ЗАРУБЕЖНОЕ ПРАВО

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Legal aspects of eHealth development in North Macedonia*

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The article aims to provide insight into the process of developing eHealth law in North Macedonia. For this purpose, the work, firstly, analyzes the meaning of the basic terms of eHealth and eHealth law providing comparative definitions as well as custom definitions adopted by the authors, which cover the meaning of the terms used in this research. The main part of the article focuses on the chronological review of the development of eHealth through relevant legal documents and provisions, as well as the original research results of the process in practice. To be more precise, this development is presented as seen through two aspects: the prism of domestic legislation, as well as the influence of the European Union's tendencies and regulation in the matter and the prism of the practice and the eHealth system, activities and functionalities that currently exist in the Macedonian healthcare system as seen by the general population and relevant international organizations (World Health Organization). Emphasis is placed on the legal aspects and the authors aim to determine if this aspect of eHealth has been supportive or opponent to the process of its development. An analysis of relevant legislation is presented in the article. Concluding remarks and recommendations are given in regard to the analyzed process in the Republic of North Macedonia.

Keywords: eHealth law, regulation, development, personal data protection, My Time.

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1. Introduction

At the beginning of its use (during the 1990s and early 2000), the term eHealth was characterized as a neologism that was widely used despite the lack of an agreed upon clear and precise definition. Certain research points out that the term eHealth encompasses a set of disparate concepts, including health, technology, and commerce although the degree of emphasis varies depending on the definition and the person/institution that is providing it (Oh et al. 2005, 36). It has also been noted that the term "health", as used in these definitions, refers explicitly to health care as a process, rather than to health as an outcome. 'Technology' is seen both as a tool and as an embodiment of eHealth itself, and the term "eHealth" is always used in a positive connotation associated with benefits, improvement, enhancement, efficiency and enabling (Oh et al. 2005, 36).

One of the earliest definitions that appeared at the beginning of the use of the term "eHealth" is that eHealth is an emerging field of medical informatics, referring to the organization and delivery of health services and information using the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a "new way of working, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology" (Pagliari et al. 2005).

The European Commission, in one of the first working documents on this subject, stated that "eHealth means information and communication technologies (ICT), ICTs tools and services for health that can improve prevention, diagnosis, treatment, monitoring and management and can benefit the entire community by improving access to care and quality of care and by making the health sector more efficient"[1].

The World Health Organization (hereafter referred to as WHO) defines eHealth as broad group of activities that use electronic means — information and communication technologies to deliver health-related information, resources and services such as treatment of patients, conducting research, education of healthcare workers, disease monitoring and monitoring of the public health[2].

In the domestic (Macedonian) legal doctrine and legislation there is only a definition for telemedicine which is provided with the Law on Health Care[3]. Telemedicine is considered as a part (type) of healthcare activity (Article 26 of the Law on Health Care) and it is stated that telemedicine is the exchange of medical information with the help of information and communication technology in order to improve the treatment of the

[1] Commission staff working document eHealth Action Plan 2012–2020 — innovative healthcare for the 21st century accompanying the document eHealth Action Plan 2012–2020 — innovative healthcare for the 21st century, available at Commission Staff Working Document — eHealth Action Plan 2012–2020 — innovative healthcare for the 21st century Shaping Europe's digital future (europa.eu). Accessed March 23, 2021. https://ec.europa.eu/digital-single-market/en/news/commission-staff-working-document-ehealth-action-plan-2012-2020-%E2%80%93-innovative-healthcare-21st.

[2] From Innovation to Implementation-eHealth in the WHO European Region. Official Report. Copenhagen, WHO, 2016. P. 7. Accessed March 15, 2021. https://www.euro.who.int/en/health-topics/Health-systems/digital-health/publications/2016/from-innovation-to-implementation-ehealth-in-the-who-european-region-2016.

[3] Law on Health Care (Закон за здравствена заштита). *Official Gazette of the Republic of Macedonia.* No. 43/12, 145/12, 87/13, 164/13, 39/14, 43/14, 188/14, 10/15, 61/15, 61/15, 154/15, 192/15, 17/16, 37/16, 20/19, 101/19, 153/19, 180/19, 275/19; Decree with the force of Law. *Official Gazette of the Republic of Macedonia*. No. 76/20. Accessed April 23, 2021. https://www.slvesnik.com.mk.

patient in the field of diagnosis, treatment and monitoring of the patient, as well as in the field of professional exchange of opinions. This definition is consistent with the definitions found in comparative literature and in the framework of European law according to which "telemedicine is simultaneously a healthcare service and an information service (a service normally provided for remuneration, remotely and by electronic means at individual request), therefore, both regulations — the ones regarding healthcare and the ones regarding information society services — apply" (Rapuso 2016, 3).

