

TELEMEDICINE: ADVANTAGES AND RISKS

Guryleva ME¹, Nezhmetdinova FT² ✉

¹ Kazan State Medical University, Kazan, Russia

² Kazan State Agriculture University, Kazan, Russia

New forms of medical aid have been widely used in the presence of global digital transformation of medicine. This concerns not only medical equipment and ensuring access to health services, but also the entire healthcare system and doctor-patient relationship. It's impossible to imagine modern medicine without digital decisions. Digitalization of the available information and making it available for all participants of the doctor-patient system form the basis of subsequent development of clinical practice, breakthrough in scientific research, improved patient-centered healthcare, and comfort of system operation for people. This requires a general culture of values and ethical standards that should correspond to digital decisions. The article deals with the reasons for actualization of remote forms of doctor-patient communication during the COVID-19 pandemic illustrated by telemedicine. Principle forms of telemedicine under modern conditions caused not only by the pandemic but also by digital transformation of medicine have been reviewed. Special attention is given to possibilities of telemedicine from the point of view of benefit, as well as to legal and ethical aspects from the point of view of risks.

Keywords: telemedicine, doctor-patient relationship, digital transformation of medicine, advantages, risks, ethics, law

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✉ **Correspondence should be addressed:** Farida T. Nezhmetdinova
ul. K. Marxa, 65, Kazan, 420015, Russia; nadgmi@mail.ru

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ТЕЛЕМЕДИЦИНА: ПРЕИМУЩЕСТВА И РИСКИ

М. Э. Гурылёва¹, Ф. Т. Нежметдинова² ✉

¹ Казанский государственный медицинский университет, Казань, Россия

² Казанский государственный аграрный университет, Казань, Россия

В условиях цифровой трансформации медицины в мире получили распространения новые формы оказания медицинской помощи. Это не только коснулось медицинского оборудования и организации доступности медицинских услуг, но и затронуло всю систему здравоохранения, взаимоотношений врача и пациента. Современную медицину уже невозможно представить без цифровых решений. Оцифровка имеющейся информации и обеспечение доступа к ней всем участникам системы «врач — пациент» — основа дальнейшего развития клинической практики, прорывов в области научных изысканий, повышения уровня пациентоориентированности здравоохранения, комфортности работы системы для людей. Это требует выработку общей культуры ценностей и этических норм, которые должны соответствовать цифровым решениям. В статье рассматриваются причины актуализации дистанционных форм общения врача и пациента в условиях пандемии COVID-19 на примере телемедицины. Рассмотрены основные формы телемедицины в современных условиях, вызванных не только пандемией, но и цифровой трансформацией медицины. Особое внимание уделяется возможностям телемедицины с точки зрения пользы, правовым и этическим аспектам с точки зрения риска.

Ключевые слова: телемедицина, взаимоотношения «врач и пациент», цифровая трансформация медицины, преимущества, риски, этика, право

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✉ **Для корреспонденции:** Фариды Тансыковна Нежметдинова
ул. К. Маркса, д. 65, г. Казань, 420015, Россия; nadgmi@mail.ru

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Telecommunication technologies appeared not today and not even yesterday, but owing to the restrictions of COVID-19, the so-called Black Death of the 21-st century, humanity came across a need to fundamentally change the interrelation process by limiting personal contacts to the maximum extent. Thus, remote methods of communication were developed. COVID-19 made humans look at communication both within and between the countries from a different perspective, produced a significant effect on organization and development rate of all spheres of a human activity, urged to seek for new possibilities of building interpersonal relationships. Under such conditions, medicine has been at the forefront as people still suffer from various diseases and require medical aid on a

constant basis, whereas epidemiological limitations need new forms of safe interaction. Telemedicine has turned into a form of human interaction.

RELEVANCE

In his Address to the Federal Assembly, the President of Russia V. V. Putin has stated as follows: 'Healthcare information support should make a contribution to the increased accessibility of medical aid; it's necessary to establish electronic cooperation between medical institutions, pharmacies, doctors and patients within three years' [1]. And it makes so. Telehealth consultations constitute a relevant and operating method.

