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Ethics and bioethics in telemedicine in primary health care

Andrey Oliveira da Cruz [1], *Jene Greyce Souza de Oliveira* [2]

1. Secretaria de Estado da Saúde de Santa Catarina, Florianópolis/SC, Brasil. **2.** Universidade Federal do Acre, Rio Branco/AC, Brasil.

Abstract

Telemedicine in primary health care through the National Telehealth Brazil Networks Program emerged as a technological tool to support health professionals in the follow-up of patients in the Unified Health System. This paper reports the experience of using the program in primary care and discusses the ethical and bioethical implications involved in the mandatory adherence of the program to the local regulatory system to reduce referral queues and organize access to specialized services. Difficulties in user access to specialized health care, limitations to medical autonomy and conflicts in the doctor-patient relationship were identified. The use of telemedicine in primary care presents different ethical and bioethical aspects that need to be analyzed. In addition, it lacks its own legislation and standards to ensure the rights of patients and value the doctor-patient relationship, as well as the work of the medical professional who works at the Unified Health System gateway.

Keywords: Telemedicine. Primary health care. Bioethics.

Resumo

Ética e bioética em telemedicina na atenção primária à saúde

A telemedicina na atenção primária à saúde por meio do Programa Nacional Telessaúde Brasil Redes surge como uma ferramenta tecnológica de apoio a profissionais de saúde no seguimento de pacientes do Sistema Único de Saúde. Neste trabalho relata-se a experiência sobre o uso do programa na atenção primária e discutem-se as implicações éticas e bioéticas envolvidas na adesão obrigatória do programa ao sistema de regulação local para diminuir filas de encaminhamentos e organizar o acesso aos serviços especializados. Identificaram-se dificuldades de acesso do usuário à assistência em saúde especializada, limitações à autonomia médica e conflitos na relação médico-paciente. O uso da telemedicina na atenção primária apresenta diferentes nuances éticas e bioéticas, que necessitam ser analisadas, e carece de legislação própria e normas, de modo a assegurar os direitos dos pacientes e valorizar a relação médico-paciente, assim como o trabalho do profissional médico que atua na porta de entrada do Sistema Único de Saúde.

Palavras-chave: Telemedicina. Atenção primária à saúde. Bioética.

Resumen

Ética y bioética en la telemedicina en la atención primaria de salud

La telemedicina en la atención primaria de salud a través del Programa Nacional Telessaúde Brasil Redes aparece como una herramienta tecnológica para apoyar a los profesionales de la salud en el seguimiento de los pacientes del sistema único de salud. Este trabajo relata la experiencia sobre el uso del programa en atención primaria y discute las implicaciones éticas y bioéticas involucradas en la adhesión obligatoria del programa al sistema regulatorio local para reducir las colas de derivación y organizar el acceso a servicios especializados. Se identificaron dificultades de acceso de los usuarios a la atención de salud especializada, limitaciones a la autonomía médica y conflictos en la relación médico-paciente. El uso de la telemedicina en la atención primaria presenta diferentes matices éticos y bioéticos, que necesitan ser analizados, y carece de legislación y normas propias; con el fin de garantizar los derechos de los pacientes y valorar la relación médico-paciente, así como el trabajo del profesional médico que actúa en la puerta de entrada del sistema único de salud.

Palabras clave: Telemedicina. Atención primaria de salud. Bioética.

The authors declare no conflict of interest.

Research

Law 8,080/1990 [1] established the Brazilian Unified Health System (SUS) and defined its operating guidelines, such as the organization of health actions and services networks, especially regarding institutional organization and integration with the so-called federative pact for SUS consolidation.

As the SUS consolidation progressed, the Ministry of Health (MS) published Ordinance 4,279/2010, which established guidelinesfor organizing the Health Care Network (RAS). According to the text, RAS is defined as *organizational arrangements of health actions and services, of different technological densities integrated by technical, logistical, and management support systems that seek to guarantee comprehensive care* [2], seeking to *promote systemic integration of health actions and services by providing continuous, comprehensive, quality, responsible, and humanized care, as well as increasing the System's performance in terms of access, equity, clinical and health effectiveness, and economic efficiency* [2].

Its main foundation is the understanding of primary health care (PHC) as the first level of care to solve the most common health problems and perform the so-called "care coordination." PHC thus focuses on the health needs of the population, continuous and comprehensive accountability, multidisciplinary care, longitudinality, and sharing of objectives and commitments to health and economic results [2,3].

