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# Regulating Digital Health: Navigating Legal Challenges and Innovations in E-Health

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## ABSTRACT

*The fast forward of Internet in the health and medical industry is experiencing an detonation of cyberchange from health care, e- communications to e-commerce and e- care. Day by day and hour by hour new developments were emerging which may have pros and cons. Patients who seek health care through online were termed as e-patients and they can conveniently consult the physicians so called cyberdocs from their home throughout internet. The e- health care system has been gradually converting the hospital centric system to patient centric. Though e-health is one of the saviour for many patients during this pandemic, the ambushments behind this technology were unknown to the people. E-health poses ethical challenges like online professional practices, informed consent and equity issues. It also leads to numerous legal problems like jurisdictional issues, privacy issues and many other issues relating to remedies available for the affected parties. This article signifies the power of internet on E- health and thereby analyse the existing laws regulating electronic health.*

***Keywords**: E-Health, Law.*

## I. INTRODUCTION

Due to the advent of science of technology the society has been witnessed several changes and developments. As a result of this new technology like other ecommerce industry the doctors and clinicians are also entered into the cyber space so as to enhance their profession by way of e-health practice. Initially traditional health care practice was supplemented by tele- health practice but later due to the development of computer technology and its convergence with improvements in telecommunications has provided the means through which the delivery of health services by distance has evolved radically in recent times. By the day to day development in cyber space, the e- health practice has paved ways for storing the patients' health records in clouds and thereby disseminating health information. Thus this technological advancement

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which is partially replacing the traditional health care providers is considered as a revolution in the field of modern health system. There are great varieties of Internet applications popping everyday due to the urgent need of medical care in this pandemic era which can be brought under the umbrella of e- health. It includes EHR (Electronic Health Records) which is one of the fundamental components of e-health followed by m-health which means the use of mobile wireless technologies for providing healthcare, which often needs a smart phone. The other developments includes sensors and wearable were Bluetooth enabled smart devices will measure the signal and collect data which will be transmitted to the smart phones or computers to track data and it will be send to the concerned health care provider. Initially this type of technologies are not much influenced in the developing or under developed countries, but now after the Covid-19 pandemic, the pros of this e-health has made a great revolution in the field of healthcare. This technology ensures that the patients in the rural area are well connected with the doctors in the urban area through online medium. The marketing teams of these modern health care providers facilitate the patients with simple and advance mobile applications. There is no doubt that the e-health practice is the saviour for many patients which minimized the problems regarding the accessibility of health care services especially during the pandemic but the ambushments behind this technology were unknown to the people. E- health poses ethical and legal challenges like online professional practices, informed consent and equity issues in accessing ICT services, lack of awareness of, and confidence in e-Health solutions among patients, citizens and healthcare professionals, lack of interoperability between e-Health solutions, lack of legal clarity for health and wellbeing mobile applications and the lack of transparency regarding the utilization of data collected by such applications, inadequate or fragmented legal frameworks including the lack of reimbursement schemes for e-Health services, privacy, jurisdictional issues, burden of proof and many other issues relating to remedies available for the affected parties. This article signifies the power of internet on E-health and thereby analyse the existing laws regulating electronic health.

## II. E-HEALTH

World Health Organisation defines Electronic Health as "the use of information and communication technologies for health". [3]This definition is succinct. A more detailed definition has been put forth by European commission as "tools and services using information and communication technologies that can improve prevention, diagnosis, treatment, monitoring and management".[4] Thus both tools and services that use ICTs for purposes connected to health can

[3] World Health Organization. eHealth [Internet]. <https://www.who.int/ehealth/en/>.
[4] European Commission, Consumers, Health, Agriculture and Food Executive Agency, *eHealth : digital health*

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be included under the umbrella of e-health.

