

TELETIP VE TIBBİ MALPRAKTİS

TELEMEDICINE AND MEDICAL MALPRACTICE

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ÖZET

Sağlık hizmetlerinde dijitalleşme; yapay zekâ, robotik cerrahi, giyilebilir sağlık teknolojileri, nanoteknoloji, 3D yazıcılar, sanal gerçeklik uygulamaları, elektronik reçete ve uzaktan sağlık sunumu hizmetleri (teletıp) gibi birçok konuyu kapsamaktadır. Bu gelişmeler arasında teletıp, yakın gelecekte klasik hasta-hekim ilişkisinde önemli değişikliklere neden olması beklenen uygulamalardan biridir. Teletıp, mesafenin sorun olduğu durumlarda sağlık hizmetlerinin sağlanması ve desteklenmesi için elektronik bilgi ve iletişim teknolojilerinin kullanılması olarak tanımlanmaktadır. Dünya Sağlık Örgütü'ne (DSÖ) göre teletıp uygulamaları teleradyoloji, teledermatoloji, telepatoloji, telepsikiyatri ve telemonitorizasyon olmak üzere beş ana kategoriye ayrılmaktadır. Türkiye'de COVID-19 salgını sonrasında artan ihtiyaç ve talep nedeniyle 10.02.2022 tarihli Resmi Gazete'de "Uzaktan Sağlık Hizmeti Sunumu Hakkında Yönetmelik" yayımlanmıştır. Hızlı, etkin ve mali açıdan sürdürülebilir bir sağlık hizmeti olan teletıp uygulamalarının çeşitli avantaj ve dezavantajları bulunmaktadır. Bu sistem, sağlık hizmetlerinin kalitesinin artırılması, ekonomik maliyetlerin azaltılması, farklı yaş gruplarında ve/veya kırsal kesimde yaşayanlar da dâhil olmak üzere herkese eşit ulaşılabilir sağlık hizmeti sunulması, acil servisin iş yükünün hafifletilmesi, sağlıkta artan şiddet olaylarının önüne geçilmesi gibi başlıca avantajlar sunmaktadır. Yüz yüze iletişim eksikliği, sigorta ödeme kapsamı ve dijital güvenlik sorunlarının yanı sıra sistemin olası dezavantajları da bulunmaktadır. Gerekli yasal altyapının olmaması ve teletibbin yeni uygulanmaya başlaması malpraktis açısından önemli riskler oluşturmaktadır. Bu durumlarda aydınlatılmış onam, tanı, takip, tedavi, konsültasyon ve tıbbi kayıt süreçlerinin yanı sıra teletibbin klasik tıp eğitimi öğretilerinden farklarının ortaya konulması ve hukuki çerçevesinin net bir şekilde çizilmesi tıbbi uygulama hatası değerlendirmesi için önemlidir. Çalışmamızda teletibbin uygulandığı ülkelerin uygulamalarındaki malpraktis yaklaşımları dikkate alınarak Türkiye'deki olası süreçlere yol gösterilmesi planlanmaktadır.

ANAHTAR KELİMELER: Giyilebilir elektronik cihazlar, Teletıp, dijital teknoloji, Malpraktis, Robotik cerrahi işlemler.

ABSTRACT

Digitization in healthcare covers many topics such as artificial intelligence, robotic surgery, wearable health technologies, nanotechnology, 3D printers, virtual reality applications, electronic prescription, and remote health delivery services (telemedicine). Among these developments, telemedicine is one of the applications that are expected to cause significant changes in the classical patient-physician relationship in the near future. Telemedicine is defined as the use of electronic information and communication technologies to provide and support health services in situations where distance is a problem. According to the World Health Organization (WHO), telemedicine applications are divided into five main categories: teleradiology, teledermatology, telepathology, telepsychiatry, and telemonitorization. Due to the increasing need and demand after the COVID-19 epidemic in Turkey, the "Regulation on the Delivery of Remote Health Services" was published in the Official Gazette dated 10.02.2022. Telemedicine applications, which are fast, effective and financially sustainable healthcare services, have various advantages and disadvantages. This system offers main advantages such as increasing the quality of health services, decreasing economic costs, providing equally accessible health services to everyone, including those living in different age groups and/or rural areas, alleviating the workload of the emergency service, and preventing the increasing incidence of violence in health. Besides lack of face-to-face communication, insurance payment coverage, and digital security problems are the possible disadvantages of the system. The lack of the necessary legal infrastructure and the new implementation of telemedicine pose significant risks in terms of malpractice. In addition to informed consent, diagnosis, follow-up, treatment, consultation, and medical record processes, in these cases, it is important for medical malpractice evaluation to reveal the differences between telemedicine from classical medical education teachings and to draw its legal framework clearly. In our study, it is planned to guide the possible processes in Turkey by considering the approaches to malpractice in the practices of countries where telemedicine is applied.

