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AI in Medicine: A Futuristic Insurgence

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ABSTRACT

The emergence of Artificial Intelligence (AI) in the recent decades has been surprisingly met with monumental acceptance. With its application limitless, it has been introduced or at the verge of being integrated into numerous sectors worldwide. The field of healthcare is no exception, and with digitalization taking hold over its activities, application of artificial intelligence in medicine is not a question of 'if', but 'when'. While ideally people prefer to trust human medical practitioners over machines, artificial intelligence is a gateway to the nearest possibility of achieving perfection while discarding human errors. However, there exists an issue of how morally acceptable it is to trust machine learning over human capabilities and there is an ethical and legal dilemma of subjecting human life to a machine that lacks humanity and sentience over humans who lack precision.

With major corporations being invested in artificial intelligence and machine learning pertaining to healthcare, it is no surprise that in near future, it will turn into another commercial pawn to rule over the market. It is imminent that adequate legal framework is introduced for its regulation.

The author of this paper has made an attempt to discern the rise of artificial intelligence in the public health sector, identifying its many issues, and the impact it had globally in the detection and control of the spread of COVID-19.

Keywords: *Artificial Intelligence, Machine learning, COVID-19, healthcare, medicine.*

I. INTRODUCTION

Humanity has been capable of evolution and creation and we have arrived at a point in history where our creation has overtaken us in terms of evolution, exceeding human capabilities, transcending our existence and essentially replacing us in the near future.

The term AI was first described by John McCarthy as the science and engineering of making intelligent machines in 1956. Alan Turning (1950) being one of the many founders of what has evolved to become the modern artificial intelligence had led to the emergence of "Turning Test", which indicated that the intelligent behaviour of a computer was its ability to achieve human level performance in cognition related tasks[2]. Over the past great many decades, it grew

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[2] Mintz Y, Brodie R. *Introduction to artificial intelligence in medicine*. *Minim Invasive Ther Allied Technol*. 28. 73–81 (2019)

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from being an idealistic notion in the far dystopian future to a limitless possibility waiting to be unearthed.

Artificial Intelligence incorporates computers and technology with an aim to stimulate intelligent behaviour accompanied with critical and analytical thinking to rival that of a human being. With its growth and the rising demand for its application in innumerable fields, 2016 witnessed the highest amount of investment relating to artificial intelligence concerned research made within the healthcare sector[3].

The birth of digitalization has been witnessed by humanity in the distant past and artificial intelligence has also since been integrated into medicine for a good amount of time. However, the possibilities are limitless and every waking moment heralds the dawn of a new demand and every single time, humans have come to rely on machines to resolve it. AI algorithms and technologies based on artificial intelligence and its subsets have now grown to be an inseparable and integral part of modern healthcare.

Artificial intelligence has found its application in medicine under two major heads- physical as well as virtual. While the physical application involves the incorporation of assistance of robots in surgery or use of intelligent prosthetics for the special abled for the elderly amongst many other such uses, the virtual mode of application finds itself under a vast majority of utilizations including determination of treatment, medical diagnosis and prognosis, drug and pharmaceutical development, contact-tracing and maintenance of Electronic Health Record (EHR) systems[4].

Yet, artificial intelligence is limited to the extent of programming input which is ultimately made by human developers. It is neither self-evolving nor sentient, and thus remains dependent highly upon the human insight that it lacks. Not free from its own flaws, the use of artificial intelligence in medicine is largely welcomed with skepticism by millions across the world. There is a demand to thus strike an unequivocal balance between the need for humans to adapt to artificial intelligence in the same extent as AI adapts to humans.

II. IMPLICATIONS OF ARTIFICIAL INTELLIGENCE IN THE FIELD OF MEDICINE

Artificial intelligence in its virtual application depends on the exposure to data feeds provided

[3] CB Insights Research. Healthcare remains the hottest AI category for deals. 2017. Available from: https://www.cbinsights.com/research/artificial-intelligence-healthcare-startups-investors/. (Last accessed on 10th January 2022).

