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Telemedicine: Responsibilities and Contractual Framework

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Abstract

The rapid growth of telemedicine has created a need for a definition of the responsibilities of the doctors involved. These responsibilities must be analyzed according the tort of negligence as a function of the level of competence of each doctor, their unequal access to the relevant information and their command of the telemedicine system. This analysis leads on to a study of the legal value of the electronic records kept and the ways in which the doctors are remunerated.

Keywords

Telemedicine; Responsibility; Burden of Proof; Electronic Records; Medical remuneration.

Introduction

Within less than five years, the development of national and international digital networks has led to the appearance not only of new medical technology but a new medical practice: telemedicine.

Using this, doctors can exchange diagnostic opinions on a daily basis, or give assistance to patients in emergency or isolated situations where the presence of a doctor is not possible.

This medical practice, which is likely to become more widespread and perhaps even commonplace, however requires a proper legal and ethical framework; the lack of this could detract from its advantages and lead to unjustified risks to patients.

We will begin by describing the different situations where telemedicine can justifiably be used today, and then propose a scheme for assigning responsibility which could be used in case of injury to a patient; and the financial arrangements which would allow the system to continue while giving doctors a proper reward for their work and investment.

1. The fields of application of telemedicine

1.1 Telemedicine for diagnostic purposes: current applications

The first applications of telemedicine developed in the fields of pathological anatomy and radiology. They were initially conceived as a system for assisting diagnosis for colleagues faced with difficult decisions, by exchanging images and commenting on them by telephone.

In parallel with this function of assistance and training, there was also a need for remote aid to patients who could not receive specialized medical attention in an appropriate time scale, either because of an emergency or an isolated situation. A classic example of an emergency and isolated situation is the crew of a ship on the high seas without a doctor on board, and others range from humanitarian aid situations to those arising from shortage of doctors in depopulated areas.

Telemedicine has a role in humanitarian aid by providing medical care in developing countries where health professionals are not yet available in sufficient numbers to satisfy the health care requirements of the population. For example, dermatological or anatomo-pathological opinions could be used to supply effective support to primary health care actions taken by health personnel or general practitioners providing day-to-day care in field clinics.

The problem of the shortage of doctors in less populated areas of developed countries arises from the economic constraints of health systems and the demographic changes which make it difficult to provide costly specialized medical care in regions with low population. Telemedicine however offers the possibility of equitable access to medical resources for the inhabitants of these regions with low demographic density. In the case of a surgical operation requiring for example an unscheduled anatomo-pathological examination, this examination could be performed by the surgeon who would transmit, with the help of a technician, images of the lesion to a duty anatomo-pathologist in a larger hospital. Before the era of telemedicine, microscopic diagnosis of the lesion would have required the presence of an anatomo-pathologist, often travelling from a distance.

In general, telemedicine is a means of maintaining access to specialist care in sites where low demography does not justify the provision of specialists.

All these applications have in common the provision of an effective response to a practical request for an opinion. The development of more interventionist processes can now be anticipated.

1.2 Interventionist telemedicine: developing applications

The arrival of networks with very high information flow rates enabling the transfer of animated images, such as the ATM network, improves the possibility of remote diagnosis since they introduce the possibility of direct observation of the patient. This opens up the way to a new practice: interventionist telemedicine.

In the majority of critical situations, once a remote diagnosis has been obtained, the only solution is to transfer the patient as quickly as possible to a hospital with the necessary expertise and resources. However, this is not always possible, or would represent a major risk for the patient. Direct observation of the patient would allow a doctor to teleguide the persons attending the patient so that they could correctly perform the initial treatment steps, or even to give advice to a colleague performing a difficult operation.

This assistance could be fundamental in surgery where it is already potentially operational, as the Hospitals of Strasbourg successfully demonstrated in a recent conference in Montreal where a Canadian operation was commented on live from France. A doctor unexpectedly faced with a difficult act for which he had not the experience could thus benefit from the experience of a colleague who performed this act regularly.

2. Medical responsibility in telemedicine

The generalization of the practice of telemedicine is certain to rise, as does any medical technique, medico-legal problems if a patient suffers injury. The doctor participating in telemedicine activities must be aware of the different aspects of his professional responsibility in the area, and the conditions in which he may be required to produce proof of his actions.

2.1 The assignment of responsibilities

The responsibilities of the doctors must be clearly identified to avoid their dilution, which would be prejudicial to the interests of the victim of the injury. This identification must take account of several factors: the principle of care, the competencies of the doctors, their unequal access to the relevant information, their knowledge of the operation and limitations of the telemedicine system, and also of possible malfunctioning of the technology.