On the other hand, a definition on eHealth is not found in Macedonian doctrine and literature, although it can be noted that the term eHealth ("е-здравство" in Macedonian) is being frequently used in legislation and by the authorities. Even eHealth Administration as a body of the state administration was established as an upgrade of the National System for Electronic Health Records[4].

Therefore, it is necessary to present the position of researchers regarding the meaning of eHealth. For the purposes of this work, the term eHealth will be used with the meaning of a concept that includes numerous activities aimed to deliver health care using modern electronic information and communication technologies when health care providers and patients are not directly in contact and their interaction is mediated by electronic means. We consider that eHealth as a concept applied (used) in the healthcare system includes both the application of information and communication technology when dealing with economic, financial, ethical and/or administrative aspects of healthcare as well as the application of information and communication technologies to human health. All of these components have one goal — empowerment of the patient and achieving better individual and public health.

2. Basic research

2.1. Methodology

The process of collecting data and information for the purpose of this research was conducted mainly on the level of national legislation. The Strategies, Action plans, regulations, and other relevant documents on the level of the European Union were consulted in manner that provides a general comparison between the processes of development in North Macedonia and the EU.

Also, part of the data collecting process was the original research carried out for the purpose of this research and this work. The research included a survey conducted on a representative sample of the public in North Macedonia. This involved 151 respondents, from the age of 14 to 85 years old, who responded to 17 questions online through Google Forms. The main disadvantage of the online method of collecting responses was that it was not accessible to the elderly respondents (over the age of approximately 64 years) because they do not use the technology and they were unable to access the form on their own. In these cases, the survey was completed with the help of another person (family member with access to the form) and valid and relevant results were collected from the elderly population as well.

[4] This will be elaborated on later in the article, in the scope of the corresponding legislation that regulates this matter.

Questions regarding the following applications were formulated: existence and deployment of patient and healthcare provider identifiers, My time (Мој термин), eCards, electronic health record (hereafter referred to as EHR), patient summaries, ePrescription, standards, telemonitoring and telecare. All questions were developed based on the existing legal framework in North Macedonia and were aimed at adding value to the research on the national legislation. The results of the research (survey) are presented within the work alongside the analysis of the legal aspects of eHealth, where it was considered proper and necessary to present the development process of the research subject and provide relevant conclusions in regard to the legal framework as well as its efficiency in practice.

To create a baseline for the assessment of the progress of eHealth development in North Macedonia, the available data of other research is used in instances where a comparison was deemed necessary to make certain conclusions.

2.2. Foundations of eHealth

The foundations of eHealth can be found in the strategies and policies that states provide regarding health in general, or eHealth. According to research conducted on behalf of the World Health Organization, "84 % of respondents (38 Member States) have a national universal health coverage policy or strategy, of which 74 % (28 Member States) report that the policy or strategy specifically refers to eHealth or information and communication technologies in support of universal health coverage. Furthermore 70 % (30 Member States) have a national eHealth policy or strategy, of which 90 % (27 Member States) indicate that their policy or strategy refers explicitly to objectives or key elements of universal health coverage"[5]. North Macedonia was not included in this report on the status of eHealth in the WHO European region, although North Macedonia (at that time referred to as FYROM) is part of the SEEHN (South-Eastern European Health Network). In North Macedonia in 2007 and again in 2016, national health strategies guided health system developments in accordance with European Region health policies:

— *Health Strategy of North Macedonia 2020 (1) from 2007* that was "based on the Constitution of the Republic of Macedonia which guarantees the right of every citizen to health care, the World Health Organization's 'Health for all in the 21st century' strategy for the European region, the Millennium Declaration of the United Nations, the public health policy of the EU, as well as on finished policies and strategies in various fields of health and health care"[6]. It has set out a long-term health strategy to achieve a safer, more efficient, and fairer health system in addition to setting the goal of all primary care doctors becoming family physicians by 2020;

— *Health 2020 Strategy of North Macedonia (2) from 2016* which can be defined as a strategic health policy document in the context of Health 2020, the WHO European policy framework for health and well-being, and the United Nations

[5] From Innovation to Implementation-eHealth in the WHO European Region. Official Report. Copenhagen, WHO, 2016. P. 11.

[6] Health Strategy of the Republic of Macedonia, 2020. Safe, efficient, and just health care system. Skopje: Ministry of Health, 2007. Accessed March 26, 2021. https://extranet.who.int/countryplanningcycles/sites/default/files/planning_cycle_repository/the_former_yugoslav_republic_of_macedonia/health_strategy_2020_eng.pdf.

2030 Agenda for Sustainable Development. The Health 2020 Strategy from 2016 can be viewed as, setting out through a participatory process, the vision and strategic goals based on a multisectoral, systemic and life-course approach in the context of the WHO European policy framework for health and well-being and the 2030 Agenda for Sustainable Development (2)[7].