They can be conducted in real time or be delayed [2]. Online consultations require good technical means and provide excellent results. Thus, they allow communication of different medical specialists parted by distance, examine a patient here and now, interrogate a patient, hold a discussion and arrive at a collective decision, which is extremely important in case of a medical emergency, for patients without typical symptoms and with severe complications. Delayed consultations are effective, successful, and can be conducted by highly trained specialists from the leading clinics. Delayed (or asynchronous) telecommunications are commonly used to interpret X-ray films and other digital images, results of functional tests (for instance, ECG, spirometry), and to assess their dynamics. The President's appeal was followed by development of Healthcare National Project. It is assumed that its implementation (including implementation of Telehealth Consultations subsystem) will enable to achieve the following goals of healthcare in the country: decline in mortality in the working-age population (up to key values of 350 cases per 100,000 of population), cardiovascular disease mortality (up to 450 cases per 100,000 of population), neoplasm related mortality including malignant ones (up to 185 cases per 100,000 of population), infant mortality (up to 4.5 cases per 1,000 of newly born babies); mitigation of staff shortage in medical organizations providing primary health care; optimal availability of medical aid for population (including residents of remote populated areas); and optimizing healthcare organizations [3, 4].

HISTORICAL BACKGROUND

The idea of telecommunications is not new. The first remote visual examination of children was carried out in 1924. Later telehealth consultations were used to control health of sailors and astronauts. Doctors have been using the Internet for remote monitoring of patients' condition, storage and transfer of data since the 1990s [5]. Remote monitoring is especially good to control health of cardiac patients, patients with diabetes mellitus, and subjects participating in clinical trials [6]. The term 'teleconference' has become part of contemporary practice. But it must be remembered that using a telehealth consultation is the right of both a doctor, and a patient; and this right should not prevent patients from obtaining medical aid in person, but needs just add to it, as solicitation of medical services is inadmissible. It's not an intention to avoid personal conversation with a patient, but a forced necessity. Provision of medical care through telehealth consultations is not a separate type of a medical activity. It is used as a technology constituent when performing works not included into a medical activity [7, 8]. In our country, telehealth services are covered with compulsory health insurance based on targeted tariff agreements generated by regional Territorial Funds of Compulsory Medical Insurance, regional public authorities and insurance companies, additional medical insurance and personal finances.

According to the World Health Organization, telemedicine is provision of aid to healthcare specialists who use information and communication technologies to exchange the required information for diagnostics, treatment and prevention of diseases and traumas, conduct trials and estimate the results, and ensure continuous education of medical specialists in order to improve population health and develop professional communities [2].

Among information and communication technologies (IT-technologies) used in medicine, telehealth technology is most widely utilized to support decisions, manage (material and intellectual) resources, optimize logistics and interaction

between different medical institutions and levels of medical aid. Telemedicine standardizes values of accessibility and quality of obtained medical aid and is absolutely irreplaceable when the geographic distance between a patient and a healthcare professional is a critical factor. Telemedicine is implemented in two directions: 1) when doctors interact with patients and their relatives; 2) among medical workers. The basic trends in telemedicine for the 'doctor-patient' system are represented by remote online, and delayed medical consultations at all stages of medical work (when rendering primary, specialized, high-tech, urgent, palliative medical care), home telemedicine (especially for remote and hard-to-reach areas), and control of health in limited groups (military personnel, sportsmen, participants of clinical trials) [6, 9]. The doctor-doctor system successfully uses telecommunication-based education (almost the entire system of continuous medical education (CME) is based on remote methods — edu.rosminzdrav.ru -, streaming surgeries live), holds urgent consultations of severely ill and emergency patients, and conferences on the basis of the Federal Telehealth System of the Ministry of Health of the Russian Federation (<http://tmk.rosminzdrav.ru>) [9, 10] generating an electronic medical opinion. Medicinal agents (including narcotic drugs or psychotropic substances) can be prescribed remotely. E-prescriptions are sent directly to allocated pharmacies where patients can obtain medicinal agents prescribed by doctors [11]. If a patient needs prescription to treat a condition that wasn't confirmed during a personal visit, it is necessary to visit a real medical institution as medicinal agents can't be virtually prescribed in this case.

