Telehealth: confidentiality and informed consent

Telessaúde: confidencialidade e consentimento informado

Edson José Carpintero Rezende¹, Eduardo Carlos Tavares², Claudio de Souza³, Maria do Carmo Barros de Melo⁴

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ABSTRACT

As our societies experience advances in the field of information technology, new resources provide tools for the health sciences and create other forms of care. Despite the benefits of those innovations, ethical and legal principles must be observed. This literature review aims to stimulate a discussion on confidentiality, privacy, safety, and veracity of information on the services using telehealth systems. Scielo and Lilacs databases were researched for articles published in the last 12 years in Portuguese, Spanish, or English, which approached matters of confidentiality and consent in the services provided using telehealth systems. To avoid infringement and make sure procedures are ethical in their use of health related information, systems must be electronically certified according to international standards. System users must use digital signature verified by an authoritative public organ. Informed consent forms must be signed by patients before all teleconsultation.

Key words: Telemedicine; Remote Consultation; Remote Consultation/ethics; Informed Consent; Ethics, Medical; Bioethics; Trust; Software Validation.

INTRODUCTION

The advances in information and communication technologies (ICT) have resulted in numerous innovations and offer new perspectives in different fields of knowledge. It is no different in the healthcare field. These resources present ways to offer...
people better healthcare, particularly in developing countries. It is thus possible to improve assistance and reduce the current morbidity and mortality rates.

Developing countries face a number of problems concerning the demand and management of health services. In these countries marginalized communities struggle with poor infrastructure in basic health units, communication problems between remote locations, and lack of knowledge about data transmission and use of computers.

Despite the structural difficulties, new ways of delivering health services must be implemented. In this sense, the use of information and communication technologies presents good possibilities for improving this scenario. The use of internet has created a favorable environment for the exchange of information because it is easy to use and the cost of information transmission is low, allowing images, text, and sound to be sent efficiently from any computer. Initially, this association was called telemedicine, which meant “the evaluation and review of patient information (exams, history or investigations) by a health professional who is temporarily and/or spatially separated from the patient.” Other terms – such as e-health and telehealth – are being widely used to refer to healthcare services using communication technology, whether in the private or public sectors. Recent publications have also mentioned m-Health, which corresponds to the use of mobile and wireless communications for delivering healthcare.

Because the term telemedicine is restricted to medical activities, telehealth is currently preferred since it is more comprehensive and still broadly used, especially given that health services advocate for the dynamics of multidisciplinary care, in which healthcare assistance includes activities of other related health professionals.

The practice of telehealth represents a new paradigm and sets out to reduce geographical boundaries, offering the possibility of better service to populations whose basic care is precarious or non-existent, as well as access to professional experts. This area, which is currently undergoing major developments, will allow diagnostic advice with distance consulting despite traffic limitations and budgetary constraints.

It is a good option for connecting reference centers with basic health units located in the peripheries, allowing diagnostic questions to be answered, guiding the conduct, and fostering distance learning. It is important to mention that telehealth may be the only solution for isolated populations, especially in large countries such as Brazil where health services are unevenly distributed.

Another premise of telehealth is the possibility of reducing costs in the provision of distance health services. It can be seen as a resource that helps improve the quality of health care and reduce the time between diagnosis and therapy. Despite offering interesting benefits for healthcare, this new resource also brings risks related to human factors and technological issues. The loss of confidentiality of the information provided by patients is one of the risks incurred when patients receive care by telehealth – whether the information is filed or transmitted by computer.

This study aims to review the literature on the topic and to reflect on the confidentiality of information provided, as well as consent in healthcare provided using the technology resources of telehealth.

METHODS

This article is based on a research conducted in English and Portuguese language journals from the Lilacs and Scielo electronic databases, from 1998 to 2010, with the following clinical descriptors: confidentiality, informed consent, bioethics, ethics, and telemedicine; and from the Brazilian standards and resolutions by the Federal Councils of Medicine (FCM), Psychology, Dentistry and Nursing. The material was analyzed and selected for the best contributions to the issue at hand.

