

Medical Legal Aspects of Telemedicine in Italy: Application Fields, Professional Liability and Focus on Care Services During the COVID-19 Health Emergency

Journal of Primary Care & Community Health
Volume 11: 1–9
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DOI: 10.1177/2150132720985055
journals.sagepub.com/home/jpc



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Abstract

Telemedicine services can be classified into the macro-categories of specialist Telemedicine, Tele-health and Tele-assistance. From a regulatory perspective, in Italy, the first provision dedicated to the implementation of Telemedicine services is represented by the Agreement between the Government and the Regions on the document bearing “Telemedicine—National guidelines,” approved by the General Assembly of the Superior Health Council in the session of 10th July 2012 and by the State Regions Conference in the session of 20th February 2014. Scientifically, several studies in the literature state that information and communication technologies have great potential to reduce the costs of health care services in terms of planning and making appropriate decisions that provide timely tools to patients. Another clear benefit is the equity of access to health care. The evolution of telemedicine poses a series of legal problems ranging from the profiles on the subject of authorization and accreditation to those concerning the protection of patient confidentiality, the definition and solution of which, in the absence of specific regulatory provisions, is mainly left to the assessment of compatibility of the practices adopted so far, with the general regulatory framework. In terms of professional liability, it is necessary to first clarify that the telemedicine service is comparable to any diagnostic-therapeutic health service considering that the telemedicine service does not replace the traditional health service, but integrates the latter to improve its effectiveness, efficiency and appropriateness.

Keywords

telemedicine, legal medicine, medical professional liability, Covid-19

Dates received 30 September 2020; revised 30 November 2020; accepted 9 December 2020.

Definition

Telemedicine can be defined as a method of providing health care services, through the use of Information and Communication Technologies (ICT) in situations in which the health practitioner (or two of them) and the patient are not in the same place.

Telemedicine is a term coined in the 1970s which literally means “healing at a distance”¹ and signifies the use of ICT to improve patient outcomes by increasing access to care and medical information. Recognizing that there is no definitive definition—a 2007 study found 104 peer-reviewed definitions of the word “telemedicine”—the World Health Organization (WHO) has adopted the following broad description:² “*The delivery of health care services, where distance is a critical factor, by all health care*

professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of diseases and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities.”³

Sharpening the WHO broad description telemedicine can be defined in a clear and simple way as a method of

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relationship between medical staff and patients, set in different locations, which results in a significant benefit to the care process through the reduction of time and distances so that health system primary objectives (assistance and therapy) are fulfilled.

Telemedicine in Italy: Legislation

In Italy, the first provision dedicated to the implementation of Telemedicine services is the Agreement between the Government and the Regions which led to the production of the “Telemedicine—National guidelines,” approved by the General Assembly of the Superior Health Council in the session of 10th July 2012, and by the State Regions Conference in the session of 20th February 2014.⁴ The guidelines have the purpose of responding to the need to standardize the experimental initiatives activated in the area and to outline a global framework that also identifies the priorities for the application of Telemedicine.

On the one hand, the document recognizes the substantial equivalence between services provided in telemedicine and traditional services so that Telemedicine corresponds to a different way of providing health and social health services. On the other hand, it highlights the need to evaluate the effectiveness, efficiency and appropriateness of the National Health System (NHS), through the integration of traditional services and telemedicine that should be framed organically within the diagnostic-therapeutic-assistance paths (PDTA).

The vision of a digital innovation as a technological appendage of traditional procedures, practices and methods, highlighted some critical issues that necessarily require a review of the medical-assistance procedures, of the general organization of the NHS, and of bureaucratic practices. Moreover, the aforementioned Agreement on National Guidelines also establishes that the activities deriving from the activation of the Guidelines can be provided only within the limits of available resources, without further burden on public finance. This results in a substantial lack of resources to invest in the design and implementation of new technologies, also considering the generalized cuts in health expenditure that characterized the last decade. However, several studies have shown that a company providing Telemedicine services can generate considerable savings.

Twenty-one reviews concluded that telemedicine is effective, 18 found that evidence is promising but incomplete and others that evidence is limited and inconsistent. Emerging themes are the particularly problematic nature of economic analyses of telemedicine, the benefits of telemedicine for patients, and telemedicine as complex and on-going collaborative achievements in unpredictable processes. Therefore, due to the numerous advantages related to digital health, the Government has decided to adopt a strategic line for the development of

digital health coordinated and shared at national level. Three documents currently constitute the main regulatory references for the development of Telemedicine services in the area: the Pact for health for the years 2014 to 2016; the Pact for digital health and the National Chronicity Plan.