Apart from these two strategies, Macedonia has not adopted a national eHealth strategy, but it can be noted that development of eHealth is part (one of the targets) of the mentioned strategies. To be more precise, the Health Strategy of North Macedonia 2020 (1) from 2007 (in target 19) made the establishment of health information and communication systems a priority for the period from 2007 to 2017. The idea is consistent with the fact that health care systems are part of larger systems, such as social welfare systems and society. Therefore, evolutions in society, such as developments regarding information and telecommunication technology, as well as the rules related, will and do influence health care systems (Callens 2010, 562). The idea presented in this strategy was to create integrated an Information and Communication Technology (ICT) system for the whole health system, which, together with the electronic systems in the health care organizations, will enable communication, networking, and integration of the health care organizations[8]. This system was named Integrated Health Information System (hereafter referred to as IHIS). Participants in the Macedonian IHIS are the following: Ministry of Health, Health Insurance Fund of Macedonia, Centers for Public Health, public hospitals, general practitioners, insured people, Pharmacies, and all stakeholders involved in the primary, secondary, and tertiary healthcare system. The realization of this target also imposed the necessity for the adoption of new laws, as well as harmonization of the existing laws and by-laws and development of a new law for the regulation of the new IHIS. This legislation will be elaborated on further in the text.

To initiate the actual development of the envisioned IHIS, the Ministry of Health around the same period, had prepared the Strategy for the Development of Macedonian Integrated Health Information System which contained a description of the current legal provisions, scientific, organizational, and functional environment, as well as the requirements for a basic Health Information System architecture and functionality[9]. When this strategy was adopted, there was an absence of a health information and communication system in general and integrated hospital information system, and only individual systems existed in several of the participants in the health sector. At the national level, the Health Insurance Fund stood out in terms of the level of development of the information system, but other segments of health, especially hospitals, make minimal or no use of Information and Communication Technologies. Furthermore, in institutions where systems existed, they were used to cover a narrow part of operations and were not interoperable with other systems and participants. So, at that time, it was a priority for the government to carry out intensive activities for the development and application of information systems among key participants in the health system.

The last strategy, Health 2020 Strategy of North Macedonia (2) from 2016, unfortunately did not establish any development targets for the eHealth system in North Macedo-

[7] Primary health care organization, performance and quality in North Macedonia. Copenhagen, World Health Organization, 2019. P. 11–12.

[8] Health Strategy of the Republic of Macedonia, 2020. Safe, efficient, and just health care system. P. 47.

[9] Available in Macedonian. Accessed March 29, 2021. http://zdravstvo.gov.mk/strategii.

nia, nor did it illustrate any kind of vision in this area. The fact that eHealth does not take part in any of the general strategic goals of the Ministry of Health of North Macedonia in the period of 2016 till this day, as well as the fact that there is also lack of national eHealth strategy, only leads to the conclusion that in a crucial period of half a decade North Macedonia was left without strategic objectives, framework for action and implementation of improvement and further development of the eHealth system and eHealth services that were established and put into motion in 2007. However, one of the areas of interest of the research was also the opinion of the citizens about the traditional method of work at the healthcare institutions and the issuance of documents in paper form. The survey results showed that approximately half of the respondents (51,7 %) are only partially satisfied with this traditional method of communication between the patient and the institution. 33,8 % of the respondents are satisfied with this method, and 14,6 % are not at all satisfied with the operational method. Keeping in mind that the majority of respondents are not fully satisfied or are not satisfied at all with the traditional method of issuing documents on behalf of the healthcare institutions, our conclusion is that there is a need for further development of the eHealth activities that were established in North Macedonia. We consider integrated information technologies (hereafter referred to as IT) solutions to be the key to a successful and optimal clinical and administrative workflow.

We would also like to point out that patients' lack of satisfaction regarding the dominant[10] traditional method of providing healthcare services is not the only indicator that points out the need for development of new methods in the healthcare sector — for example eHealth. There are other indicators that substantiate the need for changes, even more objective ones, and one of them is the rate of increasing mortality and prevalence of non-communicable diseases, especially cardiovascular diseases, diabetes, and cancer[11]. From the data, once can also better understand how the needed reforms should be conducted for the system, especially in providing primary health care[12].

2.3. Legal aspects of eHealth

Since the start of the development process of eHealth in the EU, the legal and regulatory issues are considered to be among the most challenging aspects of eHealth. This aspect of eHealth includes questions regarding privacy, confidentiality, data protection, and liability, and they all present challenges that need to be addressed to enable sustainable implementation and use of eHealth applications. In most EU countries the use of eHealth is regulated only by a general legal framework, by laws on patient rights and data protection, and by regulations on professional conduct and any new legislation is often still in the process of being drafted. The number of countries that have a coherent set of laws specifically designed to address these aspects of health law is very small and refers only to certain legal matters (Stroetmann, Artmann, Stroetmann 2011, 9). "Amongst the forerunners in designing a legal framework adapted to the use of eHealth are Denmark,

[10] We use the term "dominant" because it is not the only method used in the Macedonian healthcare system, and to a certain point eHealth activities and solutions are introduced and present as well.

