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# Evolving Ethical and Regulatory Framework for Artificial Intelligence for Health

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***Abstract: International Telecommunications Union (ITU) / World Health Organization (WHO) / Focus Group (FG) on artificial intelligence for health (FG-AI4H) works in partnership with the (WHO) to establish a standardized assessment framework for the evaluation of Artificial Intelligence (AI)-based methods for health, diagnosis, triage or treatment decisions. This working group of ITU/WHO "Regulatory considerations for AI" is helping to guide the FG in navigating the regulatory landscape; facilitating contacts, information exchange, and collaborative opportunities of the FG with regulatory bodies. This paper has outlined the key regulatory considerations that are relevant to regulatory agencies for AI development and to define ways to successfully benchmark the AI for health algorithms.***
***Keywords: Artificial Intelligence, Algorithm Accountability, Data Privacy, Electronic Health Records Standards 2016,***

## I. INTRODUCTION

Artificial intelligence (AI), which includes the fields of machine learning, natural language processing, and robotics, can be applied to almost any filed in medicine, its potential contributions to biomedical research, medical education, and delivery of health care seem limitless. With its robust ability to integrate and learn from large sets of clinical data, AI can serve roles in diagnosis, clinical decision making and personalized medicine. AI and robots that support, diagnose and treat people are already in homes, workplaces and clinical environments all over the world.

And how we embrace AI and Robotics to complement and enhance current healthcare services over the next 10 years will define our ability to deliver a more responsive health service with improved health outcomes, while at the same time enabling people to take more control over their day-to-day health needs. Artificial Intelligence market for healthcare applications is poised to increase from 663.8 million US $ in the year 2014 to 6662 Million US $ in 2021. In this background, it is important that there is need for clear understanding on the aspect of 'Evolving Ethical and Regulatory Framework for AI4H.' It can be further elaborated as below:

### *A. Descriptive*

Descriptive AI is the most widely used in healthcare technology today, and holds the most promising in terms of short-term potential. For instance, such technology can be used to identify patterns in fracture detections and skin lesions. Additionally, these technologies have been shown to outperform humans in detecting subtle wrist fractures.

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### *B. Predictive*

Predictive AI uses descriptive data to attempt to make predictions about the future. AI is used by medical professionals to provide insights and suggest actions in a predictive manner. AI can play a significant role in predictive healthcare technologies and hospital management.

### *C. Prescriptive*

Prescriptive AI furthers the purpose of predictive AI, and not only detects trends that may not be predicted by humans, but also suggests possible treatments based on nuances in the diagnosis.

## II. STAKEHOLDERS IN THE AI AND HEALTHCARE ECOSYSTEM

There are a number of stakeholders that make up the healthcare ecosystem and work together towards the successful adoption and implementation of AI in healthcare. Acceptable behavior' for an AI system must be clearly defined for its respective application domain, and should ideally drive design considerations, engineering techniques and reliability AI system actions should therefore be explainable and easily understandable by humans. This is especially important in healthcare, where diagnosis and treatment need to be backed by a solid chain of reasoning to earn patient trust.

In order to map the stakeholder ecosystem, the basis of entire AI ecosystem can be visualized by identifying the key stakeholders that have an impact on the AI and healthcare industry. The stakeholders are divided into five categories: practitioners, developers, research and industry bodies, government, and funders and investors.

Different cultural norms must also be accounted for, and tasks carried out by machines must be culture-specific depending on the country or region where it is deployed.

## III. ETHICAL CHALLENGE FOR AI IN HEALTH SECTOR

This powerful technology creates as novel set of ethical challenges that must be identified and mitigated since AI technology has tremendous capability to threaten patient preference, safety, and privacy. However, current policy and ethical guidelines for AI technology are lagging behind the progress AI has made in the health care field. While some efforts to engage in these ethical conversations have emerged the medical community remains ill-informed of the ethical complexities that budding AI technology can introduce.