[4] Amisha et al., *Overview of Artificial Intelligence in medicine*, 8, Journal of Family Medicine and Primary Care 2328–2331 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6691444/. (Last visited on: 10th January 2022).

to a sophisticated algorithm. This entry of data must be made in a manner where it is easily recognizable by the algorithm. In a sense, it must be organized and fed to the algorithm for it to analyze the same and provide any sort of output. Artificial intelligence and machine learning algorithms already in use in the field of healthcare are highly based on neural networks and finds its use in various fields of healthcare sector.

A million-dollar question while contemplating about the increased application and dependance on artificial intelligence and other means of technology in the healthcare sector is, 'how can an algorithm develop human cognition and be termed as *intelligent*?'. AI does not automatically emerge with incompatible intellect and emulative sentience. They are trained to complete tasks such as pattern recognition and data analysis done by humans in an arduous manner, with humans programming them and teaching them what to look for in the previously assembled data delivered for analysis. With adequate exposure to data sets, the algorithms performance is closely evaluated to generate accuracy, and based on its performance and its potential, modifications are made to it by the developers in a struggle to attain perfection.[5]

AI aids in the prognosis and diagnosis of a wide range diseases and illnesses, depending upon medical imaging as a major input. A highly proved example of the same is where X-rays are utilized as inputs to machine learning algorithms to teach them to identify various symptoms of lung conditions[6], or detect bone age, bone maturity, as well as any fractures suffered[7]. Another highly coveted evidence is that neural networks were able to identify chronic obstructive pulmonary disease and even predict mortality when they were fed with computed tomography (CT) of the chest of smokers[8].

Machine learning and artificial intelligence based on neural networks have also been similarly used prominently for cancer diagnosis alongside its widespread application in the fields of ophthalmology, gastrology, gastroenterology, nephrology, endocrinology, cardiology, neurology and pathology[9] and has been proven far superior, or at the least non-inferior, to

[5] Daniel Greenfield, *Artificial Intelligence in medicine: Applications, implications, and limitations.* Science in the News (2019), https://sitn.hms.harvard.edu/flash/2019/artificial-intelligence-in-medicine-applications-implications-and-limitations/ (last visited Jan 23, 2022).

[6] Lakhani P et al., *Deep learning at chest radiography: automated classification of pulmonary tuberculosis by using convolutional neural networks*, 2, 574-582. (2017). https://pubmed.ncbi.nlm.nih.gov/28436741/. (Last visited on 9th January 2022).

[7] Larson DB et al., *Performance of a deep-learning neural network model in assessing skeletal maturity on pediatric hand radiographs*. Radiology.287(1). 313-322 (2018), https://pubmed.ncbi.nlm.nih.gov/29095675/, DOI: 10.1148/radiol.2017170236. (Last visited on 9th January 2022).

[8] Gonzalez G t al., *Disease staging and prognosis in smokers using deep learning in chest computed tomography*. 2. Am J Respir Crit Care Med. 193-203. (2018). https://pubmed.ncbi.nlm.nih.gov/28892454/. (Last visited on 10th January 2022).

[9] Giovanni Briganti et al. *Artificial Intelligence in Medicine: Today and Tomorrow.* Frontiers in Medicine. (2020). https://doi.org/10.3389/fmed.2020.00027. (Last visited 22 January, 2022)

humans in the detection of diseases through screening magnetic resonance imaging (MRI), computed tomography (CT), and positron emission tomography (PET) scans[10].

AI has been used in treatment of various diseases. While its well noted use has been in the field of surgery in the way of surgical robots that aid and assist operations, it has also found its use in the field of psychiatry where it is used to regulate and manage dosages of medicines given to patients, or even used to detect any symptoms of PTSD[11] or bipolar behaviour that may go unnoticed by its human counterparts. AI also has massive potential for aiding biomarker identification for the purposes of diagnosis, prognosis and even tracking the progress of treatment or a response to any drug, while possibly leading to development of targeted biotherapies[12].