[11] For example, in the period from 2007–2017 strokes and ischemic heart disease, two leading causes of death in North Macedonia, saw a 2,5 % increase. There was a 21,5 % increase in lung cancer as the third leading cause of death. In general, the top ten leading causes for death have increased in the period from 2007 to 2017.

[12] Primary health care organization, performance and quality in North Macedonia. P. 6.

England, Estonia, Finland, France, Norway, Scotland, Slovak Republic and Sweden. Almost all countries which do not (yet) have specific regulations with regards to one or more fields of eHealth, such as Austria, Cyprus, Latvia, Malta or Portugal, do have some regulation on health data" (Stroetmann, Artmann, Stroetmann 2011, 13). As a result of the fact that North Macedonia was granted candidate status for European Union membership in 2005, eHealth development in the EU has significantly influenced the development of health policy in North Macedonia. The EU plays a significant role in policy development, through the European Union *acquis communautaire* and transposition of European Union regulations into national legislation, pertaining to the political criteria of democracy and rule of law, economic criteria for financial sustainability, functional market economy and competitiveness as well as social criteria, including social protection, health, and well-being[13]. It also can be noted that the current Macedonian legislation regarding eHealth regulation is related to the implementation of the Health Strategy of North Macedonia 2020 (1) from 2007, which, as we previously noted, imposed the requirement for the adoption of new laws, as well as harmonization of existing laws and by-laws. A main goal was the regulation of the new IHIS.

2.3.1. Law on Health Care

The Law on Health Care is *lex generalis* regarding health care in North Macedonia. It regulates issues related to the system and organization of health care and performance of health activity, guarantees rights and identifies the needs and interests of the state in providing health care, health facilities, employment, rights and duties, responsibility, evaluation, termination of employment, protection and decision-making for the rights and obligations of health professionals and health care associates, quality and safety in the healthcare activity, chambers and professional associations, advertising and advertising of healthcare activity, performing healthcare activity in emergency conditions and supervision over the performance of the healthcare occupation (Article 1, Law on Health Care). Since its adoption, the law has established the organizational structure of the system with the Ministry of Health and the Government in charge of determining the health policy and its implementation, the Health Insurance Fund responsible for the collection and management of funds, and the health care institutions responsible for providing services (Kjosev, Nedanovski 2008, 72). It is believed that with this law the Health Insurance Fund was enabled to contract services from private providers at the secondary and tertiary levels "as well as to establish a health network of certified providers to ensure geographical access to health and introduce an accreditation system for quality of care"[14].

The law also includes provisions on eHealth[15] which refer to the integrated information healthcare system, previously mentioned in the scope of the Health Strategy of North Macedonia 2020 (1) from 2007. Since 2015, a Management for eHealth ("Управа за електронско здравство" in Macedonian), a state administrative entity within the Ministry of Health, has been responsible for maintaining, developing, and managing the health information system.

[13] Developing the National Health 2020 Strategy in North Macedonia — A case study. Copenhagen, World Health Organization, 2019. P. 10.

[14] Primary health care organization, performance and quality in North Macedonia. P. 11–12.

[15] This is Section H-a titled: Electronic Health (from Article 249-a to Article 250) of the Law on Health Care.

The established IHIS, regulated with the mentioned provisions, is a centralized eHealth system, that consolidates data from more than 70 sources, including primary care doctors, health care centers, hospitals, institutes, clinics and pharmacies. At present, 1 950 000 records have been created, and it is the sole system used by primary care doctors to refer patients and prescribe medication. However, it is still not open to patients to book appointments with their primary care doctors or to access their data in a personal health record[16].

The Ministry of Health refers to these eHealth activities as health informatization processes that include construction and implementation of numerous software solutions and systems[17]:

— National system for electronic scheduling of operations and examinations — My term or often referred as My Time in international documents ("Мој термин" in Macedonian);
— Introduction of Electronic Referral (eReferral) with a unique referral number linked to the Health Insurance Fund;
— Introduction of electronic prescriptions (ePrescription);
— Electronic medical diary to record medical operations performed on the patient;
— Electronic health record for patients (EHR);
— Drug register and virtual warehouse;
— Register of health facilities;
— Electronic Health Card (EHC, or eCard).

The survey included questions aimed at providing answers for the researchers regarding respondents' eHealth literacy. The results are presented in Table 1.

Table 1. **eHealth literacy**

Question	I am familiar, %	I am partially familiar, %	I am not familiar at all, %
Are you familiar with the electronic services provided by the health institutions on their web sites	9,3	47	43,7
Are you familiar with the possibility to use your EHC to choose your doctor and use health services through the web portal of the Health Insurance Fund of Macedonia	25,2	32,5	42,4
Are you familiar with the possibility to access data regarding your health insurance through the web portal of the Health Insurance Fund	13,2	33,1	53,6

Source: Original research provided by the authors for the purpose of this paper.

