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# Ethical Dilemmas and Legal Questions Involved in Use of AI in Surgeries: Discrepancies in Indian Medical Jurisprudence

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## ABSTRACT

*The legislative framework governing medical practice in India has gone too far in favour of therapeutic immunity. The primary legislations like the Indian Medical Councils Act, 1956, the Charter of Patients' Rights, et al impose multifarious ethical obligations on medical practitioners but imbibe no corresponding strict penal provisions. This concern is more felt in the usage of artificial intelligence in medical procedures. The current legal infrastructure makes the apportionment of liability in artificial intelligence-assisted surgeries having unfortunate outcomes arduous. The Information Technology Act, 2000, and the Copyright Act, 1957 impose liability on the manufacturer or developer when an AI-driven technology is involved. However, given that AI has "intelligence" of its own and imitates human "thinking" and decision-making processes through the technology of Deep Machine Learning, the designer of algorithms cannot be solely held liable. This predicament is alarming, considering the dismaying statistics of the dystopia of robotic surgeries.*

*Further, the absence of informed consent or tiered consent might connote medical malpractice in the context of AI-assisted surgeries. The practitioner being the "expert" is ethically expected to render such treatment that is best for the patient, but the patient's right to self-determination also cannot be disregarded. The Bolam and Bolitho Tests impose liability on the medical practitioner in case of the application of unconventional treatment methods, but so far, precedents have ruled in favour of the doctors exploiting the grey area surrounding the informed nature of the consent.*

*It is also argued that AI-assisted surgeries can be classified as clinical trials under the law. This further raises questions concerning the fundamental right to health of the patient enshrined in Article 21 of the Constitution. Therefore, it is imperative to introduce appropriate legislation regulating the use of AI in surgical procedures to address the lapses and inadequacies in the current legal infrastructure.*

**Keywords:** *AI-assisted surgery, medical ethics, tiered consent, machine learning, right to health.*

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## I. INTRODUCTION

Law is inherently dynamic, constantly and consistently adapting to evolving times to stay potent and relevant. The application of artificial intelligence is at the forefront of the pharmaceutical industry, diagnostic services, robotic surgeries, and other areas of Medical Science.<sup>2</sup> However, the law regulating artificial intelligence is quite open to interpretation. It creates intriguing confusion regarding the proper procedure for licensing, imposition of liability in case of any unfortunate accident or wrong diagnosis, and the complications of deep learning involved in procedures involving something as precious as human life.<sup>3</sup>

Whether machines possess the intellect, skill, and acumen equivalent to that in homo sapiens is a long-debated topic. The questions of ethics and morality go hand-in-hand with the nuances of AI and are as such reflected in the slowly-evolving jurisprudence.

The Asilomar AI Principles proposed at the Conference on Beneficial AI, 2017,<sup>4</sup> for instance, lay down 23 guidelines for the research and development of AI. It is subdivided into three categories: research, ethics and values, and longer-term issues. The research principles highlight the culture of AI research. The ethics and values principles focus on safety standards, transparency regarding the causes of failure of the AI system, involvement of a competent human authority in crucial decision-making processes, alignment with the values of dignity, privacy, and equality, and the ulterior motive of upholding the right to health of the society at large. The longer-term goals focus on creating a limit on the extent to which AI may supersede humans, upholding the widely acclaimed ethical ideas of humanity.<sup>5</sup>

The Beijing Principles, 2019 also outlines the research and governance of artificial intelligence, acknowledging that AI holds the future of humanity.<sup>6</sup> However, the focus that AI is meant to serve humanity should never be diluted. It proposes a controlled, risk-free, and inclusive system of artificial intelligence upholding ethical standards. Further, postulates for informed consent of the stakeholders which ensures that they are aware and possess reasonable data in case of unfortunate or unforeseen circumstances associated with the use of artificial intelligence.

Ministry of Electronics and Information Technology (hereinafter referred to as “MeITY”) has

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<sup>2</sup> Homa Alemzadeh, Jaishankar Raman, Christopher Leveson, and Ravishankar K. Iyer, "Adverse Events in Robotic Surgery: A Retrospective Study of 14 Years of FDA Data," 2016 PLoS One 11(4): e0151470. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4821395/>.

<sup>3</sup> *Whitehouse v. Jordan*, 41 U.S. (16 Pet.) 177 (1842).

