

<https://doi.org/10.25143/socr.23.2022.2.015-027>

Problems and Opportunities for Improvement of Legal Framework for Provision of Telemedicine Services: Experience of the Republic of Latvia and Ukraine

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Abstract

In recent years technological progress has had a huge impact on healthcare sector. New products, services are becoming popular among patients and healthcare providers. Long waiting periods, to see healthcare specialists and COVID-19 pandemics have influenced the situation as well. As a result of the COVID-19 pandemic, there was a need for non-contact healthcare due to prevalence and infectivity of the disease, which has led to active provision of remote healthcare, both for COVID-19 patients and remote consultations. The aim of the article is to analyse the international regulatory framework of

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telemedicine, problems, and opportunities for Improvement of the Legal Framework for the Provision of Telemedicine Services. The article will analyse both national regulatory framework of Latvia and Ukraine.

Keywords: law, medical technologies, patients' rights, telemedicine.

Introduction

Legal definition of telemedicine is given in Article 1(29) of the Medical Treatment Law. It describes telemedicine as a set of processes and covers a wide range of concepts that belong to a specific category – provision of remote healthcare. Describing telemedicine, several types of telemedicine service provision can be distinguished that differ in specifics and general feasibility of their implementation, depending on the national concept, state of development, amount of funding, and experience.

The EU regulatory framework and the EU-funded Report on the EU State of Play on Telemedicine Services and Uptake Recommendations contain different definitions of telemedicine services, which would be important to clarify at the level of national regulation, e.g.:

- 1) Teletriage which involves determining the severity of a patient's condition (assessing urgency of treatment or care rather than diagnosing and identifying symptoms) and providing advice via mobile communication networks, mainly by doctors and medical support persons, as well as emergency medical dispatchers, etc. (Joint Action to Support the eHealth Network, 2022, Art. 15);
- 2) Teliagnosis which comprises the process of identifying a patient's symptoms and recognising the disease, based on information received in the form of images, video or remote communication using information communication technologies (Joint Action to Support the eHealth Network, 2022, Art. 15). It should be noted that the field of telemedicine in the Republic of Latvia has not been yet developed to the level where remote diagnosis of patients could be actively implemented. However, certain fields (e.g., psychiatry, dermatology, etc.) could, where feasible, perform identification of health conditions and diseases. While such consultations will not be applicable to all patients and telemedicine cannot fully replace face-to-face healthcare, it is important to define possibilities of remote diagnostic services and distinguish them from face-to-face healthcare services;
- 3) Teleconsultation which involves communication between a patient and a healthcare professional or between two or more healthcare professionals related to assessment of a patient's health condition using information communication technology (Joint Action to Support the eHealth Network, 2022, Art. 15);
- 4) Telemonitoring, a type of telemedicine service implemented to remotely monitor a patient's health condition (Communication from the Commission of

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the European Communities, COM/2008/0689, 2008). In the Republic of Latvia, it could currently only be implemented with active involvement of the patient through regular submission of their health indicators (e.g., blood pressure, blood sugar, etc.) to attending physician within a set timeframe. This ensures that a patient's health status is continuously monitored, also in cases where the attending physician finds it necessary to see a specific healthcare professional based on a patient's general health indicators.

The above identifies problematics of international regulatory framework of telemedicine, as well as challenges for Improvement of the Legal Framework for the Provision of Telemedicine Services.

The article aims to analyse Latvian and Ukrainian national regulatory framework in the field of telemedicine. The legal interpretation methods will be used to identify the problems and solutions from the comparative perspective.

Limitations of Providing Telemedicine Services: Experience of Latvia

The Medical Treatment Law states that competence of medical practitioners as well as the amount of theoretical and practical knowledge required to practise in a given specialisation is determined by the Cabinet of Ministers of the Republic of Latvia. To provide telemedicine services, a medical practitioner must be able to use the necessary information and communication technologies, communicate with patients, including underaged patients, at a level to obtain all the necessary information and to implement other measures that would result in quality healthcare. This means that medical practitioners need a high level of communication skills with prior knowledge of psychology. Furthermore, it requires the Ministry of Health of the Republic of Latvia to develop provisions in the form of policy guidelines or Cabinet regulations that would reflect the scope of competences and knowledge of medical practitioners providing telemedicine services (Ashfaq, Memon, Zehra, et al., 2020).