Artificial intelligence has a noteworthy role to play in the process of formulating and developing new drugs. The process of drug development is time-consuming, expensive and complicated, which involves formation of hypothesis, identification of potential targets, and clinical trials prior to receiving approval for its commercial outreach. The initial stages revolve around probability, the recognition and establishment of patterns, and corelating the same for the analysis and derivation of conclusions. AI finds itself to be immensely reliable for this purpose where it can be sufficiently taught to imitate the skills of the professionals while eliminating any margin of human errors or bias.

In an era of customization, artificial intelligence also has a lot of potential for developing medical treatments personalized for the requirements of the individual seeking it. The patients' symptoms and test results are evaluated to recommend any treatment plan. AI compensates for human errors and identifies signs that may have been overlooked by physicians owing to their neglect. With sufficient data, it may even outperform human physicians or experts in terms of formulating treatment plans or diagnosis of illnesses that may run undetected otherwise[13].

III. ARTIFICIAL INTELLIGENCE AND ITS APPLICATION DURING THE REIGN OF COVID-19

[10] Andreas L et al., *Artificial Intelligence (AI) in medicine as a strategic valuable tool*, 38, Pan African Medical Journal. (2021). https://www.panafrican-med-journal.com/content/article/38/184/full. (Last visited on 10th January 2022).

[11] Lucas GM et al., *Reporting mental health symptoms: breaking down barriers to care with virtual human interviewers.* 4(51). Frontiers in Robotics and AI. (2017). (Last visited on 8th January 2022).

[12] Andreas L et al., *Artificial Intelligence (AI) in medicine as a strategic valuable tool*, 38, Pan African Medical Journal. (2021). https://www.panafrican-med-journal.com/content/article/38/184/full. (Last visited on 10th January 2022).

[13] Andreas L et al., *Artificial Intelligence (AI) in medicine as a strategic valuable tool*, 38, Pan African Medical Journal. (2021). https://www.panafrican-med-journal.com/content/article/38/184/full. (Last visited on 10th January 2022).

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Crises and catastrophes are nothing unseen in the history of humanity. Wars and diseases, floods and droughts, have plagued civilizations for millennia and we have survived and evolved for aeons. COVID-19 is one such great evil haunting almost all nations indiscriminately, claiming the lives of rich and poor, young and old alike.

The novel Coronavirus emerged as an outbreak in 2019, tracing its origins to Wuhan, China. Since then, it has only grown into a global pandemic, affecting millions of people across most countries, not only preying on the lives of people, but also wreaking havoc amongst the population and destroying economies. The most devastating impact has been the death of millions globally, and healthcare sector is at an all-time alert, striving at an accelerated pace in a race against time to save the lives of those struggling at the brink of death.

AI has materialized as a miraculous aid in this hour of need. Artificial intelligence and its multiple appendages have been deployed for assisting in the detection of disease clusters, determination of mortality risk, contact-tracing, monitoring affirmative cases, identification of symptoms, and prediction of possible outbreaks through pattern recognition[14].

AI had been harnessed for the purpose of contact-tracing and prediction and tracking by most countries, primarily as a software in form of an application. Over 50 countries worldwide had opted to utilize AI to develop mobile applications, which included[15]:

i) Applications for alerting users as well as authorities of COVID-19 infected patients;

ii) Applications for contact tracing;

iii) Information and Resource based applications;

iv) Applications for medical reporting;

v) Applications which are not COVID-19 specific;

vi) Applications for quarantine enforcement;

vii) Self-diagnostic applications.

Early warning systems were developed by deploying data collected from social media interface and news to predict regions vulnerable to the risks of higher concentration of infection. Publicly available data and geo-tracking were brought into play for making data backed predictions based on pattern recognition and analysis. Thermal scanners were embedded onto phones as

[14] Arora, Neelima et al. *The role of artificial intelligence in tackling COVID-19*. (2020). Future Virology. doi:10.2217/fvl-2020-0130. (Last visited on 11th January 2022).

[15] *Artificial Intelligence and the control of COVID-19*, Artificial Intelligence, https://www.coe.int/en/web/artificial-intelligence/ai-covid19 (last visited Jan 11, 2022).