The “*Pact for health for the years 2014 to 2016*” stated that AFT (Functional Territorial Aggregations) and UCCP (Complex Primary Care Units) must constitute the only forms of aggregation of Primary Care. These units were born initially and mainly for logistical-organizational reasons to cope with on-going assistance, but as it is also necessary in developing countries that need telemedicine applications.⁵ Over time, the function of the AFT will also be to share care paths, guidelines, auditing and professional tools by operating a true integration between these networks both in the territory and in the hospital “*through an adequate telematics network.*” Furthermore, explicit reference is made to the “*new information and telephone technologies,*” especially referring to the urgent emergency functions carried out by the operational centers in managing and coordinating requests for medical assistance. In particular, it should be emphasized that these technologies make it possible to coordinate the rescue interventions safer and in a more standardized way, to manage high volumes of activities, to reduce the number of call reception centers, and to activate integrated and interacting operational functions at regional level. This document provides a series of priorities, which must be implemented and subsequently monitored. (Table 1)

Another key document is “*The National Chronicity Plan*” (PNC that consists of 2 parts: the first contains the general guidelines for chronicity; the second providing thoroughly information on pathologies with specific characteristics and care needs. The purpose of the PNC is to activate all the necessary and useful initiatives to promote the dissemination of ICT tools and technologies to support chronicity, enhancing the ability to access resources and promoting innovation in the organization and management of health services. Referring to the specific use of Telemedicine services in favour of the chronically ill patients, the health purposes to be achieved are indicated (Table 2)

With regard to the feasibility of health services in Telemedicine, it should be noted that already with Law No. 189 of 2012, containing “*Urgent provisions to promote the development of the country through a higher level of health protection*” it was clearly indicated that the Complex Primary Care Units “*operate in coordination and telematics connection with hospitals.*” Therefore, already in 2012, the Law established that the telematics connection between UCCP and hospital structures “*is used, and consequently also designed, as an ordinary*

Table 1. The “Pact for Health for the Years 2014 to 2016” Main Stated Priorities.

1	Organizational models and tools for the rationalization of the information technology (IT) infrastructure of Public Health.
2	Unified Communication and Collaboration as a new way of multidisciplinary interaction between professionals in the hospital and in the territory
3	Solutions and services for hospital-territory continuity of care (PDTAs as a new approach and Patient Workflow Management systems).
4	New information-providing platforms for citizens;
5	New organizational models for Primary Care and for sharing medical records;
6	Integrated Hospital Information Systems;
7	Business Intelligence solutions for monitoring the appropriateness of pharmaceutical prescriptions;
8	Teleconsultation, telereferation, telediagnosis, telemonitoring, telerehabilitation;
9	Telemedicine and integration with the Electronic Health Record.

Table 2. Telemedicine in Chronically Ill Patients According to “The National Chronicity Plan” (PNC).

1	Prevention, people at risk or already suffering from diseases such as diabetes or cardiovascular diseases must undergo constant monitoring in order to reduce the risk of complications);
2	Diagnosis, rapid and safe circulation of diagnostic information between the various healthcare professionals involved;
3	Treatment and rehabilitation, the transmission of data relating to vital parameters between the patient and a monitoring station, their interpretation, and the adoption of the necessary therapeutic choices as in Teledialysis services.

working tool and does not provide for further authorization and accreditation procedures for it due to the telematics nature of the connection”.

With regard to the reimbursement of services and benefits, Legislative Decree 502/12 assumes that “the types of assistance, services and health services that present, for specific clinical conditions or risk, scientific evidence of a significant benefit in terms of health, at an individual or collective level, in relation to the resources used”. This concept is applied to all essential levels of assistance, where recognized as such, and therefore also to those types of, services and health services, provided between UCCP and hospitals, connected electronically.

Monitoring patients in their homes can lead to better healthcare at lower costs which implies an increased demand of new healthcare strategies like telemedicine.⁶

Classification

Telemedicine services can be classified into 3 macro-categories: Specialized Telemedicine, Tele-healthcare and Tele-assistance.