The high percentage of respondents that answered that they are not familiar with the e-services provided by the health care institutions shows that there is low level of eHealth literacy among the population. In general, it is believed that barriers to access to and use of

[16] Primary health care organization, performance and quality in North Macedonia. P. 20.
[17] General information provided by the Ministry of Health of North Macedonia. Accessed March 27, 2021. http://zdravstvo.gov.mk/moj-termin-opsti-informacii.

online health information can result from the readability of content and poor accessibility of eHealth services. In addition, there is need for new health literacy screening tools to identify skills for the adequate use of eHealth services, for example mobile apps as they are perceived to hold great potential for eHealth and mHealth services tailored to people with low health literacy (Kim, Xie 2017, 1080). Furthermore, the survey showed that 60,9 % of respondents do not use services provided by the eHealth system in North Macedonia, while 39,1 % do.

Table 2 presents the scale of the most used eHealth services by the respondents who were familiar with the eHealth services that they have been using, although the survey also showed a high percentage of respondents 29,1 % who do not know if they are using eHealth services or which eHealth services they have been using, which only confirms the researchers' conclusion regarding the existence of a low level of eHealth literacy among the Macedonian population.

Table 2. **Most used eHealth services**

Scale of the most used eHealth services	Respondents that use the service, %
Issuing ePrescription	45,7
Issuing Referral in My Term System	35,1
Use of services with the EHC	7,9
Services provided by the Drug register of the Agency for Drugs and Medical Devices	4
eServices provided by the Health Insurance Fund	3,3

Source: Original research provided by the authors for the purpose of this paper.

Taking into consideration the development of eHealth activities on the domestic level, but also through the prism of the relevant reports from international subjects, it is safe to say that My Term (Moj Термин) is the activity within the eHealth concept that had the most success in North Macedonia. My Term resulted from a pilot project that was launched in 2011 to improve the scheduling of clinical appointments and reduce long wait times to see a doctor or to have diagnostic tests. It was initially used in three public institutions and it soon expanded to public hospitals and primary care providers. According to one report, "with a strong vision for eHealth and the specific goals of improving scheduling and waiting times for clinical appointments and diagnostic tests, Moj Termin has achieved goals and demonstrated how strategic eHealth planning leads to success"[18]. It has also been a subject of various research, including our survey. In a 2015 survey conducted by the Ministry of Health, over 80 % of Macedonian and Albanian patients reported being satisfied with the system. Doctors noted improvements in notifying patients of cancelled or delayed appointments, and over 70 % of patients were satisfied with the appointment and wait times at the doctor's office. Fewer than 7 % of patients failed to attend their scheduled appointments without cancellation[19].

[18] From Innovation to Implementation-eHealth in the WHO European Region. Official Report. Copenhagen, WHO, 2016. P. 9.

[19] Ibid.

Additional research from 2017 indicates that 42,9 % are not satisfied with the concept of My Term while 21,4 % of the respondents are satisfied with how it functions[20]. This research also illustrated that the following situations were emphasized as downsides of the My Term concept: people cannot select the specialists they prefer and very often they wait more than two to three months for an appointment, and the appointed time does not correspond to the real situation at the hospital and often the appointed time is extended (still there are long waiting lines) (Misheva 2017, 507).

Our research and the survey conducted for the purpose of this work demonstrates that the public is familiar with My Term and the meaning of it. Most of the respondents defined it as an instrument of the healthcare system for making appointments to the family doctor and for medical examination provided by a specialist. A portion of respondents associated it with the use of information and communication technologies. Regarding the level of patients' satisfaction from the functioning of My Term in the Macedonian eHealth system, the survey shows that most of the respondents are partially (not fully) satisfied with it, and the percentage of respondents that are satisfied with the functioning of My Term is very similar. The results are presented in Table 3.

Table 3. **My Term functioning**

Question	Yes, %	No, %	Partially satisfied, %	Partially unsatisfied, %
Are you satisfied with the functioning of My Term	39,1	13,2	44,4	3,3

Source: Original research provided by the authors for the purpose of this paper.

This survey also shed light on respondents' opinion regarding the advantages of using My term. The results are presented in Table 4.

Table 4. **Advantages of using My Term**

Advantage from the functioning of My Term	Respondents that consider it to be an advantage of My Term, %
Less time needed for getting medical service	48,3
Facilitation of procedures for patients	40,4
Improved communication between primary, secondary, and tertiary level of healthcare	23,2
Increased efficiency and quality of healthcare	20,5
Transparency in the use of health services	12,6

Source: Original research provided by the authors for the purpose of this paper.