2.1.1 The principle of care

The determination of the respective responsibilities of the doctors contributing to the diagnostic and therapeutic decisions is a classic aspect of the legal and ethical analysis during proceedings instituted by a patient in which several doctors are involved.

The object of this analysis is the search for the medical behaviour which led to the error, since it is this behaviour that determines the possible responsibility of the doctors, and not the diagnostic or therapeutic error itself. It is accepted in the jurisprudence that the duty of the practitioner is only a duty of means. If the means, technical or intellectual, normally used by a competent and diligent professional have not been used, this represents criminal negligence.

A doctor cannot be censured for not having been able to make a difficult diagnosis, for example in studying a x-ray film or an anatomo-pathological examination slide. On the other hand, if the lesion is common and obvious, the facts show that the professional has not given the care founded on data known to science. In other words those normally known by a competent and diligent practitioner who must always make use of if necessary, the aid of competent third parties [1]

2.1.2 The level of competence of the doctors

Three situations are possible in telemedicine. The doctors could be a general practitioner and a specialist, two specialists from different disciplines or two specialists from the same discipline. When a general practitioner asks for an opinion from a specialist, it seems legitimate that the latter takes responsibility for his reply. He is effectively being appealed to because of his expertise in the specialist field where he practices exclusively, and the requester of the opinion would normally follow the advice he gives. If, on the contrary, he takes the risk of not following it, the general practitioner could see his conduct censured. The situation is identical if a specialist asks for an opinion from a specialist in a different discipline.

When the two doctors practice in the same speciality, it would be tempting to analyze the situation in the same way by considering that the doctor asking for the opinion is acknowledging the superiority of his colleague in a pathological field. This analysis would implicitly lead to the creation of a category of "superspecialists" or the artificial creation of a multitude of new specialities with no recognized status. It is true that, in some cases, specialists in the same discipline exchange views, but this is not a regulated and normal conduct. In the presence of the patient, the specialist acts as such, and if faced with a difficulty which he cannot resolve, he is obliged either to decline to give an opinion, or to avail himself of the necessary advice but while completely and personally assuming his responsibility as specialist [2]

This duality which governs the behaviour of the specialist is reflected in the approach taken by the health insurance schemes. Although they recognize the existence of two different medical acts when a general practitioner asks for a specialist opinion or when a cardiologist refers his patient to a nephrologist, this is not the case if a cardiologist refers his patients to other cardiologists. The specialist must justify his status, which is the reason for his being consulted by the patient. He assumes this responsibility towards his patient, and will if necessary take action against a referent doctor who has badly advised him, according to the terms of the contract which they should have established for this assistance in diagnosis.

The case of telemedicine differs from the normal conditions of a request for a specialist opinion in that the specialist cannot examine the patient and does not have access to all the information. The doctors who request and give opinions are thus not in the same situation with respect to the information on which the diagnosis is based.

2.1.3 The unequal access of the doctors to the information

During a telematic consultation, the conduct of the doctors must also be evaluated as a function of the respective roles which they have in reaching the diagnosis. In fact, although the two doctors involved, the requester of the opinion and the referent,

exchange information between each other, their situation with respect to the information to be examined is nevertheless not equal. The requester of the opinion has access to all the available information, while the referent in general receives only a part of that information, selected by the first doctor. This selection must be made by someone competent, capable of choosing the information relevant for the diagnosis and of interacting effectively with the referent. This is the most common situation in telemedicine, where the two doctors are most often of the same speciality and are accustomed to such a dialogue. The use of the method by doctors from different specialities is justified in particular by emergency situations and difficulty in access to the specialist consulted via telemedicine [3]

The fact of not having available all the information does not exonerate the specialist from his responsibility with respect to the advice which he gives. In case of doubt or of difficulty in diagnosis, it is up to him to ask for additional information, and to decline to give an opinion if this information is insufficient for his needs, or if he feels not competent to do so.

2.1.4 The command of the telemedicine system

The use of a telemedicine system also requires each doctor to have a complete knowledge of its use and limitations. The duty of means of the doctor in fact includes a full knowledge of the handling of the instruments used and their instructions. If an image has been badly taken, or if the information characteristic of the lesion has not been captured, both the referent and the requester of the opinion could see their responsibilities challenged if this lack of quality leads to an error. It is relevant to note that radiologists for example have a duty of result as to the quality of the technique used in taking a x-ray.

The responsibility of the doctors may also be challenged if the transfer of data leads to information, which is deformed, damaged or communicated to unauthorized third parties, whether this breach is due to them, or to a third party.

The main difficulty in analyzing these responsibilities could be to distinguish between that which results from incomplete command of the system and of its malfunction.

