

Editorial

LEGAL ASPECTS OF TELEMEDICINE: TELEMEDICAL JURISPRUDENCE

The development of information technology has had a dramatic impact on society. Telemedicine is the transfer of medical information and expertise via telecommunications and computer technologies, to facilitate diagnosis, treatment and management of patients. Telehealth includes distance learning, medical peer review, patient education initiatives, etc. The internet, cell phones and e-mail are new areas, and if health care providers want to enter this domain, they should do so with caution. There are medicolegal implications of telemedicine relating to registration, licensing, insurance, quality, privacy and confidentiality issues, as well as other risks associated with electronic health care communication. Another important aspect is the physician patient relationship, the standard of care and informed consent. These intricate issues are further complicated by the absence of any statutes or laws, especially relating to the issues like professional negligence, duties, liabilities and penalties in such situations. Further issues in telemedicine, telehealth, teleconsultation, telemonitoring, teleretreatment and patient information record also need to be addressed.

International Consultation Group of WHO, which met in Geneva in 1997, has defined telemedicine as delivery of health-care services, where distance is a critical factor, by health-care professionals, using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, and for continuing education of health-care providers as well as research and evaluation, all in the interests of advancing the health of individuals and their communities

This is possible by either by Asynchronous method in which information is stored and forwarded like radiological reports, histopathological reports or by Real-Time Interactive Video in which videography is done, when patient is being examined and same information is transferred from the referring doctor to the expert. Along with this Electronic Patient Records, Digital Libraries, Databases, Intranets, Local Area Networks, Internet, World Wide Web, E-mail are used depending upon the facilities available at a given centre. Through MMS, photographs and CT scans can be sent and expert opinion obtained just with the help of the mobile phone having a camera. This information is utilized for consultation between doctor and doctor or between patient and the doctor.

Currently telemedicine comprises only three thousandths of one percent of all medical consults. However, it promises dramatic growth in the days to come. It will improve access and communication and will provide satisfaction to the patients. Telemedicine is utilized in a variety of circumstances e.g. Tele-health, Tele-care, Tele-radiology, Tele-pathology, Tele-consultation, Tele-diagnosis, Tele-monitoring, Tele-psychiatry, Tele-dermatology, Tele-emergency, Tele-surveillance, Tele-pharmacy, Tele-cardiology, Tele-endoscopy, Tele-dentistry, Tele-dialysis, Prison Telemedicine, Military Telemedicine, Tele-surgery, robotic surgery and robotic follow-up.

For all this Standard communication facilities involving Standard telephone services, High-speed wide bandwidth transmission, Digital signals, and Computer enhancement will be required. These services will give better results if there are Fiber optics, satellite connections and sophisticated peripheral equipment & software. Decision-making aids, remote sensing and collaborative arrangements for real-time management of patients at a distance will greatly enhance the scope of telemedicine.

As telemedicine will be practiced, it will bring with it various medicolegal problems like any other medical field. Problems of confidentiality of the patients, standards of treatment, credentialing of doctors, and consent from the patients, misconduct, licensure, reimbursement, professional negligence, duties, penalties and legal liability will have to be solved. Due to absence of any statutes or laws, especially relating to the issues this problem will be further complicated.

Every individual has a right to privacy and this includes rights in relation to telemedicine. There are more chances that there can be leakage of privacy of patients as all records are computer based. Searches are very convenient and any person can have data access of any patient if there is carelessness in file addition and deletion security. One has to be careful that information is being sent

at the right address. Password security should be maintained so that no person can have unauthorized access to the information at the receiving end or at the sending end. Electronic audit trail can be used to keep a check on unauthorized use along with encryption and return receipt. Standards for maintenance of records and information related to the practice of telemedicine are confidential information as it is obtained from patients.

Standard of care has to be maintained in telemedicine, which can be defined by the location of the experts, their specialty and the media being used for practicing telemedicine. Telemedicine will naturally enhance the standard of care, as diagnosis will become quick and more accurate. As it will increase standard of care simultaneously it will increase risk also if not properly used.

In western countries credentialing is required e.g. that this much numbers of operations or procedures must be performed in one year, but in India it is not required yet.

In telemedicine, informed consent is as important as in routine practice, fully explaining the benefits, consequences and the risks. It will be professional misconduct if consent is not obtained

Elements of professional negligence remains same for the local provider and distant provider and has to be proved by the patient that there was a duty of care due to relationship between the patient and caregiver and this standard has not been maintained by caregiver due to which injury has been caused to the patient. In such cases, shared responsibility will be an issue to face.

