



УНИВЕРЗИТЕТ У БАЊОЈ ЛУЦИ
UNIVERSITY OF BANJA LUKA
ПРАВНИ ФАКУЛТЕТ
FACULTY OF LAW



МЕЂУНАРОДНИ НАУЧНИ СКУП
„ИЗАЗОВИ И ПЕРСПЕКТИВЕ РАЗВОЈА
ПРАВНИХ СИСТЕМА У XXI ВИЈЕКУ”
ЗБОРНИК РАДОВА

МЕЂУНАРОДНИ НАУЧНИ СКУП
„ИЗАЗОВИ И ПЕРСПЕКТИВЕ РАЗВОЈА
ПРАВНИХ СИСТЕМА У XXI ВИЈЕКУ”
ZBORNİK RADOVA

INTERNATIONAL SCIENTIFIC CONFERENCE
“CHALLENGES AND PERSPECTIVES OF THE DEVELOPMENT
OF LEGAL SYSTEMS IN THE XXI CENTURY”
CONFERENCE PROCEEDINGS

Бања Лука - Banja Luka
2022.

INTERNATIONAL SCIENTIFIC CONFERENCE
“CHALLENGES AND PERSPECTIVES OF THE DEVELOPMENT
OF LEGAL SYSTEMS IN THE XXI CENTURY”
CONFERENCE PROCEEDINGS

Publisher:

Faculty of Law, University of Banja Luka
Bulevar vojvode Stepe Stepanovića 77, Banja Luka
phone: +387(51)339-002
email: info@pf.unibl.org
web: <https://pf.unibl.org/>

Editor in chief:

Prof. Željko Mirjanić, PhD

Editors:

Prof. Igor Milinković, PhD
Asst. Prof. Bojan Vlaški, PhD

Proofreader:

Asst. Prof. Dijana Zrnić, PhD

Lector:

Prof. Dragana Milinčić

Print:

Grafid d.o.o. Banja Luka

For Print:

Branislav Ivanković

Edition: 100

Scientific Committee:

Prof. Željko Mirjanić, PhD, University of Banja Luka
Prof. Rui Nunes, PhD, University of Porto
Prof. Bojan Milisavljević, PhD, University of Belgrade
Prof. Vladimir Čolović, PhD, Institute for Comparative Law in Belgrade
Prof. Vojin Rakić, PhD, Center for Bioethical Studies
Marta Sjeničić, PhD, Institute of Social Sciences in Belgrade
Prof. Francesco Palermo, PhD, Institute for Comparative Federalism
Prof. Jens Voelk, PhD, University of Trento
Prof. Igor Milinković, PhD, University of Banja Luka
Prof. Vladimir Đurić, PhD, Institute for Comparative Law in Belgrade
Prof. Mateja Đurović, PhD, King's College London
Prof. Snežana Pantović, PhD, University of Montenegro
Prof. Ivana Tucak, PhD, University of Osijek
Asst. Prof. Dijana Zrnić, PhD, University of Banja Luka
Asst. Prof. Bojan Vlaški, University of Banja Luka
Asst. Prof. Nina Kršljanin, University of Belgrade
Asst. Prof. Dr. Anka Kekez Koštro, University of Zagreb
Maja Sahadžić, PhD, University of Antwerp

Organizing Committee:

Prof. Željko Mirjanić, PhD, Dean
Prof. Zoran Vasiljević, PhD, Vice dean for teaching
Asst. Prof. Bojan Vlaški, PhD, Vice dean for scientific research
Prof. Igor Milinković, PhD
Prof. Milijan Buha, PhD
Asst. Prof. Mirjana Miškić, PhD
Igor Popović, MA

INTRODUCING TELEMEDICINE – LEGAL AND OTHER CHALLENGES¹

Sofija Nikolić Popadić²

Institute of Social Sciences, Belgrade

Abstract: *Technological developments and progress enabled different changes in the health system. One of them is the application of telemedicine, or so-called „healing at distance.“ This way of providing health services enables multiple benefits, such as regular monitoring of patients without the necessity to physically go to a clinic, which consequently saves time and financial expenses for transport, contact with patients located in remote areas, contact with specialists in other cities, with doctors from abroad. Besides the benefits, this way of providing health services also opens different questions related to the protection of patients’ data, privacy, the relationship between patients and doctors, etc. Introducing telemedicine is a challenging process that necessitates multisectoral co-operation. Along with the required technical equipment, financial support, education of healthcare providers and users, one of the prerequisites for the application of remote treatment is the establishment of a strategic framework, the adoption of appropriate regulations, or amendment of existing ones. That process could be challenging for countries. This research aims at perceiving the level of application of telemedicine globally and within the European Union, identifying challenges and obstacles to wider implementation, especially in the context of the adoption of appropriate legislation, and analyzing the impact of the Covid 19 pandemic on the application of telemedicine. One part of the paper is dedicated to the possibilities of implementation of telemedicine in the Republic of Serbia, identifying obstacles to its application, and further changes that have to be made in order to allow its introduction and implementation in practice.*

Keywords: *Telemedicine, health care, Covid19 pandemic, digitalization, health services, protection of health data, the European Union.*

1. INTRODUCTION

Technological advancements, especially in the field of telecommunications technology, were one of the prerequisites for the introduction of so-called „healing at a distance.“ The first steps towards the development of telemedicine were connected to the invention of the telegraph and the telephone. Those devices were the first to be used to establish a connection between patients

¹ This paper was written as part of the 2022 Research Program of the Institute of Social Sciences with the support of the Ministry of Education, Science and Technological Development of the Republic of Serbia.