The COVID-19 pandemic resulted in an increased demand for psychiatric health services. Statistics show that the risk of psychiatric illnesses was exacerbated during this period and the number of psychiatric illnesses grew (Veselības ministrija, 2021). Article 1(22) of the Medical Treatment Law defines psychiatric assistance as “individual prophylaxis, out-patient or in-patient diagnosis, medical treatment, rehabilitation and care for persons with mental health disorders” (Ārstniecības likums, 1997, 1). The legal definition implies that psychiatric assistance can only be provided on an outpatient or inpatient basis, both of which require face-to-face contact. Article 66 of the Medical Treatment Law states that persons “have the right to receive medical assistance and care of a quality that conforms with accepted standards of general medicine” (Ārstniecības likums, 1997, 1).

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Article 67(1) of the Medical Treatment Law provides that psychiatric assistance may be provided at a patient's place of residence if the patient's health condition allows it (*Ārstniecības likums, 1997, 1*). Thus, it should be possible to provide and receive psychiatric assistance remotely if the patient's state of health and other circumstances allow it. Telemedicine cannot fully substitute face-to-face healthcare, nor is it applicable to all patients, which should be objectively assessed by the clinician. However, under favourable conditions, it can be an effective alternative to face-to-face consultations, contributing to increased access to psychiatric assistance. It is especially valuable in a period when psychiatric illnesses are on the rise, both as a result of particular COVID-19 symptoms (which can lead to mental health complications) and the impact of changes experienced during the pandemic period (*Veselības ministrija, 2021*).

The legislation of the Republic of Latvia not only lacks professional requirements for medical practitioners but also a distinction of medical institutions that provide exclusively telemedicine services. Currently, only inpatient and outpatient institutions that primarily provide face-to-face services are recognised in the legal framework.

Mandatory Requirements for Telemedicine Institutions in Latvia

Article 54(2) of the Law on Medical Treatment provides that medical institutions may be outpatient and inpatient institutions (*Ārstniecības likums, 1997, 54*). Pursuant to Article 55 of the Medical Treatment Law, medical treatment may only be provided in medical treatment institutions that meet the minimum requirements set by the Cabinet in accordance with Regulation No. 60 "Regulations Regarding Mandatory Requirements for Medical Treatment Institutions and Their Structural Units" of 20 January 2009 (hereinafter Regulation No. 60). Paragraphs 23 and 92 of Regulation No. 60 define outpatient and inpatient treatment institutions. Namely, an outpatient treatment institution "provides primary healthcare or outpatient secondary healthcare to patients, including inpatient care", and an inpatient treatment institution is an institution where the "patient is under the constant and continuous 24-hour care and control of medical practitioners". Simultaneously, the second subparagraph of paragraph 2 of Regulation No. 60 states that all medical institutions must "provide availability of an environment to persons with functional disorders" (*MK Noteikumi Nr. 60, 2009*). However, paragraph 4 of Regulation No. 60 sets out the provisions that a medical institution must ensure if it does not provide an environment that enables persons with functional disabilities to receive healthcare in accordance with the approved medical technologies, as well as information on medical institutions where it is possible to receive specific healthcare services, and the possibility of independent access to the medical institution (*MK Noteikumi Nr. 60, 2009*). Thus, within the scope of the regulatory framework, healthcare institutions are created for physical reception of patients and provision of

medical treatment. This is also confirmed by Cabinet Regulation No. 555 on Procedures for the Organisation of and Payment for Health Care Services of 28 August 2018, which states that for a healthcare institution to practice the provision of telemedicine services, it must comply with the requirements set out in Regulation No. 60. Thus, although there are exceptions in Regulation No. 60 that relate to the provision of access to the environment, this does not make it possible to provide healthcare services that primarily consist of telemedicine services.

