CHAPTER

13

Medicolegal, ethical, and regulatory guidelines pertaining to telehealth

Maurice Mars

University of KwaZulu-Natal, Department of TeleHealth, Durban, South Africa

Telemedicine covers a wide range of activities in countries with different laws, health systems, regulations, needs, expectations, cultures, and approaches to ethics. This chapter explores legal, regulatory, and ethical issues of telecare. It is not intended to be a legal text or offer legal and ethical opinion, but aims to raise awareness in general.

There are many legal and ethical issues related to telecare. Interpretations and solutions will differ, based on local and national contexts. Because of such diversity, there will never be one "correct" approach to all telehealth matters, legal and/or ethical. The reader will need to analyze his/her own environment and the services offered to determine how these issues are addressed and the possible solutions, taking into account existing laws, regulations, and professional society guidelines. In the absence of ethical guidelines for telemedicine within a jurisdiction, it is suggested that the World Medical Association's 2009 "Statement on Guiding Principles for the Use of Telehealth for the Provision of Health Care" can be followed—their definition of telehealth includes telemedicine.[458]

As with other healthcare activities, health professionals have to comply with existing legislation, associated regulations, and the medical ethical guidelines adopted and followed in their country. Telemedicine may be covered in specific telemedicine laws or in aspects of other laws such as health, telecommunication, information communication, data security, and privacy. These may not always be called laws but may be found, for example, in directives within the European Union or guidelines and guidance in China.

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Telemedicine law

Telemedicine law may be at a national or state/regional/provincial level. Malaysia was the first country to have such a law in 1997,[459] followed by France and Brazil. These three laws differ in their definition of telemedicine. Malaysian law refers only to teleconsultation; French law refers to teleconsultation, teleexpertise, telemonitoring, teleassistance, and telesurveillance; but in Brazil, teleconsultation allows for physician-to-physician or healthcare worker-to-physician consultation and explicitly excludes patient-physician consultation.[460] A similar situation exists in the United States. As of mid-2017, 44 states had over 200 telehealth-related pieces of legislation, many of which addressed remuneration, with no two states having concurrence.[461] The definition of telemedicine varies among states, with some excluding email, phone and/or fax from the definition, and in some instances store and forward telemedicine.

Regulations appear to be interpreted differently or made more onerous for telemedicine. Radiologists and pathologists can routinely report at a distance without the need for a prior doctor-patient relationship or even meeting the patient, but telemedicine regulations deem similar scenarios in other specialties unacceptable.[462] There are numerous concordance studies in various branches of medicine that report telemedicine diagnosis to be as good as or comparable with face-to-face diagnosis.[216,463,464] Many studies have reported that patients are satisfied with telemedicine consultation and diagnosis.

Data privacy and security rules called HIPAA[a] in the United States were initially created for health insurance purposes, but do hold relevance for telecare. In India, a draconian law called Digital Information Security for Healthcare Act (DISHA)[465] has been proposed, but fortunately not yet in place. It calls for high fines and even jail for a practitioner for any perceived breach of data privacy. The objection raised is that the healthcare practitioner is being assumed guilty even if the issue could be a software glitch or poor storage of the data.

Medical ethics and telemedicine

The term "medical ethics" was introduced by Thomas Percival, an English physician, in 1803.[466] Medical ethics are defined as the "moral principles that govern the practice of medicine".[467] They have evolved from at least the 4th century BC, with the Hippocratic oath dealing with two of the four foundations of modern medical ethics, beneficence (do good) and nonmaleficence (do no harm), to which respect for autonomy (the right of a competent person to make informed decisions about their

[a]See glossary for terms.

own medical care) and justice (fairness and equality) have been added. Modern medical ethics are largely a product of the mores of the developed world. The individual is recognized as an autonomous entity who must make informed decisions for him- or herself. But local culture and customs differ across the world. In patriarchal societies or those in which decisions about a person's health and treatment are made by the family or community, autonomy is not a priority. This needs to be considered when developing or assessing telemedicine ethics in different settings.