<sup>4</sup> Asilomar AI Principles, Future of Life Institute, accessed March 3, 2023, <https://futureoflife.org/ai-principles/>.

<sup>5</sup> WHATIS.COM, <https://www.techtarget.com/whatis/definition/Asilomar-AI-Principles> (last visited 20<sup>th</sup> June, 2023).

<sup>6</sup> Beijing AI Principles, The Beijing Academy of Artificial Intelligence, accessed March 3, 2023, <https://www.baaiglobal.org/ai-principles>.

formulated four committees for policymaking on artificial intelligence. Of these, the Report of the Committee on Cybersecurity, Safety, Legal, and Ethical Issues deserves mention in this research.<sup>7</sup> It raises concerns about privacy in relation to AI, as data and its open accessibility. In light of AI penetration in society's proliferated data flow, India stands as one of the leading data consumers worldwide: a reality that has computational, cultural, and psychological implications.<sup>8</sup>

The NITI Aayog has also laid down the National Strategy for Artificial Intelligence (#AIforAll).<sup>9</sup> Despite being a propagator of the AI revolution, India is faced with the multifarious challenges of affordability, access, effective implementation, and skilled expertise. The approach towards the healthcare sector, however, is restricted to easy access and affordability of quality healthcare in the Strategy. It is evident that the focus is primarily data-centric, and policies or regulations governing the usage of artificial intelligence in medical screening and treatments are not so much in the limelight.

## **(A) Review of Literature**

### **1. Application of Artificial Intelligence in Surgery**

A study by **Imperial College London**<sup>10</sup> highlights the recent influential applications of AI in surgeries. AI is soon to metamorphose surgical procedures through the instruments of navigation, imaging, and robotic intervention. The introduction of surgical robots is not too distant a practice. AI is already widely used for pre-operative planning, intraoperative guidance, and post-operative monitoring. Human-robot interactions in surgeries include cooperative control, touchless manipulation, and intention understanding and prediction among others. However, the future of AI in surgeries is not free from risks. Along with ethical dilemmas between the patient and the AI, surgical robotics is advancing towards autonomy.

### **2. Explaining the absence of surgical procedure regulation**

**Jonathan J Darrow**<sup>11</sup> explains how the lack of surgical procedure regulation even in developed countries like the USA leads to multifarious problems, including lack of generation

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<sup>7</sup> Constitution of Four Committees on Artificial Intelligence, Ministry of Electronics and Information Technology, Government of India, [https://www.meity.gov.in/writereaddata/files/constitution\\_of\\_four\\_committees\\_on\\_artificial\\_intelligence\\_0.pdf](https://www.meity.gov.in/writereaddata/files/constitution_of_four_committees_on_artificial_intelligence_0.pdf).

<sup>8</sup> MEITY, [https://www.meity.gov.in/writereaddata/files/Committees\\_D-Cyber-n-Legal-and-Ethical.pdf](https://www.meity.gov.in/writereaddata/files/Committees_D-Cyber-n-Legal-and-Ethical.pdf), accessed June 20, 2023.

<sup>9</sup> NITI AAYOG, <https://niti.gov.in/sites/default/files/2019-01/NationalStrategy-for-AI-Discussion-Paper.pdf>, accessed June 20, 2023.

<sup>10</sup> <https://www.imperial.ac.uk/news/200673/application-artificial-intelligence-ai-surgery/>

<sup>11</sup> Jonathan J. Darrow, *Explaining the absence of surgical procedure regulation*. CORNELL J LAW PUBLIC POLICY 189-206 2017.

of systematic evidence in cases of surgical failures. Further, different and differentiated techniques are used across various geographical locations. There is also a hue and cry that the surgical profession should be self-regulated with the view to uphold the patient's trust. The doctor does what is in the best interest of the patient and excessive regulations might dilute this doctor-patient fiduciary relationship. The author also highlights the existing dilemma between innovative as against established procedures. The author argues that only indirect regulations govern surgical procedures. He further submits that regulated innovative processes in surgeries might not be completely uncalled for.