KEYWORDS: Wearable electronic devices, Telemedicine, Digital technology, Malpractice, Robotic surgical procedures.

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INTRODUCTION

The term 'technology' is derived from the words 'craft/skill/handicraft' and 'science.' By definition, technology is the common name for all skills, methods, processes, a compilation of techniques, or scientific research used in the production of goods or services or the realization of the purposes for this (1). Technology in the health field is defined as the organized application of devices, drugs, vaccines, procedures, and systems developed to increase service efficiency, solve individuals' health problems and improve their quality of life (2).

The way to reduce costs while increasing the quality in the field of health is to use technology most accurately, and one of the most important ways is digital transformation. Some of the steps taken so far within the scope of the digitalization of health services in Turkey can be counted as Electronic Document Management System (formerly name EBYS in Turkish), Accessible Health Communication Center (formerly name ESIM in Turkish), Personal Health System (formerly name e-Nabız in Turkey), Medulla, Central Physician Appointment System (formerly name MHRS in Turkish) (3). Digitization in healthcare covers many topics such as artificial intelligence, robotic surgery, wearable health technologies, nanotechnology, 3D printers, virtual reality, electronic prescription, and telemedicine (2, 4). Among these are telemedicine applications that can change the dimensions of the patient-physician relationship in the future. According to the origin of the word, it is understood that the content of telemedicine is the combination of technological activities in the field of informatics and medicine. Although the terms telemedicine, remote health care, or telehealth can be used interchangeably or as a sub-topic in different sources, the most frequently used term is telemedicine. Telemedicine, in other words, remote health services, is expected to be used more widely in Turkey soon and is defined as the use of electronic information and communication technologies to provide and support health services in cases where distance is a problem.

The principles of telemedicine applications are to provide the connection between distant

users by using various telecommunication tools, to solve patients' health problems, and to provide medical benefits using these applications.

According to WHO, telemedicine applications are classified into five main categories: teleradiology, teledermatology, telepathology, telepsychiatry, and telemonitorization. However, telemedicine applications exist in many clinical branches apart from these topics. According to its application areas, it is used in a wide spectrum of branches such as teledietetics, teleophthalmology, teledialysis, teleoncology, telepharmacy, teleneurology, telecardiology, teleconsultation, televisiting, telementoring, and even tele(robotic) surgery (5).

Telepsychiatry, one of the common areas of use of remote health services, is used in diagnosing, following up, and treating mental pathologies. It is possible to prevent fatal outcomes in cases with delayed admission to the hospital through remote follow-up (6, 7).

While telepathology is the digital examination of pathological samples, tele-dietetics is the diet practices via remote connection. Tele-dermatology, a type of application in which skin diseases are followed up and treated remotely without the patient's application, provided that a high-resolution telecommunication system is used, provides beneficial results in clinics such as wound care centers (8).

Telemonitoring is used in patient populations that need constant monitoring, such as hypertension, chronic heart and lung diseases, diabetes, pregnancy processes, and geriatrics. Real-time alerts reach the health center through the systems established with the appropriate infrastructure and save time for the necessary interventions in risky situations.