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applications to screen the masses[16]. Further, mobile health applications and softwares were made accessible on a myriad of compatible devices contact tracing and monitoring of infected persons, the same reported to relevant authorities. AI was also used to detect COVID-19 from chest CT scans and X-rays[17], by developing deep learning models based on neural network.

This automation of various interim functions in detection and diagnosis of Covid greatly unburdened the healthcare professionals. AI algorithms could now be wielded to classify patients based on a multitude of factors, including that of the severity of their symptoms, easing the hurdle to determine the level of care required and the treatment to be delivered to each category of patients[18].

The rise in popularity of artificial intelligence in the realms of telemedicine, analysis of Electronic Health Records, data sets from trials and online consultation greatly contributed in providing efficient treatment to patients who were asymptomatic. AI could critically examine the data at hand and recommend treatment options, greatly improving their chances of survival. It was also used to support timely decision making, allowing for proper planning and prioritization. The populace residing in remote areas were diligently monitored through AI based telemedicine options, allowing them to track the severity of any symptoms they would exhibit. The use of telemedicine also decreased crowded in-person interactions of the infected patients and the hospital staff and even the general public, thereby contributing to the regulation of patient inflow.[19]

AI was also of great prominence in development of therapeutics and vaccines as it elevated the quality of research made by a huge margin while monumentally reducing the time taken for the same. Pharmaceutical companies were dependent upon artificial intelligence to identify the efficiency of various potential drugs tested against COVID-19[20], which expedited the drug discovery. AI assisted in rapid acceleration of pace of discovery of vaccines by aiding in various stages of development of the same. Machine learning was applied as a tool to predict the proteins which were identified as the most favourable vaccine candidate[21]. In a similar fashion,

[16] Kumar A et al. A review of modern technologies for tackling COVID-19 pandemic. 14. Diabetes Metab Syndr. (2020). 569-73.
[17] Sethy PK et al. *Detection of coronavirus disease (COVID-19) based on deep features*. Preprints (2020)
[18] Arora, Neelima et al. *The role of artificial intelligence in tackling COVID-19*. (2020). Future Virology. doi:10.2217/fvl-2020-0130. (Last visited on 11th January 2022).
[19] Samer Ellahham. *Artificial Intelligence in the Diagnosis and Management of COVID-19: A Narrative Review*. 4. Journal of Medical Artificial Intelligence. (2021). https://jmai.amegroups.com/article/view/6026/html.
[20] Gurjit S Randhawa et al. *Machine learning using intrinsic genomic signatures for rapid classification of novel pathogens: COVID-19 case study*. 15(4). PLoS One. https://pubmed.ncbi.nlm.nih.gov/32330208/. (2020)
[21] Ong E et al. *COVID-19 coronavirus vaccine design using reverse vaccinology and machine learning*. Front Immunol. doi: 10.3389/fimmu.2020.01581. (2020).

various vaccine targets were predicted which had the potential to become the vaccine for treatment of COVID-19.

In addition to artificial intelligence, various other digital technologies were resorted to by the public healthcare sector upon recognizing their untapped potential for[22]-

i) The time efficient detection and diagnosis of infection

ii) Means of prevention and control of spread of infection

iii) Curbing spread of misinformation

iv) Contact tracing and tracking movements of infected and quarantined individuals

v) Predictions as to outbreaks and rates of infection and mortality

vi) Development of vaccines and pharmaceuticals effective against COVID

vii) Assisting medical professionals

viii) Telemedicine, remote monitoring and online consultation

ix) Maintenance of Electronic Health Records

With countries imposing lockdowns for indefinite periods, another aspect of human life that took a major hit was mental health. The rates of suicides shot up and cases of domestic violence sky rocketed with the collectively rising frustration. AI was again a major part of bringing help to those in need. Online therapy increased in popularity and artificial intelligence softwares were used to connect individuals in need with qualified therapists across the world while ensuring their privacy and prioritizing their mental health.