2.1.5 Equipment malfunctions

According to the jurisprudence, it seems that the technical malfunction of a telemedicine system calls into question the responsibility of the doctor. The patient has the right to expect that the instruments used by the doctor are not defective. However, in this context, it is possible for him to take action under guarantee against the equipment supplier. All vendors have a duty to supply a product suitable for the use for which it is intended, and companies marketing telemedicine systems are no exception to this rule. In telemedicine, this suitability must be expressed in terms of quality of production and transmission of information. The compression and decompression of images, aimed at increasing their transmission speeds on the network and at reducing the size of memory required, must therefore not do so at the expense of their readability. It is therefore necessary to evaluate teletransmission systems to know if it is justifiable to use them and to define the conditions and limitations of their use [4]

This scientific evaluation of the quality of the product, and of its suitability for the service, which it is supposed to fulfil, will be a decisive factor in the case of litigation between the manufacturer and the doctor using it. The manufacturer could be censured for not having performed an evaluation of his product, but the responsibility of a doctor who had bought a system without having inquired as to its guarantees could also be questioned.

In addition, the supplier is obliged to provide an instruction book written in comprehensible terms.

2.2 The methods of proof

The determination of responsibilities requires a precise analysis of the facts and their context, i.e. the exact content of the telematic exchange at the origin of an injury. This implies that this information should be archived and that the validity of its archiving as an element of proof before a court must be studied.

2.2.1 Records in telemedicine

In the case of medico-legal litigation, the doctors must present proof that they have behaved diligently and in accordance with the usual practices of the profession, by producing the images transmitted and the replies given. The quantity of information generated by image storage in practice requires the use of optical memories, since only these have the enormous storage capacity for storing several tens of images per day. For the legal reasons discussed in the next paragraph, the non-rewritable CD-ROM is the preferred option. This stored information nevertheless does not provide evidence of the telematic transaction, particularly in the case of disagreement between the doctors. They could in fact deny having transmitted or received the images or the replies in question. There must therefore be proof of the emission and reception of the images and the replies by the doctors.

The health professional's card, which will shortly be available, allows for the electronic signature of transmitted documents, and thus ensures the identification and authentication of the sender, so that he cannot deny being the author. This is referred to as non-repudiation. The electronic signature also enables the content of an electronic exchange to be sealed, and guarantees its integrity [5]

The coupling of the transmission to a time standard testifies to the time of the request and the delay before the reply is given. Finally, an authenticated acknowledgement must be sent on the reception of images and replies.

The complexity of the security mechanisms will mean that, with the generalization of telemedicine, the majority of electronic transactions will be made not directly from doctor to doctor, but via a central server. It is this, which will perform the reception of requests for opinions, direct them to the available referent doctors, implement security procedures and play the role of third-party guarantor.

Although, from the technical point of view, these solutions offer better security than the exchanges by letter used up till now, their legal recognition has not yet been clearly established. Analysis of existing legislation however shows that there are few obstacles.

2.2.2 The legal value of electronic records

Law should soon take formal notice of the necessary extension of hard-copy media to non-material media by defining records as a set of documents, irrespective of their date, form and material support but the conformity of non-material documents to the notion of records is not sufficient to establish their value as evidence. The rules applicable to evidence moreover vary as a function of different jurisdictions, but nowadays all contain elements favouring the legal value of records on non-rewritable optical disk and the electronic signature.

3. Remuneration of the doctors

"All effort deserves reward" and telediagnostic equipment is expensive. It would thus be unreasonable to expect a doctor in the future repeatedly to give diagnostic opinions to his colleagues without financial reward, either for himself or his parent establishment.

This association of competencies and the resulting financial exchanges must be included in a contractual framework, which clearly eliminates any risk or suspicion of divergence from medical ethics.

This contract must provide that they send, with a defined frequency, a summary of examinations performed for each requesting doctor. In return, the requesting doctors must pay the appropriate amount for the acts performed, less any justifiable expenses for the administration of samples and administrative documents.

However, it is advisable that the number of requests for opinions does not exceed a given volume. Excessive use would represent a misapplication of the purposes of telemedicine, and could create *"medical"* structures which would be no more than sites for sample collection or the taking of radiological images, for example. A maximum volume of two thirds of the total volume of acts carried out by the requesting doctor could be fixed.

Conclusion

Apart from the reticence of practitioners with regard to computer technology with which they are not familiar, the fear of legal vagueness, which surrounds telemedicine, is a cause for hesitation by potential users.

The clarification of the legal framework in which telemedicine is practised, and in particular the identification of responsibilities and the specification of doctors' remuneration within a contractual framework, seems now to be an essential condition for its more widespread use

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