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The Charm of Artificial Intelligence in Health Care: An Insight into the Challenges of Implementation

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ABSTRACT

Artificial Intelligence is considered to be the most transformative technology in the 21st Century since Alan Turing's comment in 1950 on machines intelligence capacity. One of the early candidates to be revolutionized was Health Care. Artificial Intelligence is increasingly proliferating in the health care landscape. The implementation of such a transformative technology has an immense promise to improve and amend the health outcomes in a resource-constrained setting like India. Artificial intelligence has been implemented in order to ease down upon the pressure of the health care staffs, lower down costs and ultimately improve the lives of the patients. The implementation of Artificial Intelligence in Health Care is welcoming, however, it seems that these implementations of Artificial Intelligence in Health Care has substantial legal and ethical ramifications. Thereby, the author puts forth the issue of ethical and legal perspective in the backdrop of the Legal framework existing in India with regards to the field of Health Care. The mapping of the paper is in four folds. Firstly, the author sets out the definition and meaning of artificial intelligence in health care followed by the trends and strategies followed in the field of health care in India. Secondly, the author sets out the implementation of AI in Health Care. Thirdly, the author evaluates the ethical and legal ramifications by the implementation of Artificial Intelligence. Fourthly, the author analyzes that albeit India is at a developing and implementing stage of artificial intelligence in Health Care, there ought to be legal framework in order to regulate the same. And lastly, the paper outlines the limitations within which the regulators for health technology operate. The paper furthermore, offers recommendations for a system thinking approach to regulate Artificial Intelligence in Indian Health Systems.

Keywords: Artificial, Care, Ethics, Intelligence, Health, Legal, Regulatory

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I. INTRODUCTION

Once considered to be a utopian idea created in the imagination of fiction writers and movies, Artificial Intelligence (AI) has become an everyday fact of our life. The term “Artificial Intelligence,” or in an abbreviated form AI has become a trending word used by almost anyone in the society but its precise meaning has not yet been consented upon either by the international forum or by the domestic forum. Artificial Intelligence in medicine relies on what is known as the ecosystem of health data to train machines that learn responses to diagnose, predict, or perform more complex medical tasks.

Artificial Intelligence, according to some has been considered to be the most promising equipment for development in future. However, in another perspective, it is regarded as a threat to the continued existence of human kind. Artificial Intelligence and its related technologies are prevalent specifically in the business world, however, with due time, such technologies also have been started to be implemented in healthcare.

Although Artificial Intelligence is considered to be one of the major development improving the lives of the patients, however, with the existing framework in India, the implementation of AI in healthcare may be considered to portend various challenges including ethical and legal ramifications. Also, it is to be understood that the liability regime and regulatory framework is the desideratum of today’s world considering the increasing use of AI in HealthCare.

II. AREAS OF IMPACT OF AI IN HEALTH CARE: A GENERALIZED VERSION

AI in healthcare majorly is exciting as well as scaring. The above chart has been sketched in order to lay down just few of the aspects wherein AI will have an impact on health care. It is to be understood that AI has a multitude of impacts on our daily lives even when it comes to health care landscape.

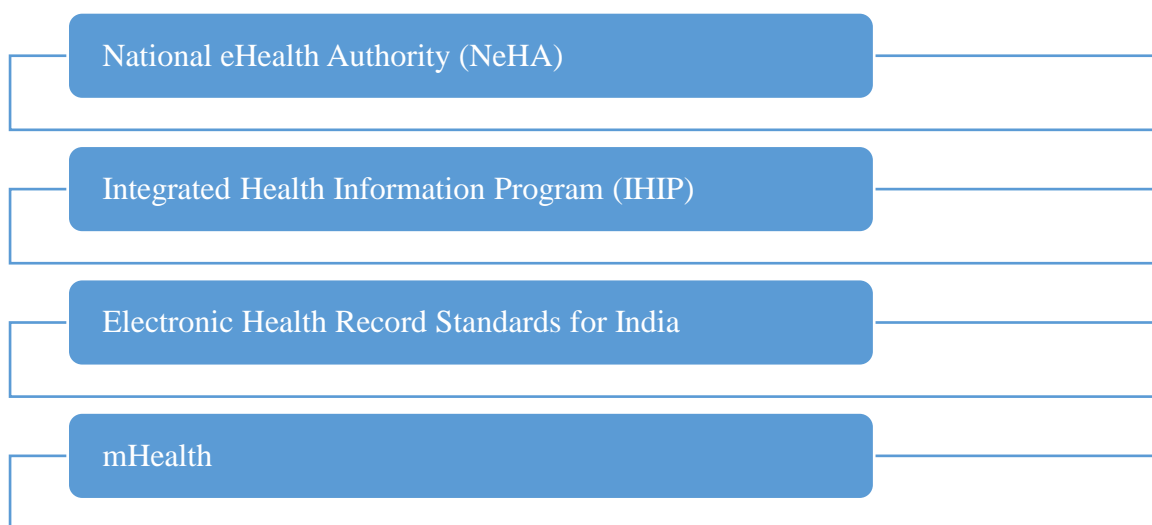
With these impact of AI in healthcare it definitely has the potentiality to focus on the major idea of mitigating the shortages of health care providers. The severe deficit to the health care and patient ratio as seen in a developing nation like India, could be overcome with the implementation of AI in the healthcare landscape. Also, AI being used for clinical decision support, risk scoring is some of the major and significant areas for revolutionizing the healthcare sector. With various apps and chatbots being developed by the Government of India to improvise the health care system in India (example: Aarogya Setu) is considered to be providing self-care and care delivery on a very immediate basis. This helps mitigating the pressure on the Doctors and the health care staffs.

