# THE LEGAL ASPECTS OF TELEHEALTH*

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*ABSTRACT*

*Telehealth seems to be the new normal in this fast-changing environment. According to the European Commission eHealth was among the highest priorities before the COVID -19 pandemic. Transformation of health and care in the digital single market is among the EU`s six political priorities of the Commission 2019-2024 (2018 Communication on Digital Health and Care). The pandemic caused by COVID-19 just accelerates the necessity of the inclusion of digital health into the traditional healthcare systems. Telehealth services are among the biggest eHealth trends in EU. Therefore, one of the challenges is the national, regional and regulatory priorities regarding telehealth. There is lack of telehealth special legislative and governmental policies that needs to stimulate the developing and innovative solutions in medicine through technology and to envisage the upcoming innovation technology. Therefore, the government support and adequate policy making is important to support the development of the telehealth services. One of the main challenges is the electronic transactions of patient data among the telehealth providers and services and the cross-border patient data share. Another issue is the exchange of information among the national health institutions and providers and their interoperability.*

*The Macedonian legislation does not have special legislation (policies, or laws) about telehealth. Telehealth is regulated as a term in the Law on health protection. Additionally, there is a lack of national acts, literature, and research in this subject matter. Thus, this paper will*

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*explore the telehealth from two main perspectives: scientific theories and legal practice and the users' practice.*

*Hence, this paper will analyze the legislation about the telehealth on the EU level and the EU Member States and the Macedonian legislation and the impact on the e-health that was made during COVID-19 pandemic. Furthermore, it will make comparative analyses among different countries into the EU zone compared with the EU aspirant country- the Republic of North Macedonia. A survey conducted among doctors in private and public healthcare institutions in the primary, secondary, and tertiary healthcare levels in the city of Stip and in the city of Skopje will provide data about the challenges, risks, and trends in telehealth before and during COVID -19.*

***Keywords***: *Data Protection, e-Health, EU Digital Strategy, Macedonian healthcare legislation, Telehealth*

## 1.   INTRODUCTION

The telehealth became the main cornerstone during COVID-19 among the healthcare providers, the beneficiaries, the healthcare system, and the doctors and patients. This complex system of involved stakeholders and procedures requires high level of caution and knowledge that goes beyond the traditional accessibility and use of the healthcare services in the traditional healthcare system.

Comparatively, on EU level, since early 2020, the EU countries have rushed to introduce remote health consultations and other telemedicine services at an unprecedented deployment rate. Thus, the global telehealth is expected to grow to US$218.5 billion by 2025 (European Parliamentary Research Service, April 2021). It seems that all countries were challenged to create appropriate regulatory frameworks that will safeguard the rights of the individuals and the society, on one hand, and to stimulate the use of technology and innovations in healthcare, on the other hand. The pandemic has rapidly accelerated the use of ICT in the health care system in the EU countries. Since the pandemic began, 58 % of countries have been using telemedicine to replace face-to-face consultations, as family doctors' surgeries and hospitals restrict face-to-face contact to essential visits.[1] In December 2021, the Macedonian government enacted the Health Strategy 2021–2030, in which one of the key questions to be considered is to: enhance the health systems and the role of eHealth; assess health technology; and improve the healthcare information system.[2]

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[1]   Negrero, M., *The rise of digital health technologies during the pandemic*, European Parliamentary Research Service, 2021, p. 2

[2]   For more, see: The Announcement of the Government in its 125th session: [https://vlada.mk/node/27191], Accessed 5 May 2022

Therefore, this paper aims to explore the relevance and importance of telehealth as part of the eHealth developments in the country; the adequacy of the policy making in the process of the development of the telehealth services, the need to empower eHealth literacy among professionals; the access to quality eHealthcare service delivery, and overview the legal basis for interoperability in the national healthcare system.

