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Physiology

Application of Telemedicine: Promise or Peril?

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bandwidth for medicine, health, and education. Telemedicine in India developed as a fortuitous and well-funded byproduct of aggressive space and technology policies and programs. The telemedicine satellite services are provided with no user fees to the vast rural areas of the country.

The telemedicine program operates with approximately 400 nodes (access points) located in 350 hospitals that result in the provision of approximately 400,000 consults annually. The commitment to connect the highest-level specialty care hospitals to district level hospitals is profound and not driven by profit or any form of monetary gain, but by a deep commitment to health care services and professionalism. India is curiously classified by most of the wealthiest industrial nations of the world as a developing country. However, the original drivers for much of the world development are to be found in India, more so than any other nation in the world. While the telemedicine programs in India are already in place but not fully operational, the leaders in telemedicine are already sharing their considerable experiences through program development, United Nations advisory activities, free consultations and satellite time, and scholarly reports that critically analyze the outcomes of telemedicine[1-6]

In countries such as India, with a population of more than one-billion people and where the distances between regional towns and capital cities are considerable, and where there is a scarcity of specialty medical facilities and services, there is a need to develop alternative methods of delivering healthcare services to people who live in remote areas. In India, healthcare is state-run as a three-tier system:

- Primary health care (PHC), which provides services for a select group of villages;
- Secondary level health centers located at district levels;
- Medical college hospitals that are located in major cities and that deliver tertiary-level healthcare.

In addition, a few advanced medical institutes of national importance provide specialty clinical services, teaching and research.

In spite of the well-networked healthcare system, access to healthcare in rural areas is far from satisfactory. Currently, 75% of qualified consulting doctors practice in urban areas, 23% in semi-urban (towns) areas, and only 2% in rural areas, where the vast majority of the population live. There is approximately one hospital bed per 10,000 people in rural areas compared with 2.2 beds per 10,000 people in urban areas. Furthermore, large north and northeastern regions of the country are mountainous or remote, making access to healthcare difficult, at best. The concept of telehealth care is not new to the country. Both government and private agencies have tried it. Some Indian companies are able to provide hardware and software for telehealth, and reputed overseas companies in the telehealth industry are involved. Efforts are being made to set up standards and an ITenabled healthcare infrastructure in the country [7-9]. Telemedicine has become a God sent resource amongst hospitals are seeking ways to serve the underserved population that cannot access medical care. Telemedicine provides a means for physicians -0.25 million of them produced versus the 0.7 million that it needs every year in the country, to attend to multiple patients all across the country, or even the world, without ever leaving their hospitals. A doctor can diagnose a patient, prescribe medication and treatment, or simply educate a patient on a particular issue without having the patient spend time and money travelling to a major medical facility for a diagnosis and reduce cost in medical care without sacrificing the quality of care [10]. Hospitals benefit by being able to reach areas that may eventually become revenue centers. Benefits of telemedicine Patients in rural and far remote areas are able to consult specialists at nodal centers. It would help these patients by saving time and money and providing access specialists. Telemedicine allows healthcare professionals to use medical devices in their evaluations, diagnoses and treatment of patients at distant locations. The devices are enhanced with Telecommunications Technology, network computing and videoconferencing systems. Telemedicine has given flexibility to healthcare service providers and allows has given them to expand the scope and quality of services. However, initial consultations still require face-to-face interaction.

Three Traditional Modalities

Telehealth traditionally encompasses three main modalities, each with distinct applications within the broader telehealth industry.

- Real-time is a live, two-way, synchronous interaction between a patient (and the patient's caregiver) and a health care provider using audiovisual technology. Real-time telehealth services can be used to consult, diagnose and treat patients.
- Store-and-forward involves asynchronous transmission of a patient's recorded health history (e.g., prerecorded videos or digital images like X-rays and photos) through a secure electronic communications system to a health care provider, usually a specialist. The information is used to evaluate a patient's case or, in some cases, render a service outside of a real-time interaction. Store-and-forward technologies have the advantage of providing access to patient data after they have

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been collected, and are particularly beneficial to patients who require specialty care when providers are not available locally. This modality also is used to provide services to patients in other countries.

• Remote patient monitoring involves collection of a patient's personal health and medical data via electronic communication technologies. Once collected, the data are transmitted to a provider at a different location, allowing the provider to continue tracking the patient's data once the patient has been released to his or her home or another care facility.