Coordination is understood as the *ability of primary care providers to coordinate the use of services in the Brazilian territory and at other levels of care to solve less frequent and more complex needs and to ensure continuity of care* [4], which relates to continuity of care between health professionals and services, follow-up of clinical cases through information tools, and the existence of referrals and flows between services [5].

To ensure resoluteness in the care network, SUS must consider some fundamentals, such as economy of scale and quality of resources; vertical and horizontal integration; substitution processes; health region or coverage; and levels of care [2]. Accordingly, strategies were implemented to reinforce the Pact for Health and current national policies.

The first strategy – the telehealth service – emerged as a proposal to develop logistic and support systems for RAS, seeking to assist health professionals of the "formative second opinion" [2]. In 2006, the National Telehealth Project started as a pilot to support the Family Health Strategy (FHS) in nine Brazilian states [6,7].

First, telehealth centers were established in public universities, being responsible for implementing other state points and qualifying approximately 2,700 FHS teams throughout the country, as to improve the quality of care in PHC, reduce costs and travel time, establish health professionals in hard-to-reach places, speed up care, and optimize resources within SUS [6].

With Ordinance 2,546/2011 [8], the MS expanded the program, naming it the Brazilian National Telehealth Program, and reorganized the project's service provision, which now provides RAS professionals and workers with the following services:

- Teleconsulting: recorded and held consultation between health professionals and managers to clarify questions on clinical procedures;
- Telediagnosis: use of information technology for diagnostic support;
- Formative second opinion: systematized response based on the best scientific and clinical evidence to questions originated from teleconsulting;
- Tele-education: conferences, classes and courses in health care.

According to the same ordinance, the program's Technical and Scientific Center is also responsible for articulating the Brazilian National Telehealth Program with the creation of access protocols that include prior request for teleconsulting on procedures, evaluation of the need for referrals or requests to the Emergency Medical Regulation Center [8].

The federal government consolidates thus its interest in establishing a close partnership between the program and the process of regulating SUS vacancies and specialized services, as provided in Decree 9,795/2019 [9]. The ordinance imbues the Department of Digital Health with the role of promoting activities and strategies of assistance support in the SUS for strengthening, integration, and clinical regulation in health care networks.

The development and use of health technologies has been monitored by the Federal Council of Medicine (CFM) for some time. With CFM Resolution 1,643/2002, the entity recognized telemedicine as *practicing Medicine via interactive methodologies of audiovisual communication and data, for assistance, education, and research in Health* [10]. This resolution, however, did not directly mention the term "telehealth."

Resolution CFM 2,227/2018 updated the resolution on telemedicine [11] and recognized teleconsulting as a mediated consulting act with the purpose of clarifying questions on procedures, health actions, and issues related to the work process. It also introduced the concept of teleconsultation-liaison as an exchange of information and opinions between physicians, with or without the patient, for diagnostic or therapeutic, clinical or surgical assistance. Both updates are applicable to the reality of the Brazilian National Telehealth Program [8].

This resolution, however, generated a great number of proposals for amendments regarding the use of information and communication technologies to practice telemedicine and telehealth. This raised ethical and bioethical questions with undefined answers, including the interaction between the new regulation, the existing public and private telemedicine services and the new propositions for their use in the Brazilian health scenario. Accordingly, CFM revoked Resolution CFM 2,227/2018 and expressly established the validity of the previous document, to promote further studies and search for contributions from entities, medical professionals, and society in general [12].

In 2020, due to the state of public calamity caused by the new coronavirus pandemic (SARS-CoV2), CFM authorized, exceptionally and for the duration of the pandemic, the practice of telemedicine, in addition to the teleguidance, telemonitoring, and teleconsultation-liaison provided by the original resolution [13]. Similarly, the Brazilian National Congress approved Law 13,989/2020, which provides for the use of telemedicine during the COVID-19 pandemic, reinforcing CFM's responsibility to regulate telemedicine after the coronavirus combat period [14].

The center *Telessaúde Santa Catarina* (Telehealth SC) offers teleconsulting to PHC professionals since 2009. But even with the disclosure in collegiate bodies and management guidelines, the service was little used, with data indicating low resolvability in PHC and excessive referrals to specialties [15]. In this regard, in 2014, Telehealth SC implemented the first systematized actions to support the regulatory centers in the state and municipalities, via workshops and technical discussions on referral flows and teleconsulting conducted by focal experts [15,16].