For the purpose of this research paper we have use comparative legal methods, mainly based on the national healthcare Strategies and positive law, the WHO reports and resolutions, the EU policies, Directives, and Regulations and other potential sources such as releases from a state's executive offices (national and international) and online research articles from which the findings in this introduction are taken. In addition to this research paper, at the beginning of 2022, an online survey with close-ended questions was conducted among doctors in private and public healthcare institutions in the primary, secondary, and tertiary healthcare levels in the city of Stip and in the city of Skopje. There were some restraints that referred to the low interest of the doctors in contributing to the online survey through Google Forms, 69 responses were collected. In terms of the complexity of the work these respondents were doctors in medicine (27.5%), specialists (59,5%) and subspecialist (13%) employed in the public and private healthcare organizations in the city of Shtip and the city of Skopje. Given the focus of this research on secondary healthcare level, specialists are the dominant respondents. In order to clarify and deepen this research, we have made direct contact with 11 doctors and conduct an open interviews and conversations. Also, considering the lack of clarity around the terms like mHealth, eHealth, telehealth, and telemedicine in the country among the health professionals, efforts were made to adjust terminology where was needed.

## 2.    SOME GLOBAL AND EU LEVEL ASPECTS OF TELEHEALTH

eHealth trends have been on the rise in recent years. There are many examples of successful eHealth developments including health information networks, electronic health records, telemedicine services, wearable and portable monitoring systems, and health portals.[3]

Most of the research papers in this area emphasise the advantages of the use of telehealth "Four systematic review papers suggest that telehealth is "promising",

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[3]    e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area, COM (2004) 356 final, Brussels,  p. 4, [https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2004:0356:FIN:EN:PDF], Accessed 4 April 2022

or has a potential benefit, although the evidence included in their reviews is not powerful enough for the effects to be labeled as causal."[4]

The European Commission, in one of the first working documents on this subject, stated that "eHealth means information and communication technologies, 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"[5]. Additionaly, the World Health Organization defines eHealth as "broad group of activities that use electronic means – information and communication technologies to deliver health-related information, resources and services as treatment of patients, conducting researches, education of the healthcare workers, disease monitoring and monitoring of the public health".[6] Most researchers follow the WHO guideline: recommendations on digital interventions for health system strenghenght[7] to define the temedicin as: "The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities"[8]. According to A Global Guide telehealth "refers to the delivery of healthcare services where patients and providers are separated by distance, using information and communications technology for the exchange of information for the diagnosis or treatment of diseases and injuries."[9]

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[4]    Abbott, P. A.; Liu, Y., *A Scoping review of Telehealth*, IMIA Yearbook of Medical Informatics, 2013, p. 6

[5]    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 Accompanying the document COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS eHealth Action Plan 2012-2020 – innovative healthcare for the 21st century - Publications Office of the EU (europa.eu)], Accessed 23.March 2021

[6]    World Health Organization, Regional Office for Europe, *From Innovation to Implementation-eHealth in the WHO European Region,* Official Report, Copenhagen: WHO, 2016, [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], p.7

[7]    WHO guideline: *Recommendations on Digital Interventions for Health System Strengthening*, Geneva, World Health Organization, 2019 [https://apps.who.int/iris/bitstream/handle/10665/311941/9789241550505-eng.pdf], Accessed 5 May 2022

[8]    ISSA, *Telemedicine: Good practices from Latin America,* Analysis, 11 May 2021 [https://ww1.issa.int/analysis/telemedicina-buenas-practicas-en-america-latina], Accessed 5 May 2022

[9]    Telehealth around the world: A global guide, DLA PIPER, 2020, [Telehealth around the world: A global guide | Insights | DLA Piper Global Law Firm], Accessed 15 May 2022

The telehealth is part of the eHealth. Although similar, the terms "ehealth", "telehealth" and "telemedicine" should not be used interchangeably. Telehealth refers to "the use of telecommunications and information technology (IT) to provide access to health assessment, diagnosis, intervention, consultation, supervision and information across distance".[10] Therefore, telehealth can be considered as "a more broad concept of telemedicine that includes technology used to collect and transmit patient data such as telephones, email and remote patient monitoring (RPM) devices for the purposes of providing health education or ancillary healthcare services".[11] Telemedicine is viewed as "a cost-effective alternative to the more traditional face-to-face way of providing medical care (e.g., face-to-face consultations or examinations between provider and patient) that states can choose to cover under Medicaid".[12]

