INTERVIEW

Mobile Healthcare and the Law

Dr Milind Antani
Head - Pharma & Life Science
Nishith Desai Associates

Q. What are the laws that cover mobile health activities? How stringent are these laws in the current day practice?

A. There are no specific laws which govern the process of providing medical guidance through mHealth. What would be applicable are those laws which govern a normal patient/doctor relationship. The question of liability of the application provider would be governed by contract law.

In fact, the patient's rights are basically indirect rights, which arise or flow from the obligations of a physician or healthcare provider under the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002.

The basic principle is that medical doctors and associated medical professionals are responsible and liable for wrongs and failures in the performance of their medical duties towards patients.

In India, generally, Section 304-A of the Indian Penal Code (IPC), 1860, is the relevant provision under which a complaint against a medical practitioner for alleged criminal medical negligence is registered. Section 304-A provides that whoever commits culpable homicide not amounting to murder shall be punished for life or imprisoned for a term up to 10 years and fined as well. Section 337 of the IPC deals with hurt caused by an act endangering the life or personal safety of others.

However, the simple lack of care attracts only civil liability. Therefore, only civil negligence may not be enough to hold a medical professional criminally liable.

Q. What are the possible legal liabilities that we could expect with the delivery of health through mobile phones? What are the legal aspects that physicians practicing mHealth should be aware of?

A. Negligence and possibility of malpractice is what the providers of mHealth services should be aware of. The courts in India have generally followed the decisions and practices of the English law. The cases of negligence in India are directly related to existing facilities, infrastructure, and level of acumen of medical professionals. In many cases, doctors have been held liable for negligent acts, such as removal of a wrong eye or a kidney, or surgery on wrong limb, based on pecuniary interest or where minimum facilities were available. In this regard, an important example is of eye camps or health camps where operations are performed without proper facilities.

The Supreme Court of India in its landmark judgment in the *Indian Medical*

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Association vs V.P. Shanta[1], laid down the law relating to professional negligence under Consumer Protection Act 1986, and enunciated certain principles that medical practitioners, government hospitals, and private hospitals and nursing homes are also covered under the consumer law in the following categories:[2]

1. Where services are rendered free of charge to everybody availing of the said service
2. Where charges are required to be paid by persons availing of services, but certain categories of persons who cannot afford to pay are rendered service free of charge

The services provided in the first category by doctors and hospitals would not be covered by the services under section 2(1) (0) of the Consumer Protection Act, 1986,[3] but those rendered by the second and third categories of doctors and hospitals would be covered within the ambit of the service defined in the above provision of the Act.

Q. What could be the consequences of malpractice by a physician outside the geographical jurisdiction treating a patient remotely?

A. In the past, courts would use the standard of the particular locale where the tortuous act took place, invoking the so-called 'locality rule.' This was based on the belief that different standards of care were applicable in different areas of the country, e.g., urban or rural. However, this rule has been largely abandoned in favor of a uniform standard, because medical training and board certifications all adhere to a national standard. Telemedicine has further propagated this uniformity. With the erosion of the locality rule, courts now readily allow out-of-state experts to testify on behalf of the opposing parties. This has been especially helpful for plaintiffs who are far less likely to be able to secure willing experts from the local community. Geographical considerations are not entirely irrelevant. Where the local medical facilities lack state-of-the-art equipment or specialists, courts will look at the existing circumstances. However, there is always the duty to refer and transfer to an available specialist, and the failure to do so may form the basis of liability.

In a key decision on this matter in the case of *Dr Laxman Balkrishna Joshi vs Dr Trimbak Bapu Godbole*, the Supreme Court held that if a doctor has adopted a practice that is considered 'proper' by a reasonable body of medical professionals who are skilled in that particular field, he or she will not be held negligent only because something went wrong.

Q. How will a technology as dynamic as telecommunication be able to abide by privacy and security issues?

A. To answer this question, it would entirely depend upon what the doctor has communicated to the patient. From a legal point of view, any recommendations or advice by a doctor shall not constitute a prescription; however, courts have allowed doctors to recommend in acute emergency cases.

If the patient already has an established relationship with the physician, there is a risk, just as there is if the physician takes a phone call over a standard landline. When the physician is asked a question of a professional nature, he's being called upon to make a professional judgment and recommend a course of action to deal with the patient's problem. In the diagnostic effort or the recommended therapy, one could make a mistake. When there is the possibility of a mistake, that's where malpractice risk arises. On the other hand, if there was no prior relationship between the two, there is greater risk.

If X is Y's doctor and Y has been X's patient and Y has been communicating his condition, and if they decide to engage in communication via smartphone, the communication isn't different, just the mechanism differs. The symptoms are still spoken about and advice is being given on that basis. If with a patient, the doctor doesn't have a relationship and the doctor doesn't have a great deal of history or information to help, it becomes a harder job to do.

The treating doctor is bound by the code of ethics regulations

[1]AIR 1996 S.C. 550

[2]Id. at 563-6

[3]Section 2(1) (0) Provides: 'Services' means service of any description is made available to potential users and includes the provision of facilities in connection with banking, financing, insurance, transport, processing, supply electrical or other energy, boarding or lodging or both, (housing construction), entertainment, amusement, or purveying of news or other information, but does not include the rendering of any service free of charge or under a contract of personal service.

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prescribed by the Medical Council of India regarding the confidentiality of information pertaining to patients. At the same time, doctors have to abide by the Information Technology (Reasonable security practices and procedures, and sensitive personal data or information) Rules, 2011.

Q. Do you think that there should be an additional certification for healthcare professionals to practice mHealth? Will there come a time when mobile devices would have to be certified by regulatory bodies like FDA and CCHIT?

A. Though additional certification may not be necessary for doctors practicing on mobile health platform, new regulatory changes are likely to come.

Q. Do you think that the lack of a regulatory framework is a deterrent to technological advancements in tele or mobile healthcare delivery?

A. Lack of a clear, regulated, and mandated structure would allow for a leeway to utilize the loopholes of the law to the advantage of the mHealth service providers. While this can promote an atmosphere of proactive competition, it should not reach a stage where any monopolistic tendencies come into existence or worst of all, if the patient is not getting any healthcare promised by the companies. So, while at the international scenario, it can be said that there is adequate regulatory framework, the same cannot be said for India. Proper regulatory framework should definitely help the telemedicine industry.

Q. What in your opinion is the way forward to meeting these regulatory challenges, globally?

A. Various mobile technologies are creating an explosion of mHealth solutions and devices. While foreign regulatory bodies have already taken steps to provide a structure, the same cannot be said of the Indian equivalents. Thus, when a system is established abroad and is effective, the Indian bodies may adopt the same, which would be beneficial to the mHealth providers and the patients/users as well. To meet the possible challenges, one way would be to set up a means of communication between regulatory bodies of different countries and try to implement best practices from all over. As mentioned earlier, to have a comprehensive law covering telemedicine in India is the need of the hour.

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