Specialized Telemedicine includes the ways in which remote medical services are provided within a specific medical discipline. Performing the equivalent of a complete clinical examination by telemedicine would be unusual. However, components of a more traditional clinical examination are part of the telemedicine workup for specific conditions.⁷ Telemedicine can take place between physician and patient or between physicians and other health professionals. The Telemedicine Services of the

Territory provided by General Practitioners and Family Paediatricians can be included in Specialized Telemedicine.

Depending on the type of relationship between the different individuals involved, the services of Specialized Telemedicine can be achieved in different ways.

Televisit is a medical act in which the physician interacts with the patient at distance.⁸ The medical act of diagnosis resulting from the visit can result in the prescription of drugs or treatments. During the Televisit a healthcare professional who is close to the patient can assist the physician. The connection should allow the physician to see and interact with the patient and can be in real time or deferred.

Teleconsultation is an indication of diagnosis or choice of therapy without the physical presence of the patient and provides the use of video to facilitate real-time, remote interaction between healthcare practitioners and patients.⁹ This is a remote consulting activity between physicians that allows the professional to ask for the advice to 1 or more colleagues (second opinion), based on specific training and expertise, and on medical information related the management of the patient.

Health Tele-cooperation is the assistance provided by a physician or other health professional to another physician or health professional, especially in the consultation provided to those providing emergency aid. It takes place on a telecooperation platform.¹⁰

Tele-healthcare refers to all the services and systems that connect patients, especially the chronic ones, with physicians engaged in the diagnosis, monitoring, and management. Telehealthcare involves the use of ICT to deliver healthcare at a distance and to support patient

Table 3. Tele-Healthcare Through Telemonitoring: Most Relevant Systems Currently Used Divided by Clinical Area and Patient Type.

Cardiology	
Chronically ill out-of-hospital patients	Cardiac telemonitoring: for the continuous recording of cardiac activity carried out by a point of care (electrocardiograph capable of storing ECG traces), with subsequent online transmission of the recorded data thanks to a software that also allows the received data to be integrated with patient information (eg, patient card, technical measures, etc.). ¹³ This data are transmitted to a processing center, in order to monitor and possibly contact the patient promptly.
Chronically ill out-of-hospital patients who face emergency situations	Telecardiology service: this system applies in the occurrence of cardiac emergencies, when a specialist is required in order to rapidly adequate therapy. This service can be very useful in those healthcare settings (eg, doctor's office, private rest homes or long-term care facilities) in which a 24-hour cardiac consultancy service is not constantly available resulting in delays.
Nephrology	
Chronically ill out-of-hospital patients who could face emergency situations	Telemonitoring in dialysis: the patient's clinical data are transmitted to a specialized management center, which processes and controls the operations and if, during a home dialysis session, emergency situations or serious anomalies in the equipment occur action is taken immediately. ¹⁴
Endocrinology	
Chronically ill out-of-hospital patients	Telemonitoring in Diabetes: glucose meters are equipped with a standardized interface that allows the glucose value to be stored in an internal memory with time indication. These values can then be transmitted to a remote specialized center, using a PC or smartphone, together with any note directly introduced by the patient in order to remotely monitor the daily trend. Currently, on the market are available multiple tools capable of collecting data (objective and subjective) useful for monitoring diabetes such as glucose levels and blood pressure, laboratory data (glycated haemoglobin), behavioral information, diet food and exercise, drug dosage, allergies, description of symptoms, check-up or specialist visits, possible hospitalizations, and vaccines. ¹⁵
Gynecology	
Healthy out-of-hospital patients who could face emergency situations	Perinatal Telemonitoring: allows the control of fetal heartbeats and uterine contractions; the evaluation of periodically collected data via scheduled calls allows an immediate intervention in case of incipient birth or fetal suffering. ¹⁶

self-management through remote monitoring and personalised feedback.¹¹ It allows a physician to remotely interpret the data necessary for the Tele-monitoring of a patient and for the management of the patient. The recording and transmission of data can be automated or carried out by the patient himself or by a healthcare professional. Telehealthcare requires an active role of the physician and an active role of the patient (self-care).

The most relevant and frequently used telemonitoring systems are summarized in Table 3.

