

HEALTHCARE CHALLENGES: ARTIFICIAL INTELLIGENCE PROMISES QUANTUM LEAP

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ABSTRACT

Since the dawn of history, humans have constantly been working towards developing ways to perform their daily tasks quickly and with ease. One such development, in the field of computer science, is Artificial Intelligence (AI). AI emphasizes on the development of intelligent machines that think and work like humans. This influx of new technologies in the information era has hit various industries, healthcare industry being one of the biggest beneficiaries. Medical literature extensively discusses the advantages of AI. Especially, as the profession requires greatest accuracy.

Before deployment, AI systems are trained via data generated from various clinical activities such as screening, diagnosis, treatments and so on, so that they can learn and process the information and then later apply the same. These systems are also equipped with self-correcting abilities so that they can improve their accuracy based on feedback received. They are increasingly being used to detect diseases, such as cancer, neurological and cardiovascular diseases, more accurately and in their early stages.

Furthermore, one can avail of certain medical services such as virtual nurses, wearable health trackers and consumer health applications within the comfort of their homes without the need of any healthcare professional. Consumer becomes in-charge of his own health and well-being. This rise of Internet of Medical Things (IoMT) gives rise to speculations that AI might eventually replace human physicians.

The intent of this paper is to survey and analyse the present status and future of AI in the healthcare industry, their regulations, and possible legal challenges.

I. INTRODUCTION

"I think AI is coming about and replacing routine jobs is pushing us to do what we should be doing anyway: the creation of more humanistic service jobs."
- Dr. Kai-Fu Lee | Chairman and CEO of Sinovation Ventures

Our ubiquitous friend, Artificial Intelligence, has played a crucial role in revolutionising healthcare. Artificial intelligence (AI) can be defined as *"the ability of a digital computer or computer-controlled robot to perform tasks commonly associated with intelligent beings"*.¹ The intent of AI is to assist and sometimes even replace human beings for the purpose of effectively

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¹ *Artificial Intelligence*, Britannica, available at <https://www.britannica.com/technology/artificial-intelligence>, last seen on 06/12/2019.

performing simple as well as complex tasks. Human beings codify and develop the machines and the machines perform all the medical tasks. Unlike an average surgeon, these AI systems are capable of simultaneously observing and processing almost limitless number of medical inputs.²

Just like the inception of the internet disrupted the modern culture, AI in 2020 has the potential to change our lives completely. According to Forbes, the healthcare AI is projected to be an almost \$200 billion dollar industry by 2025.³ It is exciting for both the investors, who are seeing the sector as a lucrative option for investing, as well as consumers, who are more than eager to get their hands on the AI technology and the newest healthcare applications. The present AI trends have a patient-centred approach as they address the issues of rising medical costs and limited medical resources. The changing medical environment places patient-centric care back to the front seat. The emergence of data-driven medicine, democratization of access to Electronic Health Records (“HER”) and emergence of smartphone applications for ensuring health at home are changing the dynamics of healthcare.⁴

While the AI is growing at a rapid pace worldwide, the adoption of new technologies in India is slow, but significant. The public is super keen to participate in the healthcare cycle and Artificial Intelligence is striving to take this trend forward.

II. HEALTHCARE INDUSTRY IN INDIA: THE ABYSMAL SITUATION

For India, a country with the second highest population in the world and having demographic dividend in its favour, it is needless to say that promotion of healthcare and well-being is the need of the hour. Presently, the state of our healthcare system is abysmal. The ratio of doctors to patients is very low. We are facing an acute shortage of doctors and nurses in hospitals. The World Health Organisation recommends a ratio of 1:1,000, whereas in India, 1:1,700 is the prevailing ratio and there is only one government doctor for every 10,189 people.⁵ The number of hospitals, clinics and public dispensaries is highly disproportional to our

² V.H. Buch, *Artificial intelligence in medicine: current trends and future possibilities*, 68(668) British Journal of General Practise, 143–144 (2018), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5819974/> last seen on 29/01/2020.