### **3. Laws Applicable to Medical Practice and Hospitals In India**

**Singh**<sup>12</sup> puts forth the history of medical laws in India. He further highlights informed consent, necessity, and good faith to be the three elements essential in the medical profession, which, if proven, absolve the physician of all liability. The surgical procedures must be performed by a qualified medical practitioner only. He highlights the various laws governing the commissioning of hospitals, qualification, practice, and conduct of professionals, storage of drugs, environmental safety, patient management, etc.

### **4. Consent and medical treatment: The legal paradigm in India**

**Nandimath**<sup>13</sup> argues the importance of consent in medical treatments. The right to life and health enshrined under Article 21 of the Constitution of India extends to the legal right to autonomy and self-determination. The author discusses the validity of consent on legal grounds: including tortuous and criminal liability for involuntary or coerced consent. The suits may vary from trespass to negligence, and in extreme cases, assault or battery. However, no law explicitly mandates the requirement for written consent by the doctor. That is to say, the Medical Council of India guidelines apply only to surgeries and not other forms of treatment.

### **5. Artificial Intelligence and Machine Learning in Clinical Development: A Transnational Perspective**

A study in the Journal **Nature**<sup>14</sup> showcases how machine-learning algorithms would pave the way for the future of clinical developments. Therefore, the accountability of computational

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<sup>12</sup> Madhav Madhusudan Singh, Uma Shankar Garg, Pankaj Arora, *Laws Applicable to Medical Practice and Hospitals in India* INTERNATIONAL JOURNAL OF RESEARCH FOUNDATION OF HOSPITAL AND HEALTHCARE ADMINISTRATION 19-24 2013.

<sup>13</sup> Omprakash V. Nandimath, *Consent and medical treatment: The legal paradigm in India*. IJU : JOURNAL OF THE UROLOGICAL SOCIETY OF INDIA, 343-347 2009.

<sup>14</sup> Pratik Shah, Francis Kendall, Sean Khozin, Ryan Goosen, Jianying Hu, Jason Laramie, Michael Ringel, Nicholas Schork, *Artificial intelligence and machine learning in clinical development: a translational perspective*, NPJ DIGITAL MEDICINE, 1-5 2019.

evidence should be in place. The biotechnology industry must be well aware, and biomedical and clinical data sets should be made publicly available for analysis. The authors highlight clinical drug development as an emerging trend. Therefore, risk-aversion and reduction of adverse events should be made a priority. Clinical trials for AI-based drugs should be well monitored. It is high time that a well-informed future workforce be prepared in light of the widespread penetration of AI in the medical industry.

### **(B) Research Methodology**

The research methodology adopted in this paper is predominantly interpretive and analytical. Doctrinal sources such as books, journals, articles, and blogs related to the vast subject area have been referred to. Reference has also been made to various cases, international conventions, government websites, and policy documents. The provisions of several statutes have been interpreted, including the Indian Medical Council Act, 1956, the Constitution of India, 1950, the Information Technology Act, 2000, etc. Further, some statistics are provided through secondary sources.

### **(C) Research Question**

Whether proper legislations and guidelines are required for regulating the use of artificial intelligence in medical procedures in context of the advancing socio-legal framework in India?

### **(D) Hypothesis**

Medical Science has progressed. The application of artificial intelligence is the latest development which has penetrated the health sector. However, the law has not appropriately kept up with this development, and there exist loopholes in the existing legal framework governing artificial intelligence laws. Therefore, appropriate regulatory mechanisms are the needed ensure responsible usage of AI in medicine.

### **(E) Objectives of Research**

The research does not give an in-depth analysis of the intricate scientific nuances of artificial intelligence mechanisms but rather presents a broad overview of its functioning. It is focused on highlighting the gaps in law and suggesting recommendations that may address them.

### **(F) Scope of Research**

The scope of the present study is limited to—

- a. A basic understanding of the intricacies of artificial intelligence, machine learning, and deep learning and their application in robotic surgeries.

- b. The current policy framework proposed by MeitY and the NITI Aayog.
- c. An overview of the national and international ethical standards governing and regulating the usage of artificial intelligence.
- d. A broad analysis of the role of consent in medical procedures.
- e. A broad understanding of the concept of liability in cases of dysfunction of AI-based devices primarily in light of Intellectual Property laws and legal personhood of AI.
- f. An overview of licensing requirements for medical devices, including AI-based devices, and medical malpractices.
- g. A set of secondary data showcasing robotic surgery dystopia and risks.