Some eHealth stakeholders implies that the telemedicine there are two types of telemedicine services. Firstly, those considered as a medical act, this means that it is an extension of the existing practice of medicine, performed by healthcare professionals – the 'teleologies' such as teleradiology, teleneurology, telecardiology and so on. By default these are services provided by medical doctors or other healthcare professionals. Secondly are telemonitoring services, these services are remote monitoring technologies that provide health professionals or call centre personnel with biological parameters of the patient/ citizen. The analysis of the data can even be done by computers.[13]

Having in mind the comparative resources and definitions widely used in some point of the paper there will be overlapping of these terms.[14]

In 2019, the telemedicine was marked as the second biggest e-Health trend with expectation to hold this position in the next years almost everywhere. Compared to last year's results, "the only significant exception is the rising importance of telemedicine services, which are often related to video-conferencing solutions".[15]

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[10] Kichloo, A, *et al.*, *Telemedicine, the current COVID-19 pandemic and the future: a narrative review and perspectives moving forward in the USA*, in: Li, L. (ed.) Family Medicine and Community Health, BMJ Journals, Vol.8, No.3, 2020, p.1-9

[11] *Ibid.,* p. 1

[12] This definition is modeled on Medicare's definition of telehealth services, [https://www.medicaid.gov/medicaid/benefits/telemedicine/index.html], Accesed 20 April 2022

[13] Schillebeeckx, J., *Legal Aspects of Telemedicine*, Health Menagament, Vol. 13, No. 3, 2013, [https://healthmanagement.org/c/imaging/issuearticle/legal-aspects-of-telemedicine], Accessed 1 May 2022

[14] Ampovska, M.; Miseva, K., *Legal aspects of eHealth development in North Macedonia*, Vestnik St. Petersbourg University, Vol. 12, No. 3, pp.660-661

[15] HIMSS Analytics, eHealth Trendbarometer, Annual European eHealth Survey 2019, 2019, p.11, [PowerPoint-Präsentation (mckinsey.de)], Accessed 15 May 2022

The widespread deployment of eHealth technologies in Europe was one of the key actions to be achieved by 2020. This can improve the quality of care, reduce medical costs and foster independent living of individuals and the society. New telemedicine services such as online medical consultations, improved emergency care and portable devices allowing monitoring the health condition of people suffering from chronic disease and disabili ties have the potential to offer a freedom of movement that patients have never previously enjoyed.[16]

This is part of the Digital Agenda for Europe[17]. The Digital Agenda for Europe is one of the seven flagship initiatives of the Europe 2020 Strategy, set out to define the key enabling role that the use of Information and Communication Technologies (ICT) will have to play if Europe wants to succeed in its ambitions for 2020.[18]

The eHealth Action Plan (2012-2020) was adopted by the European Commission on 7 December 2012. It updates the first Action Plan from 2004 and proposes a set of 16 actions[19] to boost the deployment of eHealth with a focus on four areas: Achieve wider interoperability in eHealth services; Support research and innovation and competitiveness in eHealth; Facilitate deployment and adoption of eHealth (through CEF, cohesion policy, digital literacy, measuring eHealth added value); Promote international cooperation on eHealth at global level.[20]

However, despite these rules and policy attention, the existing legal framework is not yet complete. The current European rules often remain too vague. The issues confronting health care players have to be addressed at the European level, as some important legal issues, as well as technological developments, need a clear legal answer. Regarding the legal issue, specific attention should be given to the need to enact European criteria on the reimbursement of e-health activities and on the (no-fault) liability issue.[21]

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16 Communication from the Commission to the European Parliament, the council, the European Economic and Social Committee and the Committee of the Regions, COM (2010)245 Final, Brussels, 19.5.2010, pp.29 [https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:0245:FIN:EN:PDF], Accessed 1 March 2022. For more see: The eHealth Lead Market Initiative, Cf.COM (2007) and SEC (2009)1198

17 A Digital Agenda for Europe COM (2010)245 final, Brussels, 19 May 2010

18 Communication from the Commission to the European Parliament, the council, the European Economic and Social Committee and the Committee of the Regions, COM (2010)245 Final, Brussels, 19.5.2010, pp.3 [https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:0245:FIN:EN:PDF], Accessed 1 March 2022

19 For more see: Ehealth Action Plan, European Trade Association, Brussel, [https://www.cocir.org/regulations/digital-health/ehealth-action-plan.html], Accessed 01 March 2022

20 *Ibid*.