In order to be able to provide telemedicine services, a healthcare institution must meet the following conditions:

- 1) It must be registered in the Register of Medical Institutions in accordance with the procedure set out in Cabinet Regulation No. 170 on the Register of Medical Institutions of 8 March 2005. It can only be achieved by meeting the requirements on the need to ensure accessibility of the environment for persons with functional disabilities set out in the third subparagraph of paragraph 2 of Regulation No. 60;
- 2) Medical practitioners and medical support staff employed in the institution shall be registered in the Register of Medical Practitioners and Medical Support Staff in accordance with the procedure established by Cabinet Regulation No. 317 on the Establishment, Update, and Maintenance of the Register of Medical Practitioners and Medical Support Staff of 24 May 2016;
- 3) The healthcare institution must be able to ensure secure processing of medical data and information necessary for medical treatment, as provided for in Article 1(29) of the Medical Treatment Law;
- 4) According to the principles set out in the first subparagraph of paragraph 17 of Regulation No. 60, to ensure high quality and safe treatment services for patients, unambiguous identification of patients must be implemented and ensured throughout the treatment process. Furthermore, not all patients are eligible to receive telemedicine services and there are several factors that a healthcare professional must take into account to assess a patient's eligibility for telemedicine services. This implies that the healthcare institution must provide secure remote communication channels for accurate patient identification;
- 5) In accordance with paragraphs 18 and 19 of Regulation No. 60, the medical institution must provide "information technologies connected to the internet and software that provides patient data storage and processing, observing the limitations of availability of information" and must develop "information protection provisions and provisions regarding procedures for medical information processing". Consequently, the medical institution must ensure the quality, content, and protection of records in medical and accounting documentation, and the procedures and time limits for their storage in accordance

with the requirements of Cabinet Regulation No. 265 on Procedures for Keeping Medical Documents of 20 January 2009;

- 6) Patients' rights under the Law on the Rights of Patients must be ensured (MK noteikumi Nr. 60, 2009).

The regulatory framework setting out the minimum requirements for healthcare institutions is broad and includes most important core principles that should be respected by both outpatient and inpatient healthcare institutions and health centres, as well as healthcare institutions that only provide telemedicine services. Nevertheless, institutions primarily providing face-to-face healthcare would be very different from telemedicine institutions, which, given the limited awareness and funding, are likely to continue to be established as call centres and telemedicine consultation centres. They would focus on teletriage and teleconsultation; thus, providing clinical support to patients (telemedicina.lv, 2022). Such services could not replace face-to-face healthcare but would contribute to the overall healthcare system.

The possibility of issuing electronic documents is fundamental for the implementation of comprehensive telemedicine services. In the Republic of Latvia, distribution of sickness absence certificates and prescriptions for state reimbursable medicines has been carried out through the e-health system, with doctor referrals added since 2019 (E-veselība, 2022).

The legislation of the Republic of Latvia does not restrict the issuance of referrals for telemedicine services. Similarly, there are no restrictions on the procedure for issuing electronic prescriptions. According to Article 60 of the Medical Treatment Law, the issuance and production of prescriptions is determined by the Cabinet, specifically, Cabinet Regulation No. 175 on the Manufacture and Storage of Prescription Forms, as well as Writing out and Storage of Prescriptions of 8 March 2005. Paragraph 29 states that prescriptions "shall be written out electronically in the health information system" and only the cases specified in paragraph 29 require prescription to "be written out on the form of a specific sample" (MK noteikumi Nr. 175, 2005). In addition, prescriptions for medicinal products issued in a Member State are recognised if they contain the information required by Commission Implementing Directive 2012/52/EU of 20 December 2012. This implies that prescriptions for medicinal products may also be issued in the case of telemedicine services, since the decision to issue a prescription is taken by the attending physician. In contrast, the procedure for issuing a sick note in telemedicine cases is limited.

