An Ethical Analysis of the Regulation of Medical Teleconsultation in Brazil

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Uma Análise Ética da Regulamentação da Teleconsulta Médica no Brasil

RESUMO

Objetivo: analisar as principais leis, normas e regras que regulamentam a teleconsulta médica no Brasil, do ponto de vista bioético. **Método:** Trata-se de uma análise documental dos principais instrumentos regulatórios da teleconsulta médica no Brasil. Foram analisados a Lei 14.510 de 27 de dezembro de 2022 e a Resolução do CFM 2.314/2022 que versam sobre a telemedicina no Brasil e, a Lei 14.442/2022 que diz respeito à normatização do teletrabalho no país. **Resultado:** As principais questões bioéticas na telemedicina são abordadas no conjunto dos documentos. Como autonomia e consentimento, confidencialidade e privacidade, beneficência, relação médico-paciente, equidade e as relações de trabalho. **Conclusão:** Ainda existe um olhar muito voltado para a ética principialista nos documentos regulatórios e, mesmo que tenha abordado as principais questões, ainda há um vazio de regras, normas e leis para questões bioéticas até o momento, que se mantém sem amparo legal.

PALAVRAS-CHAVE: Telemedicina; Telessaúde; Ética; Bioética; Legislação.

ABSTRACT

Objective: to analyze the main laws, norms, and rules that regulate medical teleconsultation in Brazil, from a bioethical point of view. **Method:** This is a documentary analysis of the main regulatory instruments for medical teleconsultation in Brazil. Law 14,510 of December 27, 2022 and CFM Resolution 2,314/2022, which deal with telemedicine in Brazil, and Law 14,442/2022, which concerns the standardization of telework in the country, were analyzed. **Result:** The main bioethical issues in telemedicine are addressed in all documents, such as autonomy and consent, confidentiality and privacy, beneficence, doctor-patient relationship, equity, and labor relations. **Conclusion:** There is still a very focused focus on principlist ethics in regulatory documents and, even though the main issues have been addressed, there is still a void of rules, norms, and laws for bioethical issues to date, which remains without legal support.

DESCRIPTORS: Telemedicine; Telehealth; Ethics; Bioethics; Legislation.

RESUMEN

Objetivo: analizar las principales leyes, normas y reglas que regulan la teleconsulta médica en Brasil, desde el punto de vista bioético. **Método:** Se trata de un análisis documental de los principales instrumentos regulatorios de la teleconsulta médica en Brasil. Se analizaron la Ley 14.510 de 27 de diciembre de 2022 y la Resolución del CFM 2.314/2022 sobre la telemedicina en Brasil, y la Ley 14.442/2022 que se refiere a la normativización del teletrabajo en el país. **Resultado:** Las principales cuestiones bioéticas en la telemedicina se abordan en el conjunto de los documentos. Como la autonomía y el consentimiento, la confidencialidad y la privacidad, la beneficencia, la relación médico-paciente, la equidad y las relaciones laborales. **Conclusión:** Aún existe una mirada muy centrada en la ética principialista en los documentos regulatorios y, aunque se han abordado las principales cuestiones, aún hay un vacío de reglas, normas y leyes para cuestiones bioéticas hasta el momento, que siguen sin respaldo legal.

PALABRAS CLAVE: Telemedicina; Telesaúde; Ética; Bioética; Legislación.

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INTRODUCTION

Medical teleconsultations have recently been authorized in Brazil, motivated by the challenges imposed by providing access to healthcare during the COVID-19 pandemic [1]. Teleconsultations are one of the possible forms of telemedicine [2]. But what is telemedicine and what is teleconsultation?

According to the World Health Organization, telemedicine is defined as:

> The provision of health care in which distance is a critical factor, carried out by professionals who use information and communication technologies to exchange data and make diagnoses, recommend treatments and prevent diseases and injuries, as well as for continuing education of health professionals and in research and evaluation activities, in order to improve the health of individuals and the communities in which they live (WORLD HEALTH ORGANIZATION, 1997, 10p.).

According to the Federal Council of Medicine (CFM) in its resolution 2,314/2022, telemedicine can occur in several modalities, such as: teleconsultation, teleconsultation, teleinterconsultation, telediagnosis, telesurgery, telesurveillance and teletrigem [2]. In Brazil, some modalities were already regulated and had been occurring since 2007 in the Telessaúde Brasil Redes Program, for example [4]. However, medical teleconsultation was not authorized until the COVID-19 pandemic, being authorized in March 2020 [1]. According to the CFM, teleconsultation is characterized as a non-face-to-face medical consultation, mediated by TDICs, with the doctor and patient located in different spaces [2].