### **(G)Relevance and expected contribution of the Study**

The study brings forth the everlasting dilemma of balancing therapeutic immunity and accountability. It highlights the concern for introducing proper laws governing the usage of artificial intelligence in medicine. It draws further attention to the importance of patient autonomy and tiered consent, especially for emerging AI technologies. It presents a future-oriented outlook that fosters legal and technological innovation in changing times.

## **II. ANALYSIS AND DISCUSSION**

### **(A)What Is Machine Learning AI?**

Artificial intelligence can be defined as a combination of advanced technologies that enable machines to imitate and emulate human capabilities of comprehension, thinking, and acting.<sup>15</sup> It uses data analysis programs, statistics, and neural network models. In simpler terms, artificial intelligence is the ability of a machine to make decisions through algorithms. It involves the processing of large amounts of “big data” through the process of machine learning. Big data in computation refers to huge data sets that, when analysed, particular reveal trends and patterns especially associated with human thinking. Therefore, machine learning depends on the process of “standardization”, where the machine endeavours to imitate human intelligence in decision-making. The propagator of the term “machine learning”, Arthur Samuel, defined it as “the ability to learn without being programmed”. The machine learns from the data provided to it, and forms predictions on that basis.<sup>16</sup>

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<sup>15</sup> Saikat Das et al., Machine Learning in Big Data Analytics, Special Issue - 2021 Int'l J. Eng'g Res. & Tech. (IJERT), Conf.Proc., ISSN: 2278-0181.

<sup>16</sup> Lidong Wang & Cheryl Ann Alexander, Machine Learning in Big Data, 1 Int'l J. Math. Eng'g & Mgmt. Sci. 52 (2016).

Deep Learning is also known as the neural network model.<sup>17</sup> It is akin to the brain structure consisting of numerous interconnected neurons transmitting signals. It functions through Artificial Neural Networks (ANNs). This specific type of machine learning “learns” through several layers, increasing the depth of learning, and hence the nomenclature. For example, Dr. Stephen Thaler’s creativity machine mimics the thalamocortical loop of the human brain. The amount of human intervention involved in systems of artificial intelligence depends on a case-to-case basis.

Artificial intelligence systems, machine learning, and deep learning are widely used for diagnosis and patient monitoring. With time, surgical robotics is gaining prominence as well. It finds applicability in various instruments like the electronic microscope. The processing of “big data” becomes schematic and the precision remains accurate and cognition error-free throughout the procedure with the use of AI. In that aspect, artificial intelligence is free from human limitations. According to a recent report by Forbes,<sup>18</sup> AI can serve as a gateway to automated care.

However, what happens when this AI-assisted decision-making proves erroneous? What happens if consequently, based on such a faulted decision, the surgeon perpetrates an error in the surgery, risking the life of the patient? These intriguing questions ameliorate the predicament of liability.

### **(B) The Jurisprudence of Accountability**

The liability of AI-based technologies is mostly analytically drawn from Intellectual Property laws. As early as 1867, the Court in **Blanchard v. Puttnam**<sup>19</sup> held that machines are no more mere spectators. In a legal fiction, they act as substitutes for skilled persons. A judicial doctrine is now evolving that computers can also be “inventors” because AI can perform innovative mental acts.<sup>20</sup>

However, AI is not bestowed with intellectual property rights, especially in India, as its legal personhood is not recognized. It is merely perceived as a tool or technology.<sup>21</sup> The application of an idea is given IPR protection, but the idea itself is not. Therefore, since the majority of

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<sup>17</sup> Serag, A., Ion-Margineanu, A., Qureshi, H., McMillan, R., Saint Martin, M.J., Diamond, J., O'Reilly, P. and Hamilton, P., 2019. Translational AI and deep learning in diagnostic pathology. *Frontiers in medicine*, 6, p.185.

<sup>18</sup> Joseph Nathan, *Intelligence can Benefit Robotic Surgery*, FORBES, ACCESSED JUNE 20, 2023 <https://www.forbes.com/sites/forbestechcouncil/2023/02/15/four-ways-artificial-intelligence-can-benefit-robotic-surgery/?sh=42d1826a859f>.

<sup>19</sup> *Blanchard v. Puttnam*, 3 F Cas 633, 635, (1867).