² Dr Sofija Nikolić Popadić, Research Associate, Institute of Social Sciences, Centre for Legal Research, Belgrade, Serbia, e-mail: snikolic@idn.org.rs

and doctors without physical contact, and to give instructions on the treatment of patients.³The development of modern telemedicine began in the second half of the 20th century.⁴Along with the technological progress and evolution of telemedicine, the definitions of what telemedicine is and what it encompasses have also changed over time. According to the research from 2006, conducted by Sanjay Sood et al, there have been 104 different definitions of telemedicine between 1970 and 2006.⁵The definition which is widely accepted is the one given by the World health organization (WHO), which explains that telemedicine and telehealth are synonyms and they encompass “the delivery of health care services, where patients and providers are separated by distance. Telehealth uses information and communication technology for the exchange of information for the diagnosis and treatment of diseases and injuries, research and evaluation, and for the continuing education of health professionals.”⁶Understanding what telemedicine is, what falls within its scope is necessary in order to adequately regulate it, to enable its implementation in practice. For that reason, definitions, such as the one given by WHO are important as a valuable source of information. This definition shows the possibility of the wide application of telemedicine, both in diagnosis, treatment, and monitoring of the health condition of patients, as well as in scientific research, training, and education. It also indicates the complexity of the introduction and application of telemedicine and shows the necessity to regulate various fields before its implementation.

Telemedicine offers numerous advantages, such as saving time and money, the possibility of regular monitoring of the patient’s condition without going to the clinic, contact with patients located in remote areas, rural areas, places where there are no clinics, contact with specialists in other cities, connections with doctors from abroad. In addition to contact between doctors and patients, telemedicine also enables the connection between doctors. The application of telemedicine can shorten the period from diagnosis and treatment initiation, with a faster exchange of necessary information, results, etc.⁷

Introducing telemedicine is a challenging process that necessitates multisectoral co-operation. The readiness of states and health systems, both in terms of legal regulations and in terms of technical capabilities, equipment, education of health care providers, patients, etc. is necessary so that this complex system could function and lead to the achievement of the desired goals. One of the prerequisites for the introduction and wider application of remote treatment is the establishment of a strategic framework, the adoption of appropriate regulations, or amendment of existing ones, which is a challenging process for countries. This research aims to perceive the level of application of telemedicine globally and within the European Union, to identify obstacles to wider implementation, especially in the context of adopting the appropriate legal regulation, and

3 Robert H Eikelboom, “The Telegraph and the Beginnings of Telemedicine in Australia”, *Studies in Health Technology and Informatics*, 182 (2012): 67, 69, 71; Anton Vladzomyrsky, Malina Jordanova and Frank Lievens, *A Century of Telemedicine: Curatio Sine Distantia et Tempora* (Sofia: Malina Jordanova, 2016), 10.

4 See: John Craig, Victor Patterson, „Introduction to the practice of telemedicine“, *Journal of Telemedicine and Telecare*, 11, 1 (2005): 4-6.

5 Sanjay Sood, Victor Mbarika, Shakhina Jugoo, Reena Dookhy, Charles R Doarn, Nupur Prakash, Ronald C Merrell, “What Is Telemedicine? A Collection of 104 Peer-Reviewed Perspectives and Theoretical Underpinnings”, *Telemedicine and e-health*, 13, 5, (2007): 574.

6 World Health Organization, *Global diffusion of eHealth: making universal health coverage achievable. Report of the third global survey on eHealth, Global Observatory for eHealth*, 2016. Available at <https://www.who.int/publications/i/item/9789241511780> (14.4.2022)

7 N M. Hjelm, “Benefits and drawbacks of telemedicine,” *Journal of telemedicine and telecare*, vol. 11, 2 (2005): 60-66.

to analyze the impact of the covid 19 pandemic on the application of telemedicine. One part of the paper is dedicated to the possibilities of implementation of telemedicine in Serbia, identifying obstacles to its application and further changes that have to be made in order to allow its introduction and implementation in practice.

2. THE LEVEL OF IMPLEMENTATION OF TELEMEDICINE BEFORE THE COVID 19 PANDEMIC

Preparing the system for introducing telemedicine is a challenging process that requires years of work and the involvement of experts from different fields. The slowness of introduction and implementation of telemedicine on a global level is reflected in data obtained in the Second global survey on eHealth conducted by the WHO Global Observatory for eHealth in 2009.⁸ One of the steps towards implementation of telemedicine is a preparation of strategies and policies, which should give guidelines and clear goals to be achieved in this field. Unfortunately, the WHO survey showed that only 25% of countries had a national strategy or policy on telemedicine.⁹ When it comes to the implementation of telemedicine in practice, the WHO divided telemedicine into four fields. The most widespread was teleradiology. In over 60% of countries, there was some form of service in that field. Telepathology was present in 41% of countries, teledermatology was applied in 38% of countries, while telepsychiatry was present in 24% of countries.¹⁰ Some of the main obstacles to the wider implementation of telemedicine, that have been identified in developing countries, are the lack of financial resources and equipment, problem with availability of internet connection, lack of legislation, etc.¹¹ When it comes to developed countries, the challenges and reasons for the insufficient implementation of telemedicine are mostly related to legal issues, especially regarding confidentiality and patient's privacy.¹² One of the conclusions regarding the legal issues is that "in order to overcome these challenges telemedicine must be regulated by definitive and comprehensive guidelines, which are applied widely, ideally worldwide. Concurrently, legislation governing confidentiality, privacy, access, and liability need to be instituted."¹³ Other priorities of a health system that put the implementation of telemedicine in a non-priority place, were also identified as a problem.¹⁴ It is interesting that "lack of demand" was also identified as one of the obstacles to wider implementation of telemedicine.¹⁵

8 The survey covered 114 countries - 59% of WHO member states, which includes about 81% of the world's population. World Health Organization Global Observatory for eHealth, *Telemedicine: opportunities and developments in Member States: report on the second global survey on eHealth*. World Health Organization, 2010, 34. <https://apps.who.int/iris/handle/10665/44497>.