It can be noted that the satisfaction level among patients differs from research to research, but also among different periods of time. We would like to point out that during the COVID-19 pandemic, the Macedonian healthcare system has been under significant

[20] This survey was conducted among the patients in the Eastern part of Macedonia, mostly in the city of Shtip.

pressure which has also affected, in a negative way, the normal functioning of eHealth services through the My Term system. For example, the number of canceled and unfulfilled medical appointments within the system My Term, from the start of the pandemic till the middle of June 2020, has reached 128 000. According to the data kept in the National System My Term, it is not possible to conclude which service is most awaited, primarily because the principle of scheduling an examination or procedure is done by issuing a referral. Since no appointments are being made for regular examinations and the elective surgeries for which waiting lists are created are not performed, we do not have insight on the wait times and for which services during this period[21].

2.3.2. Law on Health Insurance

The Law on Health Insurance[22] regulates the Health Insurance Fund as one of the institutions connected within the eHealth system, which manages healthcare financing and is primarily funded through payroll contributions and revenues from the Pension Fund, the Unemployment Fund and general revenues (Kjosev, Nedanovski 2008, 72), as well as the electronic card as part of the functioning eHealth system in North Macedonia. According to Article 27 of this Law, compulsory health insurance rights within the scope of the rights determined by this Law are exercised by insured persons on the basis of an electronic card for health insurance and proof, i. e., entry in the electronic health insurance card that the contribution for compulsory health insurance has been paid. The form and content of the electronic card for health insurance, the manner of its issuance, and keeping records is determined by the Health Insurance Fund with a by-law on which the Minister for health gives consent. This by-law was adopted for the first time in 2010[23] and later, due to amendments of the Law on Health Insurance through the years, new by-laws were adopted. The version from 2013 remains in effect today[24].

In Macedonia, the basic conditions for the introduction of Electronic Health Records (EHR) at different levels of the healthcare system has been provided. All citizens (insured people) are provided with a smart card called an electronic health card (hereafter referred to as EHC). It contains basic administrative information such as a unique health number of the insured, name, gender, the insurer, etc. EHC is used for patient identification primarily by healthcare institutions (Gavrilov, Trajkovik 2016).

EHR's data is currently distributed in the different IT systems in private and public healthcare institutions and structured data must be documented during patient care through the use of national or international sets of terminologies. From an IT point of view, there are certain concerns in regard to how much of this data is relevant and sufficient for clinical research and which data elements are relevant for feasibility analyses

[21] Informative article published in the online media. Accessed March 29, 2021. https://www.24.mk/details/otkazhani-rechisi-128-000-pregledi-od-moj-termin.

[22] Official Gazette of Republic of Macedonia. No. 25/00, 96/00, 50/01, 11/02, 31/03, 85/05, 37/06, 18/07, 36/07, 82/08, 6/09, 67/09, 50/10, 156/10, 53/11, 26/12, 16/13, 187/13, 43/14, 44/14, 97/14, 112/14, 113/14, 188/14, 20/15, 61/15, 98/15, 128/15, 150/15, 154/15, 192/15, 217/15, 26/16, 37/16, 120/16, 142/16. Accessed April 25, 2021. https://www.slvesnik.com.mk.

[23] By-law on the form and content of the health insurance card and on the manner of its issuance, management, use and proof of paid contribution for compulsory health insurance. *Official Gazette of Republic of Macedonia.* No. 159/2010. Accessed on 25 April 2021. https://www.slvesnik.com.mk.

[24] Official Gazette of Republic of Macedonia. No. 62/11, 159/12, 57/13. Accessed April 25, 2021. https://www.slvesnik.com.mk.

as well as what kind of data, besides data for reimbursement and administrative data, are available across Macedonian healthcare IT system. These concerns are an indication that the present model is not the most adequate one, and that a centralized model of EHR would be more appropriate (Gavrilov,Trajkovik 2016, 92).

Apart from the concerns regarding the framework as well as technical and functional characteristics of the chosen model of EHR, the research demonstrates serious concerns also in regard to its functionality in practice. Although a majority of the respondents do have one (possess EHC), the EHC does not have actual value when it comes to receiving healthcare services or using its functionalities as provided by the laws and by-laws. The results of the survey are presented in Table 5.

Table 5. **Electronic Health Card usage**

Question	Yes, %	No, %	I do not know, %
Do you have an EHC	78,1	10,6	11,3
Do you use your EHC for acquiring/receiving e-health services	15,9	67,5	16,6

Source: Original research provided by the authors for the purpose of this paper.

2.3.3. Law on the Protection of Patients' Rights

The Law on the Protection of Patients' Rights[25] defines the scope of the rights and obligations that are incorporated in the term patients' rights under Macedonian legislation. Patients' rights include the rights provided within this specific law, another law or ratified international agreement, convention, declaration, or other international documents related to the protection of patients' rights.