21 Callens, S., *The EU legal framework on eHealth*, Health Literay Center Europe, 2015, p.561-588, [9780521761383pre_pi-xxii.indd (healthliteracycentre.eu)], Accessed 5 May 2022

Today, with the advancement of mobile and electronic technologies, telemedicine is more accessible than ever before. According to a 2019 report by the Pew Research Center, 90% of Americans use the internet.[22]

## 2.1. The legal foundation and (possible) developments of telehealth in North Macedonia

North Macedonia is a candidate country for membership in the European Union. Therefore, it follows the EU recommendations and EU eHealth policies and strategies, as well as the reports, recommendations, resolutions, and strategies of the WHO European Region for strengthening the health care systems, eHealth standardisation and interoperability and Data Protection Regulation. The National Health Strategy 2021-2030 follows the European framework for health policies that supports actions in all sectors of government and society (Health 2020).

Based on previous legal research and analisis regarding the legislation in North Macedonia that regulates the eHealth activities, we can note that the main characteristic is that it is not comprehensive, as there is no specific law that refers to eHealth activities but instead, we note several patterns of eHealth regulation:

- 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 data used in the eHealth system/activities.

- No specific legislation but existence/adoption of specific legal provisions or several provisions in the general healthcare legislation. This is the case with the Electronic health card regulation which legal framework has been set in the Law on Health Insurance, and the Integrated Health Information System which legal framework is set in the Law on Health Care[23]

Having this noted it is expectable that the country does not have special acts or legislation for telehealth and telemedcine. In addition, we may say that there is a lack of clarity in the *lex scripta* and in the use of the terms telehealth and telemedicine on a national level. The Law of Health Care[24] does not operate with the term "telehealth,". According to Article 15 paragraph 1 item 33, "telemedicine" is the exchange of medical information with the help of information and communica-

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[22]  Kichloo, A., *et al. op.cit.,* note 10, p. 2

[23]  Ampovska, M.; Miseva, K., *Legal aspects of eHealth development in North Macedonia*, in: Stoyko, N. (ed.), Vestnik St. Petersbourg University, Vol.12, No. 3, pp.660-661

[24]  The Law of Health Care, 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 N. Macedonia 76/20

tion technology in order to improve the health treatment of the patient in the field of diagnosis, treatment and monitoring of the patient, as well as in the field of professional exchange of opinions.

The use of ICTs in medicine (the Health care services) and the use of Health is inseparably connected with the internet availability of the users. Therefore, we should emphase that the eHealth is unenforceable in practice without internet access. In 2004, at least four out of five European doctors have an internet connection, and a quarter of Europeans use the Internet for health information.[25] Using internet has become an integral part of daily life for many European. Yet, 150 million Europeans – some 30% - have never used the internet. Often they say they have no need or that it is too expensive.[26]

Our country follows the EU recommendations and stays in line with the core objectives of the Europe 2020 Strategy, [27] the Digital Agenda for Europe[28] and the eHealth Action Plan[29] and eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century[30]. In 2019 the Ministry for Information Society and administration has prepared National operative broadband plan[31]. By this Plan (2020-2029) starting from 2023 until 2029 it is expected that all public institutions (e.g. public health institutions) will have symmetrical internet access at a speed of at least 1Gbps[32] this will easier access to e-health services[33] and will provide more effective use of telecommunication technology in health and improve the public health care of the citizens. In the first quarter of 2020, 79.9% of households had access to the Internet at home. The participation of households with broadband connections in the total number of households as 87.8% in 2020. In the first quarter of 2020, 81.4% of the total population aged 15–74 used the Internet, and

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[25] e-Health - making healthcare better for European citizens, *op. cit.,* note 3, p. 4

[26] A Digital Agenda for Europe, COM (2010)245 final, European Commission, Brussels, 19.05.2010, p. 25

[27] Europe 2020: A strategy for smart, sustainable and inclusive growth, COM (2010)2020, European Commission, Brussels, 03 March 2010

[28] Digital Agenda for Europe, COM(2010)245 final, European Commission, Brussels, 19.05.2010