In addition to these traditional modalities, a growing number of mobile health, or health, technologies, applications and online services are being sold directly to patients, such as wearable devices to track health and wellness [11].

The peril

Section 72 A of IT Act

Breach of confidentiality and privacy- Any person who has secured access to any electronic record, book, register, correspondence, information, document or other material without the consent of the person concerned discloses such electronic record, book, register, correspondence, information, document or other material to any other person shall be punished with imprisonment for a term which may extend to 3 years, or with fine which may extend to 5 lakh rupees, or with both.72A. Punishment for Disclosure of information in breach of lawful contract.

Section 75 of IT Act

Offence or contravention committed outside India by any person if the act or conduct constituting the offence or contravention involves a computer, computer system or computer network located in India.

Section 43A of IT Act

Compensation for failure to protect data. -Where a body corporate, possessing, dealing or handling any sensitive personal data or information in a computer resource which it owns, controls or operates, is negligent in implementing and maintaining reasonable security practices and procedures and thereby causes wrongful loss or wrongful gain to any person, such body corporate shall be liable to pay damages by way of compensation, not exceeding five crore rupees, to the person so affected. (Change vide ITAA 2008)

Explanation: For the purposes of this section

- "Body corporate" means any company and includes a firm, sole proprietorship or other association of individuals engaged in commercial or professional activities.
- "Reasonable security practices and procedures" means security practices and procedures designed to protect such information from unauthorized

access, damage, use, modification, disclosure or impairment, as may be specified in an agreement between the parties or as may be specified in any law for the time being in force and in the absence of such agreement or any law, such reasonable security practices and procedures, as may be prescribed by the central government in consultation with such professional bodies or associations as it may deem fit.

• "Sensitive personal data or information" means such personal information as may be prescribed by the central government in consultation with such professional bodies or associations as it may deem fit.

Indecent representation of women (Prohibition) Act, 1986

Section 66E of IEA- Punishment for publication or transmission of image of females without their consent, under circumstances violating the privacy of females in indecent representation of women(Prohibition) Act, 1986.

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. Ideally, telemedicine should be employed only in cases in which a prior in-person relationship exists between the patient and the physician involved in arranging or providing the telemedicine service. The physician asking for another physician's advice or second opinion remains responsible for treatment and other decisions and recommendations given to the The possibilities and weaknesses of patient. telemedicine in emergencies must be acknowledged. If it is necessary to use telemedicine in an emergency, the advice and treatment suggestions are influenced by the level of threat to the patient and the expertise and capacity of the persons who are with the patient.WMA and National Medical Associations should encourage the development of national legislation and international agreements on subjects related to the practice of telemedicine, such as e-prescribing, physician registration, liability and the legal status of electronic medical records.

The physician needs to give clear and explicit direction to the patient, as to who has ongoing responsibility for any required follow-up and ongoing health care. Physician supervision regarding protocols, conferencing and medical record review is required in all settings and circumstances. The physician needs to clarify ongoing responsibility for the patient with any other health care providers who are involved in the patient's care. The physician will take steps to ensure that quality of communication is maximized. Any significant technical deficiencies should be noted in the documentation of the consultation. 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. Consent can be taken by sending online the consent format to the user before advising. User has to sign the consent by signing digital signature on form in mobile, scan & send to the doctor online, than doctor should issue prescription. MCI regulate advertising by doctors in telemedicine via mobile apps & online by backs Advertising Standards Council of India (ASCI) for taking action against doctors whose advertisements violate the Medical Code of Ethics Regulations, 2002. In their letter, The Ethics Committee of MCI has strongly backed ASCI for its efforts and self-regulatory mechanism of ensuring ethical advertising practices. ASCI has observed and processed a large number of complaints of health care products, services and clinic advertisements that has mention of or promotions of doctors. As per MCI rules, doctors cannot promote themselves in advertisements. Important landmark for ASCI in our efforts for protecting the consumers from misleading advertising. The Medical council is asking all doctors to withdraw their names from online registries, and remove any advertisements with their names, photographs, Specialty and contact details, as this violates the Medical Council of India's Code of Ethics Regulations, 2002."Most doctors advertise online, claiming that it is just information. Many think that is acceptable. However, this is not supposed to be done. We have decided to send warning letters to 100 doctors giving those 15 days to remove these ads from Practo, Lybrate, SuperDoc, DocsApp, MeraDoctor, Prescribez& other mobile apps. Unethical conducts by virtual Smartphone Apps - These Smartphone Apps can Fraud with users by claiming false association with famous doctors virtually, without any contract with concerned doctor. Doctor can face charges of unethical conduct by medical councils for advertising unethically.

