

The doctor-patient relationship in telemedicine and mobile health

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Abstract

Telemedicine falls under the broader term of eHealth and involves the delivery of health care services, where distance is a critical factor. Thanks to telemedicine patients can access treatments that would otherwise be unavailable.

The authors focus on whether doctor-patient relationship exist in telemedicine and mobile health. The answer should be found on a case-by-case basis. There is a doctor-patient relationship when the two are connected, possibly electronically, for purposes related to the prevention, diagnosis or treatment of diseases. But the doctor-patient relationship is absent when the patient downloads apps to self diagnose rather than seeing a doctor. These apps encourage the use of 'DIY' medicine, making the doctor superfluous and can often lead to misdiagnosis and misunderstanding.

Informed consent to the use of telemedicine should have the same prerequisites as those used in traditional medical practice. However, telemedicine requires some additional information: risks related to the privacy of personal data and precautionary measures to reduce them; further risks involved in the use of technology (for example, quality and efficiency of the telematic tools).

With regards to the processing of personal data in mobile health, informed consent should be even more specific than that for medical treatment via telemedicine. In order to respect the requirement of specificity, the app should be structured in a way that allows the user to express consent for each type of data that the app intends to collect. But such a solution presents various difficulties. In conclusion, direct contact between a doctor and their patient should continue to be the preferred practice with which to carry out the relationship. Telemedicine can be used when it is deemed to be in the best interest of the patient, for example when it can offer the possibility of surgical treatment otherwise unavailable, or where contact is not possible.

Keywords: *Telemedicine, mobile health, doctor-patient relationship, informed consent, privacy.*

Introduction

Since the beginning of this new Millennium, the health sector has been experiencing profound structural and organizational transformation, thanks to the large scale application of Information Technologies that have changed and improved the social aspect of the health system. One of the most significant innovations that involves approximately 500 million users worldwide, is represented in the 'mobile revolution' that has brought with it the phenomenon of 'mobile health' [1].

According to the definition by the Foundation for the National Institutes of Health (FNIH) in the mHealth Summit of 2010, the term mobile health or mhealth is used to indicate "The delivery of healthcare services via mobile communication devices" [2] namely mobile technologies or rather the use of wireless communication (such as mobile phones, smartphones and tablets, digital devices with or without wearable sensors), applied in a healthcare environment. The mobile revolution is referred to as a pervasive phenomenon both in the society in which we live and in the healthcare environment: where information is transmitted to anyone, anywhere, it is received and saved anywhere at any given moment using a number of devices. The ubiquitous, global and instantaneous have become intrinsic elements to the network of our digital society [3].

The development of such technologies is fast and in constant growth. A recent research in 2013 revealed that in the current market there are approximately 97,000 applications on various platforms; around 70% of these are related to health and well-being and 30% are dedicated to patient monitoring, diagnostic imaging and to pharmaceutical information [4].

It is estimated that in 2016 the number of patients monitored by such technologies will be up to 3 million and by 2017, up to 3.7 billion people in the world will be in possession of a smartphone and will be using applications related to their health. By 2018 it is estimated that there will be 1.7 billion health app users in the world [5].

Those figures are confirmed in the Italian environment. Research by the Milan Polytechnic Observatory in 2016 confirmed that citizens (in particular the age group 35 to 54) and General Practitioners (GP's) communicate more and more via digital channels; 83% of doctors use email, 70% sms messages, 53% of GP's use WhatsApp (+33% compared to 2015), above all because this method 'enables an exchange of data, images and information, that can avoid an actual examination' [6].

These technologies have pathed the way for global communication and allow large quantities of data, images and audio messages to be exchanged. This enables the

breakdown of barriers such as time and distance, which benefits the patient and the doctor, who can access vital information at any time in any location [7]. The introduction of e-health has huge potential to improve both public health and individual health. In spite of these interesting aspects, however, one is obliged to highlight several risks of a legal nature that hinder the full deployment of telemedicine [8,9].

