CHALLENGES TO DOCTOR-PATIENT RELATIONSHIP IN DIGITAL HEALTH

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ABSTRACT

Digital health has enhanced the concept of access to healthcare by breaking geographical limitations. Digital health is the delivery of health services via electronic means. The outbreak of the covid-19 pandemic has resulted in widened use of digital health services due to the inability to approach the medical professionals due to COVID-19 restrictions.

Digital health is a concept that is undoubtedly associated with the ethical and legal challenges in the doctor-patient relationship. The doctor-patient relationship is of utmost importance and integral to medical ethical principles. Since Hippocrates' time, an ideal doctor-patient relationship encompasses philosophical, sociological, and literary attention. It demands respect, compassion and trust among each other. The contemporary concept of digital health is patient-centric based on their demands and well-being. The legal and ethical challenges in digital health are overlapping and inseparable. It includes medical negligence, privacy and confidentiality, autonomy and informed consent, challenges in cross border services, prescription and delivery of drugs, mental health services, and end of life decision making.

This paper deals with identifying the concept of digital health, the ideal doctor-patient relationship and the applicability of medical ethical principles to the contemporary notions of digital health. It also looks into existing legal positions and case laws to identify the lacuna in this area and gives suggestions and recommendations.

Keywords: Doctor-Patient Relationship, Medical Ethics, Digital Health

INTRODUCTION

Access to healthcare is the most significant component of the right to health. In today's world of technological advancements, there are several ways by which it can be ensured. Digitalization in

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the health sector has revolutionized it. Sometimes, e-health and digital health are used synonymously. E-health is the area of medical information and communication technologies for health[1], while digital health is an umbrella term that also includes e-health[2]. The wide use of the internet and other communication technology helps patients communicate with medical professionals through e-mail, telephone, and other services in a person-to-person exchange of information. It is the delivery of health services via electronic means. Digital Health is particularly effective in areas where medical professionals could not physically reach. The outbreak of the COVID-19 pandemic has re-examined the conventional face-to-face doctor-patient communication, due to which digital health has risen to prominence mainly in the time of the pandemic. During the COVID-19 pandemic, telemedicine practices have been widely used, enabling contactless medical consultation, diagnosis, and treatment. It even extends to provisions of mental health services. It expanded the geographical coverage of health systems.

In every form of health service, the doctor-patient relationship is essential. It is an integral part of medical ethical principles[3]. The doctor-patients relationship encompasses mutual knowledge, trust, loyalty and regard[4]. Unless a principled approach between doctors and patients, the services cannot be ensured completely. A patient is a recipient of medical services, and a physician or a doctor is the service provider. The physician should observe ethical and legal principles to ensure the patient's best interest. The doctor-patient relationship has undergone several transformations due to the commercialization and privatization of the health sector and technological advancements. The introduction of digital health and other e-services has played a significant role in this transformation.

Several factors are to be considered to recognize the challenges in the doctor-patient relationship in the context of digital health. Understanding the concept, components, and variants of digital health is necessary. After thoroughly applying legal and ethical principles to digital health services, a conclusion could be reached.

THE CONCEPT OF DIGITAL HEALTH

[1] World Health Organization, https://www.who.int/ehealth/about/en (last visited May. 22, 2021).
[2] Sydney Health Partners, https://dhin.net.au/ehealth-digital-health-name/#:~:text=eHealth%20has%20been%20broadly%20defined,eHealth%2C%20telehealth%2C%20and%20more, (last visited May. 22, 2021).
[3] Smith Yolanda, *Doctor-Patient Relationship*, https://www.news-medical.net/health/DoctorPatient-Relationship.aspx.
[4] Ridd M, Shaw A, Lawis G, SalisburyC, *The Doctor-patient relationship: a synthesis of the qualitative literature on patients' perspectives,* 59 BJGP 116 (2009).

There is no uniform definition for the term "digital health". Most definitions highlight the need and way digital means are used to provide health care services. Some definitions also include the components of digital health. The following definitions can be considered to deduct its essential features and components.

The World Health Organization (hereinafter referred to as WHO) defines digital health as "*a broad umbrella term encompassing eHealth, as well as emerging areas, such as the use of advanced computing sciences in big data, genomics and artificial intelligence*[5]". According to WHO, digital health is vital in achieving Sustainable development goals.[6] Digital health is the field of knowledge and practice associated with developing and using digital technologies to improve health[7]. Digital health expands the concept of eHealth to include digital consumers, with a broader range of smart devices and connected equipment. It also incorporates other digital technologies, such as the internet, artificial intelligence, big data, and robotics.

Health Informatics Society of Australian Digital Health Agency defines digital health as *"any application of information and communication technologies to improve healthcare and health outcomes*"[8].Digital Health involves using information technology or electronic communication tools, services and processes to deliver healthcare services or facilitate better health[9]. The main focus is the improvement of health rather than technological advancements[10].

The essential features of digital health are as follows:

- It is a broad concept that involves the use of information and communication technologies,
- It uses digital technologies such as the internet, big data, genomics, artificial intelligence, and robotics,

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[5] World Health Organization, https://www.euro.who.int/en/health-topics/Health-systems/digital-health, (last visited May. 22, 2021).
[6] World Health Organization, Global Strategy on Digital Health 2020-2025, https://www.who.int/docs/default-source/documents/gs4dhdaa2a9f352b0445bafbc79ca799dce4d.pdf (last visited May. 22, 2021).
[7] *Id* at 20.
[8] David Rowlands, *What is Digital Health and Why does it Matter?,* DHWA 7, https://digitalhealth.org.au/wp-content/uploads/2020/02/DHWA_WHITEPAPER_2019.pdf.
[9] Canada Health Infoway, https://www.infoway-inforoute.ca/en/what-we-do/benefits-of-digital-health/what-is-digital-health#:~:text=Digital%20health%20refers%20to%20the,through%20innovative%20digital%20health%20solutions (last visited May. 22, 2021).
[10] Fatehi F (et.al), *What is Digital Health? Review of Definitions*, Stud Health Technol Inform. 2020, https://pubmed.ncbi.nlm.nih.gov/33227742/.

