulos et al., 2021; Sidiropoulos et al., 2022), and can play a vital role addressing these issues.

Additionally, it has been globally observed that e-Health is an ever-growing sector. Starting in the United States of America, where e-Health was originally established and valued several years ago, its useful application is becoming more and more dominant in Europe and in Greece over the last few years (Jordanova, 2009; Katehakis & Kouroubali, 2019). The financial crisis has made saving more vital than ever, thus healthcare is no exception to that rule, ideally finding the satisfying solution in the development of the e-Health system. The development of new applications in Greece and abroad involves the political will and especially that of the health ministries. It seems that so far the policies of the Greek government are in line with European priorities. It is certain that both in Greece and in the rest of the European continent, public-private partnerships and the contribution of corporate social responsibility have played an important role in health developments (Kritas et al, 2020).

However, nothing comes without risks and limitations. E-Health is no exception to this rule. Beyond its significant benefits; namely the reduction of health services cost provided by the state, the rapid and direct patient service, the high levels of transparency, its risks are equally worth examining. In fact, the exploitation of health data of millions of patients for profit is the most important of them. This essay presents the e-Health system both in Europe and in Greece along with the legislative framework concerning the protection and preservation of personal data within the system (Iakovidis, 2000; Scott, 2007).

2. Defining the meaning and purpose of e-Health

As far as e-Health is concerned, it can be explained as a variety of tools based on ICT aiming to aid and enhance prevention, diagnosis, treatment, monitoring and management of health services. Artificial intelligence is key to enhancing the role of telemedicine and eHealth. Nowadays, in the dawn of artificial intelligence, the human factor becomes more valuable than ever as it acquires a great ally, the computing capacity that it controls but which at the same time educates itself (Efthymiou et al, 2020a). According to the terminology provided by the World Health Organization (2004), e-Health is “The combined use of electronic communication and information technology in the health sector’’. Focusing on the purpose behind the use of e-Health one can focus on 1) Clinical Information Systems, such as specialized tools for healthcare professionals in institutions and tools for primary care and/or for outside healthcare institutions 2) Telemedicine systems and services, 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.

Telemedicine as one of the priorities of eHealth breaks the known barriers of geographical exclusions and gives equality and equity to citizens regardless of where they live. The contribution of innovative medical practices in cases of chronic diseases, rare diseases and oncological cases requiring frequent monitoring and special care will be significant (Efthymiou et al, 2019a). Telemedicine can also address serious problems of prevention and the treatment of health emergencies in areas where populations are overwhelmed by migratory and refugee flows. In addition to the phenomena of exclusion in this particular case, the use of new methods offers the possibility of getting rid of cultural incompatibilities between practitioner and patient (Fouskas et al, 2019; Vozikis et al, 2021). In this sense and due to the need for a holistic approach and individualized application of medical knowledge to each case, it is necessary to implement a Sociocybernetic model in the field of Health Management. The challenges are many and the trials of humanity in the coming years even greater due to the circumstances. The use of new practices is imperative (Efthymiou et al, 2019b).

3. Health Data

The term “Health Data” does not hold a definition within any European or Greek legislation. However, it is widely accepted that health data as a term includes any information characterizing the physical or mental status of an individual (Kardasiadou, 2011). Thus, it included data on medical diagnosis, surgeries, laboratory tests and medication regardless of the need of an existing disease. Even certifying any individual’s good health can be characterized as ”health data”, since any medical examination negative result may reveal that the specific person visited a doctor driven by a concern about a possible existing illness. Genetic data are also included in the term “health data”. Furthermore, any other information in a patient’s medical record is part of the term in question. Last but not least, health data as a term also includes any evidence about a patient’s activity related to health services. For instance, data concerning the importation or hospitalization date, the patient’s identification number

or even address and contact information. All these data can be justifiable parts of the term since they suggest that the patient sought medical care, possibly what type of medical care he/she sought, and thus one can draw conclusions about the patient's health. Furthermore, systematically gathering and monitoring the evolution of such data can help to identify in time trends in the health of the population and act accordingly. Issues as, for example, the adverse effects of austerity on the dietary habits and the overall rise in obesity (Kyriazis et al., 2018), can be identified, monitored and acted upon sooner when such data are processed effectively.