IV. ARTIFICIAL INTELLIGENCE AND LEGAL LIABILITY IN MEDICINE

AI with its indefinite potential to forever transform the healthcare sector, falling nothing short of a marvel, is not free from the evils it casts upon humanity. In a desperation ingrained within us to trust accuracy over errors, we lost sight of why professions in healthcare are deemed 'noble', and chose apathy over empathy. Part of the healing process is the mental determination and will to recover, a state of mind that is forged by the trust between patients and their physicians. With that human connection being replaced with the cold, lifeless entities that are fueled by numbers as opposed to emotions, there are bound to be legal and ethical affairs manifesting regarding the same.

[22] Malliga Subramanian et al. *The role of contemporary digital tools and technologies in Covid-19 crisis: An exploratory analysis*. (2021). https://onlinelibrary.wiley.com/doi/10.1111/exsy.12834.

Ethical Challenges:

Machines, no matter how advanced, can never imitate sentient behavior to the extent exhibited by humans, despite artificial intelligence having to possess the complete range of human cognition, by definition. Consciousness remains a biological phenomenon, reserved for the living, and thus, the use artificial intelligence AI to replace human connections gives rise to a host of ethical dilemma.

The monumental challenge regarding artificial intelligence in healthcare is the question of safety and transparency. AI, no matter how advanced, is still a machine, dependent on human interference for its functioning. There is scope for errors, albeit at a smaller margin as compared to humans, and such errors may cost many lives if solely dependent upon. An instance very much grounded in reality was the 'Watson' supercomputer which had recommended 'unsafe and incorrect' treatments for cancer patients[23]. To ensure that this failure is not repeated, transparency must be maintained to assure the reliability of the data sets by the AI developers, and there must be a balance found between providing such transparency and protecting IPR.

There are real life examples wherein algorithms had demonstrated inherent biases relating to race and gender[24], while there is always a possibility of discrimination resulting from it based on disabilities or age. This may be because of faults within data sets which cannot account for minority of the population being represented or how the data was analyzed and fed by the developers[25]. There also exists growing concerns as to privacy of data and patient confidentiality with Electronic Health Record systems being adopted.

Workforce impacted by artificial intelligence will be a major hurdle. Humans should be trained to work alongside machines instead of the latter. The machines may duplicate the actions of humans but it can never emulate or augment an individual doctor's capabilities[26]. The human insight lacking will always impact the work ethic, with the growing distrust as to the capabilities of the AI. The knowledge of medicine will be reduced to mere predictions based on pre-analyzed patterns, failing to take into account the novelty of individuals, with each nothing like the other. Humanity cannot be generalized without exceptions and failing to take into account

[23] 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. (Last visited 20th January, 2022)

[24] Obermeyer Z et al. *Dissecting racial bias in an algorithm used to manage the health of populations*. Science. 366. 447–453 (2019). DOI: 10.1126/science.aax2342. (Last visited 20th January, 2022)

[25] Gerke Sara et al. *Ethical and legal challenges of artificial intelligence-driven healthcare*. Artificial Intelligence in Healthcare. 295–336. (2020) doi:10.1016/B978-0-12-818438-7.00012-5 (Last visited 18th January 2022)

[26] Ivana Bartoletti. *AI in Healthcare: Ethical and Privacy Challenges*. Artificial Intelligence in Medicine: 17th Conference on Artificial Intelligence in Medicine, AIME 2019, Poznan, Poland, June 26–29, 2019, Proceedings. Germany: Springer International Publishing. 7-10. (2019).

these exceptions, especially when their lives are dependent on it, will be the biggest flaw in deploying artificial intelligence into medicine.

There are also distress as to managing accountability. Judicial adjudication mechanisms in force can take into consideration the probability of human errors. Patients can accommodate human fallacies but there is no way to predict their reactions to oversight by machines that may cost their lives. The legal system has to find a way to mitigate this thin line of acceptance laid down by the community.