<sup>20</sup> Lizansha Birla, Raj Pipara, *Legal Identity of Artificial Intelligence*, JLAI 2022.

<sup>21</sup> Shubham Singh, Attribution of Legal Personhood to Artificially Intelligent Beings, 10 *Bharati Law Rev.* 194 (2017).



artificial intelligence instruments serve as generators of ideas, they are not granted intellectual property rights. Consequently, the judicial approach in this matter has remained human-centric. Therefore, the law would make either of the human stakeholders liable, or absolve everyone of any liability.

If AI were a tool without any automated functioning, liability would vest on the manufacturer for any defect or omission following the principle of strict liability, as elucidated in **Donoghue v. Stevenson**.<sup>22</sup> Such liability had been extended to repairers, assemblers, and fitters in **Andrews v. Hopkinson**.<sup>23</sup> In such cases, fault-based liability suits could be initiated arising out of malfunctioning or error on part of the AI mechanism. However, the intellectual property generated by machine learning is a product of the “intelligence” of the AI system, not the operator. Therefore, the principle of strict liability finds straight-jacket applicability here.

The developer of the software system can be held as a stakeholder.<sup>24</sup> The subject matter of machine learning would come under the purview of the Information Technology Act, 2000 as well because the Preamble to the Act brings storage of information in electronic form under its ambit.<sup>25</sup> The Act attributes electronic records to the originator and does not hold intermediaries responsible for any third-party data made available by him if he does not select the receiver of the transmission. The liability thus is again entrusted to the manufacturer or developer.<sup>26</sup>

It is interesting to note that in any surgical process, it is generally the medical practitioner who acts as the human intervention factor in AI-assisted procedures. However, he is treated as the end-user. Therefore, in none of such cases, the doctor is held responsible for any negligence or malpractice.

### III. UNNERVING STATISTICS

Notwithstanding the absence of an unequivocal liability, the statistics of unfortunate outcomes arising out of robotic surgeries are disturbing. Robots such as da Vinci and RAVEN II have been in use for over a decade now.<sup>27</sup> According to the MAUDE database, this practice has led to a type of surgical dystopia: 144 deaths, 1,391 injuries, and 8,061 device malfunctions over

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<sup>22</sup> *O'Brien v. Intuitive Surgical, Inc.*, 139 A.3d 304 (Pa. Super. Ct. 2016), *Mracek v. Bryn Mawr Hosp.*, 2017 WL 1379913 (Pa. Super. Ct. Apr. 18, 2017).

<sup>23</sup> *Andrews v. Hopkinson*, [1898] 2 QB 724.

<sup>24</sup> Shamnad Basheer, Debanshu Khettry, Shambo Nandy, and Sree Mitra, *Exhausting Copyrights and Promoting Access to Education: An Empirical Take*, 17 *J. Intell. Prop. Rts.* 335 (2012).

<sup>25</sup> Information Technology Act, 2000, Preamble, No. 21, Acts of Parliament, 2000 (India).

<sup>26</sup> Information Technology Act, 2000. § 11. No. 21, Acts of Parliament, 2000 (India).

<sup>27</sup> Homa Alemzadeh, Jaishankar Raman, Christopher Leveson, and Ravishankar K. Iyer, "Adverse Events in Robotic Surgery: A Retrospective Study of 14 Years of FDA Data," 2016 *PLoS One* 11(4): e0151470. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4821395/>.

13 years in the USA alone. For cardiothoracic and head and neck surgeries, which are more complex, the number of injuries and deaths was 232.9 per 1,00,000 cases with confidence intervals of 95%. These figures are not negligible. What is more alarming is that India to date has no such centralized database in relation to AI-assisted medical procedures which can serve as a statistical backdrop to introduce certain overdue changes in the system.