[29] eHealth Action Plan, COM (2004) 356 final, European Commission, Brussels, 30.04.2004

[30] eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century, COM(2012) 736 final, European Commission, Brussels, 06 December 2012

[31] National Operative Broadband Plan, MIOA, North Macedonia, 2019, [https://mioa.gov.mk/sites/default/files/pbl_files/documents/reports/nacionalen_operativen_brodbend_plan_finalna_verzija_02.04.2019.pdf], Accessed 5 May 2022

[32] National operative Broadband Plan, Ministry of Informatic Society and Administration (MIOA), North Macedonia, 2019, p. 4

[33] *Ibid.,* p. 40

70.9% used the internet every day or almost every day.[34] According to the state statistical office, 40.7% of the population sought health-related information (e.g., injuries, diseases, nutrition, improving health, etc.) during this time period, while only 4.7% made an online (via web or application) appointment with a doctor (e.g., of a hospital or health care center).[35]

The pandemic caused by COVID-19 has accelerate the use of communication technology in the healthcare, this was the only sustainable "distance measure" in the health crises. And this remained as a post-pandemic solution that became a standard that must be followed. But at the same time the research didn't show that legal or ethical principles were established or maintained when using new forms of communication and technology in healthcare.

## 2.2. Survey results

In February 2022, an online survey was conducted among the doctors from the primary, secondary, and tertiary health care levels ( private and public health care sector) among doctors, doctors-specialists, and doctors-subspecialists in the city of Shtip and the city of Skopje. In the survey, we collected 69 responses, 26 from men (37.7%) and 43 from women (62.3%). In terms of the complexity of the work these respondents were doctors in medicine (27.5%), specialists (59,5%) and sub-specialist (13%) employed in the public (53,6%) and private (46,4) healthcare organizations in the city of Shtip and the city of Skopje. Some additional issues were discussed face-to-face or on the phone with eleven doctors by random choice. For the purpose of this research, we will present only the results that are relevant to this topic.

Most of the respondents (63 or 81.3%) were totally or partially familiar with the essence of term digital health (eHealth).

"In effect, telemedicine allows remote group collaboration between various health-care professionals from different locations, sometimes even from different countries. Practitioners can communicate with distant colleagues, thus improving the quality of the services provided. The continuous flow of communication between healthcare professionals is motivated by the growing complexity of medicine,

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34 MAKSTAT database, State Statistical Office of Repubic of North Macedonia [https://www.stat.gov.mk/pdf/2020/8.1.20.31_mk.pdf], Accessed 1 December 2021

35 Misheva, K. *Authorized lectures EU eHealth Law*, ICT and Bioethics (2020-2022) within the Jean Monnet Project EUEHL, Official data used from MAKSTAT, State Statistical Office of the Republic of North Macedonia, year LVIII, No. 8.1.20.31 from 16 November 2020

which forces doctors to consult with more experienced colleagues or experts in a particular field or just to request a second opinion."[36]

The Macedonian doctors recognize the potential of the use of Internet of things in medicine. They all agree that the IoTM (Internet of Things in Medicine) enable the process of daily working. See **Table 1.**

**Table 1**

| Question: The use of ICT (information and communication technology) in medicine facilitates the work of health professionals | Totally agree | Partially Agree | Partially disagree | Totally disagree |
|---|---|---|---|---|
| Number of Respondent/s | 38 | 27 | 1 | 3 |

*Source:* online survey for the purposes of this research and the JM Project EUEHL

It seems that providing health services consumes more time (**see Table 3**) that entering data from the *tete-a tete (*physical) examination (see **Table 2**). From the survey and the comments made by the doctors that are made through the tele-communication, it is estimated that they spent almost 10% of their daily working hours. This extends their working hours.