Establishment of a compulsory flow using teleconsulting for referral to other levels of care is a management decision. Nevertheless, teleconsulting is foreseen as an orientation and continuing education strategy: the obligation refers to the request before referral, but the decision to continue with the case in PHC or to make a referral to specialized care is up to the attending physician, based on the support received [15,16].

The Brazilian National Telehealth Program analysis report identified that the financing and management impasses result from the fragile institutionalization of the program, with intermittent financial transfers among centers, periods without funding sources, difficulty of interaction among managers in the federative levels, and lack of integrated planning. While in the federal sphere, managers focused the Brazilian National Telehealth Program numbers on results and impacts on primary care, at the local levels, centers showed deep interest in professional training, seeking to qualify primary care in the medium and long term and in a more sustainable manner, causing numerous tensions and clashes of expectations [17].

In 2019, a letter was published informing the end of the Telehealth SC program activities, similar to what occurred in other centers. The closure resulted from proposed changes in the program's logical-strategic design and changes in funding from the federal government, including the reorganization of its scope and reduction of activities [18]. In early 2021, the center announced the return of its activities, after reformulating the contract and federal funding [19].

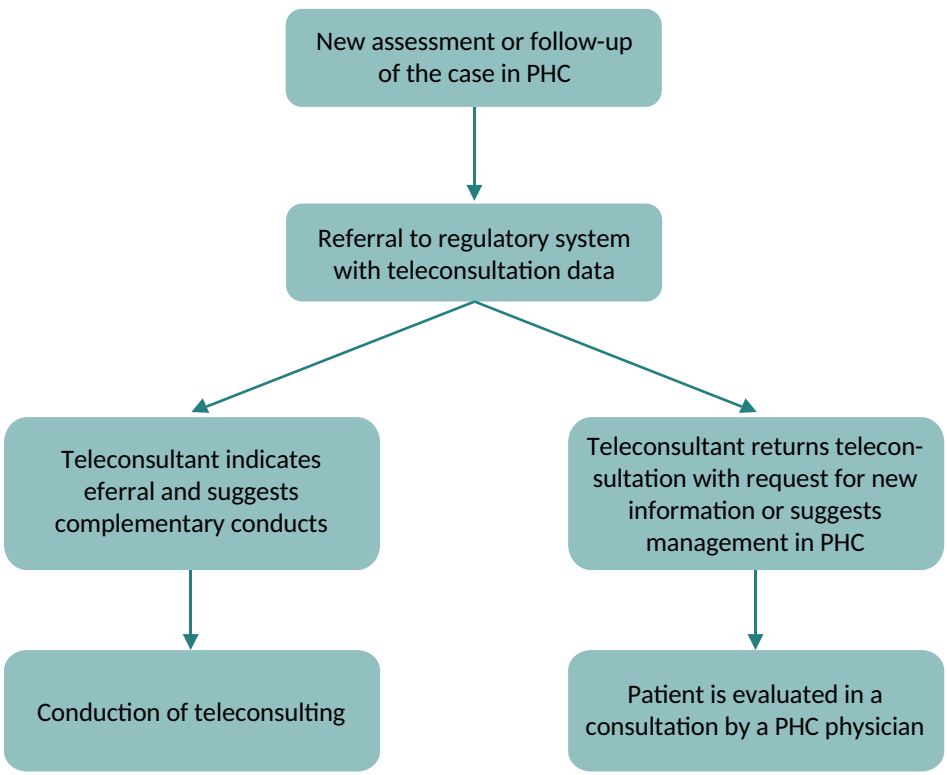
Experience report

In the state of Santa Catarina, Brazil, the mandatory performance of teleconsultations to follow the flow of referrals to medical specialties was defined by ordinances of the Bipartite Interagency Commission in 2016 [20,21]. These ordinances defined the evaluation criteria for each focal specialty, as well as the obligation to include the number and description of the teleconsultation in referrals made by the PHC assistant physician [22].