- Its objectives are to improve healthcare facilities and to ensure quality health outcomes.

Some examples of digital health are e-health, telemedicine, robot-assisted surgery, self-monitoring healthcare devices, electronic health records, health service aggregation, big data in healthcare, mobile-health or m-Health, targeted advertising, e-pharmacies, and e-Learning in the healthcare sector[11]. Health services are also provided through mobile applications such as Apple-health[12], Health-Pal[13], etc.

The Ayushman Bharat Pradhana Mantri Jan Arogya Yojana-SEHAT in India enables digital health services[14]. The health services include free diagnosis, treatment and medicines for people below the poverty line. The National Digital Health Authority, or NeHA, is a proposed Ministry of Health and Family Welfare authority intended to develop India's integrated health information system. It aims to enable telemedicine in India is to achieve universal health coverage envisaged in the 2017 National Health Policy. In addition to this, the National Digital Health Mission aims to develop the backbone necessary to support the integrated digital health infrastructure of the country. It will bridge the existing gap amongst different Healthcare ecosystem stakeholders through digital highways. The Ministry has also initiated teleconsultations and outpatient treatment through the portal called "e-Sanjeevani"[15]. It provides video-based clinical consultations.

The digital health era is patient-centric based on their demands and well-being[16]. The components of digital health give insights into the transformation in the healthcare sector and its effect on the doctor-patient relationship. They are discussed hereunder[17].

Electronic Health Records, Big Data, and access to medical information

[11] Digital Health in India, https://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research_Papers/Digital_Health_in_India.pdf (last visited May. 22, 2021).
[12] Apple.Inc, https://www.apple.com/in/ios/health/, (last visited May. 22, 2021).
[13] Health-Pal, https://healthpal.sg/, (last visited May. 22, 2021).
[14] Pm-Jay, https://pmjay.gov.in/about/pmjay, (last visited May. 22, 2021).
[15] E-Sanjeevani, https://esanjeevaniopd.in/About, (last visited May. 22, 2021).
[16] David Rowlands , *Supra* note 8.
[17] Health Management, https://healthmanagement.org/c/cardio/news/the-impact-of-digital-technology-on-healthcare#:~:text=Some%20of%20the%20areas%20where,retrieve%20patient%20data%20from%20anywhere (last visited May. 22, 2021).

Big data refers to the datasets whose size is beyond the ability of typical database software tools to capture, store, manage and analyze[18]. Digital health first took the form of storing and transferring medical records. Electronic-Health record is the digital version of patients' health records[19]. It can be stored and accessed anytime, irrespective of its physical location. Such data can be transferred among the physicians and the patients and their relatives. However, the collection of individuals' data raises privacy and confidentiality concerns[20]. These issues are also relevant in health service aggravation.

Better communication between medical professionals and patients

Effective communication is an integral part of good quality healthcare services[21]. Digital health has made communication easy. The doctors and patients can stay in touch through e-mail, phone calls, text messages, etc. It is more cost-effective and straightforward. Now, the patients or their relatives do not need to go and wait in queues to get medical reports and other data. However, it is difficult to determine the credibility of medical consultancy through mobile applications.

Telemedicine Practices

Telemedicine is the use of telecommunications technology to provide health care. Telemedicine is one of the most prominent forms of digital health. According to American Telemedical Associations, "*it is the natural evolution of health care in the digital world"*[22]. In *American Well* v *Teledoc*[23], a patent infringement suit was filed for using the same algorithm for telemedicine practices. It is one of the initial instances where the matter was brought to Court. It includes diagnosis and consultations, e-prescriptions, etc.

Telemedicine is defined by WHO as follows[24]:

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[18] Manyika J, Chui M, Brown B, *Big Data: The next frontier for innovation, competition, and productivity, https://www.mckinsey.com/mgi/overview* (last visited May. 22, 2021).
[19] Digital Health in India, *supra* note 11.
[20] NCBI, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6859509/ (last visited May. 22, 2021).
[21] Fong J, *Doctor Patient Communication: A Review,* 10, Ochsner, 38-43, (2010).
[22] Sageena G, *Evolution of Smart Healthcare: Telemedicine during COVID-19 Pandemic,* J. Inst. Eng. India Ser. B 102, 1319–1324 (2021).
[23] American Well v. Teledoc, 191 F Supp. 3d 135 (D. Mass. 2016).
[24] World Health Organisation, https://www.who.int/goe/publications/goe_telemedicine_2010.pdf (last visited May. 22, 2021).

"*The delivery of health care services, where distance is a critical factor, by all healthcare professionals using information and communications technologies for the exchange of valid information for the diagnosis, treatment and prevention of disease and injuries, research and evaluation, and the continuing education of healthcare workers, with the aim of advancing the health of individuals and communities"*.