³ T. Mills, *The top AI Healthcare trends of 2019*, Forbes (28/06/2019), available at <https://www.forbes.com/sites/forbestechcouncil/2019/06/28/the-top-ai-healthcare-trends-of-2019/>, last seen on 08/12/2019.

⁴Tbid.

⁵ PTI, *India facing shortage of 6,00,000 doctors, 2 million nurses: Study*, The Economic Times (14/04/2019), available at <https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/india-facing-shortage-of-600000-doctors-2-million-nurses-study/articleshow/68875822.cms?from=mdr>, last seen on 08/12/2019.

ever-growing population. Most of the hospitals under the centre's flagship scheme are not even accredited.⁶ Another cause of downfall of our healthcare system is the lack of specialist doctors such as cardiologists, pulmonologists, neurologists and others.⁷ An ordinary MBBS doctor is not equipped to deal with diseases that are amongst the leading cause of deaths in India, such as brain stroke, chronic lung disease, heart disease, neo-natal pre-term birth and certain accidents.

Another pitfall, and probably the greatest one, is numerous barriers to accessing healthcare facilities, especially in the rural areas where there is shortage of medical personnel and problems of poor connectivity. There also exists a certain level of unwillingness of doctors to serve in rural areas. This creates social inequality in the healthcare arena where the rural citizens remain under-served while the health facilities are being well deployed in rich urban areas. This neglect of the rural population drives them to rely only on the traditional and cultural methods of treatment of diseases.

Furthermore, the private sector is the dominant player in the healthcare industry. The problem that lies herewith is that there is a lack of regulation in the private sector. The cost of treatment varies from one hospital to another and there is a huge difference in the quality of service. A common man cannot afford to avail of the expensive health services provided in the clinics and hospitals without burning a hole in his pocket. The alternative i.e. public hospitals may be slightly more cost effective but are generally overcrowded and have long waiting time for specialized treatment. They are never a first choice, unless one can't afford private treatment.

Finally, lack of awareness can be seen as the root cause of the problem. People do not go for regular check-ups and awareness about right to healthcare is also missing in our country. The majority of patients visit hospitals only when disease reaches an advanced stage. At this stage, the cost of treatment is high and chances of recovery become low. Consequently, "*Prevention is better than cure*" remains just an idea that does not hold weight in the Indian Healthcare scenario.

III. ARTIFICIAL INTELLIGENCE: TOOL TO ADDRESS THESE CHALLENGES

⁶ V. Mani, *Two-thirds of hospitals empanelled under Ayushman Bharat not accredited*, Business Standard (27/11/18), available at https://www.business-standard.com/article/economy-policy/modicare-covers-basics-but-complex-healthcare-mostly-outside-ambit-118112601145_1.html, last seen on 08/02/20.

⁷ K. Watts, *India's shortage of specialist doctors is still staggering*, Health Issues India (02/07/19) available at <https://www.healthissuesindia.com/2019/07/02/indias-shortage-of-specialist-doctors-is-still-staggering/>, last seen on 08/02/20.

Artificial Intelligence in healthcare can potentially be used for the purpose of early detection of diseases, diagnosis, prognosis and treatment.⁸ It can also be used for the purpose of research and training. AI can be deployed, post-treatment, for the purpose of ensuring follow-up care and well-being of the patient. The basic intent is to make the computers more useful to be able to solve problematic healthcare challenges via interpreting data. AI is used for managing, compiling and analysing data such as medical records and the patient's medical history. This is the most widely used application of AI.⁹ Since, the AI systems are used for analysis of data, the reports from a patient's file can be used along with external research to come out with a customized treatment design for the concerned individual.