In a certain sense, mobile health represents the evolution and the globalisation of tele-medicine. According to the World Health Organisation, "Telemedicine (also known as telehealth) falls under the broader term of eHealth and involves the delivery of health care services, where distance is a critical factor. The telemedicine approach uses information and communication technologies for the exchange of information for diagnosis, treatment and prevention of diseases and injuries, research and evaluation, and for the continuing education of healthcare providers" [10].

Paradoxically however, as we will see, this revolution brings with it the risk of negating medicine all together. Before examining this aspect, one must clarify whether the concept of mobile health and telemedicine constitute medical activity and whether they substitute the doctor-patient relationship.

Is the Act of Telemedicine an Act of Medicine?

Telemedicine is both a service of the national health and of the information society to provide information ("information society service"). The latter is defined as "any information service by a company", meaning, any service offered electronically at the request of an individual, at a distance in exchange for retribution. Consequently, as clarified by the European Commission, telemedicine is governed by Article 49 of the Treaty of the European Union, which states that the provision of services within the Community must follow Directive 2000/31/EC, known as the 'e-Commerce Directive'. This governs the information society services both between one another and within their own state [11].

The Court of Justice established that the main principle in freedom of movement should be applied independently to the special nature of health services and to the way in which they are organized and financed [12,13,14]. Consequentially, the users of health services are free to look in other states, independently of their own location and therefore can do so via telemedicine [11].

The classification of telemedicine services as acts of medical practice should ensure that services offered are at the same level as those offered by the traditional health service (for example radiology and tele-radiology). This

enables the prevention of two risks: 1) that highly regulated health services are substituted by unregulated digital services; 2) discrimination between various suppliers of the same service [11].

Does the Doctor-Patient Relationship exist in Telemedicine and Mobile Health?

The fact that health services can now be provided digitally undoubtedly calls into question current health structures, but it also raises the question of responsibility in the doctor-patient relationship, that of the practicing doctor or doctors and not just the structure in which they operate.

In the traditional sense, the relationship begins only when the doctor has physical contact with the patient via an examination to form a diagnosis or prescribe a course of therapy. The American Medical Association defines it in this way: "A patient-physician relationship exists when a physician serves a patient's medical needs, generally by mutual consent between physician and patient (or surrogate). In some instances the agreement is implied, such as in emergency care or when physicians provide services at the request of the treating physician" [15]. In fact, emails are only used for "supplemental encounters and informing patients clearly about the inherent limitations of e-mail communication" and only after a physical relationship has been established [16]. In any case the use of email is considered inappropriate to communicate bad news or abnormal test results, as this is considered to be a possible cause of confusion [17].

With regards to the use of the Internet, the Federation of State Medical Boards (FSMB) shares the above observations and states that the doctor is obliged to provide the patient with ample opportunity to express their concerns and the right to a timely response [18]. The Italian National Committee of Bioethics established that diagnosis should always be carried out by a direct examination and that telemedicine involves exclusively consulting activities that are necessary for the specifics of each case or to provide further information and decisional support (19).

In court, the question is more controversial. In the US, some courts have ruled that there may be a physician-patient relationship through telecommunication devices even without direct contact with the patient. Others, however, argue that such a relationship can not arise when the doctor, without seeing or examining the patient, simply gives the patient a questionnaire to fill out and then prescribes medicines via the internet [20,21].

In our view, one cannot rule out the existence of the doctor-patient relationship in telemedicine practices. For example, the practise of performing delicate surgical

procedures in which the team is located in one state and the patient in another [22, 23]. Can one really argue that in such a situation there is no relationship between the patient and the team for the mere fact that the operators see the patient through machines rather than directly with their eyes? We think not. In fact, for this reason it is clear that information should be provided electronically (and consent given) by the surgeon who will perform the surgery, despite their location in another state. The main criteria to ascertain whether there is a doctor-patient relationship seems to be based on the fact that the two are connected, possibly electronically, with a physician for purposes related to the prevention, diagnosis or treatment of diseases. If then the doctor gives a wrong diagnosis, in spite of the fact that they could physically visit the patient and/or refer them to other specialists, this means that the doctor is culpable, not that there is no doctor patient relationship because the relationship was conducted electronically [24].