The components of telemedicine are as follows[25]

i. Patient: The individual who is seeking advice or consultation.
ii. Primary Doctor: The registered medical practitioner who has physical access to the patient. The Primary Doctor will be available at the Telemedicine Consultancy Centre or TCC.
iii. Specialist: The registered medical practitioner who provides medical consultation to the patient from a distance. A Specialist is located at Telemedicine Specialty Centre or TSC.
iv. Telemedicine System: It is the system or technology created to store, transmit and control all the information or data of the patient. For example, Electronic Medical Record from the Patient to the Specialist, via TCC and TSC.
v. Telemedicine Consultancy Centre: The medical facility where the patient is present. It will be equipped with basic technology required for the exchange of medical information and medical consultation.
vi. Telemedicine Specialty Centre: The medical facility where the specialist is present. It is equipped with basic technology required for exchange of medical information and medical consultation. The specialist will provide Tele-consultancy from the TSC.
vii. Tele-consultation: It delivers health care services using information and communication technology over a distance.

The telemedicine practice takes place in the following situations[26]:

i. Between patient and specialist through the Primary Doctor.
ii. Between patient and specialist without the Primary Doctor.
iii. Between the Doctors

[25] Digital Health in India, *supra* note 11.
[26] *Id* at 29.

Several states in the USA have passed specific regulations for telemedicine consultations. They have addressed some concerns that arise from the practice of telemedicine, such as Cross-State Licensing, Reimbursements, Patient privacy and confidentiality, Online prescriptions, and m-health[27]. The European Union has also come up with recommendations and guidelines about cross border Digital Health services[28]. It also deals with insurance, data privacy, competition, electronic health records and integration of Digital Health services have been examined extensively. Australia has also taken specific steps in this regard. Australian Digital Health Agency has laid down a set of standards for various aspects of Digital Health[29]. It covers communications, data security, health concept representation, health record interoperability, patient administration messaging, prescription messaging and telehealth. In China, it is regulated by Opinions of the National Health and Family Planning Commission. Telemedicine Services promote the use and development of telemedicine services and the essential points such as the need to ensure quality and efficiency and supervision and oversight in the performance of such services[30]. In South Africa, the General ethical guidelines for good practice in telemedicine, deals with the area of digital health.[31] In South Africa, digital health services are possible only when face to face services are difficult to be provided due geographical barrier.

IDEAL DOCTOR-PATIENT RELATIONSHIP

The doctor-patient relationship has encompassed philosophical, sociological and literary attention since the time of Hippocrates Oath. It demands respect, compassion and trust among each other. The medical practices exist from time immemorial. During Stone Age, the Doctor-patient relationship was very close that the patients were ready or willing to undergo trepanning as per the directions of the doctor[32]. There are shreds of evidence of medical ethics in the Hammurabi Code where it says that a surgeon is punishable for the death of his patient. It also talks about fees for life-saving operations[33]. In India, the concept of medical ethics is in function

[27] NCBI, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7690251/ (last visited May. 22, 2021).
[28] E-health in digital era, https://ec.europa.eu/health/ehealth/electronic_crossborder_healthservices_en, (last visited May. 22, 2021).
[29] ADHA, https://www.digitalhealth.gov.au/about-us, (last visited May. 22, 2021).
[30] Wang Z, *A review of Telemedicine in China*, JTT, 23-27.
[31] General Ethical Guidelines for Good Practice in Telehealth, https://www.hpcsa.co.za/Uploads/professional_practice/ethics/Booklet_10_Telehealth_Dec_2021_v2.pdf, (last visited May. 22, 2021).
[32] PM Ambika, *Doctor Patient Relationship*, BMJ, 1011-1013.
[33] Internet Scientific Publications, https://ispub.com/IJLHE/4/2/10352, (last visited May. 22, 2021).

from the time of Charaka Samhita[34]. At that time, the role of a physician is like a family member, and a good physician nurtures affection. The Hippocratic Oath of 600BC is regarded as an illustration of medical etiquette and professional attitude of generations of physicians in modern medicine for the last 2500 years[35]. After the Industrial Revolution, the medical profession and its ethical values began to take shape in their modern form. According to the different models of Doctor-Patient Relationship as proposed by 1956 Szass and Hollander, there are activity passivity, guidance cooperation, and Mutual participation models guaranteeing the elements mentioned above[36].

An ideal doctor-patient relationship is built on the fundamental principles of medical ethics. Philosopher Beauchamp and Childress formulated the fundamental principles of medical ethics in 1979[37]. They are autonomy, beneficence, non-maleficence, and justice.

Autonomy

The term "autonomy" originates from the Greek word "*eautos*" and "*nomos*". "Eautos" means "self, and "nomos" means to rule, governance or law. The term describes a person's capacity to express their free will or freedom for action in a particular society[38]. In medicine, the autonomy of the patient is necessary to proceed with the treatment. It is the right of competent adults to make an informed decision about their medical care. Based on this principle, the physician is required to seek the patient's informed consent before the treatment commences. It is the capacity to think, decide and act based on such thoughts and take decisions freely and independently. The physician acts as an educator and shall not lead to arbitrary actions. It is based on the right to self-determination and self-rule[39]. The patients have the right to choose the treatment or the medical professional. In *Schloendorff v Society of New York Hospital*[40], the judgement delivered by Justice Cardozo was based on the principle of autonomy. It was observed that; "*every adult*