Telementorship is sharing information between physicians in different places through remote communication in the applications made to the patient. For example, while a surgeon may support the surgical intervention by directing another physician in real-time during an operation, it can be applied as remote guidance and evaluation of forensic autopsy findings of a general practitioner who does not have forensic medicine training (9).

Telesurgery is the most advanced type of telemedicine application. Surgical procedures will be possible to perform thousands of kilometers away from the patient with 3D imaging systems, fast and uninterrupted internet infrastructure, and appropriate medical technology. Today, robots such as Da Vinci and Zeus, used in several surgical procedures, are planned to operate via remote connection, and this system is also called cyber surgery (10, 11).

Telemedicine applications, considered a suitable method for the future in today's conditions, have various advantages and disadvantages for the patient to reach an effective health service and the health institution to provide fast, effective, and financially sustainable health care to the patient.

ADVANTAGES OF TELEMEDICINE

Health is one of the most important expense items in the modern world. As a result of the defensive medicine practices developed with the increase in medical malpractice cases, the number of examinations of the patients and the required examinations has increased, and an increase is observed in the financial resources allocated to health. In transforming health systems, the main expectation is a decrease in economic expenses along with an increase in the quality of health services. It is planned that telemedicine services will cause cost reduction in health expenditures in the long term (12).

Telemedicine does not only save time and cost for healthcare providers. A study from the USA determined that a patient had to travel for 37 minutes for outpatient services and 84 minutes for clinical services, and the doctor's visit took an average of 15 minutes (13). In this respect, remote health care minimizes both travel time losses and travel expenses for patients and sometimes accompanying relatives (10).

Not all people have equal conditions in accessing health services. Unfortunately, the number of specialist physicians per capita in big cities decreases in rural areas. Since the social state approach aims to provide equal health services to all citizens, telemedicine services will significantly benefit those in rural areas to reach specialist physicians (14). One of the most critical health problems in

Turkey is unnecessary emergency service applications. It is also predicted that there will be a significant decrease in the number of 'non-emergency' patients who admit to the emergency department after the opportunity to meet with the physician remotely. As a result, it is assumed that the waiting time of people in the health system will decrease.

Violence in health is one of the most important problems that disrupt the motivation of health workers in Turkey. Since remote health care does not pose a risk of physical contact at this stage, it is thought to reduce the risk of violence as well. However, although the possibility of physical attack decreases, it remains unclear how the process will affect the scope of verbal abuse and insult.

Telemedicine service ensures crucial protection in terms of processes where patient-physician contact poses a serious risk, especially in cases of infectious diseases such as pandemics. Also, providing preventive health services to many people online simultaneously in cases where the masses are affected, such as disasters and wars, is considered one of the critical advantages of telemedicine technology. It is noteworthy that it will increase survival by preventing the transmission of infection from the hospital in patients with immunosuppressive or other immune system disorders, the elderly, and infants (15).

The telemedicine system does not only include people meeting with the physician remotely within their means. Besides, providing interviews with the help of other intermediary health institutions is another advantage. In the 2nd paragraph of the 7th article of the published regulation, it is stated that "*physician can provide remote consultation service to her patient through another health institution*" (16).

DISADVANTAGES OF TELEMEDICINE

The basis of the examination between the physician and the patient consists of personal communication. One of the most critical doubts is that remote interviews will cause problems in patient compliance with the treatment process. It is predicted that problems such as insufficient understanding of the treatment and not using the drugs at the right time and doses will

come with it. Also, it is another negative situation that the professional satisfaction levels of physicians who communicate with their patients remotely may be negatively affected.

A study performed in England concluded that safe care could not be provided by telemedicine technology providers at a rate of 43%, and inappropriate antibiotic and opiate-based drug prescriptions increased without the knowledge of the family physicians of the patients (17).

The decrease in face-to-face patient-physician meetings creates question marks because it includes the possibility of missing clinical findings that patients are unaware of but that a healthcare professional may notice (15).

Telemedicine service ultimately requires a certain technological infrastructure. The fact that people do not have the same technological and economic opportunities is a limitation among the patients to be served. Besides, non-compliance with the process will be another disadvantage for elderly patients who are far from using technology.