9 Ibid. 53.

10 Ibid. 37.

11 Ibid., 18, 19.

12 Ibid., 7, 66; About the problems of mistrust in the digitization process see: Sofija Nikolić Popadić „Digitalizacija usluga u zdravstvenoj zaštiti - primer Nemačke“, *Glasnik Advokatske komore Vojvodine*, 92, 1 (2020):90-91.

13 World Health Organization Global Observatory for eHealth, *Telemedicine: opportunities and developments in Member States: report on the second global survey on eHealth*. World Health Organization, 2010, 11.

14 Ibid., 7, 66.

15 Ibid., 7, 66.

The Third global survey on eHealth from 2015 showed some improvements. When analyzing the results of the survey, we can conclude that the level of implementation of telemedicine services has increased in the WHO member states compared to the previous period. Namely, the new results showed that teleradiology was present in 77% of the countries, telepathology in 52%, teledermatology in 46% and telepsychiatry was applied in 34% of the member states that participated in the research.¹⁶ Although there has been improvement, the list of obstacles to the wider application of telemedicine services have stayed the same as in the previous period. Problems are lack of funding, infrastructure, different priorities in the health system, lack of strategies and legislation governing telemedicine.¹⁷ The survey from 2015 included 125 WHO member states, which is 11 more than in the previous research period, and the results showed that 22% of member states had a specific national policy or strategy on telemedicine. In 35% of the countries, there is no specific strategy, but telemedicine is mentioned in the national policy or e-health strategy, while in 42% of the countries telemedicine is not recognized in the strategies and policies at the national level.¹⁸ This low level of commitment to telemedicine, which is reflected in national strategies (or non-existing strategies), has a significant impact on the low level of implementation of telemedicine in practice. Strategies should provide a starting point for changes in this field and should lead toward the wider application of telemedicine. From the previous results, we can conclude that situation in that regard is not satisfying and there is a need for improvements. The lack of policies, strategies and laws regulating telemedicine affected the readiness of countries for the sudden, significantly increased need and requirements for the application of telemedicine after the outbreak of the Covid-19 pandemic.

3. INFLUENCE OF THE COVID 19 PANDEMIC ON THE IMPLEMENTATION OF TELEMEDICINE

The outbreak of the Covid 19 pandemic in March 2020¹⁹ influenced the initiation of changes in the provision of healthcare services via telemedicine. The need to reduce physical contact has actualized the necessity for the application of digital technologies in the process of prevention, diagnosis and treatment of patients. Healing at a distance, without physical contact and without waiting in waiting rooms, reduces the risk of transmission of infection, which was very important during the period of Covid 19 pandemic. Telemedicine was significant both, for patients suffering from covid 19 and for non-covid patients, who had difficulties to access health services during the pandemic.²⁰ For persons suffering from covid 19, telemedicine was most often applied for

¹⁶ The survey covered 125 WHO member states. World Health Organization Global Observatory for eHealth, Global diffusion of eHealth: making universal health coverage achievable, Report of the third global survey on eHealth, 2016, pp. 5, 59. <https://www.who.int/publications/i/item/9789241511780>

¹⁷ Ibid. 65.

¹⁸ Ibid. 13.

¹⁹ See: Sofija Nikolić Popadić, Marko Milenković, Marta Sjeničić, "The Covid-19 Epidemic in Serbia – the Challenges of Finding an Appropriate Basis for Responding to a Health Crisis", *Medicine, Law & Society*, 14 (2): 230-231.

²⁰ See: Giulio Nittari, Demetris Savva, Daniele Tomassoni, Seyed Khosrow Tayebati, Francesco Amenta, "Telemedicine in the COVID-19 Era: A Narrative Review Based on Current Evidence", *International Journal of Environmental Research and Public Health*, 19(2022): 3; Bokolo Anthony Jnr, "Use of Telemedicine and Virtual Care for Remote Treatment in Response to COVID-19 Pandemic", *Journal of Medical Systems* (2020) 44. <https://doi.org/10.1007/s10916-020-01596-5>

consultation and monitoring the condition of patients. It was especially important to monitor the condition of asymptomatic positive patients via phone or web consultation without the need to go to the clinic.²¹ In addition to the benefits for patients in home isolation, telemedicine was also important in the control of patients who were in isolation within the hospital. In this way, the risk of disease transmission among doctors and hospital staff was reduced, and contact was made only in necessary, urgent cases.²² The use of telemedicine was also important for patients who had Covid 19, to monitor their condition after they were discharged from the hospital.²³

Monitoring and treatment of non-covid patients, especially those in risk groups, was also facilitated through telemedicine. Due to the significant pressure on the healthcare system during the pandemic, it was very difficult for such patients to access healthcare, and the application of modern technologies and online monitoring of the patient's condition and treatment could be extremely important for them.²⁴ The possibility of the online consultation in periods of lockdown during the pandemic was very important for patients who must be periodically monitored by a doctor.