However, even if it is felt that in telemedicine practices there is no relationship between doctor and patient, this could perhaps rule out the responsibility of those who use such practices, but not the responsibility of the doctor who, in the context of his relationship with the patient, recommends that the use of telemedicine is unsuitable.

On the other hand the doctor-patient relationship is absent when the patient downloads apps to self diagnose rather than seeing a doctor. In this situation the patient has no contact with a doctor, but has contact with an elaborate electronic system based on scientific knowledge and guidelines, at the very best. He has contact with prestigious groups, associations or scientific companies.

This can be a dangerous deviation. These apps encourage the use of 'DIY' medicine, making the doctor superfluous or in fact dangerous and can often lead to misdiagnosis and misunderstanding. Diagnosis is made by flagging symptoms from a very long list using a mathematical selection method for which any group of given symptoms could produce the result of an illness that the patient does not have. It is a sort of two plus two equals six.

In fact, these apps are often designed as an aid in the work of doctors and interns precisely because they are based on authoritative scientific knowledge, unfortunately their purchase is not at all reserved exclusively for professionals. Rather, their minimal cost makes them accessible to everyone.

Informed consent for telemedical treatment

First, if, as is often the case, the patient has acquired knowledge about their disease and its treatment by searching the Internet, it may be necessary to correct any incorrect information or otherwise to correct very general

information, that can be misleading to a specific case [25].

This task falls upon the doctor who establishes a relationship of care, which can also be established at a distance if the physician speaks directly with the patient, even if it is done from a different and distant location [26,27]. Recent clinical trials show that in the cases of electronically acquired consent, the level of understanding of the information received electronically is equal to the level of understanding when using the traditional consensus method, that is face to face interaction between doctor and patient [28].

Informed consent to the use of telemedicine should have the same prerequisites as those used in traditional medical practice. However, the unusual nature of the phases of telemedicine require the certain additions. Even when a patient receives a service telematically, they need to be made aware of the nature of the service itself and the relative risks and benefits of said service.

Organisations should activate precautionary measures to reduce the risks involved in the use of telemedicine, especially those related to the privacy of personal information. Once the patient has been informed of the risks, they are then able to decide whether or not to consent to the use of telemedicine [29].

Above all, the doctor's obligation and the patient consent should be extended to further risks involved in the use of telemedicine. For example, a doctor that intends to perform an operation telematically should make clear to the patient the possibility of the interruption of the service in a situation such as an electrical blackout. The doctor has a duty to ensure that the patient has understood the risks before they are able to accept the patient's consent. The most prudent practice would be for the doctor to clarify all the technology that they intend to use and the risks and benefits related to each of them [30,31].

The Italian Supreme Court establishes a general rule for all consent and this can be applied to telemedicine: the doctor or surgeon has a duty to inform the patient of the risks and benefits of the treatment and therefore they also need to be made aware of the efficiency of such treatment at both an operational and structural level, related to the place in which the doctor intends to perform their duty [32]. Consequentially, information should also be provided about the quality and efficiency of the telematics tools that will be used to provide the service. If a particular case presents significant risks, it would be preferable to provide the patient with a specific form covering these or at least to draw their attention to a section of a pamphlet relevant to their case.

With regards to the possible content of such a consent form, we feel that it should contain a complete spectrum of useful information to enable the patient to make a fully informed decision. Thus it would be necessary to explain exactly how telemedical services would be

provided, to specify who would be present at a consultation and the risks involved with digitally registering the patient's information and how that information is registered. For example, if a person has to have an electrocardiogram, he should be told that he has the option to do so telematically. In this way we can obtain a balance in the choice of medical care, between care provided by a doctor who will diagnose and prescribe therapies to their patients, based on a principle of self-determination, and the telematic diagnosis and the freedom of the patient refuse the prospective telematics diagnosis. The patient must be made aware that any refusal to accept telematics diagnosis could have consequences, such as delays in starting treatment because of possible waiting lists for a traditional examination at the hospital.