AI certainly excels at performing well-defined tasks.¹⁰ The help of AI can be taken for the performance of repetitive jobs such as analysing tests, X-rays and CT scans. These are certain mundane tasks that can not only be performed faster but also more accurately by AI and robots. Especially in the disciplines of cardiology and radiology, where the amount of data to be analysed is enormous and time consuming, AI can prove to be very beneficial. Drug creation is another facet of AI. Developing pharmaceuticals via clinical trials takes years and can cost millions, therefore, various companies as well as start-ups are exploiting AI to create treatment drugs. For instance, a London based company founded in 2013, BenevolentAI, that describes its mission as “*accelerating the journey from data to medicine*”, recently raised 115 million dollars from investors to increase its value to more than \$2 billion in 2019.¹¹ This company is well established in the field of drug R&D and has collaborated with Novartis, a Swiss multinational pharmaceutical company to find potential new uses for oncology drugs. AI can be used to store data of drugs that have been proven to be toxic and withdrawn from the market post approval. In the last few decades, approximately 450 medicines world over have been taken down due to the adverse reactions and side effects caused by them,

⁸ S. Reddy, S. Allan, S. Coghlan & P. Cooper, *A governance model for the application of AI in health care*, 0(0) Journal of the American Medical Informatics Association (2019) available at https://www.academia.edu/40839463/A_governance_model_for_the_application_of_AI_in_health_care, last seen on 19/12/19.

⁹ *10 Common Applications of Artificial Intelligence in Health Care*, Novatio, available at <https://novatiosolutions.com/10-common-applications-artificial-intelligence-healthcare>, last seen on 25/02/2020.

¹⁰ *Supra* 2.

¹¹ R. Staines, *Benevolent AI and Novartis sign AI Research and Development deal*, Pharmaphorum (06/09/2019), available at <https://pharmaphorum.com/news/benevolent-ai-and-novartis-sign-rd-deal/>, last seen on 14/12/2019.

such as liver toxicity.¹² Companies like Cloud Pharmaceuticals make use of such data and train the machine learning algorithm to identify all the new molecules that come into being as toxic or not.¹³

Artificial Intelligence does not limit itself to the confines of hospitals and clinics where the technology is used only by health experts and practitioners. Certain AI applications are designed in such a way as to make patients and consumers the best in-charge of their own health. The best example is a health monitoring device such as wearable health trackers. With the infiltration of FitBit and Apple watches used for tracking activity levels and heart-rate and other healthcare applications used for calorie counting etc., there is a growing health consciousness amongst people all over the globe. There have been instances whereby these trackers have acted as nothing less than a miracle. A 73-year-old retired woman from Connecticut received FitBit as a gift. Upon using the tracker, she discovered that her resting heart rate was continuously increasing and therefore decided to consult the doctor, only to find out that there were two large blood clots in her lungs.¹⁴ The FitBit was a life-saver in this case as the condition could have proven to be fatal if it were left unattended.

Due to the rampant growth of devices such as tablets and smartphones, other common usage of AI includes applications for digital consultation. These applications are generally based on personal medical history and common medical knowledge. The UK based application, Babylon, provides the patients a platform to report their symptoms, then the system gives them recommendations on the basis of their medical history.¹⁵ They are like a personalised Google window for illnesses. SteadyMD, Sherpaa and DoctorOnDemand are some of the applications that provide for online doctor services by charging a minimum subscription fee.¹⁶ American Well application provides for virtual waiting rooms after one chooses a doctor, and after sometime, the patient gets connected to the doctor via video call. The patient also has the option to avail the service where the doctor sends the prescriptions electronically to

¹² B. Nogrady, *Artificial Intelligence shakes up drug discovery*, The Scientist (01/05/2019), available at <https://www.the-scientist.com/bio-business/artificial-intelligence-shakes-up-drug-discovery-65787>, last seen on 11/12/2019.

¹³Ibid.