Since the beginning of the Covid 19 pandemic, the number of health services provided by telemedicine has increased significantly. Previously mentioned "lack of demand" as a reason for the slow introduction of telemedicine, detected in the WHO research in 2009, was no longer the issue. According to research conducted in the United States of America, the number of services provided via telemedicine in 2019 was around 840,000, while in 2020 that number increased by 63 times, and it reached approximately 52.7 million.²⁵ The application of telemedicine has also grown significantly in the European Union Member States. It is estimated that in approximately 58% of Member States, telemedicine has replaced personal visits to doctor's office and hospitals, and the previous practice of visits was reduced to only necessary cases.²⁶ It is also interesting to mention that during the outbreak of Covid 19 pandemics in March 2020 approximately 84% of patients used telemedicine for the first time ever.²⁷ Previous data testify to the significant impact that pandemic had on application of telemedicine, as well as the importance of „healing at a distance“ during the pandemic. But the possibility for countries to introduce telemedicine or to wider apply it, depended on the level of development and application of telemedicine in the pre-pandemic period. The existence of policies, strategies and laws that regulated this field significantly

21 Raffaele Galiero, Pia Clara Pafundi, Riccardo Nevola, Luca Rinaldi, Carlo Acierno, Alfredo Caturano, Teresa Salvatore, Luigi Elio Adinolfi, Ciro Costagliola, Ferdinando Carlo Sasso, „The Importance of Telemedicine during COVID-19 Pandemic: A Focus on Diabetic Retinopathy“, *Journal of Diabetes Research*, (2020): 2.

22 Ibid.

23 Roi Suárez-Gil, Emilio Casariego-Vales, Rosa Blanco-López, Fernando Santos-Guerra, Cristina Pedrosa-Fraga, Álvaro Fernández-Rial, Iria Íñiguez-Vázquez, María Mar Abad-García, Mercedes Bal-Alvaredo, on behalf of the members of the Lugo Telea-Covid Team, „Efficacy of Telemedicine and At-Home Telemonitoring following Hospital Discharge in Patients with COVID-19.“ *Journal of Personalized Medicine*, vol. 12, 4 (2022):1.

24 Magdalena Tuczynska, Maja Matthews-Kozanecka, Ewa Baum, „Accessibility to Non-COVID Health Services in the World During the COVID-19 Pandemic: Review“, *Frontiers in Public Health*, 9 (2021): 2-4.

25 Lok Wong Samson, Wafa Tarazi, Gina Turrini, Steven Sheingold, Medicare Beneficiaries' Use of Telehealth in 2020: Trends by Beneficiary Characteristics and Location, (Issue Brief No. HP-2021-27). Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. December, 2021. https://www.aspe.hhs.gov/sites/default/files/documents/a1d5d810fe3433e18b192be42dbf2351/medicare-telehealth-report.pdf?_ga=2.263152908.1288477598.1638811694-1417522139.1637192937

26 European Parliament, The rise of digital health technologies during the pandemic, p. 2. [https://www.europarl.europa.eu/RegData/etudes/BRIE/2021/690548/EPRS_BRI\(2021\)690548_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2021/690548/EPRS_BRI(2021)690548_EN.pdf)

27 Ibid.

influenced the possibility of the application of telemedicine. Therefore, countries were in different positions when the pandemic broke out.

4. LEGAL FRAMEWORK FOR THE IMPLEMENTATION OF TELEMEDICINE IN THE EUROPEAN UNION

In the European Union (EU) primary responsibility for the protection of human health is with Member States. Namely, according to the Article 6 of the Treaty on the Functioning of the European Union, in the area of “protection and improvement of human health” Union does not have exclusive competence, but it shall “carry out actions to support, coordinate or supplement the actions of the Member States.”²⁸ Treaty also prescribes that the Union “shall complement national policies”, when acting in order to improve public health and prevent diseases and illnesses, and should respect “the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care.”²⁹ The Member States should cooperate in the area of public health protection, and should “coordinate among themselves their policies and programmes”, with the support of the Union.³⁰ When analyzing previous provisions we can conclude that health protection and providing and implementing health services is in competence of Member States, which also applies to telemedicine. Besides these general provisions related to health protection, articles of the Treaty on the Functioning of the European Union which are dedicated to services³¹ apply to telemedicine (as it is a health care service). Therefore, the freedom to provide services applies to telemedicine.³² For telemedicine services provided across borders the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare applies.³³ It is interesting that telemedicine is considered not only as a health care service, but also as “an information society service”³⁴

28 Consolidated version of the Treaty on the Functioning of the European Union, OJ C 326, 26. 10. 2012, 47–390, Art. 6. See: Nikolić Popadić, Sofija, Marko Milenković, „Uvođenje mera za zaštitu javnog zdravlja stanovništva tokom pandemije Kovid 19“, u *Primena prava i pravna sigurnost: zbornik radova 34. susreta Kopaoničke škole prirodnog prava - Slobodan Perović*, Tom 1, ured. Jelena S. Perović Vujačić, (Beograd: Kopaonička škola prirodnog prava - Slobodan Perović, 2021): 185-186.

29 Consolidated version of the Treaty on the Functioning of the European Union, OJ C 326, 26. 10. 2012, Art. 168. See: Nikolić Popadić, Milenković, „Uvođenjemera za zaštitujavnozdravljustanovništvatokompandemijeKovid 19“, 186.

30 Consolidated version of the Treaty on the Functioning of the European Union, OJ C 326, 26. 10. 2012, Art. 168.

31 Consolidated version of the Treaty on the Functioning of the European Union, OJ C 326, 26. 10. 2012, Art. 56, 57.

32 Member States are, under certain conditions, allowed to limit the free movement of services. See: European Commission, Commission Staff Working Document on the applicability of the existing EU Legal framework to telemedicine services 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, Brussels, 6.12.2012. <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0414:FIN:EN:PDF> p. 7.

33 Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare, OJ L 88, 4.4.2011, p. 45–65.