The positive effect of telehealthcare is substantially related to greater patient self-control together with better compliance with both treatment and early recognition of signs and symptoms of hemodynamic instability.¹² Particularly Home Telemonitoring reduces hospitalization times and improves the patient's quality of life, integrating with post-hospital home care. This service, which is essential in oncology and surgery, allows for an improvement in the quality of care because hospital continuity is guaranteed through the evaluation and monitoring of post-operative progress even when the patient can't reach the hospital.

The third category is Tele-assistance that is a socio-assistance system for the management of the elderly or frail persons at home, through alarms, activation of emergency services or support calls from a service center.¹⁷ Tele-assistance has a prevalently social content with blurred borders toward healthcare to which connects in order to guarantee assistance continuity.

Purpose of Telemedicine and Clinical Governance

Several studies in the literature state that information and communication technologies have great potential to reduce the costs of health care services in terms of planning and making appropriate decisions that provide timely tools to patients.¹⁸ In certain contexts, such as rural communities, telemedicine has been observed to significantly reduce costs and increase patient days in community hospitals rather than in specialized care centers, which have higher costs.¹⁹ The personal and often invisible costs incurred by the patient are also reduced with telemedicine. The use of telemedicine allows patients to save on travel costs and

medical visits and reduces the patient's loss of working time. A 2012 study by the Medical Assistance and Welfare Body calculated savings for about 3 billion euros a year with the use of digital instruments thanks to the de-hospitalization of chronic patients made possible by technologies supporting medicine in the territory and home care.

Another clear benefit is the equity of access to health care. The removal of geographic and economic barriers allows for faster and more efficient access to care by all patients. In particular, when the hospital is located far from home, patients are forced to face additional costs related to transfer organization, as well as the difficult management of emergencies and long waiting times for diagnostic/specialist examinations. In this sense, Telemedicine finds concrete application because it allows providing health care directly at home.

Furthermore, both the improvement in the quality of care and the improvement of the health system are not negligible. On the first point, it is emphasized that there is the possibility of a more immediate interaction between the patient and the physician, particularly referring to telemonitoring that allows the physician to arrive directly at the patient's home without the need for a physical meeting. Furthermore, the guarantee of continuity of care increases the patient's trust in treatments and the awareness of his state of health. In general telemedicine allows a more efficient use of the health system, thanks to a greater rationalization of the social and health processes, which allows of the social cost of pathologies. Thus, the availability of telemedicine services for disadvantaged areas or patients allows a decrease in expenditure, as well as an increase in the effectiveness of the system.

Furthermore, telemedicine can promote protected hospital discharge, reduction of hospitalization of the chronically ill, reduction of hospitalization in nursing homes, and the reduction of mobility of patients searching for better care.

Focus on Telemedicine Assistance Services During the COVID-19 Health Emergency

The report provided by the National Health Institute in April 2020 entitled "*Interim indications for telemedicine assistance services during the COVID-19 health emergency*" was drawn up in order to identify critical issues and propose solutions for the implementation of Telemedicine services during the COVID-19 emergency.

The indications can be used in various combinations to provide health services and psychological support, and to proactively monitor the health conditions of people in quarantine, in isolation or after hospital discharge, or isolated at home by the rules of social distancing but in need of continuity of care while not being infected.

In times of health emergency, 2 priorities have been identified. The first is to ensure home care for people affected by COVID-19 and for those who, although not infected, present the need for home care due to their pathological conditions or frailty. The second priority, in an era of objective lack of material and human resources, is to protect healthcare personnel as much as possible from the risk of contagion.

Therefore, given the need to keep people who are infected or suspected of being infected under health control, without neglecting those who, due to particularly fragile/chronic conditions, require health checks at home, it is possible to identify 3 clinical situations:

- Situation A: the subject is not affected by any disease prior to the time when quarantine or isolation was required, or the subject is asymptomatic and falling within the definition of close contact or confirmed case;
- Situation B: the subject is not suffering from any disease prior to the time when isolation was required, the subject has mild to moderate symptoms compatible with COVID-19 infection and can be defined as suspected, probable or confirmed case;
- Situation C: the subject suffers from chronic diseases, rare diseases, is in frail conditions, or requires long-term treatment, special assistance and/or not in hospital support; in this situation is included also who needs to maintain the continuity of service during quarantine, isolation or during the period of application of social distancing rules.