These impacts and these areas of AI in health care is not without criticisms and also, with analysis it is to be understood that without a regulatory framework for both AI in HealthCare and Data Protection, implementing such technologies would consequently negatively impact the patients in every aspect.

III. RECENT TRENDS AND STRATEGIES APPLIED FOR THE APPLICATION OF AI IN HEALTHCARE

The Government of India has taken several steps for overall digitalization in the past two decades. The workers on the frontline are being trained to adopt digitalization in health care and implement the same. This shift to digitalization has been codified in the National Health Policy of 2017 which has detailed the need to leverage such technologies³.

Within the past one decade India is slowly but gradually transforming into AI concentrated Health Care. For this some of the digitalization process that has been implemented by the Ministry of Health and Family Welfare are as follows:



(A) *NeHA*

NeHA has been adopted in order to strategize eHealth adoption and set such standards, policies and legal framework which are in consonance with the health sector requirements

(B) *Integrated Health Information Program*

The intention to enact this program was to provide EHR to all citizens of India.

³ Aayush Rathi, *Is India's Digital Health System Foolproof?* ECONOMIC AND POLITICAL WEEKLY, December 11, 2019; See also, Abhinav Verma, Kristina Rao & Ors., *Regulating AI in Public Health: Systems Challenges and Perspectives*, ORF ONLINE (July 27, 2020) available at <https://www.orfonline.org/research/regulating-ai-in-public-health-systems-challenges-and-perspectives/>.

(C) Electronic Health Record Standards for India

Standards have been set to provide Systematized Nomenclature of Medicine (SNOMED CT) for free in the country.

(D) mHealth

The Government has taken the initiative to work with various platforms to provide interactive modes of communications, treatment, data transmission, and retrieval to doctors/patients using mobile apps and websites.

IV. POTENTIAL OF AI IN INDIA

When in a nation like India, the doctor-patient ratio of 1:10, 189⁴ (It is considered to be 10 times shorter than what has been suggested by the World Health Organization) and there has been a constraint in the resources, the call for technology has never been louder to support the health care delivery in the country. The response of the implementation of AI in health care to some extent has been amazing for example, an AI based breast cancer screening device that uses a cost effective, less time consuming and solution based detection of breast cancer.

Healthcare landscape is one of the steadiest field which is accepting and embracing the digital health innovation to respond to the critical challenges posed in the health care. Regulations have definitely been enacted in order to increase the standardization of the design and functioning of these technologies. However, it is also to be accentuated that AI based implementation in health care has a potentiality of high risk which is associated with their use. When a nation or the policy makers of a nation take a step ahead in order to regulate a framework for the regulation of AI in health care, it is important to recognize the context and risks which is associated with each of these categories.

V. CHALLENGES FOR AI ADOPTION IN HEALTH CARE IN INDIA

The risks associated with AI is yet not known fully, however, even if implemented the norm of such health delivery has challenged the equitable access to the health care system which is one of the most significant challenges in the regulation of AI in healthcare. Furthermore, ethical and legal ramifications also need to be emphasized upon when dealing with the use of AI in healthcare.

(A) Absence of Healthcare Regulatory Body

India has no healthcare regulatory body and therefore, in the absence of a regulatory

⁴ Frost, Isabel, Jess Craig, Jyoti Joshi, and Ramanan Laxminarayan, *Access Barriers to Antibiotics*, THE CENTER FOR DISEASE DYNAMICS, ECONOMICS & POLICY (April 11, 2019).

framework, there lies a concern among the healthcare providers in context of reliability on medical devices and this becomes one of the reasons for the practitioners to adopt conventional medical devices.

(B) Unaffordability

As the example of oncology has already been discussed, it is imperative that we understand that these kinds of AI machines costs in thousands, whereas in consultations in person with leading oncologists can be of a smaller percentage. Considering that majority of the population belongs to either middle class or below that, why will they choose something that costs more and not something which will cost less.

