

TELEMEDICINE, BETWEEN MEDICAL BENEFIT AND MALPRACTICE: ACTUAL CONSIDERATIONS

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Abstract: *Objective.* Chronic disease is defined as a pathology that appears secondary to environmental factors, exposure, genetics, inappropriate lifestyle, or their combination. It is mandatory to emphasize the importance of chronic disease prevention strategies in order to delay their onset, reduce morbidity and mortality among patients, and decrease the costs of health systems and depletion of medical teams. Telemedicine is diagnosing and treating patients remotely through assisted telecommunication technology. Telemedicine has proven its importance, benefits, and low costs, being initially conceived to provide medical services to less accessible areas. At present, developed and several emerging economies have implemented large-scale telemedicine services. This has opened new debates regarding telemedicine’s legal, ethical, and regulatory issues. This review aims to understand the current state of the art related to the most common ethical issues in telemedicine, the real risk of malpractice and the solutions that have been found so far.

Methods. The current literature research that led to this review was carried out through the PubMed medical database, using specific words and excluding articles older than five years and articles not corresponding to ethical norms, rules, or malpractice in telemedicine. A small analysis base was created, consisting of 7 articles.

Results. Even though the malpractice case reports associated with telemedicine services are currently low, this service’s ethical and legal basis leaves much to be desired. Considering that the medical staff is the same one who practices standard medicine according to Hippocrates’ oath, we can state that the greatest danger of this service is for the medical staff and secondly for the patients, due to their legal unprotection.

Conclusion. In order to transform telemedicine into quality medical service, the ethical regulations must be uniform to those of the standard medical services and to maintain the pace of the technological development in place. The standardized ethical regulations of any country should consider patient informed consent, medical practice license, high standards of patient data protection, state-of-the-art technology to minimize verbal or imaging errors, and adequate patient education to use these services.

Keywords: telemedicine, malpractice, telehealth, ethics.

INTRODUCTION

Chronic disease is defined as a secondary pathology to genetics, environmental factors, or an inappropriate lifestyle. It is characterized by a slow progression in time, with a significant impact on the individual’s quality of life and on the society, he lives in, from a social, medical, and economic point of view. The epidemiology of chronic diseases has increased dramatically in the last 30 years, from 28 million deaths globally in 1990 to 39 million in 2016 in middle-poorly developed countries and developed ones. Life

expectancy is currently declining in future generations due to increased incidence of cardiovascular disease, lower respiratory disease, obesity, cancer, diabetes, and stroke [1, 2].

It is mandatory to emphasize the importance of chronic disease prevention strategies in order to delay their onset, reduce morbidity and mortality among patients and decrease the costs of health systems and depletion of medical teams. The prevention strategies proposed by the specialized medical associations strongly support the importance of patient education and lifestyle intervention [3, 4].

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Telemedicine diagnoses and treats patients remotely through assisted telecommunication technology [5]. It has been used in many medical specialties since the beginning, but interest in this field has grown with the advancement of technology and has become imminent during the COVID-19 pandemic [6]. New terms like connected health, e-health, and m-health have emerged, so telehealth and e-health are considered to be an extension of the original term telemedicine [7].

Telemedicine has proven its importance, benefits, and low costs, being initially conceived as a strategy to provide medical services to less accessible areas. However, developed and several developing countries have implemented large-scale telemedicine services. Thus, with the help of technology, we are able to transport medical knowledge to patients' homes in need. Nonetheless, with great power comes great responsibility, and this gradual change in healthcare services has a significant impact on the decision-making policy of the health authorities. This has opened new debates regarding telemedicine legal, ethical, and regulatory issues [8, 9].

This review aims to understand the current state of the art of the most common ethical issues in telemedicine, the real risk of malpractice and the solutions that have been found so far.

MATERIALS AND METHODS

For this review, we searched the literature using the PubMed database. In the first stage, the search was performed using the following search terms in the title and abstract as follows: (((telemedicine[Title/Abstract]) OR (telehealth[Title/Abstract])) AND ((ethics in telemedicine[Title/Abstract]) OR (malpractice in telemedicine[Title/Abstract]))).

We included full-text articles in English and applied filters regarding the year of publication, namely the last five years (2018 - 2022). After removing duplicates, the list of articles corresponding to the previously established criteria was created. The authors evaluated each article by scanning the abstract to determine whether the purpose of the research was in line with the proposed objective.