34 European Commission, Commission Staff Working Document on the applicability of the existing EU Legal framework to telemedicine services 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, p. 8.

and therefore Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market and the directive 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, apply to telemedicine services.

Data protection is one of the issues and challenges related to the implementation of telemedicine. It is one of the significant reasons for mistrust and less application of telemedicine in practice.³⁵ When it comes to the EU, the adoption of 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, and repealing Directive 95/46/EC (General Data Protection Regulation) made a contribution to the protection of personal health data, which is also important for the implementation of telemedicine. The General Data Protection Regulation recognizes data concerning health as a special category of personal data and regulates the processing of such data.³⁶

As the detailed regulation and implementation of telemedicine are left to the Member States, the possibility and level of its application in practice vary significantly between the countries. Therefore, the response of countries to the sudden significant increase in the need for the use of telemedicine in order to reduce physical contact and prevent the further spread of the pandemic was different. In the beginning, it was based on the existing system and the possibilities of telemedicine applications. Therefore, it is necessary to analyze the situation immediately before the outbreak of the pandemic. According to research on the application of telemedicine in the member states of the Organization for Economic Co-operation and Development, published in January 2020, right before the outbreak of the Covid 19 pandemic, European countries were at different stages of telemedicine application. Viewed from the perspective of national policies, strategies and laws regulating telemedicine, we can divide EU countries into different categories. Countries that did not have special strategies, policy or legislation regulating the use of telemedicine are the Czech Republic and Estonia. The EU Member States which have strategy, policy or in which the use of telemedicine is legally regulated are Belgium, Denmark, France, Germany, Greece, Hungary, Italy, Lithuania, Latvia, Luxembourg, Netherlands, Norway, Poland, Portugal and Slovakia.³⁷ In Austria, Spain, Slovenia and Sweden the use of telemedicine is possible, but it is not regulated by special regulations. Its application is allowed within "broader health care laws."³⁸ Based on this division we can conclude that countries have different approaches in regulating telemedicine. We further analyzed the legislation of the EU Member States, and we came to the conclusion that telemedicine is most often regulated within the regular healthcare laws. This significant result of our research and analysis can be an important guideline when regulating the introduction and implementation of telemedicine in the Republic of Serbia.

35 On the problems of mistrust in the digitization process, especially in connection with the issue of patient data protection in Germany see: Sofija Nikolić Popadić, „Digitalizacija usluga u zdravstvenoj zaštiti - primer Nemačke“, *Glasnik Advokatske komore Vojvodine*, 92, 1 (2020): 90-91.

36 For more details see: 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, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 4.5.2016, p. 1-88, Art. 4, 9.

37 Tiago Oliveira Hashiguchi, „Bringing health care to the patient: An overview of the use of telemedicine in OECD countries“, OECD Health Working Papers, No. 116, OECD Publishing, Paris, (2020): 12. <https://doi.org/10.1787/8e56ede7-en>.

38 *Ibid.*, p. 11-12.

The Covid 19 pandemic showed weaknesses in health systems and the necessity for improvement in different fields. Not all Member States were ready to apply telemedicine. The changes in this field were necessary before wider application. Also, the cooperation between Member States should be strengthened and supported by the Union. Therefore, the EU4Health programme 2021-2027 – a vision for a healthier European Union was established³⁹ aiming to build „stronger, more resilient and more accessible health systems.“⁴⁰ One of the specific objectives is „promoting the uptake of digital tools and services, as well as the digital transformation of healthcare systems.“⁴¹ The action that should support the achievement of that objective, among others is, „transition to telemedicine and at-home administration of medication.“⁴² This again points out the significance of telemedicine and the importance of its wider implementation in the coming years.

5. POSSIBILITIES FOR IMPLEMENTATION OF TELEMEDICINE IN THE REPUBLIC OF SERBIA

In this part of the research, we analyzed health regulations in the Republic of Serbia. Based on the results of that analysis we can conclude that application of telemedicine is not regulated, and therefore there is a need for a change in this field. The steps towards introduction and regulation of telemedicine were made in February 2022, when the Government of the Republic of Serbia adopted the *Digitalization Program in the Health System of the Republic of Serbia for the period 2022-2026*. The importance of telemedicine was recognized within this program. The benefits of application of telemedicine were analyzed, such as monitoring of patients' condition, reduction of hospital admissions and mortality related to some chronic conditions, etc.⁴³ The implementation of telemedicine should reduce the pressure on general practitioners. Namely, it is estimated that healing at distance in Serbia can reduce visits by 1,142 per doctor during the year, which will be 4.4 visits less per doctor per day.⁴⁴ It is estimated that there is the potential to transfer between 3.8 and 6.3 million examinations to telemedicine examinations.⁴⁵ In the Program, as part of the measure 2.4 Enabling electronic data exchange between authorized persons in the health care system, one of the planned activities is adoption of the “Telemedicine implementation plan in the health care system.”⁴⁶ Telemedicine was also mentioned within the measure 2.7 Establishment of

39 Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014, OJ L 107, 26.3.2021, p. 1–29.

40 European Commission, Public Health, EU4Health programme 2021-2027 – a vision for a healthier European Union, https://health.ec.europa.eu/funding/eu4health-programme-2021-2027-vision-healthier-european-union_en

41 Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021, Art. 4(f).

42 Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021, Annex I, 6.