(C) Unavailability of Relevant Data

In order to develop an AI with high accuracy, a high amount of labelled data is also required. Furthermore, this data also needs to have parameters which is similar to that one of making predictions. One of the shared concerns for the CxO Community was that of the lack of India-specific clinical data.

(D) Ethical Challenges

Artificial Intelligence when applied and implemented in the landscape of Health Care has a brilliant scope for improving and transforming it for better however, it isn't without posing ethical challenges which certainly leads to legal ramifications specially in a nation like India.

1. Informed Consent:

Informed Consent is considered to be one of the most pertinent issue to have a basic understanding of the ethical challenges posed by implementation of AI in healthcare. However, this challenge is considered to be the least reviewed aspect in literature of implementation of AI in healthcare. The question is if at all, what is the liability and obligation of the clinicians and healthcare staff to expound the complexities of AI (including Machine Learning used by the system) to the patients and individuals concerned? Furthermore, what also needs to be considered is under what circumstances shall a healthcare staff inform the patient that AI is being used at all?

In a developing nation like India, with the start of the use of apps like Aarogya Setu and several others health apps and chatbots ranging from health guidance to assessments to the help to improve medication, the issue of informed consent becomes all the more pertinent considering the user agreements and their relationship to informed consent. In a nation like

India where the literacy level is merely 74.04%⁵ and more than half the population depending on rural life, expecting these individuals to take time and understand the complexities of such agreements⁶ or for that matter of fact even understand the agreement is like expecting an individual who is not a doctor to know the causes for a disease. Moreover, frequent updates of the software make it all the more difficult for an individual to understand the terms of service they followed⁷. The pertinent issue is how many individuals per se sufficiently and substantially understand the future use of such apps and chatbots may be conditional on accepting changes to the terms of use. Furthermore, the question also is what would an ethically responsible user agreement look like in this context⁸.

2. Safety of the use of AI

One of the biggest challenges of the use of AI in health care is that of the safety. One such example is that of IBM Watson for Oncology⁹. In the instant case it uses algorithms to access the information from patients' medical records and as well help physicians explore cancer treatment options for the patients. However, recently, it has been criticized by reportedly giving "unsafe and incorrect" recommendations for cancer treatments¹⁰. The considerable problem was with the training of the software with a few "synthetic" cancer cases.

In order to ensure that AI is safe, it must be ensured that the two factors must be ensured:

- a) Firstly, the reliability and validity of the datasets¹¹

The basic requirement is that the algorithms must be further refined in order to generate results that are accurate. Another significant issue is that of data sharing.

⁵ 10 Facts on illiteracy in India that you must know, OXFAM (2015), available at <https://www.oxfamindia.org/featuredstories/10-facts-illiteracy-india-you-must-know>

⁶ Klugman C.M., Dunn L.B., Schwartz J., Cohen I.G., *The ethics of smart pills and self-acting devices: autonomy, truth-telling, and trust at the dawn of digital medicine*, 18:28 AJOB 4751 (2018); See also Cohen IG, Pearlman A., *Smart pills can transmit data to your doctors, but what about privacy?* N SCIENTIST (2018), <https://www.newscientist.com/article/2180158-smart-pills-can-transmit-data-to-your-doctors-but-what-about-privacy>.

⁷ Gerke S., Minssen T., Yu H., Cohen I.G., *Ethical and legal issues of ingestible electronic sensors*, 2:329 NAT ELECTRON 334.53 (2019).

⁸ Sara Gerke, Timo Minssen and Glenn Cohen, *Ethical and Legal Challenges of artificial intelligence-driven healthcare*, ELSEVIER PUBLIC HEALTH EMERGENCY COLLECTION (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7332220/>.

⁹ IBM. IBM Watson for oncology (2020), available at <https://www.ibm.com>.

¹⁰ Brown J. *IBM Watson reportedly recommended cancer treatments that were 'unsafe and incorrect'*, GIZMODO (2018), <https://gizmodo.com/ibm-watson-reportedly-recommended-cancer-treatments-tha-1827868882>; See also Ross C, Swetlitz I., *IBM's Watson supercomputer recommended 'unsafe and incorrect' cancer treatments, internal documents show*. STAT, available at <https://www.statnews.com/2018/07/25/ibm-watson-recommended-unsafe-incorrect-treatments>.

¹¹ *Supra* note 7.

b) transparency¹²

The use of AI in health care shall be made transparent. This transparency creates trust in all the stakeholders particularly health care staffs and patients which becomes one of the key to a successful implementation of AI in clinical practice.