This healthcare model, still new, poses new challenges in the doctor-user relationship and in the work relationships of these professionals as well. Many advantages and disadvantages have already been raised. One of the advantages of telemedicine is the expansion and facilitation of access to health services. However, there are concerns about the quality of this access if technology is also a barrier, further increasing health inequities. In addition to these, there are numerous ethical and legal concerns surrounding telemedicine [5–7]. Some ethical and legal issues surrounding telemedicine that have been raised in other countries include autonomy, privacy, confidentiality, informed consent, beneficence, physician-patient relationship, and equity [5–8].

One way to address ethical and legal issues is through the creation and adaptation of laws, rules and regulations. These seek to follow ethical precepts, such as justice [9]. In this study, we propose to discuss ethics in health, a broad and complex topic that involves specific moral concepts. Therefore, from now on we will not discuss ethical issues, but rather bioethical issues. Bioethics was a term initially coined by Fritz Jahr in 1927 and later by Potter in 1970. It is the ethics of life, which takes into account a broad understanding of ethics for human animals, non-human animals and the environment [10]. Bioethics is a transdisciplinary topic; the issues involved are usually broad, with discussions that regulations alone often cannot address. [11].

Bioethical and legal issues are a well-known problem surrounding the use of telemedicine. But after all, to what extent have the regulations on medical teleconsultation in Brazil been sufficient to address these issues? To this end, this paper aims to analyze the main laws, norms and rules that regulate medical teleconsultation in Brazil from a bioethical point of view.

METHOD

This is a documentary analysis of the main instruments that regulate medical teleconsultation in Brazil, from a bioethical perspective. Law 14,510 of December 27, 2022 and CFM Resolution 2,314/2022, which deal with telemedicine in Brazil, and Law 14,442/2022, which concerns the standardization of telework in the country, were analyzed [2,12,13]. Initially, the document files, all available online, were researched, read in full, and then the analysis itself was carried out, obtaining significant information that allowed the elucidation of the object of study [14].

RESULT

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Two bioethical schools of thought were used to analyze the regulatory documents. The already known principlism ethics of Beauchamp and Childress and the bioethics of protection of Schramm and Kottow.

Principlism was the first bioethical school of thought to be structured. The principles are prima facie – non-absolute principles that are equally valid, at first glance. Beneficence, non-maleficence, respect for autonomy and justice are considered fundamental principles [11].

Protection bioethics was originally proposed in Latin America by Fermin Roland Schramm and Miguel Kottow. Protection bioethics considers inequalities and is the emergence of a bioethics necessary to elucidate bioethical issues in developing countries, such as Brazil. Considering the principle of autonomy as an end in itself, for people who do not have access to health services and medicines, for example, could be considered exploitation of vulnerability [11,15].

The documents were analyzed from the perspective of ethical and legal issues already raised in the international literature and already cited in this work: autonomy, privacy, confidentiality, informed consent, beneficence, doctor-patient relationship and equity. They were also analyzed from the perspective of the new work relationships imposed by this new relationship that occurs through telework.

Autonomy and informed consent

Respect for autonomy, one of the principles of principlist bioethics, is to consider, after due explanation, the individual's voice in decision-making. What is considered good for the patient from the doctor's point of view may not be from the patient's point of view, for example [11]. In the documents, we have considered issues of autonomy of both the doctor and the patient. In this topic, autonomy and informed consent were analyzed together because the patient's informed consent is seen as a way of expressing their autonomy.

In resolution 2,314/2022:

Art. 4 The physician is guaranteed the autonomy to decide whether to use or refuse telemedicine, indicating in-person care whenever he/she deems it necessary.

Art. 6 § 5 Both the patient and the physician have the right to choose to discontinue remote care, as well as to opt for in-person consultation, in compliance with the Free and Informed Consent Form previously established between the physician and the patient.

Art. 15. The patient or his/her legal representative must authorize telemedicine care and the transmission of his/her images and data by means of a (consent and authorization form) free and informed consent...

Sole paragraph. In all telemedicine care, explicit consent must be ensured, in which the patient or his/her legal representative must be aware that his/her personal information may be shared and of his/her right to deny permission for this, except in a medical emergency situation.

It can be seen that in the document, the patient's autonomy is linked to the Free and Informed Consent Form (FICF). Regarding the need for in-person care, the autonomy of the doctor and user is limited, in relation to longitudinal monitoring, to the period of 180 days. As can be seen in the following paragraph:

Art. 6º § 2º In the treatment of chronic diseases or diseases that require long-term monitoring, a face-to-face consultation must be carried out with the patient's attending physician, at intervals of no more than 180 days.