[34] Hindu Scriptures and Medical Ethics, https://www.hinduscriptures.in/vedic-knowledge/vedic-medical-science/medical-ethics/medical-ethics-in-ancient-india (last visited May. 22, 2021).
[35] CCRAS, http://ccras.nic.in/sites/default/files/viewpdf/jimh/BIIHM_1995/150%20to%20169.pdf (last visited May. 22, 2021).
[36] Szas and Hollander, *The Doctor Patient Relationship and its historical context*, 522-528, https://www.upstate.edu/psych/pdf/szasz/doctor-patient-relation.pdf.
[37] BMJ, https://jme.bmj.com/content/28/5/332.2 (last visited May. 22, 2021).
[38] E Sakelleri, *Patients Autonomy and Informed Consent*, ICUS, 1-9, (2014).
[39] BMA.Org, https://www.bma.org.uk/advice-and-support/ethics/medical-students/ethics-toolkit-for-medical-students/autonomy-or-self-determination#:~:text=In%20medical%20practice%2C%20autonomy%20is,investigation%20or%20treatment%20takes%20place (last visited May. 22, 2021).
[40] Schloendorff v. Society of New York Hospital, 105 NE 92.

who is of sound mind has the right to determine what shall be done with his body. Thus, the concept of consent is covered by the principle of autonomy. It stipulates that the patients shall be informed of the degree of risk, including the mental and physical sufferings, to decide. It covers the concept of informed consent. Informed consent is the process in which a health care provider educates a patient about the risks, benefits, and alternatives of a given procedure or intervention[41]. The patient must be competent to make a voluntary decision about whether to undergo the procedure or intervention. Informed consent is both an ethical and legal obligation of medical practitioners and originates from the patient's right to direct what happens to their body.

Beneficence

The principle of beneficence simply means; "the medical procedure shall be conducted in a manner not prejudicial to the participant". Otherwise, the physician shall perform their duties beneficial to the patients[42]. It is based on the central theme of utilitarianism. Beneficence is the obligation to provide benefits and to balance benefits against risks. The physician shall only act in the best interests of the patients. Utilitarianism**,** a derivative of consequentialism, depends on the notion that it is the result of actions, laws and policies determine whether certain acts or omissions are right or wrong[43]. The primary aim is to ensure the greatest good for the greatest number. It is applied in medicine based on protecting the best interests of the patients. It is applied for resolving disputes between individuals and groups in society, based on measurement of outcome. The outcomes determine the morality of the intervention. The resuscitation of premature newborns of gestational age, treatment of burn patients, based on the availability of time and resources, is an example of a utilitarian approach in medical care[44].

Non-maleficence.

The principle of non-maleficence stands on the notion that do no harm. It is based on the principle of *primum non nocere*, which means "*do no harm*". The physician doesn't have an

[41] Pubmed, https://pubmed.ncbi.nlm.nih.gov/28613577/#:~:text=Informed%20consent%20is%20the%20process,undergo%20the%20procedure%20or%20intervention (last visited May. 22, 2021).
[42] WMA.com, https://www.wma.net/policies-post/wma-international-code-of-medical-ethics/ (last visited May. 22, 2021).
[43] Stanford Encyclopedia of Philosophy, https://plato.stanford.edu/entries/consequentialism/, (last visited May. 22, 2021).
[44] NCBI, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4778182/, (last visited May. 22, 2021).

obligation to benefit the patient but has a duty not to cause harm[45]. It states that the physician shall not do anything harmful to the patient, or shall not impose any unnecessary or unacceptable burden upon the patient

Non-maleficence is different from beneficence in two ways. According to the former, if the treatment results in more harm than good, then such practice shall be avoided; wherein the latter, any valid options could be taken to improve the patient's condition. In beneficence, the risk is taken, while in non-maleficence, it is avoided. Therefore, it means that the medical practitioner shall not intentionally create harm or injury to the patient, either through acts of commission or omission. Medical negligence thus falls under this principle, for the doctor has a duty to take sufficient care to ensure that he or she doesn't cause harm to them[46]. This principle affirms the need for medical competence. Medical mistakes may occur, but this principle enunciates a central assurance on physicians to protect their patients from harm.

Justice

The principle of justice aims to promote fair and equitable treatment of individuals. It is an inalienable and imprescriptible right inherent in every human being by their personality. The duty-based approach in deontology proposed by WD Ross obligates the duty of justice in a physician[47]. It also includes fair distribution of resources. The physicians shall respect their patients' rights and for morally acceptable laws. It is also seen that the human right to health is available to everyone irrespective of gender, race, caste, place of birth, religion, income.

Legal Theories Attributing to the doctor-patient relationship

In addition to the fundamental principles of medical ethics, some legal theories put forth the notion of ethics in medical practice from a more legal perspective. It begins with the Natural Law theory. According to Salmond[48], *jus naturale* or natural law or law of nature, means the principles of natural justice, justice as it is in itself, indeed and in truth. It is contrasted with those more or less imperfect and distorted images of it, which may be seen in civil and international law. Natural law theory argues for the inalienable and imprescriptible natural rights inherent in

[45] MN.State.Education, http://web.mnstate.edu/gracyk/courses/phil%20115/Four_Basic_principles.htm (last visited May. 22, 2021).
[46] Khan. H, *Ethics Govenrning Medical Negligence in Clinical Practices,* 5 JCRB 87 (2014).
[47] Stanford Encyclopedia, https://plato.stanford.edu/entries/william-david-ross/ (last visited May. 22, 2021).
[48] JOHN W SALMOND, JURISPRUDENCE OR THEORY OF LAW (1902).