Legal Dilemma:

Presently, the physicians are primarily implicated for liability under medical negligence or medical malpractice. Health professionals are required by law and by professional ethics to adhere to certain standards of care and act in good faith. Their primary point of interest must be the well-being of their patients and failing to display the standard of care attracts medical negligence. The healthcare sector also largely attracts vicarious liability[27] where actions of one implicates all. The present systems of judicial adjudication attempt to focus on correcting the errors committed by professionals with a rigid legal framework governing the field of medicine. However, this framework falls apart when artificial intelligence is introduced into the field of healthcare.

While generally the physicians would be liable for medical negligence, attempting to render them liable for flawed artificial intelligence would be far beyond the realms of rationality. However, some portion of liability would have to collectively lay upon the hospitals relying on such artificial intelligence, especially if they have previously failed to ascertain the accuracy of the AI so employed by them[28].

In case of AI, the manufacturers of the artificial intelligence or the developers of algorithms or any technology generating such algorithms might face tortious liability where such algorithm are flawed inherently or fail being of poor quality. However, affixing tortious liability in relation to artificial intelligence would question the core of the law itself- how can there be any legal liability for any act lacking intention, resulting in an injury?

Here lies the black box dilemma. Black box AI refers to any artificial intelligence system which remains impenetrable to a third party, its operations shrouded in mystery. It operates in the manner intended but there lacks any communication for the reasoning it holds for making any

[27] Maliha G et al. *Artificial Intelligence and Liability in Medicine: Balancing Safety and Innovation*. Milbank Q. 3. 629-647. (2021). https://doi.org/10.1111/1468-0009.12504. (Last visited Jan 22, 2022).
[28] Kyle Jorstad. *Intersection of Artificial Intelligence and Medicine: Tort Liability in the Technological Age*. 3. Journal of Medical Artificial Intelligence. (2020). https://jmai.amegroups.com/article/view/5938/html.

decision. They are based on opaque models to make decisions due to the complexity of the data involved[29]. This also results in an ambiguity as to intention of the developers of the AI to affix tortious liability of any kind, especially when the developers themselves may fail to predict the outcomes of the AI they created[30]. Any outcome of the judicial system may be received with the criticism of being uninformed.

Legal implications relating to intellectual property rights in AI pose insurmountable challenges as well. The shareholders of an artificial intelligence or any of its numerous subsets must have an opportunity to protect such investment, and development of artificial intelligence demands a great amount of it. Considering the interest of the developers would have to acquire or generate data sets to feed the algorithms, develop and train the algorithms and gather resources required to ensure this would be a success, some level of protection must be provided to the artificial intelligence so birthed as a part of their intellectual property[31]. Patent laws fall inadequate and various facets of IPR conflict while attempting to determine where would artificial intelligence fit as an intellectual property.

The final challenge is that of privacy and confidentiality. Enormous amounts of data are gathered for the purpose of analysing and developing the algorithms from the same. This data may have to be shared with authorities of the government or other bodies for evaluation or otherwise. Data fed algorithms are also bound by the risk of misuse and are vulnerable to data leaks.

V. AI AND MEDICINE IN INDIA

Various organs of the Indian Government, including the National Institution for Transforming India (NITI) Aayog, and Ministry of Electronics and Information Technology (MeitY) have redirected renewed efforts into developing policy frameworks and initiate AI programs across various sectors.

India has already engaged in vigorous application of AI in medicine, with few of its initiatives being[32]:

[29] Johan Ordish. *Legal Liability for Machine Learning in Healthcare*. PHG Foundation. (2018). https://www.phgfoundation.org/media/217/download/briefing-note-legal-liability-for-machine-learning-in-healthcare.pdf?v=1&inline=1. (Last visited Jan 22, 2022)

[30] Bathaee Y. *The artificial intelligence black box and the failure of intent and causation*. 31. Harv J Law Technol. (2018). 890-938. (Last visited Jan 22, 2022)

[31] Nicholson Price. *Artificial Intelligence in Health Care: Applications and Legal Issues*. Americanbar.org (2017). https://www.americanbar.org/groups/science_technology/publications/scitech_lawyer/2017/fall/artificial-intelligence-health-care/ (last visited Jan 20, 2022).