In any case, beyond the specific clinical situation, the guiding principle of any care activity is guaranteeing the continuity of the service, even in the course of emergency/urgent situations, as well as in the course of an epidemics. This general principle is valid also in defining the goal of creating a telemedicine service since technology, although innovative, is used correctly only when allows progress in the medical care practice. For this reason, in planning a telemedicine service, the physician must identify which are the diagnostic, therapeutic and assistance activities that can be carried out remotely, through the technologies available. The cited document also indicates that it is necessary to check the connectivity of the patient at home and the type of digital devices available and connectable to the network. Indeed telemedicine services need not only complex technological systems, but also the human capacity to interact with such systems so that to function properly, the patient must be trained in its use. Therefore, the patient or his caregiver must be autonomous in the management of digital systems. It is also essential to understand what the conditions of health service are, evaluating accessibility to the service and the possibility of fully uniform digital prescription throughout

the whole national territory. The potential and limits of telemedicine services emerge especially in the time of health emergency, such as the current one. There are no significant previous experiences relating to the use of the computerized system in pandemic health emergencies and no telemedicine system can be created, rapidly due to the aforementioned needs. In Italy, the situation regarding the start-up of telemedicine systems is still very fragmented, with a greater development of digital systems for chronic diseases characterized by a greater social and economic impact (eg, diabetes) and highly innovative projects however limited only to some Italian regions. It is evident that telemedicine has some concrete limits related to the specific case, so that the centrality of the patient and clinical symptoms in care management is reaffirmed. Naturally, the final evaluation of the instruments suitable for a specific case depends on the physician who is responsible for them.

The Physician's Liability in Telemedicine

The evolution of telemedicine poses a series of legal problems ranging from profiles of authorization and accreditation to those concerning the protection of patient confidentiality. The definition and solution of this problems, in the absence of specific regulatory provisions, is mainly left to the assessment of compatibility of the practices adopted so far with the general regulatory framework.

The use of information technologies in the health sector is not directly evaluated by the recent Law 24/2017 that deals with the provisions on the safety of care and the assisted person and with professional liability of healthcare workers.

In terms of professional liability, it is necessary to clarify that the telemedicine service is comparable to any diagnostic-therapeutic health service considering that it does not replace the traditional health service but integrates the latter in order to improve its effectiveness, efficiency and appropriateness.

In any case, from a general point of view, the health service mediated by ICT to be considered equally to the service provided in the so-called traditional forms.

An examination of the literature highlights 4 key points: the physician-patient relationship, malpractice, standardization of adopted practices, and economic reimbursement.²⁰

Some key points deserve a better definition in legislative terms.

The organizational model of the telemedicine service involves the existence of:

- a Dispensing Center, which can be constituted by structures of the NHS (authorized or accredited, public or private) or by operators of the NHS such as general practitioners, paediatricians, and specialist

physicians, who provide health services through a telecommunication network;

a Service Center, which has the function of ensuring the functionality of the information system. The Service Center is the mean by which the Telemedicine Service can be implemented because it provides the tools in the identified sites (medical facilities and patients' homes) and at the same time manages the communication between patients, physicians and other health professionals.

Considering that several operators are needed and that telemedicine services are located within the regulatory framework of the National Health Service, an adequate integration of the regulatory framework is necessary to properly assess the existence of potential liability. In this perspective, alongside the legal entity constituted by the health facility and the health care practitioner, the person (natural or legal person) who manages the Service Center or otherwise provides the related IT equipment can be added.

For this reason, it could be useful to identify accreditation and/or authorization paths that identify the Service Centers or the specific Company Structure which takes care of the maintenance of the IT equipment.

In conclusion 3 categories of responsible parties can be identified:

1. the service center or, failing this, the company that produces and distributes the device, and the IT support for operation and connection with the remote control unit;
2. the health facility that provides the telemedicine service;
3. the healthcare professional who follows the patient and manages the various clinical problems relating to the healthcare service provided with the telemedicine method.

In this sense it has to be emphasized that some conditions could generate a criticality in the telematics system such as: construction defects of the equipment; errors in the installation or implementation of the different parts of the structures; ineffective maintenance; inadequate management; erroneous use of these, including the incorrect transmission and/or evaluation of the data being transmitted.

Situations potentially at risk are those in which the malfunction of the equipment leads to incorrect data transmission or an interruption/discontinuity of data transmission. This may result in an incorrect interpretation, which could cause an incorrect diagnostic/therapeutic intervention on site or at a distance.