Pursuant to Article 53 of the Medical Treatment Law, Cabinet issued Regulation No. 152 on the Procedures for the Issuance of Sick-Leave Certificates of 3 April 2001, paragraphs 10 and 10.1 which stipulate that a "sick-leave certificate shall be issued by a doctor or the assistant to a doctor of a medical treatment institution on the basis of a personal inspection and examination of a person", but personal inspection and examination may be omitted in cases:

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- 1) where isolation is necessary during quarantine;
- 2) in connection with the care of a child;
- 3) in connection with the care of a child under 14 years of age if isolation is necessary during quarantine;
- 4) in the event of contracting a dangerous infectious disease;
- 5) after hospital treatment, for the period recommended by the hospital (MK noteikumi Nr. 152, 2001).

When receiving remote medical services, the issue of a sick-leave certificate is limited to the cases specified in the Cabinet Regulations. This restriction applies to telemedicine regardless whether the services are provided across the border or domestically. The provision of telemedicine services in cases of seriously infectious diseases is only part of the scope of remote healthcare. Telemedicine can be implemented through, for example, telemonitoring, which can improve the quality of life and access to healthcare for people suffering from chronic diseases, teleconsultation, and other forms of healthcare delivery (European Commission, 2012, art. 21). Problems arise when remote healthcare is provided for non-infectious diseases and the patient's health condition requires a sick note to be issued, but a physical consultation is not possible (due to cross-border healthcare or long distances between the patient and the attending doctor, or due to the patient's mobility problems, health condition, etc.). Thus, to facilitate access to treatment and sick leave, the regulatory framework should be improved and include a broader range of cases in which a healthcare professional would be entitled to issue sick leave, specific cases of remote treatment, and support for active cross-border telemedicine services.

In the judgment of the District Administrative Court *Rīgas tiesu nams* of 27 March 2013 in case No. A420449112, the Court found justifiable the conclusion of the Health Inspectorate that determination of inability to work without examining the applicant on that day serves as valid grounds to declare that the first sick-leave certificate issued was unjustified (Spriedums lietā Nr. A420449112). Based on this opinion, the author would like to point out that the provision of telemedicine services could, in some cases, be considered as examination of the patient even though it does not take the form of a face-to-face consultation. For this reason, it is necessary to differentiate the types of telemedicine services and to define competences of medical practitioners, because the legislature should define specifically what constitutes a "personal examination" or "examination", including provision of certain types of telemedicine services, which could be used to identify the validity of a sick-leave certificate.

The Telemedicine Experience in Ukraine

At this difficult time, while Ukraine battles the Russian army, the state's citizens face many challenges. One of the main challenges is the almost complete lack of access to proper medical services in the territories temporarily occupied by the Russian invaders.

According to published sources, nearly 900 health institutions have been damaged and 127 hospitals have been completely destroyed in Ukraine. According to Ukrainian Health Minister Viktor Lyashko, 90 ambulances were shot and rendered inoperable and will never go on duty again. In addition, 250 vehicles have been seized by the occupants (Head of the Ministry of Health, 2022). Unfortunately, these figures keep increasing every day.

Considering the circumstances, the most effective mechanism for individuals to access healthcare is complete digitalisation – accessible telemedicine, electronic health records for patients and doctors, electronic prescriptions, eSubmission and eCTD format for all drug registration procedures, and other necessary components.

According to the provisions of Order of the Ministry of Health of Ukraine No. 681 of 19.10.2015 that established the procedure for the organisation of medical care at the primary, secondary (specialised), tertiary (highly specialised) levels using telemedicine (hereinafter – the Procedure), this is a set of actions, technologies, and measures used in the provision of medical care, using remote communication by means of electronic messaging (The procedure for the organisation of medical care, 2015).

The main goal of telemedicine in Ukraine is to improve public health by providing equal access to quality medical services. The main objectives of telemedicine are:

- 1) to ensure delivery of medical aid to a patient when distance is a critical factor for its delivery;
- 2) to preserve medical confidentiality and privacy, integrity of medical information about a patient's health condition;
- 3) to create a unified medical space;
- 4) to help improve the quality of care and optimise organisation and management of healthcare;
- 5) to form systematic approaches to implementation and development of telemedicine in the healthcare system.