In law 14.510/2022:

In this document, the term telehealth is used and not telemedicine, as in the CFM resolution, justifying it as a broader term, since it is a law that regulates the use of the remote care modality in health professions and not only in medicine. Autonomy is also contemplated in it and again the patient's autonomy appears through the FICF:

I - autonomy of the healthcare professional;

II - free and informed consent of the patient...

Art. 26-C. The healthcare professional is guaranteed the freedom and complete independence to decide whether or not to use telehealth, including with regard to the first consultation, care or procedure, and may indicate the use of in-person care or opt for it, whenever he/she deems it necessary.

Art. 26-G. I - be carried out with the free and informed consent of the patient, or his/her legal representative, and under the responsibility of the healthcare professional...

The autonomy highlighted in the documents analyzed is based on the autonomy of principlist ethics, without considering vulnerable individuals who are not free to make decisions. Imagine a patient who really needs a consultation and that teleconsultation is the only alternative for him at that moment. Is his decision to agree to the informed consent form, in fact, a manifestation of his autonomy? Or, for example, if a child's guardian agrees to the informed consent form, would the child also agree?

Confidentiality and privacy

First, let us define confidentiality, privacy and another related term, secrecy. Secrecy is a right established in the Brazilian Constitution of 1988 and refers to data protection. Privacy refers to access to a person, to their private life, which they have the right to refuse. Confidentiality concerns the storage of data, in which the user has the right

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to remain anonymous. In medical care, with the patient's authorization, access to their privacy can be granted, but the data must always be kept confidential, for example [16].

In resolution 2,314/2022:

Art. 3º In services provided by telemedicine, patient data and images recorded in medical records must be preserved, in compliance with legal and CFM standards regarding storage, handling, integrity, veracity, confidentiality, privacy, irrefutability and guarantee of professional secrecy of information.

Art. 3º § 7º Personal and clinical data from telemedical care must follow the definitions of the LGPD and other legal provisions, regarding the primary purposes of the data.

In law 14,510/2022:

The bioethical and legal issues of confidentiality, privacy and secrecy are also addressed in the law that regulates telemedicine, but again, in a broad way. And, other laws that regulate the use of data, use of the internet and provision of services are cited. Art. 26. VI - confidentiality of data

Art. 26 G. II - comply with the provisions of Laws No. 12,965 of April 23, 2014 (Civil Rights Framework for the Internet), 12,842 of July 10, 2013 (Medical Act Law), 13,709 of August 14, 2018 (General Data Protection Law), 8,078 of September 11, 1990 (Consumer Defense Code) and, where applicable, the provisions of Law No. 13,787 of December 27, 2018 (Electronic Medical Record Law).

Beneficence

Along with beneficence, we will also analyze non-maleficence, a Hippocratic principle in medicine, Primum non nocere (First do no harm). Beneficence refers to doing good, while non-maleficence refers to not causing intentional harm [11]. The resolution establishes the limits of medical autonomy, reinforcing the good for the patient's health as a priority, as it should be.

In resolution 2,314/2022:

Art. 4 § 1º Medical autonomy is limited to the beneficence and non-maleficence of the patient, in accordance with ethical and legal precepts.

In law 14,510/2022:

Even without mentioning the terms beneficence and non-maleficence exactly, it can be understood that quality medical care will take these two principles into account as well.

Art. 26-A. V - safe and quality care for the patient

Doctor-patient relationship

The medical relationship in telemedicine is carried out through different means than in person, using telephones and video calls, for example. Documents are shared electronically and there is a physical distance. This implies a need to adapt to this means of communication, so that the medical professional and companies providing telehealth services can guarantee safety, trust and empathy to patients [5].

In resolution 2,314/2022:

Art. 6 § 3 The establishment of a doctor-patient relationship may be carried out virtually, in the first consultation, provided that it meets the physical and technical conditions set forth in this resolution, in compliance with good medical practices, and must follow up with an in-person medical consultation.

Art. 16 The provision of telemedicine services, as a medical care method, in any form, must follow the usual normative and ethical standards of in-person care, including in relation to the financial consideration for the service provided.

In law 14,510/2022:

Again, without specifically mentioning the term doctor-patient relationship, it can be understood that the law broadly states in Art. 26-A.

Art. 26-A. V - safe and quality care for the patient

Equity

Equity is also one of the principles of the Brazilian health system, the Unified Health System (SUS). It refers to the distribution of resources and services in a way that prioritizes those who need them most, and differs from the concept of equality, which would be equal distribution. Equity is close to one of the principles of principlism, which is justice, and would be distributing resources prioritizing those who need them most [11].

