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GDPR COMPLIANCE ANALYSIS REGARDING THE USE OF PERSONAL DATA FOR PUBLIC HEALTH PURPOSES IN ROMANIA

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Abstract: *The General Data Protection Regulation (GDPR) came into force on 25th of May 2016 and highlighted the importance of confidentiality in all economic and social areas. The medical sector is one of the best regulated areas regarding the confidentiality of patient's health information, as per the law no. 95/2006 and law no. 46/2003. Although these laws regulate many privacy aspects involving the doctor-patient relation, there is a need to update them to keep up with the latest evolutions of the emerging technologies, especially with telemedicine. Using the overview of the rules regarding the health data processing in Romania, published by the European Data Protection Board (EDPB) in 2021 and comparing it with the public health and research laws currently applied in Romania, it resulted that there is a non-regulation gap related to the secondary use of health data in terms of planning, management and improvement of the healthcare system, as well as in terms of using that data for scientific and historical research purposes.*

INTRODUCTION

The history of confidentiality dates back to 4th of November 1950 when the European Convention of Human Rights was first signed. The concept of privacy was highlighted in Convention 108 – the Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data signed in 1981, subsequently adopted as Directive 95/46/CE and becoming mandatory for all EU members or future members as a condition to join the EU.

Romania signed the accession in 2005 and became an EU official member state in 2007. One of the conditions was to adopt a national law and to create an agency to oversight all personal data processing. As a result, we have updated the law no. 677/2001 – regarding the data protection and the freedom of movement and adopted the law no. 102/2005 that created the National Supervisory Authority for Personal Data Processing, repealed by law 129/2018. Also, law no. 677/2001 was repealed by law no. 190/2018 that enforced the General Data Protection Regulation (679/2016) in Romania and added some specific limitations and derogation. Some of the derogations have been criticized by the President of the European Data Protection Board, because they offered political parties (private organizations) free access to personal data without express consent. The most important derogation was referring to the freedom of processing personal data for academic, research, journalistic and filling in purposes.

The new improvements added by the GDPR, include technical measures like pseudonymisation, encryption, confidentiality, availability and resilience of processing. Also, an important step is the continuous testing, assessment and evaluation of the effectiveness of the technical and organisational measures taken to ensure the security of the processing. As a result of monitoring and testing all measures, GDPR sets an obligation to report any incident as soon as the organization is aware of it, within 72 hours. This obligation is also stated by the NIS Directive that came into force in December 2018 as well.

A commitment to ensure that all obligations imposed by GDPR are fulfilled, the EDPB added a Data Protection Officer (D.P.O) role, to act as guardian and single point of contact with the national authority, within all organizations that process personal data on a large scale. The DPO must report to the top management of the respective organization, and the regulation offers the advantage that the respective officer cannot be fired as result of fulfilling the duties assigned according to the GDPR, although sometimes the respective officer may act against the strategies set be the management of the organization.

The COVID-19 pandemic accelerated the process of digitalization in all public sectors and forced the Romanian Government to settle the telemedicine. In accordance with the articles 12 and 14 of HG 252/2020 and OUG 196/2020, some telemedicine services were introduced by amending the law no. 95/2006.

Another important step related to the digitization process was the EU Regulation no. 745/2017 that produced effects since 26th of May 2021 regarding the use and authorization of medical devices. As time goes by, we need to learn how to operate and integrate the latest emerging technologies, but also to be aware of the cyber security risks involved.

AIM

The digitization process and the use of new technologies are raising concerns about privacy while

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processing and transferring health data between different devices and servers that store all the information.

The Romanian Government must keep up with the new emerging technologies and adopt laws according to all EU regulations and directives because, according to EU studies, we are among the last countries that implement all privacy requirements.

This analysis will highlight the need for regulations regarding the secondary use of health data for planning, managing and improving the healthcare system and also for using the data for scientific research purposes. Among the most important regulation that must be updated or detailed are: the use of health data and monitoring devices after there are introduces into the market, electronic health data exchange for abroad medical surgery, implement all GDPR requirements into national laws (creating confusion when applying GDPR and unnecessary data processing specified into outdated national laws).

MATERIALS AND METHODS

The research method used is documentary review and the starting point of my analysis is the EU overview of the rules regarding the health data processing in Romania, published by the European Commission (1) on 22th of February 2021 and updated with other data processing regulations and laws that came into force until March 2022.

RESULTS

The EU overview identifies 3 purposes for processing of health data in Romania:

1. Providing health and social care services;
2. Planning, managing and improving the healthcare system;
3. Scientific or historical research.