43 Digitalization Program in the Health System of the Republic of Serbia for the period 2022-2026, p. 51.

44 Digitalization Program in the Health System of the Republic of Serbia for the period 2022-2026, p. 52.

45 Ibid.

46 Digitalization Program in the Health System of the Republic of Serbia for the period 2022-2026, p. 35. According to the Action plan for the period 2022 - 2023 for implementation of Digitalization Program in the Health System of the Republic of Serbia for the period 2022-2026 preparing the Telemedicine implementation plan in the health care system is in responsibility of the Institute for Public Health of Serbia “Dr. Milan Jovanović Batut” and the Republic Fund of Health Insurance. The deadline for completion is 2nd quarter of 2022.

electronic services for users of health services, as the new technologies should enable remote communication between healthcare professionals and patients and monitoring of patients' conditions by telemedicine devices.⁴⁷

Based on the previous analysis of *Digitalization Program in the Health System of the Republic of Serbia for the period 2022-2026* we can conclude that finally the application of telemedicine could become the reality in Serbia in future years. However, there are still many issues and things that have to be regulated before the wider application of telemedicine in practice. Healing at distance opens a question about the relationship between the patient and the doctor, the question of liability, especially due to the wrong transfer of data and technical disturbances that can lead to misdiagnosis.⁴⁸ The questions of the protection of patients' data, as well as the way in which remote treatment will affect the health insurance sector are also raised. It is necessary to make a decision about which telemedicine regulation model will be applied. Will new specific regulations be adopted or will existing health regulations be amended as it is the case in most EU Member States, as shown in the previous section? When it comes to change of existing regulation, laws that should be amended are Law on health care,⁴⁹ Law on health documentation and records in the field of health,⁵⁰ Law on health insurance,⁵¹ Law on patients' rights,⁵² Law on Public Health,⁵³ Law on the Protection of the Population from Infectious Diseases,⁵⁴ Law on Medicines and Medical Devices,⁵⁵ Law on medical devices.⁵⁶

In addition to challenges regarding the legislation, there are also other difficulties and obstacles to overcome on the way to wider implementation of telemedicine, such as investments in technical equipment, financial support for the whole process, education of health workers and users, education of patients, etc.

There are pilot projects within the healthcare system of the Republic of Serbia which should contribute to finding possibilities and forms of telemedicine implementation in practice. One of them is e-diabetes project which enabled electronic consultations between the general physician and endocrinologist, and non-contact examinations of patients through the exchange of relevant medical documentation.⁵⁷ The basic face to face control and first examination as earlier were kept, and only when doctors decide that the physical presence of the patient is not necessary the non-contact examinations were applied. This contributed to the reduction of average time required for a patient to receive therapy from 42 days in standard procedure to 29.1 days through e-diabetes.⁵⁸ One more successful example is the use of telemedicine for mental health care. In 2019 the Clinic for

47 Digitalization Program in the Health System of the Republic of Serbia for the period 2022-2026, p. 37.

48 Sofija Nikolić Popadić „Digitalizacija usluga u zdravstvenoj zaštiti - primer Nemačke“, *Glasnik Advokatske komore Vojvodine*, 92, 1 (2020): 88-89, 92.

49 Official Gazette of the Republic of Serbia, No.25/2019.

50 Official Gazette of the Republic of Serbia, No. 123/2014, 106/2015, 105/2017, 25/2019.

51 Official Gazette of the Republic of Serbia, No.25/2019.

52 Official Gazette of the Republic of Serbia, No. 45/2013, 25/2019.

53 Official Gazette of the Republic of Serbia, No. 15/2016.

54 Official Gazette of the Republic of Serbia, No. 15/2016, 68/2020, 136/2020.

55 Official Gazette of the Republic of Serbia, No. 30/2010, 107/2012, 105/2017, 113/2017.

56 Official Gazette of the Republic of Serbia, No. 155/2017.

57 Startovao pilot-projekat telefonska konsultacija građana sa izabranim lekarom na primarnom nivou, 3.9.2022. <https://paragraflex.rs/dnevne-vesti/070922/070922-vest9.html>

58 Startovao pilot-projekat telefonska konsultacija građana sa izabranim lekarom na primarnom nivou, 3.9.2022. <https://paragraflex.rs/dnevne-vesti/070922/070922-vest9.html>

Mental Disorders Dr Laza Lazarević together with the Ministry of Health of the Republic of Serbia established free National helpline for preventing suicide, which was one of the steps towards introducing telemedicine.⁵⁹ After the outbreak of the Covid-19 pandemics the free National helpline for psychosocial support during pandemic and the helpline How are you doing? were opened, and in May 2021 they were united into “free service for mental healthcare of the Ministry of Health of the Republic of Serbia and the Clinic for Mental Disorders Dr Laza Lazarević.”⁶⁰ Via this service, around 30.000 interventions were made and they provided „support, counseling, short psychotherapy (crisis) interventions, as well as recommendations related to already prescribed medication.”⁶¹ Previous examples show numerous benefits of telemedicine application and also indicate the possibilities and the need for their application in the healthcare system of Serbia.

6. CONCLUSION

The introduction of telemedicine is a challenging process that necessitates multisectoral cooperation. Along with the required technical equipment, financial support, education of healthcare providers and users, one of the prerequisites for the application of remote treatment is the establishment of a strategic framework, the adoption of appropriate regulations or amendment of existing ones, which could be a challenging process for countries. Although the development of modern telemedicine began in the second half of the 20th century, the process of its implementation was very slow. We can conclude that the Covid 19 pandemic significantly accelerated the processes in this field, pointed out the exceptional importance of the application of telemedicine, but also revealed the shortcomings of the system in certain countries. It is necessary to use the momentum that the pandemic gave, in order to make the necessary changes and to enable the wider application of telemedicine. Countries have different approaches to legal regulation of this field. According to the results of this research telemedicine is most often regulated within regular healthcare laws. This important result can be used as a guideline when regulating the introduction and implementation of telemedicine in the Republic of Serbia.