4. Health in Europe

The pandemic showed that a holistic and coordinated approach to health at the European level must be implemented (Emmanouil-Kalos and Prokakis, 2021), especially as part of a long-term sustainable recovery strategy (Emmanouil-Kalos, 2021). It has been previously mentioned that the European Union has achieved great progress in the e-Health domain during the last years. The main parts of the European e-Health sector can be classified as following: The electronic health record architecture, online health services, teleconsultation, ePrescribing, eReferral and eReimbursement. As the European Commissions' basic objectives can be stated the following:

1) EU citizens being able to lead healthy, active and independent lives until old age

2) Social and health care systems be improved in terms of sustainability and efficiency

3) The development of innovative solutions. In this way, competitiveness and market growth can be fostered.

However, many legal issues still challenge EU legal authorities (Stroetmann et al., 2012). The most important acts in existence are 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 (European Parliament, 2011).

According to article 14, the EU is capable of supporting and enabling both cooperation and information transfer among member states working with a volunteer network, drawing connections among national authorities in charge of the e-Health system assigned by the member states. Also, the Commission's Recommendation of 2 July 2008 includes e-Health at the 2010 initiative which promotes the formation of a European Information Society and encourages the amelioration of public services on grounds of cross-border interoperability of the e-Health record system (Anastasopoulos, 2013). Finally, the e-Health Action Plan 2012-2020 as established by the European omission under the title "Innovative healthcare for the 21st century" illustrates all the necessary steps needed within the EU (European Commission, 2012a).

Within this context and based on all the abovementioned issues lies the validity of Smart Open Services for European Patients (epSOS). In detail, it provides cross-border services to European citizens traveling across Europe including their safe, secure and efficient medical treatment. E-Prescription and e-dispensation medication focus on services available to the patient and are built on already existing National e-Health projects (European Commission, 2014).

5. Health Data protection in Europe

As noted by the working document on the procession of personal data relevant to health and e-Health record data protection is of primary importance (Sellars & Easey, 2008). In other words, before we achieve e-Health in Europe, European citizens' health data security is a prerequisite. Thus, the European legislator must be in a position to address all data protection issues that may occur, aiming always to the spread of the e-Health system (European Commission, n.d.b). The specific legislative framework about the protection of health data is based on the general legal framework concerning 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 (European Parliament, 1995). Additionally, according to paragraph 3 of article 8 of 146, the lawful processing of health data is that the subject has explicitly consented to the processing of his/her personal data. Under this condition, the consent given freely is to be specific and to be preceded by related information provision.

Also, according to Article 8 (3) of Directive 95/46/EU only when all three following prerequisites are completed processing of sensitive personal data can be allowed.

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'.

Additional to E.U. legislation concerning eHealth, as mentioned above, are 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 about international interoperability among different information systems and software applications provide that all relevant settings should conform with the European Union's provisions about the protection of personal data and particularly with the Directive 95/46/EU.

Contributing to the European legislation about personal data protection, Article 81 Regulation provides specific conditions in detail about the legal health data processing (European Commission, 2012b). Main requirements are personal data processing is done in accordance to EU law or a member state's law, which states necessary and specific strategies to safeguard the subject's legitimate interests, also proving that the use of the data is related to preventative or occupational medicine, medical diagnosis, the provision of care or treatment or health care services management. Additionally, another requirement is that data are handled by a health professional subject under the obligation of professional secrecy or another person under the same obligation of confidentiality according to the member state's legislation or any other national competent bodies' rules.

Finally, the ECHR, interpreting the current law, ruled in case I v. Finland of 17-7-2008, thoughts 41, 44, that hospital units should ensure strict controls when it comes to health record access. In detail, access should only be permitted to healthcare professionals who are directly involved in the subject's treatment. Also, the hospital should keep a record of each and every person accessing the subject's medical file. This aims to enable any individual suffering personal data damage to prove any illegal access to his/her medical record by hospital personnel.

According to the Law 3892/2010, a certain procedure has to be followed in case of an e-prescription. In detail, the steps followed are the following (Kardasiadou, 2011):

1) The patient visits the doctor

2) Medicine is prescribed online, which stored in the central system

3) Then the patient visits the pharmacist

4) The e-prescription is retrieved from the central system by the pharmacist who performs the prescription and informs the system about it

5) Insurance providers and the department responsible for the costs have access to data

6) Health care providers have access to patient data produced by themselves

There is still room for improvements, especially in the sector of e-Health records (EHR) and electronic patient card. However, with the implementation of the Law 3892/2010 there has been significant progress. In this way, thanks to e-prescription Greece has saved 1 billion Euros from 2010 to date. It is also estimated that within the two following years, Greece will manage to save about 800 million Euros. Moreover it is worth mentioning that in Greece 92% of all prescriptions monthly are performed via the e-prescription system which includes 100% of the total number of pharmacies and 90% of the total number of doctors.