The telemedicine network, through which patients receive care, includes healthcare institutions regardless of ownership and legal form, and physical persons – entrepreneurs engaged in economic activity in medical practice. Participants join the system and use the internet platform for telemedicine (paragraph 1, section III of the Procedure). Healthcare institutions wishing to work with the telemedicine portal conclude a contract with the other participants. The number of telemedicine portals is unlimited. Healthcare professionals have the right to connect to different portals. The participants of the portal communicate by means of electronic messages. Each physician is required to have an electronic digital signature (Procedure for the organisation of medical care, 2015).

The telemedicine network enables one to:

- 1) streamline and systematise the process of medical aid delivery using telemedicine;

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- 2) ensure compatibility of information and data in delivery of medical aid using telemedicine;
- 3) ensure use of medical information standards in the process of medical aid delivery using telemedicine;
- 4) monitor quality of medical aid delivery using telemedicine.

Medical care with the use of telemedicine is carried out in telemedicine offices operating within healthcare institutions and ensuring provision of high-quality, timely medical care to patients (Procedure for the organisation of medical care, 2015).

By analysing the situation, some major problems can be identified that are either existent or are expected to arise in the near future in the Ukrainian healthcare system and that can be solved with the use of telemedicine:

- 1) An extremely urgent issue is provision of necessary medical care to people who have been forced to leave their homes and are temporarily living in other areas (internally displaced persons);
- 2) People who have experienced acute stress will suffer from post-traumatic stress disorder in about a third of all cases in a short term. The expected number is likely to be around two million within the country alone. The problem is just as serious for the estimated more than one million refugees who have been granted temporary asylum in European countries. This is again a real problem, as effective professional psychological assistance can only be provided by native speakers of Ukrainian or Russian, who are hard to find abroad. Very few refugees speak European languages at a sufficient level to receive psychological assistance from professionals;
- 3) Spread of COVID-19 and other infectious diseases (e.g. monkeypox, recognised by the WHO as a new world epidemic) and the like is still relevant;
- 4) Inadequate provision of healthcare and hospitals in Ukraine with appropriate computer equipment and specialised software and hardware to perform the functions of the telemedicine portal, video and audio communication software and hardware, technical devices equipped with data storage and transmission facilities and electronic messages, specialised software for the transmission, storage, and interpretation of digitally recorded images, including radiology diagnostics.

The key challenges outlined above need to be urgently addressed. Statistics show that about 6.5 million Ukrainian citizens are considered internally displaced persons. The vast majority are residents of war-torn regions and occupied territories. Since the start of the war, 3.3 million people have left Ukraine. Consequently, the humanitarian crisis is likely to spread to other European countries if the situation does not change drastically in the near future.

For this reason, online services are becoming vital. For example, the Ministry of Health of Ukraine has launched an initiative regarding the possibility for citizens of

Ukraine, even those in the temporarily occupied territories, to call a single phone number where the call is forwarded to the appropriate doctor/specialist. While this is an extremely important and useful initiative for the Ministry, the question arises as to how effective it is for the nearly seven million internally displaced people. It seems that this can only be a first, urgent step that needs to be followed by systemic solutions.

Regarding the issue of providing emergency psychological assistance to the population and preventing occurrence of consequences, including post-traumatic stress disorder, it can be claimed that Ukrainian specialists are very quick to solve the problem. There are about a thousand different online platforms providing psychological services in the state. For example, specialists at the Faculty of Humanities and Law at the M. E. Zhukovsky National Aerospace University – Kharkiv Aviation Institute in Kharkiv, Ukraine, readily provide online consultations, webinars, and other scientific and practical activities (Faculty of Humanities and Law of the National Aerospace University, 2022).

Focusing on telemedicine, many proposals have been seen from colleagues abroad who offer their own telemedicine platforms. This allows many doctors to consult Ukrainians on voluntary basis. Nevertheless, almost none of the platforms currently have a user interface in the Ukrainian language. This concerns the user interface for both medical staff and patients. After all, psychological aid can be most effective only when a psychologist or psychiatrist speaks the patient's native tongue. Unfortunately, there are very few such specialists abroad, and those who could work remotely within Ukraine are suffering from the war themselves.