However, alongside the undoubted advantages of remote control, this approach creates inevitable problems of liability. In the first place, a possible problem could be related to the obligation on the worker (physician) to perform the

service personally (pursuant to Article 2232 of the Italian Civil Code). Indeed, some services necessarily require the physical presence of the physician or his virtual participation (see the case teleconsultation) representing a sort of “grey areas”.²¹

A further problem that must be carefully evaluated, particularly referring to Telecardiology, is the sharing of device implant protocols that allows data to be correctly collected and clinical checks scheduled. Remote patient monitoring requires the device to be periodically controlled remotely with a frequency that varies according to the type of device, the patient’s clinical status, and the organizational capacity of the hospital that provides the service.

The efficiency of telemedicine and the undoubted advantages associated are particularly evident in the field of Teleradiology. However, also in this context, profiles of liability are outlined. In the teleconsultation mode in case of the occurrence of an incorrect diagnosis must be differentiated if the event is related to an erroneous reading of the report or to the poor quality of transmitted images.

And again about teleconsultation, especially in the case in which multiple interventions by different healthcare professional performing diagnostic and/or therapeutic procedures are needed.

Indeed in this situation it should be differentiated if the act performed is the final result of a consultation between the 2 stations.

This scenario opens up a sort of dual path of liability: on the one hand, a liability related to the professional behavior of the healthcare worker who performs the service and, on the other, the one related to the suitability of the equipment used. Referring to this last aspect it should be considered that the manufacturer’s sole liability may arise whenever a system faults at the level of structures or parts thereof, which do not require routine maintenance after a first more complex test have been carried out in the factory or at the time of installation.

Is thus possible to discuss the concurrence of the liability of the healthcare professional with the one of the technicians. Where it is an event/failure that is unpredictable and not caused by a violation of common medical diligence, it is obvious that the healthcare professional can’t be held responsible. However, if the construction defect can be related to superficial maintenance, the health care provider can be considered responsible if he did not bother to check that maintenance has been completed or the quality of the equipment before using it.

In jurisprudence, therefore, a hotly debated topic is the one concerning health care liability also in checking the equipment.

Considering the liability derived from an incorrect use of digital health equipment, reference to another sentence can be done (Criminal Cassation IV section, 21 January 2016 No. 2541). This sentence concerns the application of IT on

personnel organization within the hospital, and on possible profiles of medical liability.

In this case, the patient, after having undergone revascularization surgery for heart attack, was hospitalized in the sub-intensive care room of the Cardiac Intensive Care Unit ward where a portable device was applied for remote telemonitoring of any tachyarrhythmias or abnormal heart traces through sound and visual alarms on the central monitor. After a few days, the telemetry record showed 2 episodes of ventricular tachycardia during the day; the next night a fatal arrhythmia occurred causing the patient’s death. The nurses of the night shift did not intervene as the sound alarms of the device were deactivated; moreover, the device signalled the onset of ventricular fibrillation on the central monitor, but no one was checking the monitor at that time as all the nurses were busy with other patients.

The trial saw the director of the UTIC acquitted in the first instance, and then sentenced in the second instance. Finally, the Supreme Court decided to quash the sentence.

The Supreme Court specifies a series of criteria that clarify the relationship between the implementation of digital equipment in the hospital, staff reorganization, and possible profiles of medical liability.

The Court of Cassation does not recognize the responsibilities of the manager of the UTIC, recognizing those of the general management, at least referring to the inadequacy of the

Moreover, the training of the nursing staff in the correct use of the equipment, according to the Supreme Court “it was not part of manager’s duties to organize courses for the training of nursing staff on the new monitoring system of the ward or to verify full knowledge of the system by individual operators,” underlining that in other rulings a specific position of guarantee toward the patient had already been identified for the nurses. These rulings underline that the nurse is not a mere “assistant to the physician” but an actual “health professional.” Consequently, the liability for the training of the nursing staff is recognized by the regulations of the same nurses and therefore not attributable to “managerial prerogatives of the director or head of the department.”

Similarly, the head physician does not have the obligation to check the actual adequacy of the training of nursing staff so that the Director has to fully rely on the professional and organizational autonomy of the nursing staff. In fact, referring to professional skills, the Supreme Court emphasizes that within “*a hospitalization area there is direct and continuous surveillance of the patient by the nursing staff*” and that such staff in some way “*acts as a physician, being able to act independently therapeutically immediately even without the presence of the physician.*”

Some fundamental assumptions derive from this sentence.