CONFIDENTIALITY AND TELEHEALTH PRACTICES

Incorporating technological resources to healthcare presupposes that information on people’s health will be transmitted and stored. Patients have their dignity and deserve respect and attention when it comes to their personal information. Information on patients’ health is their property and must remain confidential, something that health workers and the institutions providing care are responsible for ensuring. While the terms secret and confidentiality may seem synonymous, they are different; secret refers to the fact that information cannot be revealed for the sake of public order and confidentiality refers to the means used to keep this fact unknown, i.e. it is the
keeping of this fact. If a breach of confidentiality occurs, then the secret is revealed.17

The ethical paradox of telehealth emerges from the positive impact it can have on patients' health and the possibility of it being harmful to them after it is employed.18,19 The growth of information and communication technologies raises concerns when these devices are used in public or outside the relatively safe confines of the healthcare systems and have significant implications for the integrity of information.18 The legal and ethical implications of such innovations are not new, but the context of telehealth gives each of these themes a new dimension. These issues go beyond the expectation of respect for patients' autonomy, for they give rise to obligations to ensure confidentiality, privacy, and informed consent.18,20

Confidentiality comes into play “when a person discloses information to another – either through words or medical examination – and the person to whom the information is disclosed promises not to disclose it to a third party without permission”.14 Confidentiality is the guarantee of safekeeping of information given in confidence and protection against unauthorized disclosure. It is one of the pillars of the doctor-patient relationship, between patients of whatever age and health professionals, and it extends to administrative staff.15

Privacy “is a state or condition of physical inaccessibility or inaccessibility to information”.14 Privacy is a limitation of access to a person's information, and it prevents that patients are observed without proper authorization.15 To preserve the patient’s privacy, it is necessary to establish mechanisms that ensure the security of any transmission made. The patients' consent is crucial, especially when records from teleconsultation are used and also to define who will access the information.19-22

Patients' biggest concern is the fear of having their privacy violated by means of the information they provide and the fear of being identified when this information is transmitted.15,21,22

Beauchamp and Childress14 distinguish between confidentiality and privacy as follows:

> A violation of X's right to confidentiality only occurs if the person to whom X disclosed information in trust does not protect the information or deliberately discloses it to a third party without X's consent. Conversely, a person who enters the records office or a hospital's computer database without authorization violates privacy rights, and not the rights of confidentiality. Only the person (or institution) to whom the information was provided in a confidential relationship can be accused of violating confidentiality rights.24

Confidential information must always be protected, whether it is transmitted, stored, received or granted, to ensure that a patient's confidentiality is respected and that identifiable personal information is protected.18 With regards to the confidentiality of information provided, the patient needs to give informed consent primarily for uses that might be granted to electronic records of medical nature or in videos made in teleconsultation to which he or she has access.22

The environment in which the teleconsultation happens involves, in addition to the multidisciplinary health team, other professionals such as computer technicians. A major barrier to implementing information technologies in healthcare lies in the difficulty to recruit staff with experience in the field.22 All professionals must be prepared to deal with confidential information pertaining to patients' health, a concern that also applies to medical education environments.24

Another important issue to be addressed concerns the transmission of information regarding users' health. In case patient data is sent to an incorrect address, the responsibility lies with those who sent the information, but it can be difficult to identify an individual in charge of transmission protection and control. Use of telehealth entails that data of numerous users are stored and transmitted in electronic messages. These messages can be: intentionally or unintentionally altered; received by unauthorized institutions; or sent to incorrect addresses.13

Concerns about issues involving the confidentiality and protection of a patient's data can be minimized by restricting access to the identification system.24,25 Computerized systems used in telehealth must possess mechanisms that track use of personal information, and access must require personal passwords.24,27 In the long-distance transmission of identified data from medical records, use of public and/ or private keys should be required for the purpose of ensuring the system's identity.24,25

CONSENT AND THE TELEHEALTH PRACTICE

With the increasingly intense use of information and communication technologies in healthcare, it becomes important to reflect more about informed consent and the relationship between patients and
health professionals, as well as the risks and ethical and legal implications.\(^{28}\)

On issues related to confidentiality of information provided, it is essential to use the Free and Informed Consent Form (ICF)\(^{11,21,22,25,26,29}\) – “a document that aims to protect the patients’ autonomy, in which they attest to be aware of their condition as subjects of research or undergoing medical procedures which are considered invasive”.\(^{29}\) The decision is voluntary and given by an able and autonomous individual, after all the necessary clarifications are given.\(^{30}\) The ICF, though widely used and required for research on human beings, needs to be more widely used in healthcare.\(^{23,30}\)

Healthcare users must be informed of the limitations and innovations of this kind of care when compared to the conventional care.\(^{31}\) The ICF is a document that makes the patient or his or her legal representative aware of the medical condition, prognosis, adverse effects, risks, and treatment alternatives.\(^{32}\) Relevant information of any particular patient may only be disclosed to the professionals involved in healthcare delivery if authorized by the patient or a family member who sign the informed consent form.\(^{30}\)

The importance of disseminating the use of the ICF respects the will and rights of users and draws the attention of professionals in charge of delivering healthcare to the legal responsibility of their actions,\(^{30}\) since professionals who use telehealth are directly responsible for their patients, even with their consent.\(^{30,27}\) The conduct and protocols vary in different countries and institutions that operate in the field, and hence are not universally accepted.\(^{28}\) A study consisting of a systematic literature review concludes that informed consent is still not common practice in services that use information and communication technologies.\(^{33}\) In Australia\(^{33}\) and in Canada,\(^{35}\) requesting informed consent from patients is not a routine practice. The American Telemedicine Association (ATA), however, has established in a protocol that healthcare professionals should request the patient’s informed consent.\(^{36}\)