### (A) Forms of E-Health

**a.** Telemedicine

75% of the country's healthcare infrastructure is concentrated in urban areas while more than 75% of the population lives in rural areas.[5] Telemedicine, which is the use of telecommunications technology to provide healthcare, could effectively bridge the gap between the patient and the doctor. While telemedicine is not a separate specialty in itself, its standout is the use of various technologies in providing traditional healthcare services. It is a broad concept that covers withinits ambit various aspects such as tele-radiology, tele-consultation, tele-nursing, tele-ICU and tele-surgery. Each brings its own advantages and challenges and have to be examined individually in order to be able to run the service efficiently and in compliance with the law

b. Robot-Assisted Surgery

Using the assistance of robots, doctors are able to perform surgical procedures more efficiently. Minimally invasive surgeries have been around for a while, but with the assistance of robotics, surgeons are able to maneuver more precisely and with smaller incisions.[6] This ultimately leads to reduced loss of blood, better pain management and quicker recovery for the patient. With advancements in deep learning, robots would be able to observe and replicate procedures that are simple and repetitive, while the surgeon concentrates on more complex tasks.[7]

c. Self-Monitoring Healthcare Devices

Monitors and sensors are now being integrated into wearables, which allow it to detect various physiological changes in the body. These smart devices are capable of tracking weight, sleep patterns, posture, diet and exercise.[8] The raw data that is collected can be used to self-monitor by detecting various health symptoms and alert the user in case of potential issues.

d. Electronic Health Records ("EHR")

An EHR is a digital version of a patient's health records. EHRs help eliminate the problems

*and care*, Publications Office, 2019, https://data.europa.eu/doi/10.2818/419902

[5] Ashok Vikhe Patil, K. V. Somasundaram and R. C. Goyal; Current Health Scenario In Rural India; available at http:// www.sas.upenn.edu/~dludden/WaterborneDisease3.pdf

[6] Johns Hopkins Medicine; Types of Minimally Invasive Surgery; available at http://www.hopkinsmedicine.org/ minimally_invasive_robotic_surgery/types.html

[7] IEEE Spectrum; Robot Surgeones are Taking over the Operating Room; available at http://spectrum.ieee.org/ video/ robotics/medical-robots/robot-surgeons-are-taking-over-the- operating-room

[8] Geoff Appelboom, Elvis Camacho, Mickey E Abraham; Smart wearable body sensors for patient self-assessment and monitoring; available at http://www.ncbi.nlm.nih.gov/pmc/ articles/PMC4166023/

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associated with physical records such as loss and lack of accessibility. EHRs can be stored centrally and accessed at any time, irrespective of where or when the information was collected.[9] With EHRs, doctors are able to view their patient's complete medical history even if they are treating the patient for the first time. This would help reduce duplication of tests and facilitate the secure exchange of information, which in turn helps the patient and the healthcare facilities manage costs.

e. Health Service Aggregation

Information asymmetry is one of the biggest challenges in healthcare. Patients are not privy to information which is essential in aiding with their choice of doctors, and at times doctors are not able to reach out to a large number of patients due to a lack of visibility. A numberof online platforms are springing up which attempt to solve this problem. These platforms list the names of doctors with their specialties, and allow for patients to search for and make an appointment with the right doctor to suit their specific needs. Patients are also able to rate and review the quality of the service provided by the doctor or institution, which serves as guidance for future patients to make an informed decision.

f. m-Health

Mobile health, or m-Health, is the provision of e-Health services on a mobile platform. India is home to the 3rd largest smartphone market in the world, which makes m-Health a very lucrative option. Providing access to such applications on smartphones would also not be a big hurdle, with the country expecting to reach 314 million mobile internet users by 2017. The convenience of e-Health coupled with the mobility of m-Health opens the arena for a lot more players to actively take part in the revolution.

g. Big Data in healthcare

Raw data is collected from the use of various e-Health services. EHRs in itself generates a massive amount of information that can be put to use in different ways. 25 billion devices are expected to be connected through the Internet of Things ("IOT"),[10] and the data that these connected devices are expected to churn out have to be processed. The sheer volume of information generated requires solutions such as big data processing, which then can be put to use by various companies.