Apart from the irrevocable intra-operative malfunction of the devices,<sup>28</sup> there is the risk of nerve damage<sup>29</sup> including cerebral oedema. Further, there exist risks of the inaccurate gathering of raw data and inaccurate processing of data thereof.<sup>30</sup> Thus, various factors and associated risks must be carefully assessed before robotic surgical procedures. They include the demographic characteristics of the patient, like age, associated comorbidities, or the chances of experiencing intraoperative or post-operative neuropathy.<sup>31</sup>

#### (A) Whether AI-Driven Surgeries Can Connote to Medical Malpractices?

The Bolam Test is the standard used for determining medical malpractices, as acknowledged in the case of **Jacob Mathew v. State of Punjab**.<sup>32</sup> As laid down in **Bolam v. Friern Hospital Management Committee**,<sup>33</sup> the Bolam Test states that if the mode of treatment is “unconventional”, medical practitioners are to be held liable for negligence provided they have not maintained the standard of care and requisite skills. Furthermore, as laid down in **Bolitho v City and Hackney Health Authority**,<sup>34</sup> the Bolitho test ensured that the Court must be satisfied by the logic of the opinion presented by the experts to establish negligence. There can be no straightjacket formula to establish medical negligence. However, if the procedure adopted is not capable of withstanding logical analysis, it stands prima facie negligent.<sup>35</sup>

It must not be forgotten that artificial intelligence-based techniques are mostly in the developing stage. Even after proper approval and licensing, they are relatively new in the field

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<sup>28</sup> Dharam Kaushik, Robin High, Curtis J Clark, and Chad A LaGrange, "Malfunction of the Da Vinci robotic system during robot-assisted laparoscopic prostatectomy: an international survey," 2014 Journal of Endourology 28(11): 1327- 1332. <https://www.liebertpub.com/doi/10.1089/end.2014.0316>.

<sup>29</sup> D. A. Maerz, L. N. Beck, A. J. Sim, D. M. Gainsburg, Complications of robotic-assisted laparoscopic surgery distant from the surgical site, BJA: British Journal of Anaesthesia, Volume 118, Issue 4, April 2017, Pages 492–503, <https://doi.org/10.1093/bja/aex003>.

<sup>30</sup> Tomasz M. Miklaszewski, "Fixing Liability for the Failures of Intelligent Machines," 2017 Privacy and Law in Technology (PL (IT)) April: 86.

<sup>31</sup> Halpern DK, Liu HH, Howell RS, Halpern RA, Akerman M, Conlon J, Weidler C. Neural Monitoring for Robotic Abdominal Wall Reconstruction. J Clin Monit Comput. 2018;32(5):961-965. doi: 10.1007/s10877-017-0095-5.

<sup>32</sup> Jacob Mathew v. State of Punjab, (2005) 6 SCC 1.

<sup>33</sup> Bolam v Friern Hospital Management Committee [1957] 1 WLR 582.

<sup>34</sup> Bolitho v City and Hackney Health Authority, [1998] AC 232 (UK).

<sup>35</sup> Kathleen Liddell, Jeffrey M Skopek, Isabelle Le Gallez, Zoë Fritz, Differentiating Negligent Standards of Care in Diagnosis, Medical Law Review, Volume 30, Issue 1, Winter 2022, Pages 33–59, <https://doi.org/10.1093/medlaw/fwab046>.

of medical science.<sup>36</sup> In light of these principles, AI-based medical procedures may amount to medical negligence primarily in two circumstances (apart from *prima facie* breach of duty or negligence committed by the doctor): first, when the usage of the artificial intelligence device is not compliant with the Indian Medical Councils Act, and second, when there is an absence of informed consent breaching the code of medical ethics.

Under Medical Devices Amendment Rules, 2020, all medical devices in India came to be regarded as “drugs” and thereby came under the purview of the Drugs and Cosmetics Rules, 1945. The amendment was brought by the Central Government in light of the powers granted under the Drugs and Cosmetics Act, 1940. Such devices have to be approved by the Central Licensing Approval Authority (CLAA) of India. The Central Drug Standard Control Organization (CDSCO) is also vested with the responsibility of licensing imports.<sup>37</sup> In such cases, the required application has to be submitted and registration is done. India even acknowledges the approval of medical devices in the European Union, Canada, Japan, and Australia. In the absence of proper licensing, the usage of novel technologies can be done by virtue of clinical trials, which require further approval from the CDSCO.<sup>38</sup>

The Geneva Declaration and the Helsinki Declaration have at length discussed informed consent. The World Medical Association, Declaration of Geneva, 2017 reaffirmed the Hippocratic Oath, declaring the physician’s commitment towards the humanitarian goals of medical science.<sup>39</sup> It advocates for patient autonomy and dignity. The Helsinki Declaration was developed by the World Medical Association.<sup>40</sup> It highlights that the health and safety of the patient should be the primary concern even for medical procedures that are in the stage of research. Ethical and legal standards must always be abided by. It is pertinent that the patient is well informed about the specifics of the procedure through tiered consent, including the level of risks associated.