¹⁴ N. Hinde, *73-Year-Old's Fitbit saved her life by alerting doctors to Lung Blood Clots*, Huffington Post (06/04/2017), available at https://www.huffingtonpost.co.uk/entry/patricia-lauder-fitbit-saved-her-life-by-alerting-doctors-to-blood-clots_uk_58e622f4e4b0917d347760d3, last seen on 11/12/2019.

¹⁵ Supra 9.

¹⁶ Online Medical Care, *10 Best Online Doctor & Medical Services for 2020*, available at <https://onlinemedicalcare.org/best-online-doctor-medical-services/>, last seen on 13/12/2019.

the selected pharmacy.¹⁷ It is highly advantageous as it saves a trip to the doctor for minor illnesses thereby saving time and travel expenses for other urgent needs. There are also virtual nurses to help in monitoring the patient's condition and follow up with treatment, in between doctor visits. However, these Digi-consultations cannot replace a primary care physician and order laboratory tests, therefore, are not deemed suitable for diseases and illnesses other than minor ones.

IV. AI AND THE INDIAN HEALTHCARE INDUSTRY

Government of India's Niti Aayog, came out with a discussion paper¹⁸ that places healthcare amongst one of the focus areas for AI intervention. As compared to banking, financial, automotive and other sectors, the healthcare sector is lagging behind in the adoption and exploitation of AI techniques. Despite the fact that the statistics are not in its favour, the growth of AI in healthcare is expected to be substantial in the coming years. As regards diagnostic part of treatment, young start-ups have begun to play a very critical role in assisting doctors with early-stage diagnosis. They are doing this by creating their own diagnostic tools by way of machine learning and predictive analysis. Their endeavour is to improve upon the speed and accuracy of the diagnosis. One such start-up named 'mFine' is indeed a fine example of this trend. This Bengaluru based start-up has gone on to give 85% of correct diagnosis for about 1200 diseases stored in its data base.¹⁹

India's IT service provider Tata Consultancy Services (TCS), has set up a research centre in collaboration with Tata Medical Centre to develop technology for clinical trials, risk adapted treatment, predictive outcomes and biomarkers.²⁰ Companies such as Microsoft have also partnered with SRL diagnostics to source one million biopsy samples from those patients who have been diagnosed by doctors, so as to train their AI systems to detect cancer.²¹ Microsoft has also entered into collaboration with Apollo hospitals to build a technology system that can detect heart irregularities in patients, to come out with a proper health treatment.²²

¹⁷ Ibid.

¹⁸ Niti Aayog, Government of India, *National Strategy for Artificial Intelligence*, available at https://niti.gov.in/writereaddata/files/document_publication/NationalStrategy-for-AI-Discussion-Paper.pdf, last seen 12/12/2019.

¹⁹ K. Chadha, *Incorporating Artificial Intelligence in Indian Healthcare Sector*, Inc42 (09/10/2019), available at <https://inc42.com/resources/incorporating-artificial-intelligence-in-indian-healthcare-sector/>, last seen on 21/12/2019.

²⁰ P. Sangani, *Let AI do the Health Check*, The Economic Times (02/08/2019), available at <https://economictimes.indiatimes.com/small-biz/startups/newsbuzz/let-ai-do-the-health-check/articleshow/70492061.cms?from=mdr>, last seen on 17/12/2019.

²¹ Ibid.

²² Ibid.

Companies in India are largely focusing their energies on end-stage cancer treatments. One of the major reasons for that is the enormity of the problem as the incidence to mortality rate is the highest for cancer. India sees an incidence of more than 1 million new cases of cancer every year.²³ A good quality pathology service is required, which unfortunately is not present in India. If detected on time, a large number of deaths caused by cancer could have been prevented. Another reason is the high cost of treatment. Let alone a poor person, even a middle-class man can't afford the expensive end stage treatment. Other problems include low awareness amongst the citizens and the screening efforts being very poor. There is a dire need to have cost effective and less invasive screening solutions and the tech companies are continuously working towards that. These companies see a huge potential in cancer diagnosis and prediction and are trying their level best to come up with innovative solutions.