every human being by virtue of his personality. The acknowledgement of natural law in medical ethics lays the substance for the right to health, ensuring the ethical approach of medical practice. It is found in International Human Rights documents, including UDHR, ICCPR, and ICESCR[49]. The right to health is a fundamental human right that reflects the elements of natural law inherent in it. Secondly, it is based on utilitarianism, a derivative of consequentialism. As aforementioned in the principle of beneficence, it is the consequences or results of actions, laws and policies that determine whether certain acts or omissions are right or wrong. The Deontological theory, which stands in contrast to utilitarianism, is the basis for medical ethics. It aims to provide quality treatment to patients and ensure that the medical profession has the conditions to serve the population's health better. As a part of the normative approach in ethics, Virtue theory focuses on virtues, otherwise the moral characters, in contrast to deontology and consequentialism. The theory asks what a good person would do in a real-life situation[50]. The Indian Medical Council (Professional Conduct, Etiquette, and Ethics) Regulations, 2002, says that a physician shall uphold the dignity and honour of his profession. The provisions of Chapter 1 of the Regulations can be read in the context of virtue theory. It says that a physician shall keep himself pure and be diligent in caring for the sick. He should be modest, sober, patient, prompt in discharging his duty without anxiety, conducting himself with propriety in his profession and in all the actions of the life. Similar provisions are found in Practitioners of Indian medicine (Standards of professional conduct, Etiquette and Code of Ethics) Regulations, 1982. In *State of Odisha* v *Orissa Trust of Technical Education and Ors*[51], the necessity of implementing policy regarding telemedicine practices within the State.

Considering the technological advancements and the outbreak of the COVID-19 pandemic, which led to increased access to digital health care services, the legal theories and the ethical principles could be of good use to overcome the challenges of the modern world.

LEGAL AND ETHICAL CHALLENGES TO DOCTOR-PATIENT RELATIONSHIP IN DIGITAL HEALTH

[49] World Medical Association, https://www.wma.net/what-we-do/human-rights/right-to-health/#:~:text=The%20Right%20to%20Health%3A%20A,in%20International%20Human%20Rights%20Law&text=The%20States%20Parties%20to%20the,2., (last visited May. 22, 2021).
[50] Kotzee Ben, *Virtue in Medical Practice,*29, HEC Forum, 1-19, (2016).
[51] State of Odisha v. Orissa Trust of Technical Education and Ors, MANU/SC/1185/2019.

There are specific challenges before the doctor-patient relationship based on the increasing usage of digital health services. The challenges to Doctor-Patient Relationship in digital health are privacy and confidentiality, the autonomy of the patient and informed consent, medical negligence, cross-state and cross-border tele-consultations, prescription and delivery of drugs, and issues with regard to mental health services.

Medical Negligence in digital health

Medical negligence generally means the commission or omission of an essential act in providing the medical services. The term negligence is defined by Black's Law Dictionary as, "*a conduct, whether of action or omission, which may be declared and treated as negligence without any argument or proof as to the particular surrounding circumstances, either because it is in violation of statute or valid Municipal ordinance or because it is so palpably opposed to the dictates of common prudence that it can be said without hesitation or doubt that no careful person would have been guilty of it.*"[52] The concept of 'negligence' has evolved through the law of torts. According to Salmond's subjective theory, negligence represents a '*state of mind*'. If a person has acted on his or her best ability, he or she cannot be held liable for negligence. As per the objective theory of Pullock,[53] negligence is the kind of conduct which a reasonable or prudent man having a reasonable degree of care and caution abstains from doing. The concept of negligence was first identified in the case of *Donoghue* v *Stevenson*[54]. The decision in this case laid down the foundation of the contemporary notions of law of negligence and duty of care. In this case it was observed that the manufacturer has a duty to take reasonable care and caution, and omission of such duty amount to negligence. The concept of medical negligence derives from the basic notions of negligence. A medical professional cannot guarantee a hundred percent positive result but has a duty to take reasonable care and caution while applying his skills. In India, medical negligence is dealt under Indian Penal Code. It also involves the issues of vicarious liability. Section 304A of IPC provides punishment for a person who commits a rash or negligent act which amounts to culpable homicide. Section 337 of IPC provides the punishment for a person commits a rash or negligent act due to which human life or personal safety of others gets threatened. Section 338 talks about the threat to life of another person due to the

[52] Medical Negligence Definition, Black's Law Dictionary (9th ed. 2009), available at Westlaw.
[53] Sir Frederick Pollock, Law of Torts (4th ed.), 1886.
[54] Donoghue v Stevenson, 1932 [UKHL] 100.

commission of a rash or negligent act. Indian Penal Code nor any other legislation directly acknowledges the concept of "medical negligence". The defenses to medical negligence can be availed on basis of section 80, 81 and 88 of IPC.

Though, there are no specific legislative provisions dealing with medical negligence, the concept of medical negligence has evolved to an impeccable form through various judicial decisions.

In *Dr. Laxman Balkrishna Joshi* v *Dr. Trimbark Baby Godbole*[55], and *A S Mittal* v *State of UP*[56], it was observed that when a doctor is consulted by a patient, the doctor owes to his patient certain duties including, duty of care deciding whether to undertake the case, duty of care in deciding what treatment shall be given, duty of care in the administration of such treatment. Violation or breach of the above-mentioned duties may result in negligence, enabling the patient to recover damages for the injuries sustained. The Registered Medical Practitioner shall take adequate measures, care, and caution to avoid medical negligence. In *A S Mittal* v *State of UP*[57], it was explained by the Court that, the concept of negligence has several manifestations including, active negligence, collateral negligence, comparative negligence, continued negligence, concurrent negligence, gross negligence, criminal negligence, hazardous negligence, active and passive negligence, negligence per se, and willful or reckless negligence.