The mandate of informed consent has also been laid down in the Charter of Patients’ Rights<sup>41</sup> prepared by the National Human Rights Commission and released by the Ministry of Health and Family Welfare. It enlists all the rights available to the patient. It is binding on all private

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<sup>36</sup> 35. Serag, A., Ion-Margineanu, A., Qureshi, H., McMillan, R., Saint Martin, M.J., Diamond, J., O’Reilly, P. and Hamilton, P., 2019. *Translational AI and deep learning in diagnostic pathology*. *Frontiers in medicine*, 6, p.185.

<sup>37</sup> TUV SUD, <https://www.tuvsud.com/en-in/industries/healthcare-and-medical-devices/medical-devices-and-ivd/medical-device-market-approval-and-certification/regulation-of-medical-devices-in-india>, accessed June 20, 2023.

<sup>38</sup> CDSCO, <https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/clinical-trials/>, accessed June 20, 2023.

<sup>39</sup> World Medical Association, Declaration of Geneva, amended by the 68th WMA General Assembly, Chicago, United States, October 2017, <https://www.wma.net/what-we-do/medical-ethics/declaration-of-geneva/>.

<sup>40</sup> Helsinki Declaration, as amended, WMA General Assembly, Fortaleza, Brazil, Oct. 2013.

<sup>41</sup> Ministry of Health and Family Welfare, Government of India. (2018). Patient's Charter. Retrieved from <https://main.mohfw.gov.in/sites/default/files/PatientCharterforcomments.pdf> 12.

and public hospitals where the Clinical Establishments Act, 2010 is applicable.<sup>42</sup> The Charter has also been approved and modified by the National Council for Clinical Establishments. The right to adequate information regarding the expected results of treatment and possible complications, the right to informed consent prior to surgery, the right to choose alternative treatment if options are available, the right to patient education, the right to non-discrimination, and the right to protection of patients involved in clinical trials, etc. are some of them which are in line with the international norm of patient-awareness and autonomy.

Even the hospital can be held liable for such breaches on grounds of administrative negligence under the principle of vicarious liability. The patient parties may claim compensation in any case of breach of the standard of care on grounds of deficiency of services under the Consumer Protection Act.<sup>43</sup> The principle was first established in **Jacob Mathew v. State of Punjab**<sup>44</sup> and then reiterated by the Hon'ble Court in several other instances.<sup>45</sup>

#### IV. RIGHT TO HEALTH AND THE CODE OF ETHICS

*“It is health that is real wealth and not pieces of Gold and Silver”—Mahatma Gandhi*

The right to health is primary and primordial. The 1946 Constitution of the World Health Organization<sup>46</sup>. Such a right can be derived from Article 21 of the Indian Constitution<sup>47</sup> which guarantees the right to life and personal liberty. Such interpretation has been observed in manifold judicial interpretations.<sup>48</sup> Justice Krishna Iyer rightly characterized the right to life as the procedural Magna Carta protecting rights and liberty.<sup>49</sup> Further, the goal of social justice as enshrined in the Preamble would have under its purview access to healthcare.<sup>50</sup> Equality of status and opportunity requires equality in access, availability, and quality of treatment.<sup>51</sup> The Fifth Amendment to the American Constitution also has a provision similar to Article 21 of the Indian Constitution.<sup>52</sup> Article 21 casts an obligation on the State to preserve life. Every doctor

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<sup>42</sup> Press Information Bureau, National Council for Clinical Establishments to Streamline Implementation of Clinical Establishments Act, press release, Ministry of Health and Family Welfare, Government of India, Aug. 5, 2021, <https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1797699>.

<sup>43</sup> Spring Meadows Hospital v. Harjol Ahluwalia, (1998) 4 SCC 39, Indian Medical Association v. VP Shantha, (1996) 6 SCC 651.

<sup>44</sup> Jacob Mathew v. State of Punjab, (2005) 6 SCC 1.