[9] Lise Poissant, Jennifer Pereira, Robyn Tamblyn; The Impact of Electronic Health Records on Time Efficiency of Physi- cians and Nurses: A Systematic Review; available at http:// www.ncbi.nlm.nih.gov/pmc/ articles/PMC1205599/

[10] Guy Daniels; Internet of Things to Reach 25 Billion Devices within Five Years; available at http://www.telecomtv.com/ articles/iot/internet-of-things-to-reach-25-billion-devices- within-five-years-11931/

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h. Online-Pharmacies

An interesting concept that is cropping up worldwide is online pharmacies or e-Pharmacies. There are various models that have been adopted such as online-only pharmacies and physical pharmacies with an online presence. Online pharmacies allow pharmacists to cater to a larger group of patients as the inherent geographical restrictions on physical pharmacies are removed in the online model.

## III. INTERNATIONAL CONVENTIONS RELATING TO E-HEALTH

### (A) The Universal Declaration of Human Rights

The Universal Declaration of Human Rights was adopted in 1948 by the United Nations (UN) General Assembly in a direct response to the atrocities of the Second World War. It is an internationally binding law which seeks to protect core human rights to a common standard globally. The declaration consists of some thirty articles which cover all the core issues of human rights. Privacy is addressed in Article 12 which provides:

"No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks."

### (B) The European Convention on Human Rights

The Convention for the Protection of Human Rights and Fundamental Freedoms, which is commonly known as the European Convention on Human Rights, is a treaty established by the Council of Europe in 1950 and binding all members of the Council of Europe.

Article 8 of the convention creates a right to respect for private and family life:

**1.** Everyone has the right to respect for his private and family life, his home and his correspondence.

**2.** There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others..

European Union Directive on the protection of individuals with regard to the processing of personal data and on the free movement of such data

In the European Union (EU) health care is regulated at national, not federal, EU level. At federal

level, Article168 of the Treaty on the Functioning of the European Union sets the requirement that a high level of human health protection is to be ensured in the definition and implementation of all EU policies and activities. However, the treaty also requires that decisions relating to the provision of health care services are taken at the national or local level (the legal principle of subsidiarity). The EU thus has only a limited legal competency on health matters, which can be used to adopt measures that complement national initiatives, or to adopt incentive measures designed to protect and improve human health, in particular to combat the major cross- border health scourges. In Article 8 of the Directive a special status is accorded to all medical and health related information andprohibits the processing of health related data unless one of four exceptions is met:

- Explicit informed consent has been obtained from the data subject (Article 8(2)(a)); or
- Data processing is in the vital interests of the patient or of another person who is physically or legally incapable of giving consent (Article 8(2)(c)); or
- The processing of health data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment, or the management of health-care services AND the personal data in question are processed by a health professional (Article 8(3)); or
- There is a substantial public interest in the processing (Article 8(4)). In order to help Member States interpret their duties under the Directive a data protection working party composed of the representatives of the national data protection authorities has been established. Its function is to advise the European Commission on the implementation of the Directive in the Member States.

## IV. INDIAN LAWS

### (A) The Information Technology Act, 2000 ("IT Act"), The Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules,2011 ("Data Protection Rules") and the Information Technology (Intermediaries Guidelines) Rules, 2011("Intermediary Guidelines")

E-Health involves a constant exchange of information between the patient and the service provider. The patient's personal information, such as medical history and physiological conditions, are considered Sensitive Personal Data or Information("SPDI") under the Data Protection Rules. When a body corporate collects, stores, transfers or processes such information, certain requirements under the Data Protection Rules are triggered. Consent is one

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of the major requirements under the Data Protection Rules. Before a doctor or an institution does anything with a patient's data, they are required by law to obtain the recipient's consent in writing. The patient must be informed about the fact that the data is being collected, what it will be used for and whether it would be transferred to any third parties, along with the contact details of the agency collecting the information. There is also a requirement for body corporates to have a privacy policy in place and published on its website. This consent is usually obtained by having the patient accept the terms of the body corporate's privacy policy, which is also required to have such information, in addition to the security practices the body corporate has adopted to keep the information safe. If the SPDI is planned to be disclosed to a third party, prior permission of the owner of the SPDI is to be obtained. In cases where the SPDI is being transferred, the body corporate transferring the SPDI must ensure that the receiver of the SPDI has adequate security practices in place.19 The Data Protection Rules also mandate the implementation of reasonable security practices and procedures in order to keep the SPDI secure.