Various Indian digital healthcare start-ups have stepped into the scene to bridge the gap between health service providers and consumers. Practo, a Bengaluru based start-up is cited as one of the fastest growing healthcare platforms having a funding of \$124 million.²⁴ Founded a decade back, it offers a platform for doctors to advertise themselves and highlight their area of practices, for the consumers to avail their services and even opt for online consultations. It has also taken various innovative steps such as introducing a 24x7 free consultation with qualified doctors for pollution-stricken Delhi post Diwali, 2019.²⁵ Other similar applications operating in the India include Portea Medical, Lybrate and DocEngage.²⁶ Whilst these applications offer doctor services, there are applications such as HealthifyMe which help in diet control by offering features such as calorie counting, activity tracker, weight loss/gain progress charts and online consultations with dieticians.

V. LEGAL AND OTHER CHALLENGES FACED BY AI IN HEALTHCARE SECTOR

1. Issue of Data Privacy – Insufficiency of existing laws

²³ Supra 18, at 28.

²⁴ K. Garewal, *10 Indian Digital Health Startups to Watch*, HIT Consultant, available at <https://hitconsultant.net/2015/10/29/1019-10-indian-digital-health-startups-to-watch/#.XrJRgqhKg2w>, last seen on 15/02/2020.

²⁵ *Practo introduces 24*7 free consultation with qualified doctors for pollution-stricken Delhi*, The Practo Blog, available at <https://blog.practo.com/free-consult-delhi-pollution/>, last seen on 12/12/2019.

²⁶ *Top 10 Doctor-Patient platforms in India | Most successful digital health business model in India*, Dr. Hempel Digital Health Network, available at <https://www.dr-hempel-network.com/digital-health-startups/doctor-patient-platforms-in-india-success/>, last seen on 13/01/2020.

The Ministry of Health and Family Welfare has taken steps towards standardising Electronic Health Records (EHR). The EHR Standards, 2016²⁷ are an attempt to regulate data ownership and privacy standards around the storage of health data collected from patients.²⁸ The Government has laid down standards for capturing, storing, retrieving and exchanging data. These records coupled with AI can be used for analytical as well as prediction purposes. For instance, making prediction as to how a patient will react to certain medication by studying his genetic makeup. It is used to find out the most effective medication. But the issue of privacy regarding the use of such data cannot be side-stepped. Respecting a person's privacy is a vital ethical principle in the healthcare industry.²⁹

Settling the uncertainties surrounding the issues of privacy, the progressive *KS Puttaswamy* case³⁰ recognized the Right to Privacy as a Fundamental Right. The protection of personal data is considered an essential facet of informational privacy.³¹ The health record data being extremely sensitive and of personal nature, the issue of such data protection needs to be addressed on an urgent basis. The existing data protection laws are insufficient to ensure privacy and the Personal Data Protection Bill, 2018 has been under deliberations in our Parliament for quite a while. A serious attempt has been made to draft the bill in line with the General Data Protection Regulation (GDPR)³² of the EU. It not only confers a bundle of rights on the owner of personal data but also imposes stringent fines and punishments for breach of data by other parties. Health data is part of sensitive personal data.³³ The penalty for breach of such data privacy by the fiduciary holder may extend up to five crore rupees or two per cent of its total worldwide turnover of the preceding financial year.³⁴ This will ensure that the fiduciary or data processor doesn't act in a negligent manner while handling such data.

The ownership of the data is retained by the patient and he is given complete control to decide who can access such data. The healthcare providers are mandatorily put under the obligation to inform patients about their rights and to ensure privacy of such data. In case the data is

²⁷ *Notification of Electronic Health Records (EHR) Standards 2016 for India*, MoHFW Circular No. Q-11011/3/2015-eGov (30/12/2016), available at <https://mohfw.gov.in/sites/default/files/17739294021483341357.pdf>, last seen on 10/02/2020.