The remaining articles were analyzed in full text. Articles whose main topic did not correspond to ethical norms, rules, or malpractice in telemedicine were excluded. In consequence, an analysis base of seven articles was created.

RESULTS AND DISCUSSIONS

We identified a total of 781 records; after applying the filters, 455 articles remained. After removing the duplicates, screening, and full-text assessment, we included seven articles for further analysis in this review (Table 1).

Ethical rules and regulations in telemedicine

From a legal point of view, telemedicine covers two significant areas, namely the doctor-patient relationship (anamnesis, diagnosis, and treatment) and the flow of information. First of all, the risk of misdiagnosis is, of course, increased in virtual consultations compared to standard ones and the legal basis of it is not standardized nor universal. Given that this is controlled by service providers, there is a risk of a decrease in quality to increase the market's growth and be ahead of the competition [17].

Despite the benefits that telemedicine services offer (low cost, quick access to consultations, lack of travel to medical facilities), ethical implications must be treated with consideration and attention. In order to avoid unethical situations, some countries have introduced, as part of telemedicine services, the study permit, which aims to ensure that patients fully understand the confidentiality risks to which they are exposed. Depending on the country where these training policies were implemented, they ranged from verbal to written consent [18].

Given the inequality of worldwide implementation, the novelty of the service, and the lack of precedent in this area, overcoming legal obstacles in telemedicine will be a difficult and a long-lasting process, but not an impossible one.

The World Health Organization (WHO) has defined telemedicine services as online distance health services between medical providers and patients [19]. With the advancement of medical technology and the early introduction of telemedicine services in the market in the 1980s, ethical considerations of medical services arose. Later, in 2006, the American Society for Bioethics and Humanities (ASBH) was appointed by the World Health Organization to discover and resolve telemedicine ethical issues. The development of telemedicine guidelines served medical providers and patients in ensuring the security of services. However, with the advancement of the internet, email, smartphones, new standardized regulations are in need in order to cover all the aspects of telehealth services [20].

Table 1. Clinical Studies included evaluating ethical, legal challenges, and malpractice in telemedicine

Study name and authors	Year of publication	Primary endpoint	Main findings
Langarizadeh M <i>et al.</i> [10]	Oct 2017	To detect the ethical issues for telemedicine and information technology providers.	The need to have a standardized guideline for telemedicine practitioners.
Alexander L.Fogel, Joseph C. Kvedar [11]	Apr 2019	To evaluate the medical malpractice in direct-to-consumer telemedicine	Out of 551 reported case, none claimed medical malpractice in direct-to-consumer telemedicine.
Barry G. Fields [12]	Jul 2020	To guide telemedicine users and stakeholders through the regulations, laws and ethical difficulties of telemedicine.	A detailed presentation of the professional and legal consequences for telemedicine providers when disobeying telemedicine ethics.
Hans K. Bruhn [13]	Jul 2020	A brief presentation of dos and don'ts in telemedicine consultations in order to offer a good doctor-patient experience at a low risk of liability claims.	Information obtained from patients during virtual consultations should be documented as in standard medical practice.
Alexander L. Fogel <i>et al.</i> [14]	May 2021	To asses all reported cases of telemedicine malpractice in skin cancer.	Telemedicine malpractice was not associated with any of the cases presented.
Renata Solimini <i>et al.</i> [15]	Nov 2021	To evaluate the main ethical and legal issues encountered in the COVID-19 telemedicine practice.	The need of standardized rules of application in order to provide equitability.
Paolo Bailo <i>et al.</i> [16]	Dec 2021	To identify the main issues in Telesurgery.	Legislative differences between states as a critical issue in case of malpractice.

Mostafa Langarizadeh *et al.*, 2017 conducted a study in order to detect the current ethical issues for telemedicine and information technology providers. Their research, aimed to classify the main ethical issues involved in telemedicine. According to their research, telemedicine ethics includes the following categories: technology used with the patient, doctor-patient relationship, data security, informed consent, and patient satisfaction. Regarding the technology used during virtual consultations, issues may appear regarding doctors' technological skills, the insecurity of the used devices in spite of the high-quality technology, and the continuous and rapid development of technology that requires constant updating of standards. The doctor-patient relationship is considered to be affected in any form of telemedicine services due to the lack of human contact and its resulting empathy, which is not considered beneficial for the patient. It is recommended, when possible, that patients go to doctors, they have met in real life to overcome this technological barrier. In terms of data security, this is one of the major concerns of patients. In order to avoid any ethical issues and possible malpractice allegations,

any telemedicine service should include the patient's informed consent with all the details of the consultation that he or she will sign beforehand [10].

