

Telemedicine: An Essential Requirement for the Health Care Providers, with Emphasis on Legal Aspects

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Abstract

Telemedicine is the use of telecommunication and information technologies in order to provide clinical health care at a distance. These technologies allow communications between patient and medical staff with convenience as well as the transmission of medical, imaging and health informatics data from one site to another. It is also used to save lives in critical care and emergency situations. Although telemedicine systems have many advantages, including the distribution of high quality medical services to remote areas, failure to comply with infrastructure will reduce the efficiency and quality of their services. Issues such as building the infrastructure of the medical information industry, including the legal infrastructure, and thus providing a suitable platform for the legal and ethical issues of Telemedicine, as well as obtaining the necessary permits and requirements, will play an important role in the successful implementation of a Telemedicine system. The purpose of this study was to become more familiar with the field of Telemedicine and its services, as well as to review some legal issues in the field of e-health. Telemedicine is not able to solve the problems of the health and social systems, but the problems of the health and social systems cannot be solved without Telemedicine.

Key Words: Health Care, Legal, Law, Telemedicine.

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1- INTRODUCTION

The word Telemedicine is made up of two words, Tele, which is a Greek word meaning long-distance communication, and medicine, which means therapy. There are different definitions for Telemedicine, so there is no unanimous agreement on its exact meaning. The use of communication and information technology is to transfer medical services and the exchange of medical information when the physical distance separates the parties (patient and physician). According to the International Telecommunication Union (ITU), Telemedicine is "the practice of medical care using audio-visual communications" (1). According to World Health Organization (WHO), Telemedicine is defined as "The delivery of healthcare services, where distance is a critical factor, by all healthcare professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for continuing education of healthcare providers, all in the interests of advancing the health of individuals and their communities" (2).

Today, the world has become a global village with the use of information technology and new communication technologies. These advances have also been effective in medical science and have caused the quality of services provided in this sector to have a higher level. One of the major problems of the health sector in this period is the lack of equal access to high quality medical services for all inhabitants of the planet. Telemedicine, which combines medical science and information and communication technologies, is used as a solution to provide telemedicine services. This new method of providing services in medical science has been able to eliminate physical distances, as a bridge between patients and health care providers without the need for

physical presence at the same time and to provide access to higher quality services. Telemedicine also makes it possible to train both groups of recipients and service providers. According to the economic assessments made from the implementation of telemedicine systems, the cost of establishing a system of counseling, treatment or distance education is less than the cost of traveling for training or diagnosis and treatment (3-7). Nowadays, telemedicine and electronic health have revolutionized healthcare systems. In this new technology, health care services are provided at a comprehensive level.

However, there are many concerns in terms of ethical, legal, security and confidentiality of medical information that lead to a number of problems for the patient, the medical team and the health care delivery systems including disclosure of medical information that can lead to all kinds of discrimination, objections, accusations and violations of the patient's fundamental rights (8-14). The purpose of this study was to become more familiar with the field of Telemedicine and its services, as well as to review some legal issues in the field of electronic health.

2- MATERIALS AND METHODS

This study aimed to review Telemedicine studies, benefits and challenges with emphasis on legal aspects. The search was done based on the keywords Telemedicine, Benefits, Advantages, Disadvantages, Legal, Law, and Jurisprudence. Similar keywords were extracted from MeSH, and also through manual search by reviewing the titles and the abstracts of the articles. After keywords were determined, two separate researchers searched the electronic databases Scopus, Web of Science, EMBASE and Medline via PubMed with no language or time restrictions till Mar 2020. In order to access the rest of the

papers, the articles' references were reviewed by hand searching. Moreover, the Google and Google Scholar search engines were also checked for more assurance.

3- RESULTS

"Telemedicine generally uses medical and communication technologies to exchange any information, including data, audio or video communications between physician and patient or physician and healthcare professionals in separate geographical locations and to facilitate the exchange of medical, healthcare, research and educational education purposes".

3-1. Telemedicine Parts

Telemedicine is a general term that includes the use of different technologies and the use of communication networks to communicate between different medical and educational centers. A Telemedicine system or telemedicine consists of four different parts (15-19):

1. Technology: includes communication devices and peripherals.
2. Communication networks.
3. Users (patients and medical staff), and
4. Rules and regulations.

1. Technology: Technologies used in telemedicine include hardware and software, as well as a series of peripherals that are used to perform medical activities. Various forms of technology are used in telemedicine such as: telephones, video telephones, personal computers, video conferencing systems, storage and sending systems, and fully professional telemedicine packages.