6. The initial signs of e-Health in Greece

The years before 2010, doctors in Greece devoted 85% of their time managing their clientele. Consequently, patient time occupied only 3.5 minutes of their time while the European equivalent average is 8 minutes, while the Swedish is 12 minutes. Moreover, Greek pharmaceutical expenditure refers to 2.7% of GNP while the EU average is estimated below 1.8%. Nevertheless, during the recent years e-Health in Greece has been developed and evolved to a significant extent. The first step was achieved due to Law 3245/2004 on "Primary Health Care". According to Article 9 of this specific law concerns the establishment of electronic medical records and e-Health card. However, it was only after Law 3892 for "Electronic registration and execution of prescriptions and referral medical examinations" that e-Health became feasible in Greece in the domain of e-prescribing. Been implemented the abovementioned law led to the formation/construction of two main portals: www.e-syntagografisi.gr and www.e-diagnosis.gr, via which e-Health is now nationally applied in Greece. Both

abovementioned databases (e-syntagografisis and e-diagnosis) are managed and controlled by a Greek authorized institution called "Electronic Governance Social Security - IDIKA SA» (www.idika.gr).

7. Legal framework and potential legal growth.

Firstly discussed more than a decade ago in Greece the development of an electronic medical record system was legally established in 2004, until which year there was no legal framework for its creation. However, a never issued decision of the Minister of Health and Welfare (Ministry of Health today) blocked the application and execution of this law, since it was dependent on the former. IN more details Article 9(5) of Law 3235/2004 on primary healthcare set the basis for the construction of electronic medical insurer's record. According to this law the conditions for the necessary framework and structure, type and content of this record were specifically set awaiting for its implementation a Decision of the Minister of Health and Welfare which after all was never issued. More specifically, Article 9 of Law 3235/2004 declared the establishment of an electronic medical record for each Greek citizen including their medical information input by an institution providing healthcare services.

According to the abovementioned scheme every health center would be provided with the necessary infrastructure in order to maintain and update data in the electronic medical file and be entitled to access information maintained in other healthcare entities. A similar framework would be available in private family or personal doctor offices, certified with health insurance organizations. Thus, any information produced by family and private doctors would have to be uploaded to the electronic medical files of insurers so as the platform can always be updated. Additionally, according to Paragraph 4 of Article 9, the electronic health card for citizens was to be introduced. The aim of this card would be to facilitate access to health services and to ensure direct provision of the required information and data about the card holder's health. Nevertheless, as it has been previously Article 9 (s) stated that for the competition of the project a ministerial Decision issued by the Minister of Health and Welfare (or minister of Health according to the 2004 title) was necessary. Such a decision would serve multiple purposes; identification of the necessary infrastructure, specification of the type and content of the electronic medical insurer's records, description of the system's security prerequisites, framing of the basic information to be included within the e-Health card, as well as listing of other equally important information, However, such an official decision was never adopted resulting in the relevant provisions for e-Health of Law 3235/2004 never being applied in Greece.

Seven years later, in October 2011, the Ministry of Health (2011) issued guidelines for the implementation of an electronic Health Record system based on clinical documents to all hospitals within the National Health System (ESY). Those guidelines can be characterized as a good basis for the creation and realization of an EHR System, even though in fact they were partially realized.

Only recently in Greece has the reform of the National Health System been feasible with the newly issued Law 4238/2014. According to this law the primary Greek healthcare system is being reconstructed with the establishment of Health Centers in which the already existing centers and polyclinics are being incorporated. According to Article 3 of Law 4238/2014, "The Statute of Health Centres will specify... the content and the storage process of the patients' personal file". Given many health authorities' contribution the abovementioned statutes will be issued; namely Decisions of the Minister of Health, Administrative Reform & e-Governance and Finance, following a recommendation of the relevant Regional Health Administration and the Central Board of Regional Health. Thus the new law (Article 51 (4) issues the formation of e-Health for every Greek citizen.

After all, the creation of a unique electronic Health record per citizen concerning both primary and secondary healthcare finally becomes a reality for the Greek healthcare sector. The creation of the e-Health record is assigned to either the family doctor or the authorized medical personnel of the health unit in which the patient is being monitored. Following a proposal made by the National Council of Electronic Health Governance, a decision of the Minister of Health is to provide a common national model that is a prototype for an e-Health record. According to Laws 2472/1997 and 3471/2006 the sample will provide specific details for the content, the steps for its creation, patient identification and accessibility to medical information.