When undesirable situations are encountered within the scope of remote health services with the help of an intermediary health institution, disruptions may occur in the process since it is not determined who is responsible. Especially in case of errors that may develop during image and data transfer or misdiagnosis or incomplete diagnosis due to low-resolution image transfer, determining who will be responsible from the beginning can prevent possible confusion (18). The digital world has created new risk factors such as security problems along with conveniences. A significant part of the resources used is on protection programs for cyber threats, and the digitization of health requires consideration of cyber threats. It should not be ignored that both the disruptions in the digital storage and protection of health data and the attacks on telemedicine application infrastructures can render the system unusable.

With telemedicine technology, patient-physician interviews should be recorded for both possible forensic processes and quality control. Important personal data of the patient and dialogues in the interview content should

be protected within the scope of keeping personal data. However, in the modern world, the protection of digital storage is considered a critical problem, and it is known that telemedicine interviews will result in judicial processes such as violation of private life, as they fall into the hands of non-processors. Data protection and storage will also cause significant economic expenses in the future.

EVALUATION OF TELEMEDICINE IN TERMS OF MALPRACTICE

According to the contract between the physician and the patient, the physician is responsible for applying the most appropriate treatment to his/her patient in light of current medical knowledge. This responsibility is valid both in face-to-face patient interviews and examinations as well as in procedures carried out within the scope of telemedicine. There must be real communication between the doctor and the patient to consider malpractice in telemedicine applications. Although there are necessary infrastructure facilities for communication, the disability of the patient's perception and understanding (e.g., drunkenness, hearing or vision limitations, mental illnesses) may cause the physician not to be able to communicate with the patient correctly.

Another requirement sought in the telemedicine system is that the person working as a physician must have received adequate training and that there should be no obstacles to his practice as a medical doctor per the legal rules of the region served (19). In addition to the problems we still face today, such as fake diplomas, a person who graduated from a medical school in a different country should be accepted in terms of equivalence.

The consent of the patients is required both in the face-to-face examination and treatment in the hospital and during the examination, interview, and treatment to be made through the telemedicine system. Therefore, the informed consent of the patient who will receive the telemedicine service is the basis for the operation of the system.

Telemedicine will require a period of familiarization at a certain stage with the innovations it

brings to the familiar patient-physician process. In this process, it is one of the scenarios that are likely to cause delay problems in the timely hospital referral of qualified and complicated patients and poses a risk in terms of malpractice. A study in the USA stated that a general practitioner who evaluated patients remotely after a fracture recommended an orthopedic examination within 24 hours for the complaint of leg swelling in the patient. After the patient died due to deep vein thrombosis and pulmonary embolism on the same day, a malpractice lawsuit was filed against the physician (20).

Although there are opinions that the physician's responsibility is limited in teleradiology and telepathology applications where patient-physician communication is not fully available, in a study, the pathologist defended himself/herself that the necessary doctor-patient relationship was not established since s/he did not examine the patient, did not see, did not treat or prescribe medication after the faulty examination s/he made in a study. However, the court accepted the existence of an express or implied consent contract between the patient and physician for the procedure, and the pathologist was found to be at fault. A similar situation is regularly applied in malpractice lawsuits filed against radiologists who do not frequently meet with the patients they consult (21).

In social life, physicians give advice and warnings to many people because of their social relations. These interviews are held within the scope of social communication, in which professional information is also used. Studies do not hold the physician responsible in such cases where the physician is not aware of his/her responsibility in his relationship with the patient since the communication between the physician and the patient cannot be established sufficiently (20). Studies performed in countries with a telemedicine system report that the number of lawsuits filed with the claim of malpractice is lower than the standard examinations and treatments. Possible reasons for this are listed as hospital examination is recommended for treating complicated cases, suggestions are made for many mild and simple medical complaints in the telemedicine interview, and patients prefer to apply to a hospital for severe complaints (22).