In this new context of virtuality, some authorities propose norms of international repercussion based on universal patient principles to guide the work in this new modality of healthcare.\(^{37}\) The pioneering international document on this practice is the “Tel Aviv Statement”, which defines the responsibilities and ethical standards of telemedicine and was adopted by the 51\(^{st}\) General Assembly of the World Medical Association in Tel Aviv, Israel, in October 1999.\(^{27}\) The statement underscores the importance of preserving confidentiality, secrecy, and privacy in health information and guides doctors to request the patient’s consent for the use of telemedicine. With regard to second opinions, it is thought that the doctor who responds to the teleconsultation is responsible for the quality of information provided to the requesting doctor, and the recommendations must be recorded in the patient’s clinical record.

In Brazil, the Federal Council of Medicine (FCM) has passed some rulings that are worth mentioning. Resolution 1.643/2002 defines the delivery of medical services by means of telemedicine and affirms that patient information can only be transmitted to other professionals with the patient’s free and informed consent and in compliance with the safety standards in place. Moreover, the technological infrastructure must be appropriate and comply with the FCM’s technical standards, assuring confidentiality, privacy, and professional secrecy. In case of emergency, diagnostic and therapeutic support can be offered, but the assisting physician must be directly in charge.\(^{38}\) The FCM resolution 1.718/2004 forbids the teaching medical of procedures to non-medical professionals, except in emergency situations, under medical supervision and guidance.\(^{39}\)

In 2007, the FCM passed resolution 1,821 on technical standards concerning the digitization and use of computerized systems for the storing and handling of documents with patients’ medical records.\(^{40}\) In 2009, Resolution 1,890 defined and standardized tele-radiology as a medical practice whose critical factor is distance, using electronic transmission of radiological images with the purpose of consultation or report. The technological infrastructure must be appropriate and comply with the FCM’s technical standards and ethics concerning storage, handling, and transmission of data, confidentiality, privacy, and guarantee of professional confidentiality. The patient should authorize electronic transmission of images and data by means of a free and informed consent form.\(^{41}\)

The Code of Medical Ethics sets in articles 73 to 79 the rules for professional secrecy, which must also be adhered to when using the virtual environment.\(^{42}\)

The Federal Council of Psychology (FCP) has adopted three resolutions concerning this issue. The first refers to delivery of psychological services by phone (nº 002/95, 20 February 1995)\(^{43}\), psychotherapy care by computer (No. 003/2000, 25 September 2000)\(^{44}\), and the setting up of a national commission for supervision and accreditation of psychology services via the internet (No. 006/2000).\(^{45}\)
The Federal Council of Dentistry (FCD) resolution number 92/2009 of 20 August 2009 defines and regulates delivery of services by telehealth. It considers that patient information can only be transmitted to another professional with the patient’s permission by means of their free and informed consent and under strict security standards able to ensure confidentiality and integrity of information. Dentists practicing long-distance dentistry should carefully evaluate the information they receive and should only voice opinions and make recommendations or dental decisions if the quality of the information received is sufficient and relevant. Article 4 assigns professional responsibility over patients to the assistant dental surgeon; others involved will respond jointly in proportion to their contribution to eventual harm caused to a patient. Resolution number 91/2009 of 20 August 2009 approves the technical standards concerning digitalization, use of computerized systems for keeping and handling of documents regarding patients’ medical records, and the safety requirements on electronic documents in healthcare.

Article 81 of the Code of Ethics of the Federal Nursing Council underscores that secrecy is the professionals’ duty regarding all knowledge of sensitive information, except in cases prescribed by the law, court order or with the written consent of the person concerned or a legal representative. Standards or resolutions concerning telehealth were not found.

**FINAL CONSIDERATIONS**

Telehealth appears as a new context in health services and brings back concerns about the ethical and legal aspects pertaining to this practice, especially as regards confidentiality of information provided and the use of the ICF. Some precautions are called for, such as use of passwords and control of users’ access to information. These are needed in order to avoid future problems but above all to preserve the patients and their dignity. Other important aspects concern creating space in the health services for discussion and training of professionals involved in the use of telehealth. Regulations concerning the practice of telehealth should be more disseminated internationally and also through the advice of professional and class organizations. Many innovations in the field of information and communication technologies are emerging, and it is necessary to reflect on national and international standards and protocols for the use of data, images, and patient records.

**REFERENCES**


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