In India, a doctor must be registered with state medical council before he can start medical practice and automatically he becomes registered with MCI when he is registered with any state medical council, so that he can practice throughout India. However, if he is to practice outside India with telemedicine license of that country where patient is located may be required. Since the same statute regulates doctors all over India, issues of licensure across states will not arise akin to the situation in the United States. There is no existing Indian law on the issues raised by the practice of telemedicine in India. While the Information Technology Act, 2000 provides for standards in relation to information technology in general, the same does not relate to the provision of healthcare services by using information technology

Therefore, a question arises that who should give license. Should it be Indian Medical Council, State Medical Council, and technical council of India, New council, and Special group in MCI with representatives from technical council of India or WHO?

Minimum technical standards need to be adhered to by all persons practicing telemedicine, either solely or under the supervision of a doctor licensed to practice telemedicine. Should traditional license be deemed sufficient or should there be additional educational requirements for practice of telemedicine? For practice of telemedicine there should be some quality control mechanisms mandating a minimum level of expertise to be monitored on a continuing basis.

“In the face of extraordinary technological changes in health care, it is essential to maintain a balance between ‘slavish boosterism and hyperbolic skepticism’...This stance is called “progressive caution.” “The air of oxymoron is, as ever in the sciences, best dispelled by more science” (Kenneth W. Goodman 1998)

There is no current provision in health insurance policies about telemedicine practice. If claim of reimbursement is filed due to practice of telemedicine, a question will arise about liability of equipment manufacturer, equipment seller, equipment operator, maintenance provider and Telecommunications Company. It will be further complicated that it is healthcare provider at either/both ends or sponsoring hospital. Question of inadequate training or misuse and decision to use or not or their misinterpretation will be a big problem. Questions will also arise, if this whole process was required or not or it was simply done to receive financial benefits through dichotomy.

Therefore, practice of telemedicine has the numerous above-mentioned challenges. However, it has to progress in spite of all these challenges, as it will avoid long journeys for a short follow-ups and expert opinion becoming available in remote and inaccessible areas.

There is need for determination of duties of referring doctor and the expert doctor advising via telemedicine and doctor Patient Relationship. If licensing is made compulsory for the institutions then penalties for violating the provisions of license and practicing without license will have to be determined. Confidentiality will have to be maintained of the patient’s records and improper disclosure may be a big problem in telemedicine and will have to be taken care in the proposed law.

Can the same provisions will have to be strictly followed during emergency use of telemedicine, use of telemedicine in remote areas and during wars will be a big question and will have to be taken care of in the law.

Health Information in India is not integrated with technology as is in western countries. Existing Indian law does not adequately address concerns relating to Health Information and experiences of USA & UK can provide direction for enactment of legislation. Therefore, a separate law should be enacted keeping in mind the prospective of Indian conditions covering the aspects of licensing, liabilities of doctors practicing telemedicine and the penalties for violating the act. Insurance companies and government agencies to make it feasible the reimbursement of expenditure incurred by the patients in seeking telemedicine help should frame policies.

There will be a need to provide criminal and civil sanctions for improper possession, brokering, disclosure, or sale of health information with penalties sufficient to deter perpetrators. In the proposed law, the problems associated with AIDS-related information will have to be tackled and if such a distinction is made, we will have to give reasons to take it as an exceptional case for the benefit of the society as it is disease, which is threatening humankind, and it is incurable so far.

Technical aspects of telemedicine will have to be taken care of in the law to be enacted. There will be need to protect the routes being used for telemedical practice so that there is no leakage and no person may have unauthorized access to it. There will be a need for maintaining the technical reliability in the law.

My Suggestions to improve the situation is that a law has to be enacted in which following considerations should be kept in mind. There should be a three-tier licensing system as per the field of practitioner. Those who are to practice within state, state body should give them license, those who are to practice within country national body should give them license and who are to practice it globally there should be some international body to grant them the license. It will be responsibility of the doctor seeking medical advice to choose experts carefully after verifying their credentials. Standard of treatment may be as per the state where person is practicing for determining professional negligence. Patients should expect treatment standard of state/country of practitioner. Liability of expert will be for the opinions given and the liability of referring doctor will be how opinions are carried out. To reduce the chances of patients suing the doctors, doctors should be courteous, have a good communication and rapport with their patients and should devote adequate time to each patient. They should fully explain to patient about his disease, treatment and its side effects, potential risks and benefits and alternative lines of treatment and should give the patient sufficient time to decide. Never guarantee an outcome, as patient is frustrated when this does not happen in some cases. Wherever consent is required, it should be taken, preferably, written informed consent and it should not be blanket consent. Proper records of the treatment should be maintained. Insurance companies will have to modify the policies to cover costs of telemedicine advice. Doctors dealing with telemedicine must have working knowledge of computers to safeguard privacy of patients. It may be necessary that they should have attended some course of telemedicine. Some short courses of telemedicine should be started to tell them about liability and it should be in curriculum of undergraduate courses

These views, I hope will stimulate a healthy discussion between medical, law, IT and political persons to evolve a healthy consensus for the future of telemedicine and a suitable law will be enacted to take care of the hindrances in the development and safe practice of telemedicine and prevent its misuse.

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