Informed Consent for the use of Personal Data in Mobile Health

With regards to the processing of personal data, informed consent should be even more specific than that for medical treatment via telemedicine.

The requirement of information means that the person providing the data must receive the necessary information to make an informed decision. It must be given to them before any personal data is taken, even if only at the moment of registration.

Further specificity in the process of consent to the use of data comes from the fact that the expression of consent itself must refer to the acquisition of any data or any limited category of data. Consequently, the mere fact of clicking on the button that starts the processing of information can not be considered as valid consent to its processing because it lacks the requirement of specificity.

Similarly, if an app is structured in such a way that the user can only accept (or reject) a total of all the terms of use and privacy policy, one could say that the express consent is not valid because it is not specific. In order to respect the requirement of specificity, the app should be structured in a way that allows the user to express consent for each type of data that the app intends to collect [33,34,35,31,32].

Such a solution, although plausible in theory, presents various difficulties. Above all, digital information is of a vast quantity and is written with small letters that are visible on smartphones. At times, there is no option to revoke consent once it has been given. The main concern is that informed consent, which is visible only on a screen and not on paper, encourages the user to click in agreement without taking the time to fully understand what they are agreeing to [36]. Furthermore, multiple consents push the user to agree just to hurry the registration process; again, the user does not have an

adequate awareness of what they are agreeing to. In this case, the meaning of informed consent is lost because whilst the patient has been offered the information, they have not in fact read it and is therefore not informed.

The Technological Gap

In spite of their problems, the use of telematics consent improves efficiency in health systems thanks to the reduction of costs of hospitalization. It has broadened the spectrum of ways in which to treat patients and created the possibility to reach patients that previously did not have access to medical care. These new developments present a problem for those that do not have access to technology and increases the gap between those that have both the knowledge and the tools and those that do not. Even though recent data shows that this gap is closing [37] it is important to ensure fair distribution of technological resources and to offer access to new technologies for all, including disadvantaged and vulnerable groups (elderly, disabled, poor people and those not competent enough to use technology effectively). A key element of this process is to ensure the adequate education of citizens on the use of mobile-health technology [38].

Furthermore those who do not have access to technology should not be discriminated against and alternative treatments must be guaranteed to them. This problem is known as the 'digital divide' and one of its main causes is the massive difference computer skills and the ability to comprehend information provided by an app. Nonetheless it is useful to note that there are other reasons for this gap such as the cost of smartphones and tablets and their coverage in certain areas, which is much weaker than in others. Such variables can have a great influence on the equality of access to health services via telemedicine.

Conclusion

In spite of the legal problems associated with obtaining consent for the use of personal and health information, it is hoped that the use of telemedicine and mobile health continue to spread. These tools can offer great benefits for both the patient, who can access treatments that would otherwise be unavailable, and to the health service, facilitating efficiency and offering the possibility to cut costs. However, one should be careful to avoid that telemedicine does not replace traditional medicine: direct contact between a doctor and their patient should continue to be the preferred practice with which to carry out the relationship; telemedicine can be used where

contact is not possible or when it is deemed to be in the best interest of the patient, for example when it can offer the possibility of treatment that was previously unavailable.

Other risks are created by the unmonitored growth of health apps. Allowing a tablet to make a medical diagnosis when a patient selects from a list of preinstalled symptoms, completely trivialises the practice of medicine, which is based on so much more than ticking off a list of symptoms. Consequently there is a risk of misleading the patient about their actual condition thus doing them serious harm. Therefore, this type of app can even result in the nullification of the very medicine that seeks to promote.

Authors' contributions

All the authors have made substantial contributions to conception and design of the manuscript and have been involved in drafting the manuscript and revising it critically for important intellectual content and all of them have given final approval of the version to be published.

Competing interests

The authors declare that they have no competing interests.

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