2. Communication networks: The second major part of a Telemedicine system are communication networks. These electronic connections make it possible to connect the above devices. There are different forms of communication networks. Old telephone networks, digital telephone lines

such as switches and dedicated digital networks such as Asynchronous Transfer Modes (ATMs), microwaves and satellite networks, as well as the Internet and each of these networks can be used to send information. However, each has its own advantages and disadvantages. Selecting the most appropriate network for the desired activity depends on numerous factors such as the required bandwidth and the type of connection between the two points (for example, connection from sea to land) and the cost of the network in the area and the possibility of providing local support services.

3. Users (patients and medical staff):

Public networks are a very important factor, even more important than electronic communication networks, and that is exactly why the users of this system must be carefully selected and trained and supported. As a rule, most people need training in Telemedicine regarding what the telemedicine is, how it is done and what the benefits are. If people choose to use telemedicine, then they will feel the need to learn how to use it and in the end users will need support (ideally 24 hours a day, seven days a week) unless they have a problem being able to communicate quickly with someone to solve the problem.

4. Rules and regulations: Before implementing Telemedicine plans, legal issues in this field should be specified. For example, how is it possible to pay fees, issue certificates and commitments in this field. The question that can be asked is who pays for Telemedicine when the patient and the doctor are not close? If a mistake or error occurs during this operation, for example, if there is a problem with the way the peripherals work or they have an error, who is to blame? A specialist doctor, a hospital, company selling devices and peripherals or the communication network service provider?

Such issues are still unclear in many countries around the world.

3-2. Applications of Telemedicine

Telemedicine applications are very broad and pervasive, but are divided into 4 general groups:

1. Tele consultation: Which occurs through a variety of tools such as telephone, mail or video conferencing,

2. Tele education: In today's world, it has been proven that the development of any science requires the training of specialized groups of that science. Tele-education is presented in 3 areas:

- Tele- Education.
- Access to remote information.
- Tele- health Education.

Tele- health education has many advantages, including the fact that due to the reduction of patients' travel and specialists, public spending is reduced, and also that the level of trust in health centers increases and the exchange of information between medical centers improves.

3. Medical emergencies and assistance to the injured: Because it is difficult to access medical emergencies during emergencies, with Telemedicine, the path can be shortened and relief operations can be performed more quickly.

4. Remote surgery: Remote surgery is performed by robots and advanced medical systems, but due to the cost of this method, it has not yet been properly transferred in developing countries and is limited to developed countries. There are two main problems in remote surgery: one is the lack of confidence of patients in remote surgery methods that should be solved with proper training, and the other is no direct touch of doctors which is expected to improve the touch quality of robots and solve this problem (13, 21-27).

3-3. Benefits of Telemedicine

Telemedicine has many social and economic benefits that highlight the need for this technology. Telehealth is fueled by digital technologies which allow us to reimagine the physician visit as a house call without the travel. The idea of the virtual visit has been around for decades, and telemedicine has been deployed across specialties and service lines, from primary care to radiology, cardiology to orthopedics. Telehealth lends itself well to both the primary care and the specialist, allowing them to further their reach, treating patients wherever there is an Internet connection. Telehealth platforms have traditionally been launched from a health system because they typically have the overhead to purchase large equipment kiosks and sophisticated digital technology. Some of the benefits of telemedicine for physicians and patients include (28-36):

1. Advances new business models

Telehealth as a business model is shifting the paradigm by advancing consumer-based care. With telehealth, clinicians can extend their patient base beyond brick-and-mortar facilities, extending hours, and creating new and more convenient models for their patients.

2. Improves patient engagement with remote monitoring

The increasing role of consumerism and value-based reimbursement in healthcare has led hospitals and health systems to emphasize new ways of interacting with their patients to engage them in self-care. Treating patients proactively requires clinicians to teach patients how to care for themselves between clinical visits. With an increase in chronic health conditions, using telehealth for remote monitoring is just one way that medical providers can improve outcomes while still cutting costs. Today, telehealth is being used to report patient metrics from the comfort of the patient's own home, while remote teams act as

coach and counselor as they engage patients in their own journey toward health.

3. Expands access to care and reaches more patients

We know that there is an increasing physician shortage; telehealth can help stretch our provider networks in new ways to expand access to care. Telehealth can be used to reach patients in rural areas and outside the normal care delivery systems. The tool can be used for mid-level patient education as well as physician diagnosis, reaching a variety of people in new ways.