BENEFIT

Telehealth communication has a number of benefits over a traditional doctor's appointment. It can be used when a patient is located in hard-to-reach places, allowing patients from different territories to obtain qualitative aid, and is economically reasonable. With a growth of healthcare expenses in the majority countries (in the U.S., they reached 20% of GDP by 2020), telehealth allows to optimize costs saving doctor-patient time, increasing effectiveness of medical institutions, and reducing a number of doctors' mistakes [12]. Meanwhile, telehealth development is not cheap and inhibited by financial, technical and cultural factors. The first ones include equipment and costly software purchase costs. Computer competence and ability to use equipment both by doctors, and patients is a complex issue. The same is true for organization of training for all parties of the therapeutic and diagnostic process, technical support, and availability of the corresponding infrastructure. Logistical restrictions are associated with accreditation of this type of medical aid provision [13].

A medical institution can be accredited for telehealth service provision only in the presence of a premise equipped in accordance with licensing requirements and when patients go through compulsory identification through the Unified Identification and Authentication System (UIAS). It means that telehealth services can be provided only to the citizens with a validated account on the State Services portal (<https://www.gosuslugi.ru/>), but not to the entire population including the elderly (who don't commonly have proper computer skills and are not registered in the social network), and only at those medical institutions that correspond to the submitted requirements. Moreover, it is obligatory for healthcare professionals to use the Integrated National Information Healthcare System (INIHS): only those physicians included into the Federal Registry of Doctors can provide medical aid [14]. According to the law, a

doctor can provide telehealth services only from the workplace equipped in accordance with licensing requirements, and using the equipment of a medical organization only, etc. Software must comply with all requirements of information safety of the Federal Service for Technical and Export Control, Federal Security Service of the Russian Federation, and Ministry of Health of the Russian Federation [15]. In this case, an issue about **accessibility of medical care** has been raised. It poses a serious ethical problem.

ETHICAL RISKS

Doctor-patient telecommunications require the same conditions as personal communications and exercising all the rights of patients stated in the Declaration of Policy Concerning Patients' Rights in Europe [16], Declaration of Patient's Rights in Russia [17], and Federal Law No. 323-FZ 'On fundamental healthcare principles in the Russian Federation' [18]. First and foremost, it is about **voluntary informed consent** to medical intervention or refusal from such consent and preservation of **confidentiality**. A healthcare worker can't take a medical history, conduct an examination, perform diagnostic and therapeutic activities without a patient's preliminary written consent. When performed online, all the stages of communication with a patient are specific with possible violations of the patient's rights being significantly expanded. A vast amount of confidential information is transferred via the Internet. It can include video files, audio files, texts in the form of medical reports, medical notes, case records, etc. It is exchanged between medical institutions or between medical institutions and medical aid consumers (patients).

Taking into consideration the possibilities of telecommunications, the procedure of healthcare information support is improved. Thus, the Integrated National Information Healthcare System (INIHS) was created containing personal record-keeping data and data of federal healthcare registers, data about medical organizations that provide aid to patients, their medical documentation, data about provided high-tech medical care, and supply of citizens with discount prescription drugs, etc. [14]. The electronic trace data can be posted on the State Services portal (medical certificates, COVID-9 immunization status data, etc.) [19]. This is definitely associated with ethical risks.

In Russia, much has been done during the last decade for legal support of IT-technologies in medicine. Amendments introduced to the Law 'On fundamental healthcare principles in the Russian Federation' [18] regulate the possibility and procedure of remote informed consent of a patient to medical intervention. The Law 'On personal data' describes the principles of personal data processing in state and municipal information systems, rights of personal data subjects existing during such processing, obligations of an operator who acts as a doctor-patient mediator when IT-technologies are used in medical practice [20]. Order of the Ministry of Health of the Russian Federation as of November 30, 2017 No. 965н 'On approval of the procedure of provision and rendering medical aid using telehealth technologies' and Letter of the Ministry of Health of the Russian Federation as of April 09, 2018 No. 18-2/0579 'On the procedure of provision and rendering medical aid using telehealth technologies' that regulate the telehealth method of providing medical health to patients [9, 15]. Separate telehealth standards are included into Government Resolution of the Russian Federation as of May 05, 2018 No. 555 'On the Uniform State Health Information System' [14]. However, there is still much room for improvement.