Another relevant law worth mentioning is 4213/2013 about patients' rights directive. According to Article 3(13) a medical record is defined as "all the documents that contain data, predictions and information of any kind relating to the conditions and the clinical progress of a patient throughout the treatment". The aforementioned provisions of law 4238/2014 at the abovementioned anticipated Ministerial Decision along with the given definition play a vital role for the realization of the Greek EHR.

Moreover, the Code of Medical Ethics (CME) [Law 3418/2005] can be deemed as highly significant for the development of EHR system in Greece. In fact, although the EHR system is not directly mentioned within the CME, its initial phase can be based on many of the CME provisions. In detail, according to Article 14(1) of the CME doctors are obliged to maintain medical records either electronic or in any other form containing inextricably or casually linked to the patients disease or health data. Specifically, this data includes first and last name, father's name, gender, age, occupation, address, visit dates as well as other important health information such as health related complaints made by the patient, primary and secondary diagnosis or any treatment followed, according to the specialization of each doctor (Article 14 (2) CME) Additionally, clinical and paraclinical examination results are also kept in the medical records of clinics and hospitals (Art 14(3) CME).

Furthermore, there are laws regulating the protection of personal data such as Law 2472/1997 about processing personal data and Law 3471/2006 about personal information and privacy within the electronic communications sector-whenever applicable. In the same way, health data are sensitive data according to Law 2472/1997 Article 2b. Thus, their processing should be carried out by a health professional under the obligation of professional secrecy or any other relevant code of conduct, only in case of preventive medicine, medical diagnosis, care or treatment or healthcare services management. An opinion on EHR systems can be issued by the Greek DPA if requested by legislative bodies. Medical records of employees can be kept either in print or online following the provisions of Law 3850/2010.

Finally, we should note that there are shortcomings in legislation and in the law-making process either at national, EU or international level in the health sector and this became obvious especially during the covid-19 crisis and not only in eHealth. More intensive efforts should be made so that both the healthcare system is protected from the possibility of cyber-attacks and the citizen-patient feels safer (Batakis et al, 2020).

8. Conclusion

In addition to the critical importance of the selection of staff for health services, it is now considered absolutely imperative to select the best technological means of networking databases to improve the health services provided, as well as the staff with the knowledge background. With the right implementation tools as well as the flexibility possibilities, the right selection of hospital administrators, total quality management can be implemented by the leadership as a way to improve health services provided (Kritas et al, 2021). Although health as a commodity should not be a point of inexhaustible, meaningless clashes between political factions, we have seen in the past that this seems inevitable, even though it affects the health of citizens. Surely any debate that takes place on the development of new health technologies and the legislation that will accompany them should be conducted with a patient-centred approach by all stakeholders (Batakis et al, 2019). Nowadays both in Europe and Greece important steps towards e-Health have been taken, however, there is still room for further development in the vital provision of security of patients' health data (Efthymiou et al, 2020b). Various encryption methods are used in e-Health systems (Sivan & Zukarnain, 2021), and special attention has been given in the research for the use of blockchain technology as a way to ensure reliable and secure management of patients data (Zhang et al., 2022).

For the time being legislation protecting this system can be deemed as an adequately protective framework given that in our continent e-Health is not as much developed as in the United States of America. Undoubtedly, within the following years e-Health will face rapid progress making the need for both Greek and European legislation about personal data protection more and more essential. The regulation about personal data protection as it is proposed by the European Union can be deemed as satisfying for the requirements of health data security and safety (Efthymiou-Egleton et al, 2020). Nevertheless, merely a regulation is not enough. Since general provisions for health data are still insufficient, additional arrangements are necessary. Among others, they will ensure respect towards self-determination, patients and health care professionals' identification and authentication, health data only used for specific purposes, special authorization concerning HER access for reading and writing within the system, organization and management of the system, transparency, control strategies over the use and procession of health data as well as essential matters related to e-Health (Efthymiou et al, 2020c; Efthymiou et al, 2020d). Thus, in order for the legislative support framework to completely cover e-Health systems and data protection further actions must be taken by the appropriate bodies.

The future of e-health in national health systems such as Greece depends to a large extent on political will. From this perspective, the basic pre-conditions for the sustainability of a definitive eHealth system that provides data security and the development of new applications that provide personalised services should be considered.

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Legislation

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