The flowchart of referral to specialized care at state level (Figure 1) was then defined by the following steps [22]:

1. The patient is evaluated by a PHC assistant physician, who defines the need or not for evaluation by a specialist physician. If a referral is necessary, a teleconsulting process must be completed in a virtual environment with general patient data, specifications on the clinical picture, diagnostic hypothesis and/or clinical justification and test results, according to the access protocols. It must also include the name of the professional and the corresponding professional board number, as well as possible questions regarding the case management;
2. The teleconsulting physician receives the request and formulates a response after analysis, and may: a) return the teleconsultation with sufficient information for follow-up, when it can be solved in PHC, proposing possible care; or b) indicate follow-up in a specialized level, being able to classify the case according to need and indicate possible conducts and exams to be requested as to speed up the patient's care process;
3. In case the referral interest is maintained, the assistant physician must continue the care flow, entering the case in the regulation center with the teleconsultation number and description, so that the regulator physician can give it due forwarding.

Figure 1. Flowchart of referral to specialized care in the state of Santa Catarina



PHS: primary health care

Several municipalities with their own regulatory system and specialized care services joined the system of mandatory teleconsultation to referral at the municipal level, using the same telehealth platform and service flowchart.

This is an experience report from a city in the metropolitan region of Florianópolis, Santa Catarina, Brazil, which, via normative instruction from the Municipal Health Secretariat, determined the implementation and regulation of the compulsory teleconsultation flow prior to outpatient referral for patients over 15 years old in specialties offered by the municipality's own service.

The instruction also defined the mandatory review of all referrals to specialties requested prior to its publication. Consequently, the referral queues were ended and the regulation conditioned to a new teleconsultation, carried out by PHC physicians, including cases that were waiting in line after having already been regulated with high-risk classifications and the obligation to include the full description of the teleconsultant's answer in the referral.

In this context, patients who had been waiting for evaluation with specialists for several months, who had already been seen by a PHC assistant physician and evaluated by the regulator physician, had to seek new PHC care for reassessment, teleconsultations, request of new tests, and re-entry into the center's queue. Moreover, there was a considerable increase in demand for the system's gateway services.

Based on this, this article discusses the use of telemedicine (teleconsulting) and its impacts on the direct association with vacancy regulation systems, concerning PHC users and physicians. Our guiding focus are the ethical and bioethical implications of this technological tool in health care.

Method

This exploratory research, based on a narrative literature review, was carried out between November 2020 and February 2021. We searched for studies on the theme in the Pubmed, SciELO, and Google Academic databases using the following Boolean operators: 1) "telemedicine *and* primary health care" *and* "bioethics *or* ethics"; 2) "telemedicine *or* teleregulation" and "primary health care" *and* "bioethics *or* ethics"; and 3) "professional autonomy *and* telemedicine *and* bioethics."

We selected papers in Portuguese and English, namely: 15 articles published in journals; six laws; four ordinances; three CFM resolutions; three consulting opinions from regional councils of medicine; three technical reports; three websites; two decrees; one letter; one declaration; one thesis; one book chapter; one CFM letter; and the Code of Medical Ethics (CME).

Results and discussion

Telemedicine is a relatively new area of knowledge and knowledge production, which is constantly being updated and advanced and is the object of study of researchers worldwide. Some authors point to improved access to information for health professionals and patients; provision of remote care to address local deficiencies of low resources and lack of assistance; improved health care follow-up; and reduced care costs, among others, as advantages brought by telemedicine [23,24].

Despite such significant benefits, the resource also presents disadvantages, such as chances of damaging the physician-patient relationship, due to the distance; organizational and bureaucratic difficulties related to infrastructure, regulations and payments for services; inherent risk to the confidentiality of medical care and data storage; and lack of adequate regulation on the topic, generating insecurity for users and especially for health professionals [23,25]. Such scenario raises some ethical and bioethical issues involved in the practice of telehealth.

Risks to professional confidentiality and data storage

Professional confidentiality is one of the pillars of the physician-patient relationship, a millennial rule standardized since the Hippocratic oath [26]. Regarding information confidentiality, telehealth proposes the use of its own virtual platform with data storage in which, generally, the exchange of patient information occurs between medical professionals. In this situation, the regulations governing CME apply for both professionals: assistant physician and teleconsultant physician.

The ethical aspect related to secrecy, confidentiality, and privacy of information is defined throughout the CME. In its fundamental principles, the document defines that *physicians shall keep confidentiality about information they have knowledge while performing their functions* [27]. Article 73, in turn, prohibits physicians from disclosing facts they have knowledge of in the exercise of their profession without the patient's consent; Article 75 prohibits reference to identifiable clinical cases; and Article 85 prohibits the handling and knowledge of medical records by persons not bound to professional secrecy when under their responsibility.