**Table 2**

| Question: For entering the data for the performed health examination of the patient I dedicate (I need) | Less than 15 minutes | Less than 30 minutes | More than 30 minutes | Not aware |
|---|---|---|---|---|
| Number of Respondent/s | 46 | 19 | 2 | 2 |

*Source:* online survey for the purposes of this research and the JM Project EUEHL

**Table 3**

| Question: Providing health services over the phone (telemedicine) takes me | Less than 15 minutes | Less than 30 minutes | More than 30 minutes | More that 1 hour |
|---|---|---|---|---|
| Number of Respondent/s | 37 | 13 | 12 | 7 |

*Source:* online survey for the purposes of this research and the JM Project EUEHL

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[36]     Rapuso, V., *Telemedicine: The legal framework (or the lack of it) in Europe*, GMS Health Technology Assessment, 2016, [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4987488/], Accessed 22 April 2022

It seems that using the digital tools (apps) for social communications (Viber/WhatsApp, Messenger, E-mail, Instagram, Facebook) are very popular between the doctors and the patients (see **Table 4**). More that 80 % of the doctors are using Viber for consultations, sending results, photos, asking for online diagnoses, even making appointments. Moreover, this type of personal communication with the doctor, in a way, is a frequently used tool for the patients to schedule an examination or intervention directly with the doctor-specialist by "skipping the line" through the regular national e-platform "My Term". This negative tendency has reached its peak during the health crisis caused by the COVID -19 virus. For example, the number of canceled and unrealized medical appointments within the system My Term, from the start of the pandemic (end of March) till the middle of June 2020, has reached to 128.000.[37] It is not clear why this has happened, but during the pandemic, most of the cases that were threatened were emergency cases.

**Table 4**

| Question: Although I provide health services and advices over the phone, I also use other ways of online communication with the patients | Viber / WhatsApp | Messenger | e-mail | All mentioned above | I do not use this kind of communication |
|---|---|---|---|---|---|
| Responses in % | 74.5% | 10.6% | 6.4% | 6.3% | 2.2 % |

*Source:* online survey for the purposes of this research and the JM Project EUEHL

Despite the potential of telemedicine and the benefits that provides the telemedicine, there are several restrains that should be consider. Most respondents have agreed that the health services provided through telemedicine consume more time than the regular physical **(see Table 5)**.

**Table 5**

| Question: Providing health services with the help of telemedicine consumes more working hours (increases your workload) than the usual work (with physical presence) with patients | Totally agree | Partially agree | Partially disagree | Totally disagree |
|---|---|---|---|---|
| Number of Respondent/s | 40 | 22 | 6 | 2 |

*Source:* online survey for the purposes of this research and the JM Project EUEHL

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[37]    For more see: Misheva, K; Ampovska, M., *Legal aspects of eHealth development in North Macedonia*, **in:** Stoyko, N. (eds.), Vestnik of Saint Petersburg University Law, Vol. 12 No. 12, 2021, p.10, [https://lawjournal.spbu.ru/article/view/10610], Accessed 1 March 2022

Almost 85% of the respondents have agreed that they need continuous training, transfer of knowledge, and to keep up-to-date activities to improve their competence in the area of the technological advancements in the global e-health market. (**See Table 6**). "In recognizing that digital competence is a fundamental skill for individuals in a knowledge-based society"[38], the European Commision`s Digital Agenda for Europe encourages EU Member States to enhance the digital literacy e-skills and inclusion of the digital services.[39] From 69 only 37 respondents (53,6 %) have state that their additional professional trainings and are enable by their employer. This question was subject of discussions with the interviewers, most of them answered that their additional professional trainings are paid from the healthcare services providers.

**Table 6**

| Question: New e-platforms and e-health records, e-referrals, e-prescriptions, etc.  require additional training | Totally agree | Partially Agree | Partially disagree | Totally disagree |
|---|---|---|---|---|
| Number of Respondent/s | 28 | 30 | 6 | 5 |

*Source:* online survey for the purposes of this research and the JM Project EUEHL

The national Law on Personal Data Protection[40] is harmonized with the provisions consisted in the EU Regulation for personal data protection (GDPR) that was adopted in EU and became enforceable beginning 25 May 2018. In February 2020, the Macedonian Law on Personal Data Protection was adopted. The Law prescribed a time period of 18 months (until August 24, 2021) in which the controllers and  processors are obliged to comply with the new law.

The doctors agree that they are familiar with the provisions from the Law on Personal Data Protection (see **Table 7**). From the interviews that were conducted, it seems that the doctors are partially aware, from a legal perspective, that healthcare/sensitive personal data can only be processed/transferred with patient consent, and to what extent can be shared among the heatlthcare workers and the professionals.