2.3.4. Law on Health Records[26]

This law applies to both electronic records and the processing of health and medical data and records in paper form and manual processing of health and medical data (Article 3 from the Law on Health Records). The law regulates the National System for Electronic Health Records, managed by the Ministry of Health. The National System for Electronic Health Records is an electronic system in which all medical and health data for patients, data for health workers and associates, data for health institutions, health interventions and services performed in health institutions, data from electronic referrals, electronic prescriptions, data on appointments for specialist examinations and interventions and other data determined by this and other law are stored and processed (Article 2 (36) from the Law on Health Records). The National System for Electronic Health is managed by the health workers, i. e. associates who are obliged to act in accordance with this law, the

[25] Law on the Protection of Patients' Rights (Законот за заштита на правата на пациентите). *Official Gazette of the Republic of Macedonia*. No. 82/08, 12/09, 53/11, 150/15. Accessed 27 April 27, 2020. https://www.slvesnik.com.mk.

[26] Law on Health Records (Закон за евиденции во здравството). *Official Gazette of the Republic of Macedonia.* No. 20/09. Its amendments: *Official Gazette of the Republic of Macedonia.* No. 53/11, 164/13, 150/15. Accessed April 27, 2020. https://www.slvesnik.com.mk.

regulations for protection of personal data and for the protection of patients' rights (Article 7 (2) from the Law on Health Records).

As for a legal definition of electronic health record, we cannot say that a precise one exists in this law. The law uses the terminology "basic medical documentation" as subject of the register, and an "individual medical file" as a segment (part) of the basic medical documentation. Looking into comparative European literature, we can safely say that the term electronic health record has been adopted and defined in EU documents, as well as in national legislation. Electronic health record systems in EU are defined as a comprehensive medical record or similar documentation of the past and present physical and mental state of health of an individual in electronic form and provide for ready availability of these data for medical treatment and other closely related purposes[27]. Furthermore, many EU member states provide definitions of electronic health record in legislative texts. "It is again noteworthy that several legal definitions of EHRs include a reference to the sharing of health data between health institutions. For example, in Germany EHR is defined as an application that supports the collection, processing and utilization of data concerning medical findings, diagnoses, therapy measures, treatment reports and vaccinations for a comprehensive documentation of various medical cases [of one patient] between different medical institutions. Lithuania defines health records as the patient's electronic health items collected from all health institutions operating in the system"[28]. According to the Macedonian Law on Health record, the record is managed by entering data in the basic medical documentation at different levels of the healthcare system (primary, secondary, and tertiary). The data consists of personal data about the patient, medical data which is data on health status (diagnosis, date of visit, scheduled visits, doctor number, therapy, referral, reason for temporary incapacity for work, cause of death cause of processing and social history of the family), medical care data other care-related data for the patient (diet, etc.). The type, form, and content of the templates for managing the basic medical documentation is determined by the Minister of Health (Article 6, Law on Health Record). Although the law itself has a provision that these records of basic medical documentation are also managed and stored in electronic form by the healthcare institution (Article 24 (4), Law on Health Record), it does not act as specific regulation of the electronic health record. This could be viewed as a step back since the development of electronic health record was one of the strategic goals of the Strategy for the Development of Macedonian Integrated Health Information System. This document even provided a definition, technical rather than legal, of the term electronic health record as a storehouse of information related to the health during the life of an individual in computer readable form. The system was understood as a set of components that form the mechanism by which an electronic health record is created, used, stored, and read, and it includes people, data, rules and procedures, processing and storage devices, and communication and support tools. Interchangeability of the system means a standardized information model that is independent of electronic health record systems and is available to multiple authorized users[29].

[27] Commission Recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems (notified under document number C ((2008) 3282). Accessed April 28, 2020. https://eur-lex.europa.eu/eli/reco/2008/594/oj.

[28] Overview of the national laws on electronic health records in the EU Member States and their interaction with the provision of cross-border eHealth services. Final report and recommendations. Brussels, Milieu, Ltd. 2014. P. 24.

[29] Available in Macedonian. Accessed March 29, 2021. http://zdravstvo.gov.mk/strategii.