Commonly raised legal and ethical issues are as follows:

- Physician patient relationship
- Licensure
- Jurisdiction
- Quality and standard of care
- Continuity of care
- Consent
- Confidentiality
- Privacy
- Data security
- Authentication
- Remuneration
- ePrescription

The doctor-patient relationship

The doctor-patient relationship is considered a fundamental component of the delivery of high-quality medical care. The relationship is based on mutual respect, trust, and knowledge, and if absent, is considered to impair the physician's ability to make a full assessment of the patient, making the patient less likely to trust the diagnosis and management.[468] Regulators see the relationship, or lack thereof, as one of the major problems of telemedicine. Regulations in many jurisdictions require a prior relationship before there can be a telemedicine consultation, other than in an emergency. All states in the United States now allow a physician to establish a relationship with a new patient via telemedicine, and the American Medical Association has defined several ways in which a patient physician can be established for telemedicine, including VC-based examinations, a consultation with another physician who has an ongoing relationship with the patient, and meeting evidence-based practice guidelines for establishing a patient-physician relationship.[469] How this is to be achieved in store and forward telemedicine is not commonly addressed.

The WMA 2009 statement notes the challenge that telemedicine makes to the conventional approach to a doctor-patient relationship but does not identify this as a requirement, other than the need to comply with relevant legislation and professional guidelines.[458]

Licensure

Licensure has different components. The first is that the health professional has fulfilled the educational requirements to practice. In the United States, one has to qualify through the United States Medical Licensure

Examination (USMLE), while in many other countries, there is a need for a university qualification in medicine. Thereafter, health professionals must be registered or licensed with the relevant national or local medical council or board to legally practice in a given jurisdiction.

Should health professionals require separate licensure to practice telemedicine? This implies that they will require further education or training. Some argue that this is appropriate; others point out that the telephone has been used in clinical practice over distance for over a hundred years,[8] without the need for additional licensure. The WMA's stance is, "The physician providing telehealth services should be familiar with the technology" and "The physician should receive education/orientation in telehealth communication skills prior to the telehealth encounter."[458]

The second relates to jurisdiction. In the case of cross border consultation, be it between countries or jurisdictions within countries, should health professionals be licensed/registered to practice in the other country or state? There is need to reflect on Malaysian law that imposes severe fines and/or jail for health professionals who do not comply. What of international humanitarian services offered by nongovernmental organizations?

Jurisdiction

In part, jurisdiction has been covered under licensure. It also refers to where and under which laws legal action will be taken if necessary. It is usually held that the legal jurisdiction in telemedicine is that in which the patient resides. The WMA's principle of the duty of care notes, "The legal responsibility of health professionals providing health care through means of telehealth must be clearly defined by the appropriate jurisdiction."[458] It has been generally held that the referring doctor is responsible for the patient, as in the rescinded WMA 2007 Statement of Ethics for Telemedicine.[471] The WMA's 2009 position is now more explicit and also addresses continuity of care, "The physician needs to clarify ongoing responsibility for the patient with any other health care providers who are involved in the patient's care."[458] In the absence of jurisdictional regulations, this could mean that the legal jurisdiction could shift to that of the doctor being consulted.

Quality and standard of care

The Institute of Medicine's six aims for improving quality of healthcare are the provision of safe, effective, timely, efficient, equitable, and patient-centered care.[472] While telemedicine aims to achieve all of these, is a teleconsultation as good as a face-to-face consultation, and are treatment and management plans proposed as effective? This relates in part to concerns

about a prior doctor-patient relationship. As stated, there are many concordance and satisfaction studies across a range of specialties using telemedicine that show teleconsultation to be comparable with face-to-face consultation. The effectiveness or outcomes of telemedicine are not as well researched, but ideally need to be monitored in all telemedicine services.[473]

Guidelines are a way of setting standards of practice and quality of care. These should follow existing clinical practice guidelines, which may need to be modified to meet telemedicine-specific circumstances. Guidelines should be developed by experts within the discipline and should be endorsed by the relevant professional body.[458] In addition, operational, technical, legal, and ethical guidelines should be developed.