In its Article 154, the Penal Code determines that *to reveal, without just cause, to someone a secret that is known by reason of their function, ministry, office or profession, and whose disclosure may harm others may lead to detention from three months to one year, or a fine* [28]. It also defines, in Subitem A of the same article, as a crime *to invade another's computer device, connected or not to the computer network, by means of undue violation of a security mechanism to obtain, tamper with or destroy data or information without the express or tacit authorization of the owner of the device or install vulnerabilities to obtain illicit advantage* [28], with detention of three months to one year and a fine.

The *Universal Declaration of Bioethics and Human Rights* (UDBHR) [29] broadly addresses ethical issues related to associated technologies applied to human beings. According to the document, these technologies must be used in ways that safeguard human dignity and protect individual rights regarding equitable access to medical, scientific, and technological developments, to the widest possible diffusion, to the rapid sharing of knowledge concerning these technologies, and to participation in the benefits, considering the particular needs of developing countries.

Regarding medical confidentiality and data storage [29], the UDBHR defines in its Article 4 that the direct and indirect benefits to patient arising from telemedicine practice must be maximized and any possible damage minimized. Accordingly, the privacy of healthcare users involved and the confidentiality of their information must be respected *to the greatest extent possible, and such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular the international human rights law* [29].

In the context of data security in telemedicine practice, the World Medical Association defines, in its statement on the ethics of telemedicine [30], that physicians must ensure the confidentiality, privacy and integrity of patient information in accordance with local legislation. Nonetheless, researchers around the world point out that legislation on data security through telemedicine is still scarce, with significant divergence between locations and difficulty in unifying security and sharing services [31,32].

Rogozea and collaborators [33] investigated confidentiality and telemedicine in the perspective of medical students, with the following main concerns: respect for patients' rights as to ensure that only the healthcare team involved in the treatment has access to patient information; the difficulty in ensuring the security of transmitted information; and issues related to data management and respect for confidentiality by the professional receiving telemedicine data.

In Brazil, where the defining parameters for data sharing are regulated by ordinances, standards and technical notes from different government bodies, not unified in a specific legislation, the situation of data security in telemedicine is no different [34]. The referred approval of a law authorizing telemedicine practice during the public health crisis of the new coronavirus does not specify issues inherent to data management, security of patient confidentiality or other recommendations on the topic [14].

There is consensus that the practice of telemedicine should observe the General Personal Data Protection Law (Law 3,709/2018 [35]), although it does not specifically address the topic. Hence, personal data obtained during consultation must be protected to prevent unauthorized access, with storage in a secure database and awareness of health work teams in order to avoid vulnerabilities.

Medical autonomy and the physician-patient relationship

Medical autonomy is often brought into the discussion on telemedicine. The CME [27] reinforces,

as a fundamental principle, that physicians shall exercise their profession with autonomy, not being able to renounce their professional freedom or allow restrictions that may impair the efficiency of their work.

Medical autonomy can then be defined as the freedom of the medical professional to act in favor of the patients' health based on their interest, without interference [36]. In the context of telehealth, the assistant physician's autonomy is confronted by the mandatory agreement to discuss cases and receive guidance from another professional considered to have greater expertise in a given subject so that certain treatments can be offered to the patient [37].

Teleconsulting – which initially assumed a guiding and educational character – is confused with regulatory activities and access to other levels of care. Consequently, the limitation of medical autonomy is aggravated when management measures condition the acceptance or approval of a teleconsultant physician for follow-up of certain patients by the assistant physician.

In this perspective, one should question what are the levels of responsibility of each professional in patient care: should one prioritize the evaluation of the assistant physician, usually carried out in face-to-face patient care, but without the specialized knowledge on a particular subject, or that of the teleconsultant physician, usually a specialist, but lacking the experience and evaluation of the face-to-face consultation?

Still in this context, it is practically impossible to discuss medical autonomy without associating it with patient autonomy, since the continuation of care is conditioned to the involvement of other professionals. Even in these situations, the importance of the patient's full understanding and consent – not just assent – in using the telehealth process for clinical management is emphasized [37].

Laskowski and Lyons [38] argue that establishing clinical and referral protocols has favorable effects for physicians and patients, since, when well developed, they tend to improve patient care service and facilitate clinical follow-up according to the best evidence. Likewise, overconfidence and the establishment of very rigid protocols can overshadow unique aspects of the physician-patient relationship and individual needs.