4. Improves clinical workflows and increases practice efficiency

Telehealth can increase clinical workflow efficiency. It can serve as the conduit for quicker prioritization of care delivery, triaging each case and improving communication by capturing, storing, and using patient data for better medical decision-making. The Medical Group Management Association (MGMA) reports that telehealth is a feature of some of the best performing practices in our nation. These tools can help facilitate performance improvements including increasing patient satisfaction scores.

5. Increases practice revenue

In addition to reducing overhead costs per visit, telehealth is less time-consuming, both for the patient and provider. Telehealth can allow physicians to bill for uncompensated phone calls while also extending hours to capture more billable time. Telehealth cuts down on no-shows and can improve the efficiency of a practice. Telehealth can also provide a competitive advantage, attracting and retaining more patients with new models of care.

6. Reduces practice overhead

Unlike expensive hospital systems, SaaS telehealth applications are low cost to

implement. But the cost of a telehealth visit is much less than traditional on-site visits.

7. Cuts patient costs

Our patients spend a lot of money and time seeking healthcare. With a telehealth visit, the doctor comes to the patient on their phone, laptop, or another digital device. Imagine how the costs of travel, parking, childcare, and taking time off work can accumulate. The additional effort that it takes to travel to a remote doctor's facility can be stressful, but it is the costs that can really add up. In some rural regions, patients must travel overnight to reach specialists in more urban regions.

8. Improves healthcare quality

The Agency for Healthcare Research and Quality (AHRQ) says that telehealth improves healthcare quality, particularly in rural settings. That's because the technology can improve service delivery and treatment of acute conditions. Telehealth is also being used to divert unnecessary Emergency Room (ER) visits. It also improves the convenience of receiving treatment by allowing patients to receive care without traveling long distances.

9. Reduces patient no-shows

Earlier this year, Becker's released a case study on a Nebraska Children's Hospital that struggled with frequent no-shows, in part, because rural patients drove for many miles to receive care at their state-of-the-art facility. No shows had become a significant revenue cost for the organization and the quality of care was being compromised, particularly on follow-up visits. When they expanded treatment with telehealth, the targeted service line improved no-show rates by 50%.

10. Improves patient satisfaction

Patient satisfaction is a key performance indicator of telehealth. 87% of the patients using the OrthoLive telehealth application say they would use it again.

3-4. Disadvantages of telemedicine

Next, we will focus on what the disadvantages of telemedicine are (37-42):

1. Requires additional training

It is expected that the health facilities providing telemedicine options, must spend additional time as well as money for training the experts in order to enrich them with the much needed technical knowledge. This might imply a total reconstruction of the IT employee and it might also depict additional staffing requirements thus making healthcare recruitment a challenging task.

2. Reduce care continuity

Several telemedicine events help the patients to continuously change their physicians, which results in a reduced care continuity. Also, these random physicians will not be able to gain access to the full historical backgrounds of their patients resulting in erratic treatment in the long run.

3. Licensing issues

Sometimes training telemedicine providers are required by certain states to possess a valid license for the state in which the patient is actually located.

4. Technological restrictions

Although there have been lots of innovative programs recently, telemedicine still continues to be technologically limited. It is possible for the broadband connections to malfunction, video chatting gadgets to function improperly and so on.

3-5. Telemedicine Service Rules (11, 43-49):

Due to the new, diverse and complex nature of telemedicine services, setting

rules for it has its drawbacks. Unfortunately, except for a few cases, there are no specific laws in our country on Telemedicine services. This is a problem that afflicts most underdeveloped countries, causing them to lag far behind in terms of efficient health care services. In recent years, developed countries have introduced various laws regarding the use of Telemedicine and how to store and transmit health-related data. The most important rules for storing and transmitting health data are the Health Insurance Portability and Accountability Act (HIPAA) guidelines in the United States and the General Data Protection Regulation (GDPR) in Europe. There are fewer problems in using prevention, training and data analysis services.

The main problems in telemedicine services are especially when it comes with medication. In the United States and Canada, some states allow online visits and online counseling for physicians in the same state, and physicians must obtain licenses to visit a patient online in another state, but some states do not. Visiting online and prescribing online is now legal throughout the United States. Idaho banned doctors from doing so in 2012, but the ban was lifted three years later. Given the crucial benefits of Telemedicine services (including online visits and medication prescriptions) that improve health in the most remote locations as well as huge economic savings in the macro view, we hope that this aspect of health services will also be considered by lawmakers. Currently in our country most Telemedicine services are not prohibited by law. In the field of telemedicine services, online counseling and online visits are also provided in cases where there is no need to prescribe medication (such as telemedicine, distance psychology and telemedicine counseling).