When a new technology in a hospital is implemented, the duty and guarantee of staff training is responsibility of the

General Management of the hospital, while the assessment of the suitability of the equipment is responsibility of the Service Management. There is also a direct liability for the nurses who are personally responsible for their training and also that the training itself is adequate for the functions performed.

A minor legal problem connected with telemedicine services concerns the control of information or information security, which guarantees the patient's right to privacy. A secure computer system is one in which data is easily accessible to those who are authorized, but not available to those who do not have the authorization. There is no doubt that a service that involves several figures (on several levels) necessarily requires greater attention to be paid to the protection of privacy, as the processing of health data through the use of telematics systems necessarily entails greater exposure. This results in a necessary limitation to the dissemination of data through telematics systems so that the necessary data protection is granted.

The teleconsultation officer or responsible physician as well as the data controller, must ensure that these measures are applied. In the occurrence of medical records being transmitted to another location, the original data controller can be prosecuted for the abuses. Sometimes it can be difficult to identify a specific figure, when the subjects involved in remote healthcare management are located in different hospitals, even geographically distant. In such circumstances it can be difficult to ascertain who is responsible for data protection and control. To overcome this problem, it would be desirable to have an a priori designation for responsibility making a contract between the hospital and the remote users of a telemedicine network. This can also define the technical standardization parameters in order to ensure both the security of data and their worldwide circulation.²²

Another aspect that needs to be carefully assessed is the one related to the acquisition of informed consent. Informed consent in telemedicine must have the same basic requirements as for traditional medical services.

In specialist teleconsultation systems, the acquisition of informed consent to the medical act concerns the healthcare professional who is in direct contact with the patient. In the specific case in which the patient must undergo an instrumental investigation reported to remote specialized centers, it is duty of the healthcare professional to explicitly provide the information in order to be able to perform this examination electronically, independently from the following therapeutic choices. A sort of balance should be implemented between the "faculty" of health care, which is responsible for the choice of diagnostic and therapeutic supports, and the "freedom of treatment" of the patient as derives from principle of self-determination which grants the possibility of rejecting a diagnostic/therapeutic perspective recommended by telematics consultation.

Where the service is carried out completely telematically, the physician is obliged to inform the patient also about the risks inevitably connected to the telemedicine services, or about possible technical problems.

The informed consent form should be completed electronically with the consequent problem of signing this form that could be solved by using the digital signature. The digital signature represents a suitable tool to guarantee the authenticity of the document but is also difficult to implement in particular contexts (elderly patients). In such circumstances, it might be useful to implement a preliminary information notice (in presence) that can explain in a clear and understandable way any diagnostic/therapeutic alternatives of the clinical case.

Conclusion

Telemedicine services can be classified into 3 macro-categories: Specialized Telemedicine, Tele-healthcare and Tele-assistance. The aim of telemedicine is to create an efficient system capable of addressing the problems of emergency medicine while offering tools that allow territorial decentralization of specialized assistance. Referring to Telemedicine, the ability to offer healthcare ICT-based solutions and services offers an answer to the current pressing request for more qualified and efficient socio-sanitary systems. This is also demonstrated by the current COVID-19 pandemic that is indeed triggering the implementation of telemedicine systems. Thus, telemedicine can provide better home assistance for people affected by the virus, especially if in person assistance is hindered due to lack of PPI and/or personnel. However, the evolution of telemedicine poses a series of legal problems ranging from authorization and accreditation profiles to the protection of patient's personal data.

The characterization of these problems and their solution, in the absence of a specific regulatory provision, is mainly left to the assessment of compatibility between the practices adopted so far and the general regulatory framework.

In terms of liability, 3 categories of subjects can be identified: the service center; the health facility that provides the telemedicine service; the healthcare worker. Moreover, another not neglectable aspect that should be considered is the one relating to informed consent.

Thus in order to implement telemedicine systems, countries do need a parallel regulatory development so that the safety of patients in telemedicine treatments are granted without this weighing on healthcare workers that provide the service.

Authors' Note

The article does not contain any studies with human participants requesting their informed consent or approval by Ethics Committee.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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