The first purpose is well-regulated and compliant with the GDPR, while the secondary use of personal health information is left behind but much needed for the second and the third purpose.

Table no. 1. EU overview regarding the GDPR compliance of Romanian rules for processing health data

Legal basis according to	Functions / Purposes for health data		
	Healthcare services	**Management and improvement**	**Scientific or historical research**
GDPR	6(1)(c) legal obligation & 6(1)(e) public interest + 9(2)(i) public interest in the area of public health & 9(2)(h) provision of health or social care		9(2)(i) public interest in the area of public health & 9(2)(h) provision of health or social care
Romanian national law	Order no. 1/2000, Law no. 487/2002, Law no. 46/2003, Law no. 95/2006 Government Decision 355/2007	no specific legislation on this topic.	no specific legislation on this topic, but only a few mechanisms (agreement of a research committee or DPA)

After correlating all national current regulations and laws applied until march 2022 with this EU overview, I discovered some differences:

1. Providing digital health services – law no. 45/2019 for modifying law 95/2006 (creating the Electronic Health System), Government Decision 196/2020 (regulation of telemedicine)
2. Management and improvement - Government Decision 11/2015 for modifying law 95/2006 (creating and establishing the role for The National for Management and Quality in Healthcare System), law 185/2017 – establishment the management of quality in healthcare system, law no. 134/2019 for creating The National Agency for Medicine and Medical Devices in Romania, Order of the Health Minister no. 1466/2008 – setting the flaw of transmissible diseases.
3. Scientific research – art. 3 of law no. 190/2018 – that prohibits further usage of health data only for other purposes except public health.

Reviewing the subject rights according to GDPR, it results that patients have some legal restrictions in exercising their rights:

Table no. 2. Patients' rights according to GDPR and national laws

Legal basis according to	GDPR	Romanian national law
access	art. 15	art. 24 – law no. 46/2003 & art. 9 Order of the Health Minister no. 1410/2016
rectify inaccurate data	art. 16	no specific legislation on this topic.
delete any data / to be forgotten	art. 17	unclear references: Law no. 95/2006, Government Decision 355/2007 & law no. 16/1996 – no data should be deleted and must be archived.
portability	art. 20	Patient's Electronic Health Records – actually not working

DISCUSSIONS

Romania, Cyprus and Belgium are the only countries in EU that do not have a specific legislation for the use of health data for the purpose of managing and improving the quality of the healthcare system. Although in Romania there is a national health quality management agency, this authority oversees the evaluation and accreditation of sanitary units, but also verifies the compliance with the GDPR during their evaluation process.

The overview also shows a lack of regulation in most EU countries for monitoring the safety of medical devices or pharmacovigilance.

Another serious matter is the non-regulation of secondary use for health data in public and third parties research purposes in almost all EU countries, for developing the next generation of medical technologies and treatments.

Romania does not have any regulation for monitoring the authorized medical devices used in the healthcare system and uses patient's consent, data privacy assessment (DPA) and the ethics committee agreement for research purposes.

Taking into consideration the two new rights brought into attention by the GDPR, namely the erasure (the right "to be forgotten") and the portability right, new technical measures and procedures should be adopted in order to comply with these rights.

Almost all EU countries, except Latvia, collect and process health data by automated means, the portability right stated by art. 20 of the GDPR being applied only upon patient request.

Although every member state has a digital form of processing health information, in 70% of the EU, the right to erasure cannot be accomplished because of other national laws

that restrict deleting patient's data.

These issues are solved in Romania by using the Electronic Health Record (DES) that is not fully operational and available to all citizens, but it has configured these features by design in order to anonymise and export data. The portability of patient's data is accomplished by the national healthcare system using the national health card that stores all personal health history. Unfortunately, the data cannot be exported into an international standard form and a patient cannot travel abroad with all his/personal digital medical history file.

The evolution of health technologies is for the interest of all mankind and regulation must be settled to stimulate the innovation in public-private research partnerships and exchange relevant health information for the purpose of testing and improving technologies or for developing better medical devices.

CONCLUSIONS

This study highlights that the Romanian healthcare system complies with the GDPR, but significant steps forward are needed in order to regulate the secondary use of health data for improving the national medical system and scientific research.

Even though gadgets and smartphones came into our lives with a lot of benefits, they may be our worst enemy because of the data they collect about our daily routines and health parameters. The regulation of telemedicine and eHealth technologies in Romania is raising concerns about privacy and cybersecurity issues involving collecting, processing and storing personal health information.

One of the most important challenges for EU remains an interoperability standard across all member states and a large health network capable of transferring data securely and rapidly to any healthcare provider to avoid transforming every patient into a cybersecurity target.

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