3-6. Legal Challenges in Telemedicine

Although telemedicine systems have many advantages, including the distribution of high quality medical services to remote areas, failure to comply with infrastructure will reduce the efficiency and quality of their services. Matters such as building the infrastructure of the medical information industry, including the legal infrastructure, and thus providing a suitable platform for the legal and ethical issues of telemedicine, as well as obtaining the necessary permits and requirements, will play an important role in the successful implementation of a Telemedicine system. The steps that pave the way for building a secure legal infrastructure in telemedicine systems are:

1. Establishing rules related to cyber activities.
2. Considering an appropriate identity for making decisions in the legal aspects of telemedicine.
3. Issuing licenses and determining and implementing the requirements for implementing a telemedicine system.
4. Determining how to reimburse costs in telemedicine.

Step 1: Establishing rules for cyber activities

Cyberspace is defined as a set of human internal communications through computers and telecommunications devices, regardless of physical geography. Activity in the world of communications requires special rules and regulations that are compatible with the spaces in it, because without them, the efficiency of the created systems will decrease. An online system is an example of cyberspace where users can communicate with each other via email. Unlike real space in cyberspace, there is no need for physical movements, and all actions are performed only by pressing keys or mouse movements. The history of cyberspace legislation dates back to 1891, when developed countries such as the United States enacted it against

cybercrime. Of course, at that time, the emphasis of these laws was on cybercrime, and cybercrime had no place in them. Cybercrime is any criminal act in which the computer is the means or object of the crime, and cybercrime in the general sense is any illegal behavior committed by or in connection with a computer system or network and the acquisition or illegal distribution of data by a computer system or network is in place. Based on the above, enacting laws related to activities in cyberspace and creating special legal institutions and educating users, taking into account the cultural and social infrastructure of each country, can create a suitable ground for legal and ethical issues of Telemedicine.

Step 2: Consider a proper identity for making decisions in the legal aspects of Telemedicine

Research on the legal and ethical aspects of telemedicine has been under way since the early 1980's. In Britain, one of the first attempts was made by Brahams to describe the legal framework of telemedicine. Legal and ethical issues raised in telemedicine include: political principles, the use and sharing of health information, confidentiality of information, satisfaction with telemedicine treatment, data security, human rights, accountability, commitment and proper performance (in terms of medicine), use of instructions in the field of clinical specialization, cross-border medicine, the right to judge and choose the law, hiring service providers and related laws and regulations, providing telemedicine services, earning distance, electronic commerce and signatures, standards and internal use, medical devices, production commitment and safety, and intellectual property rights.

Step 3: Licensing and Determining and Implementing Requirements for Implementing a Telemedicine System

On January 25, 2011, in the US state of Pennsylvania, telemedicine was introduced as a way for professional health care interactions between patients and medical centers, and the necessary laws and licenses were set in this area. An attempt has been made to localize the following items based on internal conditions. 1. Any medical specialist who wants to provide services through telemedicine must obtain the necessary permits at the place where the patient is present, not at the doctor's residence. Regional medical permits are:

- License related to the activities of general practitioners
- License related to the activity of a specialist in each medical field
- In some cases, permission for government consultations to consult with physicians in other countries or regions.

It is worth noting that these licenses may vary depending on the type of discipline as well as the laws of different countries.

2. According to the nursing laws related to the field of telemedicine, each nurse receives a license to operate in the electronic field from their place of residence, the possibility of working in this field and interacting with other designated countries in accordance with the laws and regulations of their country of residence. 3. Any physician who provides services to inpatients or outpatients at the site of the patient's location must have sufficient knowledge of the facilities and coordinates of the place of service. If the facilities of the remote site are also approved and the active physician has access to services similar to the central site, this site will receive evidence from the reviews and evaluations of the central site physicians and comment on the quality of physician performance and care services provided. This means that the central site must follow the decisions of the remote site. On May 26, 2010, in the state of Pennsylvania,

the basic regulations regarding the scope of authority of telemedicine doctors were formulated, and the new laws were published in March 2011, and in April, the above laws were sent to affiliated hospitals for the use of remote health workers. At that time, each of the central sites had to have separate rules for their processes. In fact, the new rules were designed to show that central site staff could rely on and trust the decisions of remote site physicians. In particular, the new law stipulated that under the agreement between the central and remote sites, the remote site would be responsible for the detection provided. The board of the central site hospital where the patient receiving telemedicine services is located can grant the above points to the remote site based on the opinions of its medical staff and rely on the information sent by them. The results of the new rules were:

1. A change in the feeling of the employees of the central site in regard to their obligation to follow the remote site was not widely accepted.
2. Following the decisions of the central site was costly for doctors who were not residents in the hospital (such as radiologists) in every way.
3. The responsibilities of both the central and remote site governing bodies were expanded. Thus, the new rules of January 1, 2012 were changed in the form of participation of both central and remote sites in decisions and qualifications.

Step 4: Determining how to reimburse costs in telemedicine

Payments in telemedicine are generally made by government agencies or by private institutions. Government agencies may impose restrictions on the payment of fees, for example, telemedicine services must be provided in rural and non-urban areas and in physicians' offices or hospitals or special treatment centers such as dialysis centers and only simultaneously to

allow reimbursement of costs or costs may be reimbursed only for the following:

- Outpatient visits through telemedicine.
- Remote counseling - Remote psychiatric diagnostic counseling tests.
- Remote individual psychotherapy - Remote patient medication management - Remote nutrition therapy - Nervous condition assessment in remote behavior.
- Follow up on consultations performed by telecommunication systems.
- Services related to per capita payment to people covered by these remote systems in connection with service rates and diagnostic tests through these systems should not be any different from similar cases performed by non-medical remote methods.

Governments can use private and non-governmental organizations to reimburse medical expenses remotely. Some methods of repaying private institutions by raising the standard level, consciously increase satisfaction and privacy with higher quality. Of course, abuse and fraud and baseless legal claims are also seen in the mentioned cases.

3-7. Cases that may cause errors or abuses in the telemedicine work process

1. Standards related to service delivery are only evolving on the remote site.
2. The cost of new equipment and technologies should be added to patients' costs.
3. In the process of doctor-patient communication: from the beginning to the end and based on the role of different people in it. For example, at different stages of payment by the patient, there is the possibility of various types of abuse by different people involved in this interaction.
4. Existence of multiple jurisdictions.

5. Existence of insurance companies in more than one country.

For example, international insurance companies operating in different countries with different legal rules can make legal mistakes. Private companies providing medical services can also be used to implement telemedicine systems, but what matters in this regard are:

- Which institution is qualified to hire doctors to provide telemedicine services?
- Are the service providers qualified to do business in all countries where patients are present?
- Which groups are the owners of these institutions and have the owners received all the necessary permits from the countries where the patients are present? (9, 11, 50-55)

5- CONCLUSION

Telemedicine technology has been proved and established and its advantages and benefits are well known but still many healthcare professionals are reluctant to engage in such practices due to unresolved legal and ethical concerns. With the spread of telemedicine, many questions about ethical and legal issues arise in this method that need to be answered. Telemedicine requires advanced access to patient clinical information and should support patient's immunity and confidentiality. Also, the responsibility for medical errors is another ambiguity because the doctor may not be in that country, and medical obligations are not clearly defined in this structure. Certainly, the use of this new technology, which transforms the traditional structure of treatment, requires the development of new legal, ethical regulations and medical obligations. In the legal system of our country, there is a vacuum of laws and regulations, as well as the analysis and explanation of legal issues. In order to benefit from telemedicine services,

patients should be aware of how these services are provided, their benefits and risks, and generally welcome these services with a clear and informed perspective. Patients' informed satisfaction is felt more than other health care services due to the emergence of these services and their negligible risks. Finally, it should be argued that the advancement of technology and the use of telemedicine services is an effective step in medical science, one of the benefits of which is access to patients in areas without the need to travel long distances and in areas deprived of Internet specialists and related technologies. However, the potential dangers of this new technology require clarification of related laws, regulations, and legal interpretations in order to better protect patients' rights. Steps that pave the way for building a secure legal infrastructure in telemedicine systems can include: enacting rules related to cyber activities, establishing an appropriate identity for decision-making in the legal aspects of telemedicine, issuance of licenses and determination and implementation of requirements for the implementation of a telemedicine system and specifying how to reimburse costs in telemedicine.

6- CONFLICT OF INTEREST: None.

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