In resolution 2,314/2022:

Art. 19. Os serviços médicos a distância *jamais poderá substituir o compromisso constitucional de garantir assistência presencial segundo os princípios do SUS de integralidade, equidade, universalidade a todos os pacientes.*

Art. 19. Remote medical services can never replace the constitutional commitment to guarantee in-person care according to the SUS principles of comprehensiveness, equity, and universality to all patients.

In law 14,510/2022:

In this document, the term equity does not appear; we have Art.26-A, which reinforces that access to health is for everyone. It can be considered that in order to have universal access to health, we cannot do so without taking equity into account.

Art.26-A. VII - promoting universal access for Brazilians to health actions and services

Labor relations

Labor relations in the medical field have already undergone a significant movement towards the "pejotization" of medical professionals. This disqualifies and undermines the recognition of

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these professionals as individuals (17). Added to this movement is this new labor relationship, which is teleworking. The law that regulates teleworking is Law 14,442/2022. It refers to teleworking more broadly, without specifying the health area.

Law 14,442/2022 defines teleworking as:

Art. 75-B. Telework or remote work is considered to be the provision of services outside the employer's premises, whether predominantly or not, using information and communication technologies, which, by their nature, do not constitute external work.

Art. 75-B. § 2. The employee subject to the telework or remote work regime may provide services by workday or by production or task.

Art. 75-B. § 5. The time spent using technological equipment and necessary infrastructure, as well as software, digital tools or internet applications used for telework, outside the employee's normal working hours does not constitute time on-call or on-call status, unless provided for in an individual agreement or in a collective bargaining agreement or convention.

§ 9. An individual agreement may establish the hours and means of communication between the employee and the employer, provided that legal rest periods are ensured.

In law 14.510/2022:

Art.26-A.IV - dignity and appreciation of the health professional

And another article that grants greater freedom to medical professionals, exempted from registrations with more than one Regional Medical Council (CRM).

Art. 26-H. Secondary or complementary registration is waived for healthcare professionals who practice their profession in another jurisdiction exclusively through telehealth.

In resolution 2,314/2022:

This resolution did not address issues regarding working hours, legal rest periods, or other issues regarding teleworking employment relationships. There are regulations on the charging of fees.

Sole paragraph. The physician must previously agree with the patient and healthcare providers the cost of the service provided, as in face-to-face care.

DISCUSSION

Medical teleconsultations have been increasingly used in Brazil. Figures released by private sector telemedicine associations show that between 2020 and 2021, more than 7.5 million teleconsultations were performed, according to the Brazilian Association of Telemedicine and Digital Health Companies [18]. In 2023, more than 30 million medical consultations were performed remotely in Brazil, according to data from the National Federation of Supplementary Health. The number is 172% higher than the 11 million teleconsultations from 2020 to the end of 2022 [19]. These data reinforce the emerging need to pay attention to the bioethical and legal issues involving medical teleconsultations.

The results presented show that there have been initiatives to regulate medical teleconsultations in the country. And that, analyzing according to the ethical-legal issues already known in the international literature, the legislation has addressed these issues to some degree. In Brazil, initiatives to regulate medical teleconsultations began in 2002 with the CFM, but until the COVID-19 pandemic, medical teleconsultations were not yet authorized in the country. The authorization took place amid the context of the pandemic, which was decreed in Brazil on March 20, 2020. As soon as the Ministry of Health published ordinance 467 in March 2020 and then, in April 2020, law 13.989/2020 was published, temporarily legalizing the use of medical teleconsultations in the national territory. Without much time and, with the emerging need to regulate the practice of medical teleconsultations in the country, the documents were created [20].

The documents analyzed are the latest to date that address the topic of medical teleconsultation in Brazil. The CFM resolution has a more complete text than the other documents analyzed, exploring more possible bioethical issues. The laws, on the other hand, are broader and more general. It is worth noting how the hierarchies between the regulatory documents are arranged. Laws have greater force than ordinances, which in turn have greater force than resolutions. Ideally, documents with less force need to be in line with those with greater force. The results show that this occurs [9].

The CFM has a supervisory role in the professional practice together with its regional units, the CRMs, which is reinforced in law 14,510/2022 in its Art. 26-D. However, it is not clear how this supervision would be carried out, other than through complaints from professionals and users.

Regulatory documents are not immutable and can be updated to meet new demands. The CFM frequently updates or drafts new resolutions. Therefore, it is important to critically analyze existing documents, understanding their importance, but also verifying the need for adaptation.