The Bolam Test, formulated in the case *Bolam* v *Friern Hospital Management Committee*[58], is often applied to determine whether there is medical negligence or not. In this case it was established that such medical professional will not be in breach of their duty if they have acted in a manner which was in accordance with practices accepted as proper by a responsible body of other medical professionals with expertise in those particular areas. The decision in *State of Haryana* v *Santra*[59]approved the applicability of Bolam test in India. It was held that only the breach of certain duties owed by a doctor in his professional capacity will become negligence.

The decision in *Jacob Matthew* v *State of Punjab*[60], is a milestone in medical jurisprudence. In this case, the Supreme Court of India has identified the instances in which an act of a medical professional would amount to medical negligence. Such instances include, if they do not possess

[55] Dr. Laxman Balkrishna Joshi v. Dr. Trimbark Baby Godbole, AIR 1969 SC 128.
[56] A S Mittal v. State of UP, AIR 1989 SC 1570.
[57] *Id*.
[58] Bolam v. Friern Hospital Management Committee, [1957] 1 WLR 583.
[59] State of Haryana v. Santra, (2000) 5 SCC 182.
[60] Jacob Matthew v. State of Punjab, AIR 2005 SC 3180.

the requisite skills, and have not exercised such possessed skills with reasonable competence in the given case. The Court also pointed out that the standard to be applied whether the person has been negligent or not, would be that of an ordinary competent person exercising ordinary skill in that profession. A failure to use special or extraordinary precautions or existence of alternative methods is not a standard for judging the alleged negligence. Therefore, it was finally concluded that, to prosecute a medical professional for negligence it must be shown that the accused did something or failed to do something which in the given facts and circumstances no medical professional in his ordinary senses and prudence would have done or failed to do.

In *Borromeo* v *Family Care Hospital*[61], it was observed that in medical malpractice cases the following factors shall be established. Firstly, the standard of care, secondly, falling of defendant's conduct below the acceptable standards, and lastly, the defendant's failure to observe the industry standard causing injury to the patient.

In *White* v *Harris*[62], an action was instituted against a psychiatrist alleging deficiency in telehealth services provided to the plaintiff's child. The child consulted the psychiatrist using telehealth services, and court observed that, the concept of standard of care, binding on medical professionals also extend to telehealth services as well.

In *Deepa Sanjeev* v *State of Maharashtra*[63]**,** criminal negligence in telemedicine consultation was pointed out, and observed the need for legislation to deal with it. The issue in this case was the accused person has prescribed certain drugs without diagnosis through telephonic instructions, which caused the death of the patient.

In this regard the patients can also claim compensation under the Consumer Protection Act, as in *Indian Medical Association* v *VP Shantha*[64], the applicability of Consumer law was extended to include hospitals. It will be applicable in case of telemedicine as well. Currently the consumer protection (E-commerce) Rules, 2020 are applicable to cases of medical negligence in digital health services.

Issues regarding Privacy and Confidentiality

[61] Borromeo v. Family Care Hospital, G.R. No. 191018.
[62] White v. Harris, 36 A.3d 203 (Vt. 2011).
[63] Deepa Sanjeev v. State of Maharashtra, SLP (Cr.) No. 6243 of 2018.
[64] Indian Medical Association v. VP Shantha, (1995) 6 SCC 651.

The digital health services are faces privacy issues due to transmission of electronic medical records, which contains confidential and sensitive information about the patients and their identity[65]. Such information shall not be revealed to unauthorized persons. According to Black's Law Dictionary, privacy means "*right to be let alone"*.[66] Article 12 of UDHR and Article 17 of ICCPR recognizes human right to privacy. In India in *KS Puttuswamy* v *Union of India*[67], it was settled that right to privacy comes under the scope of Article 21, granting it the status of Fundamental right. The duty to maintain privacy of the patients were first came for discussion in *Mr.X* v *Hospital Z*[68]. In this case, the Court pointed out the physician's duty to keep confidentiality while examining the concept of right to privacy of patients.

In context of digital health, there are certain aspects of maintaining privacy of the patients. The doctor has to make sure that the information is disclosed only to authorized persons, and such person shall be granted access only after proper identification and authentication. It shall be conducted in a manner without affecting the integrity of patients and in adherence to the legal framework. Here the patient will have autonomy or right to determine the extent to which an information could be disclosed to another person. Any disclosure without the authorization of patient will be considered as violation of privacy. In USA it is done as per the guidelines under Health Insurance Portability and Accountability Act. In India, the Government of India has proposed the DISHA Bill (Digital Information Security in Healthcare Act) and the Digital Personal Data Protection Act, 2023 to deal with the matter of digital health. DISHA is the legislation that seeks to formally establish National electronic Health Authority of India or NeHA. It aims to facilitate the online exchange of patient information with a view to prevent duplication of work and streamline resources. The Digital Personal Data Protection Act demands sensitive personal data such as medical records to be processed only with the explicit consent of the data principal or to respond to a medical emergency involving a threat to the life or a severe threat to the health of the data principal or any other individual

Patients Autonomy and Informed Consent

[65] Mukhopadyaya A, Das,S , *Security and privacy challenges in telemedicine*, IIMJ, 19-23, (2014).
[66] Privacy Definition, Black's Law Dictionary (9th ed. 2009), available at Westlaw.
[67] KS Puttuswamy v. Union of India, WP (C) No. 494 of 2012.
[68] Mr.X v. Hospital Z, CA 4641 of 1998.