²⁸ *Report on Artificial Intelligence in the Healthcare Industry in India*, The Centre for Internet and Society, available at <https://cis-india.org/internet-governance/files/ai-and-healthcare-report>, last seen on 20/02/2020.

²⁹ *Supra* 8, at 2.

³⁰ *K. S. Puttaswamy and Anr. v. Union of India*, (2017) 10 SCC 1.

³¹ Personal Data Protection Bill, 2018 (pending).

³² General Data Protection Regulation, 2018.

³³ *Supra* 31, at S. 3(25).

³⁴ *Ibid*, at S. 69.

being used for purposes other than healthcare, specific consent has to be obtained from the patient prior to such dissemination. Any unauthorised or accidental disclosure, acquisition, sharing, use, alteration, destruction, loss of access to, of personal data that compromises the confidentiality, integrity or availability of personal data would amount to breach of privacy.³⁵ This provision has been made not only to ensure protection of patient privacy, but also to gain the trust of clinicians and society in the use of AI in healthcare sector.

Though the Right to Privacy of the patient and the duty on part of doctor to maintain confidentiality are of utmost importance, it can only be compromised subject to protection of health of others. The information can be disclosed for the purpose of public health and safety and prevention of crime and disorder.³⁶ For instance, in the case of the Novel Coronavirus, it would be detrimental to public health to withhold such information. Certain situations demand placing public interest on a higher pedestal than individual rights. In such situations, the health records may be made accessible.

2. Need for a suitable intellectual property regime

A weak intellectual property regime and breakthroughs in AI can never go together. The issue of India's weak intellectual property regime should be addressed quickly to encourage local developments in AI. Here, the example of pharmaceutical industry will be pertinent. After the expiry of the patent of the original drug, the cheap generic drugs, having the same active pharmaceutical ingredients, are allowed for sale in the market. The duration of a patent being as low as 20 years, most of the pharmaceutical companies, therefore, do not prefer to engage in R&D work and rather outsource it to research organizations. Other incentives apart from the money earned on patents should be awarded to such companies. It could be in the form of a prize system,³⁷ or payment of grants, stipends, or regular salaries to incentivize drug creations. Now this should be done with AI too. If AI technology is to be made free after some years, it is important that AI-developers are adequately rewarded else they will not be too eager to make massive investments needed to develop AI for healthcare. So, either we need to change IPR regime, or have a new reward system for innovations.

3. AI Created Drugs – the issue of over-rewarding

³⁵ Ibid, at S. 3 (30).

³⁶ Mr. X v. Hospital Z (1998) 8 SCC 296.

³⁷ J.E. Stiglitz, *Economic Foundations of Intellectual Property Rights*, 57 Duke Law Journal 1697, 1719 (2008), available at <https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1362&context=dlj>, last seen on 13/02/20.

An emerging new problem spot for the Intellectual Property Rights (IPR) regime are the AI created drugs. Will the granting of IP rights to an AI programmer for autonomous-products generated by the AI, lead to over-rewarding of its creator? In the United States, the autonomous AI-generated products fall within the public domain i.e. they are free for use.³⁸ In India, a similar approach could be adopted. It would benefit the society tremendously as the right to use the medical creation would not be confined to a single group. Moreover, it would also enable the underprivileged strata to come at par as far as access to knowledge and medical developments are concerned. From legal point of view, it would also stop people from filing suits in courts upon denial of licenses or request for compulsory licensing.

So, the granting of IPRs to AI machines for products that are generated autonomously by it i.e. without human intervention, needs to be addressed quickly. Machines are believed to be capable of surpassing human intelligence in the near future. To adopt this approach and provide AI with the rights, the whole legal system that is human centric, will have to be overhauled. Whether AI will be capable of holding IPR is being deliberated by WIPO and member countries presently.³⁹ Hopefully, some universally-acceptable solution will soon come out of these deliberations.