Regarding patient autonomy, it is clear that the regulations of both the telemedicine law and the CFM resolution maintain a discussion focused on principlist ethics. Patient autonomy ends up being limited to agreement with the FICF. Even within the FICF, there is no mention that it must be adequately explained to the user and that it must be adapted to their language. It is also not clear in the documents analyzed who will forward the FICF to the user, the professional or the company providing

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the service, when the latter is mediating the care.

From the perspective of bioethics of protection, the autonomy of the user in medical teleconsultation deserves attention. At a time when the user's health is fragile, when he sees telemedicine as the only resource, will he be doing so freely by agreeing to the FICF? This context needs to be considered in public health decisions, in which the protection of the vulnerable population must be a priority. The protection of bioethics of protection should not be confused with paternalism. The proposed protection does not deny the autonomy of the subjects, but considers that the person must have the maximum possibilities to make this decision freely [11].

Still on the subject of autonomy, one must ask: what would teleconsultation be like for the elderly, children, people with certain disabilities, such as visual and hearing impairments, and for people with limited use of technology? These are questions that raise the debate on whether telemedicine really expands access or increases health inequities [21].

From the perspective of the autonomy of the medical professional, it is necessary to reflect on work relationships. Do doctors, in fact, have autonomy in professional decisions? How is the support for these professionals when faced with the imposition of unfeasible goals, excessive workload, lack of legal rest periods, for example? Given the need for employment, the professional may not feel comfortable filing a complaint and end up underestimating themselves in these working conditions [17]. Another question regarding medical autonomy is in the Brazilian context of inequalities in access to health resources [22]. Better propaedeutics may not be offered to the user due to lack of access to resources. For example, in the case of medical teleconsultations, the professional can take on the care of this user, even if the virtual care environment is not the most appropriate, based on the principle of beneficence, believing that this is the action that will provide the greatest well-being for that person, in that context.

An advance regarding professional autonomy is the possibility of working throughout the country, without the need to register with several CRMs, as considered in law 14,510/2022. This reduces the boundaries between users and doctors.

Regarding the doctor-patient relationship, both the telemedicine law and the CFM resolution agree to maintain the ethical principles of in-person consultations. The question would be how to do this given the physical distance and considering the interference of technologies that will mediate this meeting. There is a need for professionals to adapt to this form of care, which requires greater communication skills and greater attention to ensuring confidentiality and privacy, since it is a means of sharing data. There is also a need to increasingly consider the person at the center of their care. To this end, telemedicine communication approaches must be included in undergraduate medical courses and training for professionals who have already graduated [23,24].

Regarding telework, resolution 2,314/2022 establishes the right of medical professionals to charge for their telemedicine work. Law 14,510/2022 deals with the appreciation of this professional in a broad manner. It is up to the telework law, 14,442/2022, to stipulate this employment relationship in more detail. Some ethical and legal issues that are addressed in the telework law, such as the form of service provision, work regime, time of use of technological equipment, possibility of individual agreements are addressed broadly, without considering the specificities of work in health, but even if broadly, they are not directly addressed in the CFM resolution, nor in the telemedicine law. Remote work has advantages, however, its challenges, especially with regard to the health of workers and their labor rights, deserve attention. After all, what are the labor laws in this area, what are the mental overload, work overload and labor rights, for example? How can we reconcile the demands of on-site work at our units with remote work? How can employers fairly monitor working hours? How can we set limits on work messages on apps like WhatsApp outside of working hours, for example? For now, there are more questions than answers [25].

Still in relation to teleworking, the "pejotization" (consists of hiring a worker as a legal entity (PJ) instead of a registered employee) of medicine can further weaken these work relationships. On the one hand, the contract for the medical professional via Legal Entity reduces tax burdens for the professional and the contractor, can increase flexibility of contracts and working hours, but on the other hand, it can weaken the rights of this professional as a person. Without the right to vacations, thirteenth salary, assistance in case of health problems, without well-defined limits regarding the rules of the work process, such as number of patients seen and excessive working hours, for example [17].

CONCLUSION

Telemedicine has been advancing in Brazil, with many advantages and challenges, especially in the ethical and legal sphere. Regarding this challenge, Brazilian regulatory bodies have taken steps to regulate telemedicine in the country. However, there is a lack of rules, regulations and laws on bioethical issues, which are still not supported by law. Identifying and acknowledging these gaps is necessary in order to constantly update regulations together with representatives from the most varied sectors involved. The aim is to ensure that they are as fair as possible to all involved and that they can reduce health inequities. In this way, we can contribute to the structured growth of telemedicine in the country, capable of responding to most bioethical and legal issues.

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