[32] *E-health & telemedicine*, Ministry of Health and Family Welfare | GOI, https://main.mohfw.gov.in/Organisation/departments-health-and-family-welfare/e-Health-Telemedicine (Last visited Jan 22, 2022).

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i) NITI Aayog working with Microsoft and Forus Health to bring out a device to detect diabetic retinopathy using AI based retinal imaging called '3Nethra';

ii) Start-ups like NIRAMAI developing devices for early diagnosis and prognosis;

iii) Adoption of Electronic Health Records and the e-Health division of the Ministry of Health and Family Welfare laying down Electronic Health Records Standards for India;

iv) Establishing e-Hospital as an ICT based solution for hospitals in Government sector;

v) NIKSHAY- a tracking system for counselling and treating tuberculosis patients;

vi) National Telemedicine Network has been envisaged;

vii) Online portal for data entry and analysis based on weekly surveillance called the 'Integrated Disease Surveillance Programme' (IDSP) being established;

viii) Individual based tracking system called the 'Mother and Child Tracking System' (MCTS) to aid in the delivery of antenatal and postnatal care and immunization services to children.

With the dawn of COVID-19, the growth of AI in medicine was inordinately accelerated, also giving rise to a host of issues relating to artificial intelligence that previously went unnoticed. A prime example of this is the repeated privacy concerns as to contact tracing applications.

Amidst a myriad of questions surrounding the status of AI under Intellectual Property Laws, there are conflicting opinions as to whether artificial intelligence would be provided recognition under patent laws prevailing in the country or under copyright laws. AI has also bred ambiguity in its coverage under competition policies, raising the question as to whether using artificial intelligence to obtain a dominant position in the market is violative of the provisions under Competition Laws of the country, highlighting the need to evolve existing legislations to make it adaptable to the present[33].

Presently, medical devices remain regulated under the Drugs and Cosmetic Act of 1940 and the Drugs and Cosmetics Rules of 1945. However, all medical devices are not regulated under this Act. There are medical devices notified under the Act which it governs

The Drug Controller General of India (DCGI) is the primary regulatory authority for approval

[33] Divjyot Singh et al. *AI, Machine Learning & Big Data Laws and Regulations 2021: India*. GLI - Global Legal Insights - International legal business solutions, https://www.globallegalinsights.com/practice-areas/ai-machine-learning-and-big-data-laws-and-regulations/india#:~:text=There%20is%20an%20urgent%20need,of%20AI%20and%20its%20application. (Last visited Jan 22, 2022).

and regulation of imports of medical devices. Medical Device & Diagnostics Division within the Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Ministry of Health and Family Welfare remains responsible for registration and import of medical devices in India.

The Act and the Authorities in-charge have laid down guidelines as to registration, licensing, import etc., of notified and non-notified medical devices.

In addition to the same, the Ministry of Health and Family Welfare has laid down the Medical Devices Rules of 2017, which outlines provisions for regulation of medical device, authorities and bodies provided for under the same, regulation of manufacturing and sale of such medical devices meant for commercial purposes, regulation of imports of medical devices, duties of the notified body, regulations for registration of labs for testing, etc.

There are continued attempts made to regulate the widespread application of AI in medicine by laying down standards and guidelines, but no concrete law has yet been established. It is elemental that the government would consider the implications artificial intelligence has over the activities of medical field and concurrently focus on framing legislative footholds while aiding the escalation of AI in the country. While there are efforts made by the government by constituting committees, preparing reports and proposing draft regulations, it is imperative that they bring much needed laws to regulate AI into force, accompanied with India's coordination in various international artificial intelligence initiatives.

VI. COMPARATIVE ANALYSIS: STATUS OF AI IN HEALTHCARE WORLDWIDE

(A) European Union

The General Data Protection Regulation (GDPR) passed in the EU has been enforceable since 2018, aiming to regulate upon privacy and security of EU citizens. This being a legislation and not a directive remains binding on the citizens of EU and also has extra-territorial application insofar the data of its citizens are concerned. This instrument may find applicability in regulating AI where there are privacy concerns raised as it tips the balance in favour of the citizens for consenting to the collection, use and sharing of their personal data[34].