2.3.5. Law on Personal Data Protection

This law was adopted in order to transpose into national law the personal data protection regulation in the EU, consisting of the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation, hereafter referred to as GDPR)[30]. The law regulates the protection of personal data and the right to privacy in relation to the processing of personal data, and, in particular, the principles related to the processing of personal data, the rights of the personal data subject, the position of the controller and processor, and the transfer of personal data to other states. It also regulates the establishment, status and competencies of the Agency for Personal Data Protection, special operations of personal data processing, legal means, and responsibility in the processing of personal data, supervision over personal data protection, as well as misdemeanors and misdemeanor proceedings in this area[31]. Previously, the principles that required compliance from eHealth actors that were processing personal data concerning health were contained in the Data Protection Directive[32]. All activities undertaken by national health care systems or other e-health actors which included creation of health grids, electronic national records or information systems that may be used for treatment, quality review or research purposes, had to comply with the principles of the Data Protection Directive (Callens 2010, 563). In this Directive personal data was defined as "any information relating to an identified or identifiable natural person (data subject); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity" (Article 2 (a) of Data Protection Directive). The new regulation simplifies this definition and defines personal data as any information relating to a data subject (Article 4 (2) of GDPR). The Macedonian Law on Personal Data Protection follows the same tendency of simplification. Some data is considered particularly sensitive because it reveals personal information about the person, such as data concerning health or sex life (Article 8 (1) of Data Protection Directive and Article 9 (1) of GDPR). This kind of data can only be processed if some legally stated conditions are fulfilled (Rapuso 2016, 6). In Macedonian law, this data is also regulated under the term "special category of personal data" (Article 4 paragraph (1) item 13 of the Law on Personal Data Protection). As a result, data regarding a person's health is treated as special or separate category of personal data, which implies special regulation when it comes to processing. The special regulation includes the general provision that processing of special categories of personal data (among which is health data) is not allowed. It also includes the exception to this general rule and the rules and conditions under which the processing of special categories of personal data can be performed (Article 13 of Law on Personal Data Protection). The legal framework of the prohibition and its exceptions demonstrates that usually a person's consent is required

[30] General Data Protection Regulation. Official Legal Text. *GDPR*. Accessed March 28, 2021. https://gdpr-info.eu.

[31] Article 1, Law on Personal Data Protection. *Official Gazette of the Republic of Macedonia*. No. 42/2020. Accessed April 28, 2021. https://www.slvesnik.com.mk.

[32] Data Protection Directive, Council Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data. OJ. 1995. No. L281/31. Accessed April 28, 2021. https://eur-lex.europa.eu/eli/dir/1995/46/oj.

and that sensitive data processing can still be licit, even without consent, in some particular contexts: preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services. This legal regulation once again transposes the regulation provided with Article 8 (3) of Data Protection Directive and Article 9 (2) of GDPR (Rapuso 2016, 6) into Macedonian law.

3. Conclusions

In the past half-decade North Macedonia has been experiencing a step back in regard to the development of the eHealth system that was established in 2007. This is related to the analysis of the strategic goals and foundation of the Ministry of Health, and the noted lack of a specific national eHealth strategy, as well as the absence of the eHealth targets and strategic goals in the state's general health strategy. As a result, the process of development of the eHealth system remains unguided and in stagnation, without the basic incentives that will accelerate any progress towards eHealth goals. It is recommended that the authorities define and adopt a national eHealth strategy in the nearest future to achieve positive health outcomes that are in line with national health plans. A new strategy will surely lead to the need to adopt an appropriate (corresponding) legal and ethical framework, especially regarding patient safety, data security, appropriate use, and ownership of health data.

Regarding the legislation in North Macedonia that regulates eHealth activities, the main characteristic is that it is not comprehensive as there is no specific law that refers to eHealth activities. However, several patterns of eHealth regulation can be noted:

— reliance on general provisions for certain questions. General health record legislation is used to regulate the electronic records, and general data protection rules are applicable with regard to data used in the eHealth system/activities;
— no specific legislation, but the existence/adoption of specific legal provisions or several provisions in the general healthcare legislation. This is the case with the Electronic health card regulation where the legal framework has been established in the Law on Health Insurance, and the Integrated Health Information System that is outlined in the Law on Health Care.

On the other hand, regarding the results of the conducted survey, it can be concluded that the term eHealth is used as a synonym for the integrated health information system that was introduced into the Macedonian healthcare system in 2011, named My Term (Мој Термин). My Term is a cloud–based system that incorporates the booking of health services on behalf of the public and private health institutions, referrals and prescriptions, electronic health cards for citizens and electronic health records on each patient. It is also known as an e-Health system, as it is the most prominent representative of eHealth in North Macedonia. In the current work even though My Term was presented as not the only existing segment of the eHealth system that is provided with Macedonian regulations and practices[33], it surely suggests that, in the eye of the public, these two terms (My term and eHealth as a global concept) are often treated as one. The reason for this perception is

[33] Research shows that other aspects of eHealth in general are provided with domestic regulations and function in a certain manner in practice, and all of their legal aspects will be included in the text that follows.

that this eHealth activity, together with the healthcare services it provides for patients, is the most successful pilot project that was developed based on the strategies for health and development of integrated health information system, unlike the other projects that were also put into motion but did not develop or achieve the required level of functionality. We believe that the reasons for this are not the legal aspects of eHealth, but explanations can be found in other aspects. The requirements for the establishment, functionality and development of eHealth activities are being set up by the general provisions which apply to certain questions, as well as by specific provisions within general laws. Although this type of legal structure is not an ideal one, as it lacks comprehensiveness, it certainly provides a solid foundation for future development of the matter.

The research has also led us to the conclusion that there is a need (in the future strategy and policy) to prioritize the improvement of digital health literacy among the population and to develop training and education among healthcare workers in using and understanding digital health technologies and systems as well as to validate tools that will be accessible by all.

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