Leadership of the Ministry of Health and all citizens of Ukraine face another massive problem – the spread of COVID-19 and other infectious diseases. Doctors communicate with COVID-19 patients being treated at home as well as those who are unable to see a doctor in person for the duration of the self-isolation. Some health services offer free consultations with family physicians, general practitioners, and paediatricians. For example, as part of the 2022 campaign Save a Doctor – Choose Online, many Ukrainian and foreign companies provided the Telemed24 platform for teleconsultations free of charge during quarantine events.

Additionally, unsatisfactory equipment of Ukrainian healthcare institutions and hospitals with appropriate computers and specialised software and hardware to perform the functions of telemedicine is very distressing for the national healthcare system. However, Ukraine has received help from its foreign colleagues. For instance, a patient was admitted to a Lviv hospital with severe trauma after a shell had exploded next to him. As the nature of the patient's injuries was unfamiliar to civilian medicine, to provide him with the best possible care, the doctors decided to involve colleagues from other clinics and countries with extensive experience in treating similar injuries. They did it in a unique way due to an augmented reality device from the American company RealWear (The development of telemedicine, 2022).

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Ukrainian doctors will also receive 10,000 state-of-the-art laptops with the help of the Ministry of Health and the Ministry of Digital Transformation. The equipment has been purchased by the French Ministry of Economy, Finance, Industry, and Digital Sovereignty at the request of Ukrainian authorities. The provision of medical institutions with high-quality internet and computers is an important part of the plan of digitalisation of the medical sector, emphasises the Ministry of Digital Transformation. Modern equipment combined with appropriate software will make doctors' everyday work more efficient and facilitate online interaction with patients. This is expected to significantly spare customers' time in receiving medical services and make healthcare more accessible to citizens (France will hand over 10, 000 modern laptops to Ukrainian doctors, 2022).

Telemedicine in Ukraine is developing at an accelerated pace. However, the country faces several complex issues that must be addressed comprehensively, involving foreign experience in every possible way.

Conclusions

Different healthcare professionals may currently be involved in provision of telemedicine services at different operational levels. For example, some specialists could provide remote consultations where no face-to-face examination of the patient is required, and possibly perform remote diagnostic measures, but to a limited extent (if the necessary communication and diagnostic technologies are available to the patient and the medical institution). However, there is currently lack of awareness, experience, and technology in the Republic of Latvia for safe performance of remote medical manipulations. For this reason, it is necessary to define types of telemedicine services to be provided and to set limits on their implementation in the national regulatory framework, while also including the scope of knowledge and, consequently, the permissible competence of specialists in the field.

The authors believe that the existing legal framework needs to be substantially improved in order to introduce appropriate requirements in the existing regulatory framework for medical institutions providing only telemedicine services. As a result, the Latvian legal system would not only recognise medical institutions providing only telemedicine services but also regulate the minimum requirements necessary for their proper provision.

Given the fact that telemedicine is not a traditional way of healthcare delivery, it is necessary to define and outline telemedicine fundamentals, which include definitions of the types of telemedicine delivery practised in Latvia, its general implementation requirements, and limitations. This requires introduction of guidelines for the provision of telemedicine services and the basic principles for its implementation, paying additional attention to requirements for communication security. There are several aspects of the Latvian regulatory framework that would need to be improved or updated to

ensure safe and effective telemedicine practice in Latvia, while the country is currently in the early stages of integrating telemedicine into the healthcare legal system, which requires development of a comprehensive regulatory framework and core principles for telemedicine.

To implement the issuance of sick-leave certificates based on telemedicine consultations, it is necessary to ensure that telemedicine services are monitored to avoid the issuance of fictitious certificates. After remote communication with a patient, if a healthcare professional has identified a medically justifiable reason for issuing a sick-leave certificate, they could make a note in the patient's medical records whether the certificate has been issued by means of a face-to-face or telemedicine check-up.

Acknowledgements

The article is the part of the project “Conference “Legal Comparison to the Regulations for Remote Treatment Between Germany and the Baltic States””. This Baltic-German University Liaison Office project is supported by the German Academic Exchange Service (DAAD) with funds from the Foreign Office of the Federal Republic Germany.

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