### (B) Other Service Providers Regulations under the New Telecom Policy 1999 ("OSP Regulations")

Service providers who render "Application Services" - which includes telemedicine services – using telecom resources provided by telecom service providers, are required to be registered as an 'Other Service Provider' ("OSP") with the Department of Telecommunications.

### (C) The Drugs and Cosmetics Act, 1940 ("D&C Act") and Drugs and Cosmetics Rules, 1945 ("D&C Rules")

The D&C Act and D&C Rules regulate the manufacture, sale, import and distribution of drugs in India. In many foreign jurisdictions, there is a clear distinction between a drug that must be sold under the supervision of a registered pharmacist on the production of a valid prescription (signed by a registered medical practitioner) and those that can be sold by general retailers over-the-counter ("OTC"). OTC drugs have a different meaning in the context of Indian laws. The D&C Act requires that all drugs must be sold under a license. The D&C Rules clearly lay down which drugs can be sold only on the production of a prescription issued by a registered doctor, which implies that there is a distinction between prescription and non-prescription drugs. Drugs which can be sold only on prescription are stated in Schedules H, H1, and X of the D&C Rules. The D&C Act states that no person can sell any drug without a license issued by the licensing authority. However, it provides for certain drugs, namely those falling under schedule K of the D&C Rules, to be sold by persons who do not have such a license. Hence, OTC drugs in the

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Indian context would mean only those drugs that are specified under schedule K.These broadly include drugs not intended for medical use, quinine and other antimalarial drugs, magnesium sulfate, substances intended to be used for destruction of vermin or insects that cause disease in humans or animals and household remedies, among others.

### (D) The Indian Medical Council Act, 1956 ("MCI Act") and The Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 ("MCI Code")

The MCI Act provides that only those persons who have a recognized degree in medicine and are registered with one of state medical councils have the right to practice medicine in India. The MCI Code lays down professional and ethical standards of interaction of doctors with patients. The MCI Code also specifies that efforts are to be made to computerize medical records so that they can be retrieved quickly. Doctors are bound by the MCI Code and are required to submit a declaration to that effect. The apex body currently regulating the practice of medicine is the Medical Council of India. However, the proposed National Medical Commission Bill, 2016, which has been drafted by the National Institution for Transforming India ("NITI Aayog"), intends to replace the current Medical Council of India with a 'National Medical Commission'. The passing of the National Medical Commission Bill would see a change in the current regulatory framework regulating medical practitioners.

## V. CONCLUSION

Though it is evident that the e-health has removed the geographical barriers and it has increased the accessibility of health care services, but the legal issues involved in this advanced technology were overtaking. One of the main challenges is the reliability which can be rooted in the technology itself. The safety of the device, standardization, integrity of the data, input errors, privacy, data theft and many more traps are lying behind which blinds the anxiety patients. Though national(Art 21 of Indian Constitution) and international law (UDHR & ECHR) stipulates that it is the duty of the healthcare professionals and the hospitals to protect the privacy of the patients, in this sophisticated technology there is a huge lacunae and this research addresses it as a challenge. There is no effective law protecting the privacy of the patients. Moreover assume that the patient is in one jurisdiction where the healthcare provider is not licensed to practice and the patient seeks healthcare over the Internet from that professional. The law has not yet made clear where jurisdiction will be in such circumstance. This may slowdown the effective growth of the e-health care and also the grievances of the patients were not adequately addressed. Since, this is an online process, the victims of this

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technology is given the task of submitting the documentary evidence of the mal practices, which is a night mare to the technologically down patients. Presently the cyber laws (Information Technology Act 2000) of the country is also not having any effective legal provisions to meet the challenges of e-health care practice. Thus, it is an important area to have a specific solution to the above discussed problems to protect the interest of the patients without further delay.

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