As already discussed, patient autonomy envisages that "every adult human being of sound mind has a right to determine what shall be done with his own body and he/she has the right and responsibility to make health care decisions[69]". The concept of informed consent forms part of patient autonomy[70]. The issue of informed consent of patient was first discussed in *Sidaway* v *Bethlem Royal Hospital Governors*[71]. In this case the plaintiff had not been informed of specific risks, due to which as she claims has sustained injuries. Her argument was that she was legally entitled to such a warning, despite the fact that she had not asked about that outcome. The case is therefore considered as a classic risk disclosure/informed consent scenario. Her claims were rejected. It was held that the doctors do not have a duty to give an elaborate explanation of remote side effects based on Bolam Test[72]. In dissenting judgments, Lord Scarman observed that the Bolam Test cannot be applied to the issue of informed consent, making the doctor liable to disclose inherent and material risks of proposed treatment. However, in the judgment the Court has identified the ethical principle of self-determination at some point[73]. Following the decision in *Sidaway*[74], the Court of Appeal heard two cases in which identical approaches to medical law and ethics were adopted[75]. In both cases the Court refused to recognize the ethical principle of autonomy. Later in *Smith* v *Tunbridge Wells*[76] and *Pearce* v *United Bristol Healthcare NHS Trust*[77] patients right to informed consent in context of medical ethics were recognized. Finally, in 2004 decision in *Chester* v *Afsar*[78], it was held that an adult shall be furnished with complete information with regard to their condition and treatment; and it is the duty of doctor to attain their consent in such manner. Such duty also includes to warn the patient against inherent risks. The decision in Chester is important as it reflected the interrelation between medical ethics and law[79]. In digital health practices it is of utmost necessity that the physician shall obtain the

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[69] *supra* note at 37.
[70] Wagner Richard, *Importance of Informed Consent,* e-medicine health, *https://www.emedicinehealth.com/informed_consent/article_em.htm*, (last visited May. 22, 2021).
[71] Sidaway v. Bethlem Royal Hospital Governors, [1985] AC 871.
[72] *Infra*
[73] Miola, Jose, *Risk Disclosure/ Informed Consent,* Medical Ethics and Medical Law: A Symbiotic Relationship. London: Hart Publishing, 55-86, (2007).
[74] Sidaway v. Bethlem Hospital [1985] AC 871.
[75] Blyth v. Bloomsbury Health Authority, [1993] 4 Med LR 151 and Gold v. Haringey Health Authority, [1992] QB 418.
[76] Smith v. Tunbridge Wells, (1994) 5 Med LR, 334.
[77] Pearce v. United Bristol Healthcare NHS Trust, 1999 ECC 167.
[78] Chester v. Afsar, [2004] UKHL 41.
[79] Miola, Jose, *supra* note at 57.

consent of the patients before providing services. Here an important piece of law is found in Section 24(2) of the Mental Health Act, 2017 while dealing with restriction on release of information in respect of mental illness states that the right to confidentiality of person with mental illness shall also apply to all information stored in electronic or digital format in real or virtual space.

Cross-State and Cross-Border Tele-Consultations

There seems to be some dichotomy with regard to the extent to which a license to practice medicine applies. It is a classic issue of jurisdiction. Whether a physician can practice outside the State that granted his or her license to practice. In *Malay Ganguly* v. *Medical Council of India*[80], SC considered the question of liability when a medical practitioner commits an offence while practicing in an area that is outside of the jurisdiction of the relevant State from which he or she received registration. The question was sent to the MCI for deliberation, and in the meeting of the ethics committee. The ethics committee observed as such there is no necessity of registration in more than one State Medical Council because any doctor who is registered with any State Medical Council is automatically borne on the strength of the Indian Medical Register and also by virtue of Section 27 of the MCI Act, a person who is borne in the Indian Medical Register can practice anywhere in India. The committee also laid down how complaints against a medical practitioner were to be dealt with when the medical practitioner was registered with more than one State. Unfortunately, the ambiguity regarding registration was not conclusively put to rest. However, the recently issued Telemedicine Practice Guidelines have clarified that a registered medical practitioner registered in the State Medical Register or the Indian Medical Register established under the MCI Act is entitled to practice telemedicine in all parts of the country. Therefore, it should be permissible for medical practitioners qualified to practice medicine under the MCI Act to provide teleconsultation services across the nation. It also involves the question of jurisdiction of courts where its complaints could be filed. Here, the debate is whether the provisions of IT Act is applicable or pure health provisions could be applied.

Prescription and Delivery of Drugs

[80] Malay Ganguly v. Medical Council of India, WP(C) 317 of 2000.

As earlier discussed, *Deepa Sanjeev* v *State of Maharashtra*[81], whether the physicians can prescribe drugs over digital services. Though this issue was not raised in the 2018 case but in Bombay HC's decision *Priyanka Singh* v *State of Maharashtra*[82], it was held that telemedicine guidelines allow of prescription of drugs. In *Martin F. D'Souza* v. *Mohd. Ishfaq*[83] , SC has observed that prescriptions should not ordinarily be given to a patient without actual examination. They have also observed that the tendency to give prescriptions over the telephone should be avoided, except in cases of emergency However, sometime later, the prescription of drugs over telemedicine has also gained legitimacy under the Telemedicine Practice Guidelines. Also, the home delivery of medication may face challenges from a pharmacy regulation perspective. The Pharmacy Practice Regulations, 2015 regulates the practice of pharmacy by registered pharmacists in India. It states that prescription drugs are to be handed over to the patient or his caretaker directly by a registered pharmacist. Thus, it becomes practically challenging in an online set-up to have pharmacists deliver medication directly to patients. Nonetheless, the Ministry of Health and Family Welfare due the exigencies of the COVID-19 pandemic, issued a notification[84] permitting the doorstep delivery of drugs directly to consumer. It is known as Doorstep Delivery Notification. The notification also prescribes additional record keeping requirements in the event prescription drugs are dispensed. It is unclear whether the Doorstep Delivery Notification will continue to remain in force once the COVID-19 pandemic has abated.