4. AI - susceptible to manipulation

There are widespread concerns that while use of Artificial Intelligence in healthcare is quite benevolent, and revolutionary, it, without adequate AI security, can be disastrous at the same time. For example, a robot conducting a critical surgery, if infected with malware, can be used to botch it up to even commit a murder. It is not a far-fetched argument. Anything digitally enabled can be digitally infected and AI is not an exception. The eye-sensors of a robot can be made to determine a non-surgical area as surgical one or its hand movement sensors can be made to exert more pressure than necessary by manipulating its calibrations. Furthermore, hospitals themselves can use AI to manipulate medical and other scans in order to boost pay-outs or gain regulatory approvals.⁴⁰ So, this concern is real and will need lots of investment in AI security to

³⁸ K. Hristov, *Artificial Intelligence and the Copyright Dilemma*, 57 IDEA: The Journal of the Franklin Pierce Center for Intellectual Property 431, 437 (2017), available at https://ipmall.law.unh.edu/sites/default/files/hosted_resources/IDEA//hristov_formatted.pdf, last seen on 26/03/2020.

³⁹ *Artificial Intelligence and Intellectual Property Policy*, World Intellectual Property Rights Organization (WIPO), available at https://www.wipo.int/about-ip/en/artificial_intelligence/policy.html, last seen on 15/02/2020.

⁴⁰ C. Metz & C. S. Smith, *Warnings of a Dark Side to A.I. in Health Care*, The New York Times (03/12/19), available at <https://www.nytimes.com/2019/03/21/science/health-medicine-artificial-intelligence.html>, last seen on 17/02/20.

protect the patients. With this, we will have legal issues pertaining to medical negligence. Rules need to be laid down tackling issues emerging out of AI botch-ups. Whether the clinic, or the AI lab, or the outsourced AI, security firms would be held liable. Various scholars, technical and legal experts have given solutions such as conferring personhood to AI or establishing a common enterprise theory to address the AI liability.⁴¹ There is a dire need to fix the legal responsibility by either modifying the existing laws or by enacting new legislations on the subject.

5. Regulating AI, the sooner the better

It is critical that we come up with a Regulatory Framework for the AI as soon as possible. It is imperative to impart the existing authorities like the Medical Council of India or the Drug Controller General with the ability to deal with the new developments. If needed, even a new authority can be established specifically for this area. It is crucial that an appropriate certification mechanism is provided to rule out any ambiguity and to provide for uniformity in the process of certification of AI mechanisms. Not just at National level, even State level agencies should be established to oversee and monitor the development of AI in India.

6. Need to provide boost to AI research

The development of AI needs research and research demands dedicated top-quality manpower. However, we just have an abysmal 1.67 % share of the worldwide PhDs in AI, i.e., 368 out of 22,000 worldwide. So the need to put AI research and development in the fifth gear requires the kind of urgency that we can ignore only at our own peril.⁴² The situation looks even more alarming when we are confronted with the fact that not even 50 of these researchers are engaged in serious or critical research in Artificial intelligence.⁴³ This means, on an average, just one such serious researcher comes out of nearly 2.5 crore of our population. And even this talent is mostly limited to the IITs and IISc. These facts have been highlighted by Global AI Talent Report 2018 and Niti Aayog in a discussion paper.⁴⁴ Medical Colleges must be encouraged, and even financially and technological supported, to develop AI research hubs all over India.

⁴¹ H. R. Sullivan and S. J. Schweikart, *Are Current Tort Liability Doctrines Adequate for Addressing Injury Caused by AI?*, 21(2)AMA Journal of Ethics 160, 164 (2019), available at https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2019-01/joe-1902_0.pdf, last seen on 16/01/20.

⁴² *Why is AI still out of reach for India?*, The Economic Times (18/06/2019), available at <https://economictimes.indiatimes.com/small-biz/startups/features/why-is-ai-still-out-of-reach-for-india/factually-speaking/slideshow/69839691.cms>, last seen on 12/12/2019.