Some initial steps towards implementation of telemedicine in Serbia were made, especially with the adoption of the *Digitalization Program in the Health System of the Republic of Serbia for the period 2022-2026*, but there are still many changes that should be made in order to enable its implementation in practice. As it can be concluded from the pilot projects, there is a need in the Serbian health system for the introduction of telemedicine, and its implementation could lead to numerous benefits. Detail regulation of the implementation of telemedicine is necessary, particularly regarding the use of patients' data, privacy, the relationship between doctors and patients, etc. The precise regulation of this field is very important, especially as that can influence the trust of users in the whole system and willingness to accept the new approach in the provision of health care services. When introducing telemedicine, the focus should be also on training and preparation

59 Ivana Stašević Karličić, "How much has the covid-19 pandemic changed us? The experience of the Clinic for Mental Disorders "Dr Laza Lazarević"", *Serbian Journal of the Medical Chamber*, Vol. 2 No. 3 (2021): 296-297.

60 *Ibid.*, 297.

61 *Ibid.*

of patients to use such services, especially as not everyone has access to modern mobile phones, computers and the internet, particularly older citizens in remote areas, so the use should be also adjusted to them, e.g. by using regular phones for consultations. In the end, it is also necessary to explain that telemedicine is not abolishing face-to-face visits, as there are some concerns in this regard. In most countries, the first contact between patient and doctor has to be in the doctor's office and telemedicine is used in the later stage for further consultations and monitoring if live visits are not necessary. This new era in the provision of healthcare services in Serbia will certainly bring benefits, but it will be also connected with numerous challenges in the coming years and the requests for new legal solutions.

7. LITERATURE:

1. Bokolo, Anthony Jnr, "Use of Telemedicine and Virtual Care for Remote Treatment in Response to COVID-19 Pandemic", *Journal of Medical Systems* (2020):1-9. <https://doi.org/10.1007/s10916-020-01596-5>
2. Craig, John, Victor Patterson, „Introduction to the practice of telemedicine“, *Journal of Telemedicine and Telecare*, 11, 1 (2005): 3-9. doi:10.1177/1357633X0501100102
3. Eikelboom, Robert H., "The Telegraph and the Beginnings of Telemedicine in Australia", *Studies in Health Technology and Informatics*, 182 (2012): 67-72.
4. European Commission, Commission Staff Working Document on the applicability of the existing EU Legal framework to telemedicine services 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, Brussels, 6.12.2012. <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0414:FIN:EN:PDF> (24.5.2022)
5. European Commission, Public Health, EU4Health programme 2021-2027 – a vision for a healthier European Union, https://health.ec.europa.eu/funding/eu4health-programme-2021-2027-vision-healthier-european-union_en (10.9.2022)
6. European Parliament, The rise of digital health technologies during the pandemic. [https://www.europarl.europa.eu/RegData/etudes/BRIE/2021/690548/EPRS_BRI\(2021\)690548_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2021/690548/EPRS_BRI(2021)690548_EN.pdf) (4.6.2022)
7. Galiero, Raffaele, Pia Clara Pafundi, Riccardo Nevola, Luca Rinaldi, Carlo Acierno, Alfredo Caturano, Teresa Salvatore, Luigi Elio Adinolfi, Ciro Costagliola, Ferdinando Carlo Sasso, „The Importance of Telemedicine during COVID-19 Pandemic: A Focus on Diabetic Retinopathy“, *Journal of Diabetes Research*, (2020). <https://doi.org/10.1155/2020/9036847>
8. Hjelm, N M. "Benefits and drawbacks of telemedicine," *Journal of telemedicine and telecare*, vol. 11,2 (2005): 60-70. doi:10.1258/1357633053499886
9. Nikolić Popadić, Sofija, „Digitalizacija usluga u zdravstvenoj zaštiti - primer Nemačke“, *Glasnik Advokatske komore Vojvodine*, 92, 1 (2020): 88-93. <https://doi.org/10.5937/gakv92-25688>
10. Nikolić Popadić, Sofija, Marko Milenković, „Uvođenje mera za zaštitu javnog zdravlja stanovništva tokom pandemije Kovid 19“, u *Primena prava i pravna sigurnost : zbornik ra-*