Alexander L.Fogel *et al.*, 2019, evaluated in their study cases of reported malpractice in direct-to-consumer telemedicine. He collected a substantial number of 551 cases of malpractice that included telemedicine services and studied them to see if the allegations were related to the ethics of telemedicine services or not. Out of the 551 medical cases, none claimed medical malpractice in direct-to-consumer telemedicine. Despite the favorable results, it is important to consider the study limitations, given the much lower risk of malpractice in direct-to-consumer telemedicine in terms of treating pathologies with low risk of medical malpractice in the fields of pneumology, allergology, and otolaryngology [11]. Another study that aimed to evaluate case reports of telemedicine malpractice, but in this case in the skin cancers practice, led by the same Alexander L.Fogel, 2021, found no association between patients' allegations and the telemedicine services themselves [14].

Although telemedicine was thought to help the

patient, unforeseen situations arise, with unfortunate endings and criminal incrimination of the medical staff. In his article, Barry G. Fields, 2020, states that every telemedicine practitioner should know the rules of the state where he works in order to avoid possible malpractice allegations. He reports a medical case in which a Colorado psychiatrist prescribed fluoxetine online to a Californian patient who committed suicide a few weeks later. He was sued by the state of California, and although the consultation took place online, the patient resided in California, and the doctor did not have a medical license to practice there. He was sentenced to nine months in prison. Starting from this case report, the author emphasizes the importance of certain ethical aspects in virtual medical practice and the increased attention that the doctor must have, above the employing company. The categories that could raise ethical issues in this practice from his point of view are represented by patient informed consent, medical licensing, clinical/hospital credentials, internet prescribing, malpractice insurance, and data security [12]. These aspects are supported by Hans K. Bruhn, 2020, which also states the need for a medical license in the case of interstate consultation, the need for malpractice insurance to cover virtual practice, and the importance of maintaining a doctor-patient relationship as natural as possible. He concludes by stating that it should be specified to patients that online consultations are not equivalent to standard ones and that doctors should not hesitate to make recommendations for in-person assessments at the slightest doubt [13].

In the COVID-19 pandemic, telemedicine has probably been the most widely used since its inception, demonstrating its benefits and liabilities. This period has brought an impressive evolution on many medical levels and will certainly be a point of reference in terms of the technological alignment of telemedicine with ethical standards. In their article Renata Solimini *et al.*, 2021, states the need to standardize ethical norms in the practice of telemedicine in order to provide equity, quality of service, sustainable costs, and patient safety. After the experience with the COVID-19 patients, they recognize the benefits of telemedicine but as a complementary service to standard medicine and not a substitute [15]. These legislative deficits are also felt in the telesurgery category, according to the results presented by Paolo Bailo *et al.*, 2021, in their study. They acknowledge the enormous help they have had in lowering the rate of COVID-19 infection by minimizing the medical team in the operating room

with telesurgery. However, the lack of legal regulation of this service makes them vulnerable to possible future malpractice allegations [16].

The study limitations are given by the non-uniform addressability of the subject, in view of the subject novelty and the important legal differences at a global level that can be difficult to comprehend in detail.

Telemedicine is certainly a branch of medicine with an undeniable benefit that will undergo rapid development in the coming years. In order to transform it into a quality medical service, it is absolutely necessary that the ethical regulations be uniform to those of the standard medical services and to maintain the pace of the technological development in place.

Despite the fact that the malpractice case reports associated with telemedicine services are currently low, the ethical and legal basis of this service leaves much to be desired. Considering that the medical staff is the same one who practices standard medicine according to Hippocrates' oath, we can state that the greatest danger of this service is for the medical staff and secondly for the patients due to their legal unprotection.

In conclusion, we believe that the standardized ethical regulations of any state should take into account patient informed consent, medical practice license, high standards of patients data protection, state-of-the-art technology to minimize verbal or imaging errors, and adequate patient education for the use of these services.

Conflict of interest

The authors declare that they have no conflict of interest.

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