3. Equity, Fairness and Algorithmic Biases

Artificial Intelligence has the potential to globalize the healthcare system however, it shall be accentuated that the Machine Learning System or human trained algorithm will only be trustworthy and fair as it is trained with. AI also has the capability of discriminating, therefore, the one devising such a machine is ought to have the knowledge basic in nature and accordingly develop the same.

There have been various examples wherein it has been demonstrated that algorithms can exhibit biases that can result in injustice in context of ethnicity, origin and skin color or for that matter of fact gender.¹³

In the landscape of health care wherein certain genotype diseases do exist, biased AI could and in all possibility be a leading factor towards false diagnosis and render treatments ineffective for some of the sub-population and thus lead to jeopardizing their safety.

4. Data Privacy

Data privacy is considered to be one of the major concerns when a machine like AI is implemented in the health care sphere. The recent cases in United States that is of *Dinerstein v. Google* and *Project Nightingale* focus on privacy concerns of an individual patient in the context of data sharing and the use of AI. At a time when there is no such regulation specifically in a developing nation like India with regards to either the regulatory framework of the use of AI or for that matter of fact with regards to the data protection and privacy implementing Artificial Intelligence is not without such danger which would but infringe upon the fundamental rights of an individual.

¹² *Id.*

¹³ *Short E. It turns out Amazon's AI hiring tool discriminated against women*, SILICON REPUB (2018), available at <https://www.siliconrepublic.com/careers/amazon-ai-hiring-tool-women-discrimination>; See also Cossins D., *Discriminating algorithms: 5 times AI showed prejudice*, N SCIENTIST (2018), available at <https://www.newscientist.com/article/2166207-discriminating-algorithms-5-times-ai-showed-prejudice>; Fefegha A., *Racial bias and gender bias examples in AI systems* (2018), available at <https://medium.com/thoughts-and-reflections/racial-bias-and-gender-bias-examples-in-ai-systems-7211e4c166a1>; Obermeyer Z., Powers B., Vogeli C., Mullainathan S. *Dissecting racial bias in an algorithm used to manage the health of populations*, SCIENCE (2019); Sharkey N., *The impact of gender and race bias in AI*, HUMANITARIAN LAW POLICY (2018), available at <https://blogs.icrc.org/law-and-policy/2018/08/28/impact-gender-race-bias-ai>.

(E) Legal Implications of the use of AI

1. Liability

One of the most significant aspect is that of the liability regime. Hypothetically, considering that the AI based Software gives an incorrect treatment recommendation which the health care staff adopts and that leads to harming the patient. In this situation, it is likely that the clinician or the doctor would be considered liable for medical malpractice. The issue is that the doctors or clinicians would be held liable even if they adopt such treatment in good faith and in believing the AI.

2. Right to Privacy and Protection of Data

In the world of big data, it is of utmost importance that there exists a regulatory framework for data protection in place which adequately protects the privacy of the individuals in the instant case, patients. In a developing nation like India, right to Privacy has been very recently considered to be as a fundamental right guaranteed under Article 21 of the Constitution of India. This right was guaranteed and ensured by the judgement of K.S. Puttaswamy v. Union of India.¹⁴ However, the issue is with regards to the data protection. At a time when the countries are majorly focussing on enacting data protection law, India still does not have a regulatory framework for data protection.

3. Cybersecurity

When considering the legal and ethical challenges of implementing AI in health care Cyber security becomes one of the most issue which needs to be focussed upon. In the near future, the Internet of Things (IoT) a lot of healthcare related services, processes and products will operate within the framework of IoT. Unfortunately, when considering these aspects, the underlying infrastructure is vulnerable to both cybersecurity and physical threat and hazard.¹⁵

VI. WAY FORWARD

Firstly, the desideratum of a strong framework regulating the AI in the health care system must be enacted.

Secondly, that the accuracy of the data shall be so high in the AI that the ethical challenges posed by the AI in health care could be overcome.

Thirdly, to implement AI in Healthcare in a developing Nation like India one thing that is to be ensured is that of taking initiative to transform individuals into digital citizens. Given the

¹⁴ K.S. Puttaswamy v. Union of India, (2017) 10 SCC 1 (India).

¹⁵ US Department of Homeland Security, CYBERSECURITY (2019) 107.

data, India yet has low key infrastructure in the implementation of AI in health care.

Fourthly, an enactment of Data Protection is required when implementing AI in Healthcare considering that the information may be circulated without even consent.

Fifthly, legal ramifications must be done away with by ensuring that such implementation is cost effective, accessible to all and such services are provided to all with subsidy ensuring equity and fairness.

Sixthly, the budget allocation of funds for the implementation of emerging technologies is required to be increased by the Government of India. Also, the Government should take initiative to promote research and development so as to become independent in the skilful spheres.

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