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[38]  World Health Organization, Regional Office for Europe, *From Innovation to Implementation-eHealth in the WHO European Region*, Official Report, Copenhagen: WHO, 2016,  p. 53, [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], Accessed 15 March 2022

[39]  For more see: A Digital Agenda for Europe, European Commision, Brussels, COM (2010)245 final, p.24-27, [https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:0245:FIN:EN:PDF], Accessed 5 March 2022

[40]  Law on Personal Data Protection , Official Gazette of Republic of North Macedonia, No.40/20; 294/21

**Table 7**

| Question:<br>I am familiar with the provisions of the Law on Personal Data Protection | Totally agree | Partially Agree | Partially disagree | Totally disagree |
|---|---|---|---|---|
| Number of Respondent/s | 38 | 19 | 8 | 4 |

*Source:* online survey for the purposes of this research and the JM Project EUEHL

Although the doctors are aware of the advantages of telehealth and the eHealth Records of the patients, they are still obliged to keep parallel records both in hard copy (physical) and electronic format, according to the responces 66.1% of the doctors are providing parallel data records. According to Article 3 the Law on Health Records[41] applies for the electronic records and processing of health and medical data and records in paper form and manual processing of health and medical data.

## 3.   CONCLUDING REMARKS

In the European Union, telemedicine has become increasingly important in the advancement of medicine and healthcare delivery. As a result, European eHealth legal instruments and legal initiatives to stimulate the development of the EU telemedicine market have become a priority. The Member States also develop their own national legislation, particularly for the legal framework governing telemedicine.

Although many reforms have recently been made in North Macedonia, there is still a significant difference in the national regulations that will enable healthcare providers to deploy telehealth solutions. From this research, it is evident that there is a lack of a dedicated and systematic legal basis for the development of eHealth services, especially telehealth. The country needs to develop a national systematic approach to telehealth. As mentioned above, telehealth is only defined and mentioned in several laws that derive from the eHealth service. The country needs to develop a comprehensive and sustainable national eHealth strategy with a view to telehealth or to develop a separate programme, policy, or strategy for telehealth.

The delivery of the healthcare services should be developed and integrated with the European telemedicine solutions and standards to became a part of the Digital Single Market.

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[41]   Law on Health Records, Official Gazette of the Republic of Macedonia No. 20/09; 53 / 11; 164/13, and 150/15

The rules and procedures restrain the effective time of the doctors, but more importantly, they slow down the condition of the whole healthcare system. The doctors are often contacted by their patients after their working hours and during their non-working days. Therefore, it is expected that these telehealth services should be charged. The current situation spontaneously and with the COVID-19 rapidly burdens the daily work of the doctors, which prevents quality delivery of the eHealth services.

The skills required for effective use of ICT in medicine are still complex and they remain challenging for doctors and health professionals. The government should encourage all involved stakeholders in the national eHealth infrastructure to support the system and to increase the digital and health literacy. The investment in health knowledge is a high priority for any society, so it should be viewed as a "value for money" and long-term return investment rather than a burden on the healthcare system and budget. The core values for a sustainable healthcare system ask for continuous engagement in the educational process and professional career development. Additionally, the healthcare institutions should continue to enable adequate and quality education and trainings to their employees following the international standards and best practices. The education plays pivotal role in the process of practice medical acts at distance (e.g. teleinterventions, teleconsultations, telemonitoring etc.)**.**

The country must enact eHealth policies, strategies and to define the regulation of the telehealth into adequate laws and procedures that will be incorporate in practice. The legislation must ensure collaboration between the doctors and patents as well between the different stakeholders in the healthcare system (the government, the health care institutions, the health services providers and the end users). The cybersecurity of the health data also incorporates significant changes and additional skill and knowledge for safeguarding and protection of the health record data and health information about the health conditional of the patient. The doctors are aware of the provisions under the Law on personal data protection, but still they use social platforms for exchanging health information with the patients.

The employers (especially the public health institutions) should follow the trends in the ICTs in medicine and should continuously invest in the digital technologies in health systems and to support e-innovations.

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