The Medical Device Regulation in force since May 2021 was aimed at enhancing the quality and efficiency of medical devices while assuring their safety, and significantly covers the interests of its citizens using AI-based medical devices. This Regulation extends the scope for

[34] Pesapane, F et al. *Artificial intelligence as a medical device in radiology: Ethical and regulatory issues in Europe and the United States*. 9. Insights Imaging. (2018). 745–753

liability, strengthens the standards for quality, evaluation, surveillance etc., of the said medical devices, thereby assuring more transparency.

(B) United States of America

The major regulatory body of medicine and allied technology is the Food and Drug Administration (FDA). The FDA classifies any medical device into three categories for ease of regulation. The term 'medical devices' has been identified under the 21st Century Cures Act, 2016, which aimed to accelerate innovation and development of medical products.

With the present trend in development, regulating black box AI is a challenge, due to the surge in varied innovations and their opacity being maintained. FDA approval for AI systems is harder to obtain due to the complexity involved in testing and evaluation.

The FDA has entered into a collaborative effort with the International Medical Device Regulators Forum (IMDRF) to harmonize international medical device regulation, calling for an updated regulatory framework[35].

(C) China

China has established the National Medical Product Administration (NMPA) as an agency to regulate drugs and medical devices. The NMPA is in-charge of certifying the conformity of products with pre-laid standards. The NMPA has issued continued guidelines to regulate AI-based medical devices, such as the Technical Guideline on AI-Aided Software issued in 2019.

Approval by the NMPA may be by three modes- innovative, priority or emergency approval[36]. While innovative approval appears to be most tedious with numerous criteria to be satisfied, priority approval is granted based on the prominence of treatment needs for rare diseases. Emergency approvals are purely in the face of public health crises (such as COVID-19) and are not applicable otherwise.

VII. CONCLUSIVE REMARKS

The distrust in artificial intelligence, or technology in general, is not misplaced, although unfair. AI has repeatedly demonstrated its ability to excel at tasks as compared to performance exhibited by average human doctors. Yet, its aim is not to replace them, but merely act as a supporting system, undertaking tasks that are repetitive or fundamental, requiring precision, but

[35] Pesapane, F et al. *Legal and Regulatory Framework for AI Solutions in Healthcare in EU, US, China, and Russia: New Scenarios after a Pandemic*. 1. Radiation. (2021). 261–276. https://doi.org/10.3390/radiation1040022. (Last visited 27th January 2022)

[36] Hamish E S King. Medtech AI & Software Regulation in China: 5 Things to Know. MDDI. (2020). https://www.mddionline.com/regulations/medtech-ai-software-regulation-china-5-things-know. (Last visited 27th January 2022)

that merely covers the groundwork of the healthcare system[37]. Doctors, nurses and every medical profession shall still be responsible for the majority of the operations of medical field. AI can also be utilized as a substitute for much needed intellectual human resources upon their unavailability.

Scientific development is at an accelerated pace beyond anyone's wildest imagination. However, this flight to great heights must be accompanied with the same degree of caution, transparency and ethical values. The governments of the great nations have to come into terms with this ceaseless evolution and adapt their policies and economies to welcome this wave of change. The human mind is inexplicable and its creations innumerable. Legislative framework should be radically drafted and sufficient groundwork should be laid for coherent enforcement mechanisms, adaptable to accommodate the existing and upcoming developments, AI or otherwise.

AI is not impervious to inherent risks nor is it incapable of errors. The vision of perfection is ideal, but unattainable. Artificial intelligence merely enables humanity to reach this utopian dream as close as possible. There is general amelioration of human health conditions with artificial intelligence in the picture. Dismissing it for the probability of errors that presently exist anyway expresses a groundless prejudice against change and a stern dissent to embracing the inevitable.

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[37] Buch, Varun H et al. *Artificial intelligence in medicine: current trends and future possibilities.* The British Journal of General Practice: The Journal of the Royal College of General Practitioners. 68. (2018). 143-144. doi:10.3399/bjgp18X695213

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