⁴³ Ibid.

⁴⁴ Ibid.

7. Digitization, and more digitization

A major set-back to the adoption of AI techniques is the requirement of digitization. A digitized eco-system is a pre-requisite for operating AI at any level. This eco-system includes digitized medical records. However, in India, majority of the health centres still maintain their medical records on paper. Healthcare digitization to enable AI use implies the conversion of paper-based records into digitally scanned and indexed ones that are in accordance with the standards that are accepted globally. The hospitals interested in utilizing AI must be encouraged and rewarded for providing a digitized eco-system for seamless operation of AI. A digitized eco-system will also make it easier to apply laws as case information will not need to be lifted from different sources.

Finally, the biggest challenge to promote AI is lack of awareness and access to services. A large section of our population does not have access to internet connection and smartphones. Adding on to this are the vast inequalities in healthcare distribution, lack of trained healthcare professionals and infrastructural deficiencies. In such situation, it is quite likely that AI will take the backseat. However, basic healthcare and high-end AI care are not antagonistic. Even as its primary focus remains basic healthcare, the government can make efforts to promote AI-related investment by big entities and businesses. Monetary support and tax incentives should be provided by the Government to encourage the private sector to adopt AI and improve its services. It must also fund govt institutions and hospitals to invest in the future as AI is the future.

VI. GOVERNMENT INITIATIVES

The Government of India, via its recent policy initiatives, is endeavouring to address the healthcare challenges and show its commitment towards tackling the issues faced by our healthcare industry. The enactment of Electronic Health Standards, 2016 by the Ministry of Health is one such positive initiative. The National eHealth Authority (NeHA) has also been proposed by the Ministry which will develop an integrated health information system. One of the foremost objectives of NeHA is the formulation of “*National eHealth Policy and Strategy*” for coordinated eHealth adoption. It is also tasked with the responsibility of enforcement of standards and ensuring security, confidentiality, and privacy of patient’s health information and records.⁴⁵

The Union Budget of 2018 also included a commitment of Rs. 1,200 crores for Health and Wellness Centres (HWC), that aims to provide comprehensive healthcare which includes screening and management of

⁴⁵ Supra 28.

Non-Communicable Diseases (NCDs), basic dental health care; geriatric and palliative health care, and trauma care and emergency care.⁴⁶ An important component of HWC's will be universal screening for NCDs.

Other initiatives by the government includes setting up AI Task Force, formation of policy groups by Ministry of Electronics and Information Technology to explore the potential of AI and the possibility of its adoption in various industries, including healthcare. The government has also collaborated with various other countries such as the United States and has formed the United States–India Science & Technology Endowment Fund (USISTEF) for the promotion of joint activities that would lead to innovation and entrepreneurship through the application of science and technology.⁴⁷

VII. CONCLUSION

In a world that is technologically driven and technology implies advancement, the need for resolution of issues surrounding adoption of AI in healthcare is inescapable. With new technologies coming in the market every day and various companies and start-ups diving deep in the arena of healthcare technology, the role played by the law becomes very crucial.

Even though the Government has undertaken various steps to boost the adoption of AI across healthcare agencies, there still lie a few stumbling blocks. A comprehensive legislation governing technology and healthcare and constituting a regulatory framework for the same is absolutely essential. The Medical Council of India, The Ministry of Electronics and Information Technology and the Ministry of Health and Family Welfare have a crucial role in further integrating AI and healthcare. The relevant enforcement agencies should be vested with powers to check upon potential illegal usage of AI in healthcare, rampant patent violations, theft of data privacy and other undesirable situations. Setting up of fast track tribunals for settlement of such disputes will go a long way towards protecting innovations. The growth of AI world over is a revolution in the making, and the public sector, private sector, companies, government as well as end-users should make all out efforts to reap the benefits of this revolution

⁴⁶ Supra 18, at 26.

⁴⁷ Supra 28.