In addition to the innovations telemedicine brings with it, such as easy and fast access to the patient's digital health archive, personal and family medical history information, and daily variables, it also contains deficiencies such as the limitation of the physical examination with visuality. In this regard, researchers argue that telemedicine health service is a fundamental innovation in health with essential advantages and that this innovation certainly brings some shortcomings to its social acceptance. However, it should be approached more positively than face-to-face examination until the system is fully established, considering the social benefit (23).

The issue of determining the responsible person in an undesirable situation that may be encountered if the telemedicine service is mediated by another health institution has not been clarified. This issue needs to be determined by updating the regulations. One of the issues encountered with the use of artificial intelligence in almost every area of life as a result of the advancement of technology, and which still cannot be determined, is the issue of who will take responsibility for the faulty applications originating from artificial intelligence. For example, when the files submitted to the courts are examined, it remains unclear who will be blamed in the criminal process that occurs in the accidents caused by the vehicle during automatic driving within the scope of artificial intelligence (24).

APPROACHES OF SOME COUNTRIES TO TELEMEDICINE MALPRACTICE

It is accepted that the Dutch physician Willem Einthoven started to practice telemedicine with his electrocardiogram transfer. Afterward, telemedicine became widespread with the transmission of radiological images to specialists, starting from the 1950s in the USA (25).

In a study performed in France, especially in terms of online follow-up of stroke patients, the service documentation of the process, the establishment of trust between the parties, and malpractice problems still limit the applicability of telemedicine (26).

In the legal examination of teledermatological evaluations made in Spain, protection

and storage of personal data and access to technological tools are considered common problems, especially in applications that have increased during the pandemic period (26).

In India, another country where telemedicine is used, telemedicine projects were started in 2005, especially in areas such as on-site follow-up of cancer patients and evaluation of mammography examinations by transferring the images to specialists. Also, mediated telemedicine service was developed by connecting 45 remote health institutions to 15 high-level hospitals (27). Although some countries have studies within the scope of telemedicine malpractice, cases involving approaches that can be evaluated holistically were shaped in the USA. Telemedicine, which was accepted by five states in 1992 in the USA, is now legally established in 50 states. However, states have different approaches. These differences are how consent was obtained, the limits of duty of physicians, and the evaluation of negative situations encountered. The common points of the states for telemedicine, as in other countries, are that the person who will provide health services must have a valid and equivalent medical diploma, and there should be no obstacle to practicing medicine.

As it is known, informed consent means informing the patient about the interview, examination, diagnosis, treatment, and complications that will develop afterward and can be obtained verbally or in writing. In non-urgent cases, telemedicine health service delivery should include valid consent. In the USA, the acceptance of informed consent is seen at the beginning of the differences in the states' approaches (28). While some states require written consent from the relevant health institution for people who are examined and treated through telemedicine, many consider verbal and even visual consent during the interview sufficient.

Another difference also appears in the form of obtaining regional permission for telemedicine service within the borders of the states. Some states stipulate the requirement for physicians with a sufficient and accepted medical school diploma to obtain a work permit in the state for telemedicine health service delivery. In a case in 2005, it was reported that a person

with depression and suicidal ideation living in the state of California was evaluated remotely by a psychiatrist in Colorado, within the scope of telemedicine. The patient was prescribed fluoxetine, and following the patient's death due to an overdose of fluoxetine, a lawsuit was filed against the physician by the district attorney. The physician was sentenced to prison because she/he did not have a license to practice medicine in California, according to the decision accepted by the state (29).

In the USA, there are differences in approach between states in evaluating telemedicine as medical malpractice. In a few states, such as Hawaii, it has been accepted that telemedicine brings limitations in patient-physician communication and that both the patient and the physician conduct interviews considering this limitation; therefore, it should be evaluated differently from face-to-face interviews and examinations. New York and many states have accepted that the remote or face-to-face interview does not reduce the responsibility. When the literature is examined, in a case presented by *Macdonald v Schriro*, in the remote video conversation of a prisoner who fell out of a bunk bed in prison, the examination was performed with the doctor's description (23). However, the patient was examined without removing his/her pants, the doctor asked for an MRI after the examination, and anti-inflammatory and symptomatic treatment was prescribed. In the second examination performed by the same physician, three years later, due to persistent knee and leg pain, fractures were detected in the leg bones, and it was reported that the patient had a limited range of motion in the knee. In the lawsuit filed against the physician, it was concluded that the physician was faultless, pointing out that it was known the remote healthcare service carries an increased risk for the patient and the physician compared to face-to-face examinations (23).