- dova 34. *Susreta Kopaoničke škole prirodnog prava - Slobodan Perović*, Tom 1, ured. Jelena S. Perović Vujačić, 183-197. Beograd: Kopaonička škola prirodnog prava - Slobodan Perović, 2021.
11. Nikolić Popadić, Sofija, Marko Milenković, Marta Sjeničić, "The Covid-19 Epidemic in Serbia – the Challenges of Finding an Appropriate Basis for Responding to a Health Crisis", *Medicine, Law & Society*, 14 (2): 229-246. <https://doi.org/10.18690/mls.14.2.229-246>. 2021
 12. Nittari, Giulio, Demetris Savva, Daniele Tomassoni, Seyed Khosrow Tayebati, Francesco Amenta, "Telemedicine in the COVID-19 Era: A Narrative Review Based on Current Evidence", *International Journal of Environmental Research and Public Health*, 19(2022). doi:10.3390/ijerph19095101
 13. Oliveira Hashiguchi, Tiago, "Bringing health care to the patient: An overview of the use of telemedicine in OECD countries", OECD Health Working Papers, No. 116, 2020, OECD Publishing, Paris. <https://doi.org/10.1787/8e56ede7-en>.
 14. Samson, Lok Wong, Wafa Tarazi, Gina Turrini, Steven Sheingold, "Medicare Beneficiaries' Use of Telehealth in 2020: Trends by Beneficiary Characteristics and Location", (Issue Brief No. HP-2021-27). Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. December, 2021. https://www.aspe.hhs.gov/sites/default/files/documents/a1d5d810fe3433e18b192be42dbf2351/medicare-telehealth-report.pdf?_ga=2.263152908.1288477598.1638811694-1417522139.1637192937 (21.5.2022)
 15. Sood, Sanjay, Victor Mbarika, Shakhina Jugoo, Reena Dookhy, Charles R Doarn, Nupur Prakash, Ronald C Merrell, "What Is Telemedicine? A Collection of 104 Peer-Reviewed Perspectives and Theoretical Underpinnings", *Telemedicine and e-health*, 13, 5, (2007): 573-90. doi:10.1089/tmj.2006.0073
 16. Stašević Karličić, Ivana, "How much has the covid-19 pandemic changed us? The experience of the Clinic for Mental Disorders "Dr Laza Lazarević"", *Serbian Journal of the Medical Chamber*, Vol. 2 No. 3 (2021): 295-301.
 17. Suárez-Gil, Roi, Emilio Casariego-Vales, Rosa Blanco-López, Fernando Santos-Guerra, Cristina Pedrosa-Fraga, Álvaro Fernández-Rial, Iria Íñiguez-Vázquez, María Mar Abad-García, Mercedes Bal-Alvaredo, on behalf of the members of the Lugo Telea-Covid Team, "Efficacy of Telemedicine and At-Home Telemonitoring following Hospital Discharge in Patients with COVID-19." *Journal of Personalized Medicine*, vol. 12, 4 (2022):1-10. doi:10.3390/jpm12040609
 18. Tuczynska, Magdalena, Maja Matthews-Kozanecka, Ewa Baum, "Accessibility to Non-COVID Health Services in the World During the COVID-19 Pandemic: Review", *Frontiers in Public Health*, 9 (2021): 1-7. doi: 10.3389/fpubh.2021.760795
 19. Vladzimirskyy, Anton, Malina Jordanova and Frank Lievens, *A Century of Telemedicine: Curatio Sine Distantia et Tempora*. Sofia: Malina Jordanova, 2016.
 20. World Health Organization Global Observatory for eHealth, *Telemedicine: opportunities and developments in Member States: report on the second global survey on eHealth*. World Health Organization, 2010, <https://apps.who.int/iris/handle/10665/44497> (14.4.2022)
 21. World Health Organization, *Global diffusion of eHealth: making universal health coverage achievable. Report of the third global survey on eHealth*, Global Observatory for eHealth, 2016. Available at <https://www.who.int/publications/i/item/9789241511780> (14.4.2022)

22. Action plan for the period 2022 - 2023 for implementation of Digitalization Program in the Health System of the Republic of Serbia for the period 2022-2026.
23. Digitalization Program in the Health System of the Republic of Serbia for the period 2022-2026.
24. Consolidated version of the Treaty on the Functioning of the European Union, OJ C 326, 26. 10. 2012, 47–390.
25. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 4.4.2011, p. 45–65.
26. 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, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 4.5.2016, p. 1–88.
27. Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014, OJ L 107, 26.3.2021, p. 1–29.

UVOĐENJE TELEMEDICINE – PRAVNI I DRUGI IZAZOVI⁶²

Sofija Nikolić Popadić⁶³

Institut društvenih nauka, Beograd

Apstrakt: Tehnološki razvoj i napredak su omogućili različite promene u zdravstvenom sistemu. Jedna od njih je primena telemedicine, odnosno tzv. „lečenja na daljinu“. Ovakav način pružanja zdravstvenih usluga omogućava višestruku korist, kao što je redovno praćenje stanja pacijenata bez potrebe za fizičkim dolaskom u kliniku, što doprinosi uštedi vremena i finansijskih izdataka za transport, kontakt sa pacijentima koji se nalaze u udaljenim krajevima, kontakt sa specijalistima u drugim gradovima, sa lekarima iz inostranstva. Osim prednosti, ovakav način pružanja zdravstvenih usluga otvara i različita pitanja koja se odnose na zaštitu podataka pacijenata, privatnost, odnos pacijenata i lekara itd. Uvođenje telemedicine je izazovan proces koji zahteva multisektorsku saradnju. Uz potrebnu tehničku opremljenost, finansijsku podršku, edukaciju pružalaca zdravstvenih usluga i korisnika, jedan od preduslova za primenu lečenja na daljinu je uspostavljanje strateškog okvira, donošenje odgovarajućih propisa ili izmena postojećih. Taj proces predstavlja izazov za mnoge države. Ovo istraživanje ima za cilj da analizira nivo primene telemedicine na globalnom nivou i unutar Evropske unije, da identifikuje izazove i prepreke za širu implementaciju, posebno u kontekstu donošenja odgovarajuće zakonske regulative, kao i da analizira uticaj pandemije Covid 19 na primenu telemedicine. Jedan deo rada je posvećen mogućnostima primene telemedicine u Republici Srbiji, identifikovanju prepreka njenoj primeni, kao i daljim promenama koje je potrebno sprovesti kako bi se omogućilo njeno uvođenje i primena u praksi.

Ključne reči: telemedicina, zdravstvena zaštita, pandemija Covid 19, digitalizacija, zdravstvene usluge, zaštita zdravstvenih podataka, Evropska unija.

⁶² Rad je napisan u okviru Programa istraživanja Instituta društvenih nauka za 2022. godinu koji podržava Ministarstvo prosvete, nauke i tehnološkog razvoja.

⁶³ Dr Sofija Nikolić Popadić, naučni saradnik, Institut društvenih nauka, Centar za pravna istraživanja, Beograd, Srbija, e-mail: snikolic@idn.org.rs