LIMITATIONS

In accordance with the law, remote patient observation can be provided only following an in-person consultation (examination, appointment); remote correction of previously assigned treatment is justified only if the diagnosis was established and treatment was assigned during a face-to-face consultation with a doctor [18] (Federal Law No. 323-FZ 'On fundamental healthcare principles in the Russian Federation' (2011), art. 36.2 'Peculiarities of medical aid provided using telemedicine technologies'), i. e. a physician has no right to *make* remote diagnosis. Moreover, the Ministry of Health of the Russian Federation sets neither stages of medical aid provision with the use of telehealth technologies, nor structural subdivisions providing this aid that would define minimal equipment of 'a doctor's virtual room'. All this inhibits development of the trend of medical aid provision.

Introduction of new information technologies into medical practice without the corresponding legal support is associated with the risk of litigation involvement [21]. It is a vicious circle: there is a need but no technology is developed; there is liability but not a possibility to prevent it. The Federal Law No. 258-FZ 'On experimental legal regimens in the sphere of digital innovation' [22] was put into force in January 2021. It permits testing of those technologies that can't be regulated yet due to the law constraints (artificial intelligence, blockchain, big data, neurotechnologies, quantum technologies, virtual reality) but would partially settle the defined problem for a limited number of users on a certain territory and during a limited period of time [22]. It is suggested that a special procedure of determining the tariffs of compulsory medical insurance for telehealth consultations and other healthcare digital solutions be implemented. Then use of telehealth consultations and medical decision support systems could be reimbursed with the resources of the Compulsory Medical Insurance Fund.

Cultural limitations of using telehealth technologies are associated with national and age-related preferences of treatment and diagnostic process participants. Thus, the elderly patients prefer face-to-face communication with a doctor, and not all the doctors are ready to provide the aid due to available traditions. It seems that generation Z will be the principal user of this technology.

CONCLUSIONS

Use of telemedicine can violate information safety (violation of patients' personal data safety and breach of confidentiality/medical privacy). Federal Law as of July 27, 2006 No. 152 'On personal data' states that data concerning seeking medical advice, health and diagnosis, other data obtained during a patient's examination and treatment constitute doctor-patient confidentiality [18, 20]. Criminal (art. 137 of the Criminal Code), administrative (art. 13.11 of the Administrative Code) and/or civil liabilities are established for exposing data about the confidentiality [23, 24].

As telehealth consultations are provided through the Internet, data leakage is not excluded with the liability resting with the consulting medical institution. Requirements to the servers with patient-related data and the procedure of access thereto have not been set. It is implicit that when processing and storing the data it's necessary to use data storage and encryption systems and implement other measures associated with personal data storage. However, the data are not regulated in the legislation yet [25]. Moreover, it is

difficult to imagine that physicians can independently deal with information technologies, they need such intermediates as operators. Requirements to the operators who are not medical activity participants but who ensure that patients have access to telehealth services (providing information about medical organizations, online booking an appointment with a doctor, storage of materials, obtaining, acquisition and presentation of data, etc.) are regulated only partially [26]. Operators are not medical workers, they have to protect data from unauthorized access, elimination, modification, blocking, copying, presentation, and distribution, but they take no responsibility for violation of confidentiality [27]. It is obvious that the problems are intensified due to COVID-19 pandemic [28].

Patient identification is an ethical problem too. It is difficult to identify who provides consent at a distance. According to the law, informed consent can be provided either in hard or soft format. Soft format means a document signed with an enhanced encrypted and certified digital signature or a simple

electronic signature using the USIA or a document signed with an enhanced encrypted and certified digital signature of a medical worker [18]. Getting the signature is rather difficult. It significantly influences a wish (and possibilities) of patients and medical workers to use the services and ultimately inhibits telehealth development. Subsequent use of a patient's account doesn't mean that this is done by the patient and not by somebody else challenging the very essence of the patient's voluntary informed consent (geriatric population, patients with neurological and mental disorders, etc.) The issue about anonymous highly-demanded consultations is not settled at all. As a 'telehealth' patient has to enter the portal of public services via his/her record entry only, no anonymity can ever be involved.

Thus, being a technology of communications that facilitates human interactions, telemedicine occupies its own niche and is steadily expanding the sphere of activity. Multiple ethical and legal issues still remain and require to be explored for subsequent development of this direction.

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