Both cases mentioned above are of jurisprudence in this sense. Similar to Turkey, there are regulations regarding the acceptance of telemedicine in the USA, and there is no legal study on the application content, constraints, and limitations. Telemedicine ethics guidelines have been developed by the Ame-

rican Medical Association. These guidelines may be criteria for professional sanctions, but the existence of legal regulation with clear boundaries in possible criminal or compensation proceedings is also evident here (29).

Telemedicine is accepted as a new patient follow-up-treatment system developed to keep up with age with the help of technological possibilities in the digitalized world. Although the expected interest was not provided by patients and physicians a few years ago, remote health care is considered acceptable considering the risk of interruption of the pandemic process in health care studies (30). This situation presents difficulties for both the patient and the physician in terms of compliance, as it is outside the habits.

The situations in which remote health care is most beneficial, processes such as mass disasters or war situations where the health service is not accessible, and due to both climatic limitations and difficulties in mobilizing the patients are considered difficulties in hospital transportation (31). During the pandemic process, it has been realized how useful telemedicine can be, both in limited areas in Turkey and in other countries.

Although it is socially accepted, the transactions must also be legally grounded. Even though the guidelines for the remote evaluation of radiological examinations have been published in Turkey, the regulation that includes the general objectives and requirements regarding telemedicine was published in the Official Gazette shortly (16). As the process progresses, it is possible to make updates in the regulation within the scope of the needs that arise.

In telemedicine applications, it is obligatory to clarify the issues, such as in which environment and for how long the patient records will be stored and who has the authority to access them. Considering that these applications will also be used by the private sector, as stated in the opinion of the Turkish Medical Association Ethics Committee published in 2021 (32), a new trade area may arise in the health care sector with the spread of telemedicine technology, systemic medical, legal and ethical infrastructure should be provided together to solve many problems, such as ensuring

that this new system is reliable, equal and accessible for everyone, providing sustainable economic performance, and providing legal protection for practitioner health personnel in terms of unnecessary malpractice complaints.

In Turkey, the physician's performance is the determining factor in the payments made to the physicians working in public. It has not yet been clarified whether remote health service delivery will be included in the scope of face-to-face examination for public physicians. Again, how this issue will be evaluated within the scope of performance should be reported by regulations or directives. Other issues that need to be clarified are whether the social security institution or other insurances will make payments within the scope of remote health services and whether to receive contributions. In addition to performing patient interviews remotely, the fact that medical education is started with online courses means that we will see the effects of digitalization in education shortly. When examining other health-supporting activities of the digital world, heart rate monitoring and exercise recommendations of smartwatches are among the innovations used today. It is foreseen that smartwatches will measure blood pressure and hemoglobin level in the blood accurately in the future. Again, electrocardiogram shirts, electroencephalogram caps, and auscultation devices have been developed within the scope of wearable technologies. In addition to all these innovations, telemedicine is one of the most significant innovations with the ability to examine the patient remotely and issue prescriptions directly. The next stage is the widespread use of cyber surgery, which allows remote surgical interventions. Cyber surgery is defined as the remote access operation of surgical robots (Da Vinci, Intuitive Surgical, Zeus, and others) that are still actively used in today's hospitals. In cases where 5G and other electromagnetic communication is provided, physicians will be able to perform surgery by connecting to robots in a hospital in another country. As a result, the digital world is changing our habits with the innovations it brings.

The fact that there are not many publications in the literature on telemedicine malpractice

and, in some cases, the inaccessibility of the content due to the confidentiality decision constitutes a limitation to the studies (33, 34). We anticipate that a faster and more effective evaluation will be provided against telemedicine malpractice claims if problems are encountered, and solutions to be encountered with examples of fictional cases are brought forward.

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