Despite the absence of a unified CFM opinion on the topic, some regional councils have defined their own guidelines regarding medical autonomy and teleconsulting [39-41]. To recognize the ethical nature of teleconsulting as management of health system resources [40,41], the opinions also prescribe respect for the autonomy of the assistant physician, usually in PHC, to autonomously define their conducts, even if in disagreement with the teleconsultant specialist's guidance [41].

Conflicts between telehealth and regulatory systems

An important object of discussion, teleconsulting and telemedicine in public health practice assume a different character when closely associated with the regulation processes between levels of care, as provided by legislation [8,9]. To understand the conflicts between telehealth practice and regulatory systems, one should review the history of the Brazilian National Telehealth Program, when the discussion of a national proposal for telemedicine and later telehealth, based on the problems identified when establishing health professionals in distant cities, began [42]

After initial mapping of Brazilian telemedicine projects, researchers found that these were isolated and diversified. Over time, the SUS collegiate managements expanded the debates to move forward with a national process of integration between education and service, including tele-education projects, issuance of reports and remote diagnosis and, above all, educational actions to qualify and develop innovations in PHC [17,42].

From the merger of telehealth activities with SUS regulation processes and systems, some bioethical issues were brought up for bilateral discussion. The association of teleconsulting with regulatory systems is an important strategy to increase the use of the program by health teams, qualify the assistance in primary care and reduce unnecessary referrals, strengthening problem-solving at the primary level. But the risk of causing resistance in health teams due to the mandatory use of teleconsulting in the referral flow, which would cause reduction of necessary referrals or use of informal paths, remains [42].

The sophistication and technological improvement in health services has been an evident motivation for the development of bioethics. Moreover, these advances expose crucial differences between primary and specialized care services in terms of patient autonomy, family involvement, longitudinality, and several other factors that directly influence the bioethical analysis of scenarios [43].

Patient referral and service regulation are the object of study of several researchers regarding barriers in the health system [43-45]. Issues such as scheduling and referral delays, disorganization of the regulatory complex, and lack of trained human resources to meet the system's demands are examples of difficulties faced in the referral process between levels of care [44].

In terms of care, medical referral assumes a merely bureaucratic and less resolutive character for the health promotion process, distancing itself from the main actor in care: the patient [44]. In a broad analysis of the referral as medical conduct, one can also perceive the dynamics of interpersonal and interprofessional relationships that involve the process. One example is the maintenance of vertical relationships between health teams and managers, usually in authoritarian and directive behaviors, focused on hierarchy and bureaucracy [44].

The discussion on professional autonomy becomes increasingly important in cases such as the one presented here, in which the establishment of care guidelines forced a new configuration of the regulation queues. Such decision disregarded the previous work done by PHC physicians, taking up important time for the follow-up and monitoring of patients and conditioning the progress of the cases already identified to new assessments: in person and by teleconsultation.

One must also question the objectives of mandatory teleconsulting in a regulatory flowchart: despite being an offer of permanent education and an opportunity to support the professional, it greatly risks becoming a merely bureaucratic and less educational procedure when closely associated with the regulatory process.

Final considerations

The use of telemedicine in PHC brings numerous benefits for the provision of services and the expansion of health care, especially in the telehealth and teleconsulting modality in regions far from specialized referral services. However, it must observe ethical and bioethical issues inherent to each SUS level of care and aspects such as longitudinality, physician-patient-community relationship and work as a PHC gateway.

Telehealth and teleconsulting practice in primary care should be guided by training objectives, to qualify the health service and improve clinical practice. Likewise, its use must ensure the autonomy of the assistant physician regarding the definition of conducts and follow-ups, together with the patient, thus respecting global bioethical principles.

Developing a specific legislation to address the topic of telemedicine and its nuances of application in the SUS is also necessary. Likewise, the class council is expected to promote actions that regulate and standardize the practices of medical professionals for the ethical use of telemedicine.

Research

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Research

Andrey Oliveira da Cruz – Graduate – andreyocruz@gmail.com
0000-0002-6452-7077

Jene Greyce Souza de Oliveira – PhD – jene.oliveira@ufac.br
0000-0001-9274-7053

Correspondence
Andrey Oliveira da Cruz – Secretaria de Estado da Saúde de Santa Catarina. Rua Esteves Júnior, 390, Centro CEP 88015-130. Florianópolis/SC, Brasil.

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