<sup>45</sup> Nizam's Institute of Medical Sciences v. Prasanth S. Dhananka, (2009) 6 SCC 1, Spring Meadows Hospital v. Harjol Ahluwalia, (1998) 4 SCC 39; Shoda Devi v. DDU/Ripon Hospital Shimla, (2019) 5 SCC 630.

<sup>46</sup> World Health Organization. Constitution of the World Health Organization. Basic Documents, 49th ed. World Health Organization, 2014, pp. 1–20.

<sup>47</sup> India Const. art. 21.

<sup>48</sup> Parmanand Katara v. Union of India, (1989) 4 SCC 286., Olga Tellis v. Bombay Municipal Corporation, (1985) 3 SCC 545.

<sup>49</sup> Francis Coralie Mullin vs The Administrator (1981) 1 SCC 608.

<sup>50</sup> India Const. art. 38.

<sup>51</sup> India Const. art. 14.

<sup>52</sup> H.M. Seervai – Constitutional Law of India. Vol. 1, 294 (3rd ed., 1983).

whether at a government hospital or otherwise<sup>53</sup> has the professional obligation to extend his services with due expertise for protecting life. The obligation being total, absolute, and paramount, laws of procedure whether in statutes or otherwise which would interfere with the discharge of this obligation cannot be sustained and must, therefore, give way.<sup>54</sup>

The noble causes of the medical profession are manifested in the Hippocratic Oath, which every doctor undertakes.<sup>55</sup> The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 act as the moral compass for the medical practitioner. They are made binding by the Indian Medical Council Act, 1956.<sup>56</sup> The practitioner is obligated to render service to humanity,<sup>57</sup> respond to the calls of the sick and the injured,<sup>58</sup> assure the highest quality of patient care,<sup>59</sup> and devote the best of his skill and attention towards those entrusted in his care.<sup>60</sup> Therefore, ethically as well as legally, the physician is bound to do what is in the best interests of the patient. Whether the usage of artificial intelligence improves the quality of treatment remains a question to be decided on a case-to-case basis. It is evident that AI does ease the process and ensures accuracy, but the high levels of risks involved cannot be overlooked.

## V. CONCLUSION

It is high time to ponder on the pressing multitude of questions and dilemmas put forth in the study. The branches of artificial intelligence-related law in India are in contradistinction to one another. While clarity is needed with regard to the existing legislations, there is an urgent need for incorporating comprehensive regulations as well, in order to fill in an important void in the socio-legal fabric. The research hypothesis is therefore proved to be correct.

The right to health is paramount and supreme. It is in consonance with the ethos enshrined in the Constitution of India which is the supreme law of the land. The physicians should strive in their endeavour to ensure this right of the populace at large within a comprehensive ethical and legal infrastructure. The question still remains whether AI should be granted personhood and made accountable for underperformance. This issue needs to be assessed in the context of the

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<sup>53</sup> *Ramana Dayaram Shetty v. The International Airport Authority of India* AIR 1979 SC 1628.

<sup>54</sup> India Const. art. 21.

<sup>55</sup> Hippocratic Oath, in *THE HIPPOCRATIC OATH: TEXT, TRANSLATION, AND INTERPRETATION 1* (Ludwig Edelstein ed., 1943).

<sup>56</sup> The Indian Medical Council Act, 1956, No. 102, Acts of Parliament, 1956 (India).

<sup>57</sup> Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, Notification No. MCI-211(2)/2002(Ethics)/13149, Gazette of India, Extraordinary, Part III, Section 4 (Mar. 6, 2002), reg. 1.2.1.

<sup>58</sup> Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, Notification No. MCI-211(2)/2002(Ethics)/13149, Gazette of India, Extraordinary, Part III, Section 4 (Mar. 6, 2002), reg. 2.1.1

<sup>59</sup> Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, Notification No. MCI-211(2)/2002(Ethics)/13149, Gazette of India, Extraordinary, Part III, Section 4 (Mar. 6, 2002), reg. 1.6.

<sup>60</sup> Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, Notification No. MCI-211(2)/2002(Ethics)/13149, Gazette of India, Extraordinary, Part III, Section 4 (Mar. 6, 2002), reg. 2.3.

huge advancement of machine learning and the fact that AI engages in decision-making autonomously. If the impugned notion is adopted, the pendulum would swing further in favour of therapeutic immunity. Therefore, evidence-based analysis of the subject matter is very essential before any legislative reform.

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