Consent

Should there be a specific consent for telemedicine? Consent has been viewed in different ways. The extreme one is that telemedicine is new, different, and with potentially more risk to the patient, so the patient must be protected by being informed of all aspects of the telemedicine consultation process.[474] These include how a telemedicine encounter differs from traditional face-to-face consultation and care; how data is to be acquired, transmitted, and stored; what security is in place to ensure that it is not intercepted; who will see it at the other end; who will have access to it; how confidentiality will be maintained when others are present during a VC session; and how the patient and health professionals involved will be authenticated. Additionally, the patient should be informed of other options available. To ensure that this is done, informed consent should be written with records kept in the patient's file and a copy provided to the patient.

Others see video consultation as little different from face-to-face consultation and question the need for telemedicine-specific consent. The WMA takes a pragmatic approach, advising adherence to relevant legislation regulations, taking informed consent "to the extent possible," documenting the consent with consent following "similar principles and processes as those used for other health services."[458]

For informed consent to be valid, the patient must understand what he or she is consenting to. To explain data transmission and its security before, during, and after transmission by videoconference, mobile phone network, the Web, email, or instant messaging requires the doctor to have a sound knowledge of what has to be explained and makes the assumption that the patient has also fully understood this when they provide the consent. The problem exacerbates when translators gain consent. Recent studies have shown that less commonly spoken languages have not kept up with technology and do not have words for many aspects of ICT—especially the medical terms and that patients do not necessarily understand the words translated into their first language or in English.[475]

In the United States, 20 states as well as Washington DC have informed consent requirement, with two requiring written acknowledgement from the patient, as the Federation of State Medical Boards and the American Medical Association are promoting the requirement of informed consent for telemedicine.[462]

Confidentiality and privacy

The words confidentiality and privacy are often used incorrectly. Confidentiality refers to personal information about a patient that cannot be divulged by a physician without the patient's consent. Privacy refers to the right to control access to oneself. It includes physical privacy and privacy of electronic data. Privacy of electronic data entails ensuring data security, including encryption, during its acquisition, transfer, and storage, and control of who has access to the information. Access to data can be assigned and controlled using different levels of authentication including passwords, onetime pins, and biometric identification. Breach of physical privacy and confidentiality is possible when third parties, such as technicians, are present during VC consultations.

Authentication

Authentication is less commonly addressed: how can the identity, qualifications, and licensure/registration of the referring practitioners and the physician being consulted and the identity of the patient be confirmed? In some instances, services contracts and credentialing processes for the physicians can partly address this concern. For VC telemedicine, recognition of the person in view serves as a form of confirmation. Store and forward services may use a secure website with access controls and authentication. Digital signatures and certificates, which are the norm for government and legal documents, are not adopted for telehealth, but may be used in the future (remember that an image of the signature is very easy to emulate). But what of unsolicited email requests for telemedicine services or the more recent emergence of instant messaging telemedicine and direct to consumer services? Blockchain is being discussed as an answer too (see Chapter 14).

The ethics of telemedicine

In the developed world, concepts of medical ethics are well established. They are being refined as medicine advances and gives rise to new issues. Similarly, approaches to ethics related to telemedicine are evolving. Simplistically, all that is required is that health practitioners abide by laws and regulations. However, the situation can be complex and an

ethical conundrum. Is it ethical to deny a patient a telemedicine consultation with a specialist when he/she is available, because of the absence of a prior doctor-patient relationship, there is uncertainty about data security, or even a lack of understanding of the technology to be used that may invalidate consent? Is it ethical to thereby subject them to diagnosis and management by a less qualified or relatively less experienced local practitioner?

Must a patient in snowbound remote northern Canada or Russia, isolated areas of Australia, or the Sahara desert travel long distances under adverse conditions and at significant cost to themselves or the tax payer, because of ethical concerns? In the developing world, the patient may not be able to afford the travel costs or face the risk of losing a scarce job because of absence from work, thereby also being denied quality care.