Mental Health Services via digital medium

The outbreak of COVID-19 pandemic has pointed out the importance of mental well-being which led to telehealth in mental health care. Most of the nations have relied on teleconsultations to maintain the mental well-being of their citizens. Clinicians have expressed concerns about its impact on rapport building, the therapeutic relationship, privacy and safety issues[85]. The reduced non-verbal communications (e.g. inflection, tone, gestures and mannerisms) can be a deterrent for some. Some therapists are also of the view that it is less effective than in-person therapy and

[81] Deepa Sanjeev v. State of Maharashtra, SLP (Cr.) No. 6243 of 2018.
[82] Priyanka Singh v. State of Maharashtra, WP 2712 of 2020 (Bom HC).
[83] Martin F. D'Souza v. Mohd. Ishfaq, Civil Appeal No. 3541 of 2002.
[84] Ministry of Health and Family Welfare (Department of Health and Family Welfare, (Notified on 26th March, 2020), available at: https://www.mohfw.gov.in/pdf/Doorstepdelivery26B.pdf.
[85] NCBI, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7387833/ (last visited May. 22, 2021).

lack experience or interest in technology-delivered interventions[86]. The mental health care Act as aforementioned in Section 24(2) provides for right to privacy, besides which there are no legal recognition given to the challenges in mental health services.

End of Life decision through digital medium

End-of-life decision making is the process that healthcare providers, patients, and patients' families go through when considering what treatments will or will not be used to treat a life-threatening illness. Several forms of this decision making are possible[87]. The pandemic and nationwide lockdown, it is extremely challenging to provide a quality end-of-life care (EOLC) to all patients[88].When a patient's prognosis for meaningful survival is poor, physicians' traditional goals to preserve life, benefit patients, and respect patient autonomy often conflict. Contemporary ethics, law, and public policy have prioritized patient self-determination in these situations, affirming patients' right to refuse medical treatments and to complete advance directives. Here the challenges before a physician are several. Patients often lack sufficient knowledge of health states, interventions, and prognoses to make informed treatment choices. The legal position is clear that a patient cannot demand a treatment that is not in their best interests and that doctors need not strive to preserve life at all costs. However, when there is doubt the presumption must be in favor of preserving life. Family members, felt to be in the best position to know patients' values and preferences, have been found to understand patients' treatment preferences little better than would be expected by chance. The disparity between contemporary ethical standards and actual clinical practice may be a marker of poor quality in end-of-life care. Ethical dilemmas approaching the end of life commonly revolve around decisions to withhold or withdraw interventions or treatment.

Besides, the above-mentioned issues, the end of life decision making via digital medium give rise to lack of psychosocial support to the relatives of the patients, it is difficult to make proper communications, and difficulty in continuous monitoring of the patients to reach a decision. Also, the declaration of consent also becomes complex when it is done through digital media.

[86] *Id.*

[87] Critical Care Nurse, https://aacnjournals.org/ccnonline/article-abstract/25/6/28/11685/End-of-Life-Decision-Making-in-Intensive-Care?redirectedFrom=fulltext#:~:text=What%20Is%20End%2Dof%2DLife,this%20decision%20making%20are%20possibl, (last visited May. 22, 2021).

[88] Adams C, *Goals of Care in a Pandemic: Our Experience and Recommendations*, PubMed 60(1) JPSM, 15-17, 2020. https://pubmed.ncbi.nlm.nih.gov/32240752/, (last visited May. 22, 2021).

RECOMMENDATIONS AND CONCLUSION

Ensuring good quality health care is the primary concern of the State. The digital health services allow healing *at a distance*. It has helped in improving access to health care even to remote areas, as it provides convenient access to medical care for patients. It has made the consultation mechanism easier and faster. It is also inexpensive. During COVID-19, it was proven to be a good mechanism to avoid exposure to contagious diseases. However, in order to ensure the quality of health care, the State has to overcome certain challenges including privacy, information and communication facilities, legal, ethical and professional standards, etc.

In India it is a new arrangement, and there is no comprehensive legislation for its regulation. Presently the regulatory framework in this area are Information Technology Act, 2000, Information Technology Rules, 2011, IT Intermediary Rules, Regulations under Telecom Policy, 1999, Drugs and Cosmetics Act, Drugs and Magical Remedies Act, Telemedicine Guidelines 2020, Consumer Protection Act, Intellectual property laws, Clinical Establishments Act, and Telecom Commercial Communication Customer preference regulations, 2018 and certain aspects of Competition Law. However, when it comes to Public Health Law aspects, only the legislation that directly deal with such matters will have an impact.

If the Government makes a specific legislation in the near future, it may consider certain factors including, specification of system requirements and platforms should adhere to, the rights and obligations of the patient, nature of consultation, inclusion of AYUSH into it, and regarding the prescription and delivery of drugs. Also, the State is required to ensure sufficient provisions to deal with the mental health consultations made through electronic media. And there should also be a mechanism to grievance redressal.