List of Legal Acts related to Telemedicine

- Indian Contract Act, 1872,
- Drugs and Cosmetic Rules 1945
- Indecent representation of women(Prohibition) Act, 1986
- Information Technology Act, 2000
- Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Information) Rules, 2011 (the "SPI Rules"),
- (Indian) Information Technology (Intermediaries Guidelines) Rules, 2011 (the "IG Rules").

The Guidelines recommend that each healthcare provider should have a unique provider

identifier, which will flow to all its programs and telemedicine consultation centers ("TCC").Each of the telemedicine specialty centers ("TSC") and TCCs are recommended to have a separate unique and universal identifier code. It is further recommended that each patient also be identified by a unique and universal patient identifier so that one central patient information record can be assimilated, comprehensive medical databases can be built, or if the patient wants, he/she can move across multiple providers without losing data. The Guidelines also spell out the hardware and software (including detailed configuration and specifications) which is recommended for the setting up of the TCC and TSCs. In the absence of a legislation governing Telemedicine, it is suggested that the machinery and equipment of the vendor complies with the specifications given in the Guidelines to dilute potential liability issues at a later stage. The Guidelines provide adequate risk mitigation at various stages in the process of Telemedicine and thereby must be closely consulted while setting up Telemedicine organizations.

The relevant section of (Indian) Information Technology (Intermediaries Guidelines) Rules, 2011 in telemedicine

As mandated by Regulation 3(2) of the IG Rules, Mobile app hereby informs Users that they are not permitted to host, display, upload, modify, publish, transmit, update or share any information that:

- belongs to another person and to which the User does not have any right to;
- is grossly harmful, harassing, blasphemous, defamatory, obscene, pornographic, pedophilic, libelous, invasive of another's privacy, hateful, or racially, ethnically objectionable, disparaging, relating or encouraging money laundering or gambling, or otherwise unlawful in any manner whatever;
- harm minors in any way;
- infringes any patent, trademark, copyright or other proprietary rights;
- violates any law for the time being in force;
- deceives or misleads the addressee about the origin of such messages or communicates any information which is grossly offensive or menacing in nature;
- impersonate another person;
- contains software viruses or any other computer code, files or programs designed to interrupt, destroy or limit the functionality of any computer resource;
- Threatens the unity, integrity, defense, security or sovereignty of India, friendly relations with foreign states, or public order or causes incitement to the commission of any cognizable offence or prevents investigation of any offence or is insulting any other nation.

The guidelines for telemedicine in Drugs and Cosmetic Rules 1945

For all medical treatments through telemedicine or web-interface format, it is important to ensure that the prescriptions issued by the medical practitioner satisfy the requirements of being in writing and signed by a registered medical practitioner, in accordance with the Drugs and Cosmetic Rules 1945, without which, the prescription will be invalid in the eyes of the law.

The precaution is displayed by Mobile apps in telemedicine:

• No doctor-patient relationship;

• Not for emergency use

The provision of such Information does not create a licensed medical professional/patient relationship, between Mobile-app and you and does not constitute an opinion, medical advice, or diagnosis or treatment of any particular condition, but is only provided to assist you with locating appropriate medical care from a qualified practitioner."

However, legally, doctor patient relationship is established even when doctor advises anyone anything anytime anywhere online, because its documentary evidence, which creates ground for compensation in case of negligence in casually written advice in limited words.

Insurance cover available for second opinion by telemedicine

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.

Medicolegal issues involved in International Teleconsultation

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.

To bring Standardization of telemedicine

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

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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.

CONCLUSION

It 's not all bad

"Will we take advantage of the opportunities provided by the new technology, or will we be run over by it? Telehealth has the potential to make a difference in the health care of people all over the world. Whether it achieves its potential may depend on the resolution of the issues addressed. In the near future, however, do not expect to see consensus in many of these areas. One thing that is certain, given the present and future advances in technology, telehealth is here to stay. The question then becomes, how will it be used and who will benefit?

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