This issue is how to balance the benefits and risks of AI technology. There is benefit to swiftly integrating AI technology into the health care system, as AI poses the opportunity to improve the efficiency of health care delivery and quality of patient care. However, there is a need to minimize ethical risk of AI implementation – which can include threats to privacy and confidentially, informed consent, and patient autonomy as discussed below:

### *A. Liability*

In case of error in diagnosis malfunction of a technology, or the use of inaccurate or inappropriate data the question arises of who the liability would fall upon – the doctor or the software developer.

### *B. Data Integrity*

The accuracy and completeness of data sets used to power AI solutions are key to accurate and unbiased results. There is also the potential for specific cultural biases such as caste and sexuality to be carried forward in data sets.

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*C. Algorithmic Accountability*

The accurate and unbiased architecture of an AI solution and its underlying algorithm is also important in ensuring responsible AI. Adaptability, consistency, accountability, and monitoring are aspects that ensure an algorithm is learning from its mistakes and successes.

*D. Consent*

Informed consent has been seen as the key ethical requirement for medical treatment and research, to be supported by requirements for professional confidentiality and personal privacy.

The following identified measures that can be considered to handle the ethical challenges for using AI in healthcare sector:

*1)* Introducing dedicated regulations for the use and monitoring of AI in healthcare;
*2)* Encouraging research and development in AI through government and tax incentives;
*3)* Regulating the liability framework of AI and medical advice provided using AI;
*4)* Encouraging investment in, and the use of, AI by the stakeholders in the healthcare sector; and
*5)* Encouraging society to adopt and adapt to changing technology.

## IV. REGULATORY CHALLENGES FOR AI IN HEALTHCARE

The legal and health policy conflicts that arise with the use of AI in health care. AI in health care unveil legal issues such as medical malpractice and product liability that arise with the use of “black-box” algorithms because users cannot provide a logical explanation of how the algorithm arrived at its given output.

A policy gap governing the protection of patient photographic images as they apply to facial recognition technology, which could threaten proper informed consent, reporting of incidental findings, and data security.

Finally, policy on AI in health care calls for the development of thoughtfully designed, high-quality, and clinically validated AI technology, which can serve as a prototypical policy for the medical system.

The sensitivities involved in providing medical advice are extremely intricate. As a consequence, the standards of care to be observed by medical professionals are also extremely high. The current intellectual property rights regime in India continues to be a cause for concern to the developers of AI. Algorithms are specifically excluded from being patented under the Patents Act 1970. In recent times, data privacy has gained significant importance, thereby promoting the use of extensive care in the exchange of information. The following specific issues are needed to be examined from Legal perspective for implementing a robust AI in health sector:

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### *A. Data Ownership*

Although data generated by patients can be stored by providers, it will be owned by customers. Patients shall be able to view these medical records without any time restrictions.

### *B. Data Access*

Patients are in complete control of who can access data, and shall explicitly consent to disclosures. They shall also be able to correct any errors in their medical records.

### *C. Changes to Data*

Data cannot be changed once it is entered into the system. Any necessary changes must be accompanied by an audit trail, and changes to previously saved data are not permitted. Records requiring changes shall be made on a new medical record containing the revised data, which shall then be marked as “active”.

### *D. Disclosure of Health Information*

Specific consent of the patient is required for use in non-routine and non-healthcare purposes. However, data can be freely disseminated without permission after removing any personal identifiers.

### *E. Access to Records by Courts/ Government Authorities*

Health records must be produced in an “as-is” state in case of a court order. Additionally, health information can be revealed without consent to the appropriate authorities according to the law in case of national issues such as notifiable/ communicable disease.

### *F. Responsibility of Healthcare Providers*

Healthcare providers shall be responsible for storage of patient information and ensuring removal of personal identifiers. They must also inform patients about their rights, and take measures to ensure privacy of such data. They can also deny information to patients if a licensed doctor believes that releasing such information could endanger the life and safety of the patient or others. Electronic Records must not be destroyed even after the death of a patient, but they can be moved from active to inactive status if there are no pending court cases that require this data.

### *G. Encryption of Data*

Electronic health records must compulsorily be encrypted with a minimum of bit encryption keys. Secure transmission standards must be used while transferring such data between sites. All action pertaining to the data must be recorded.

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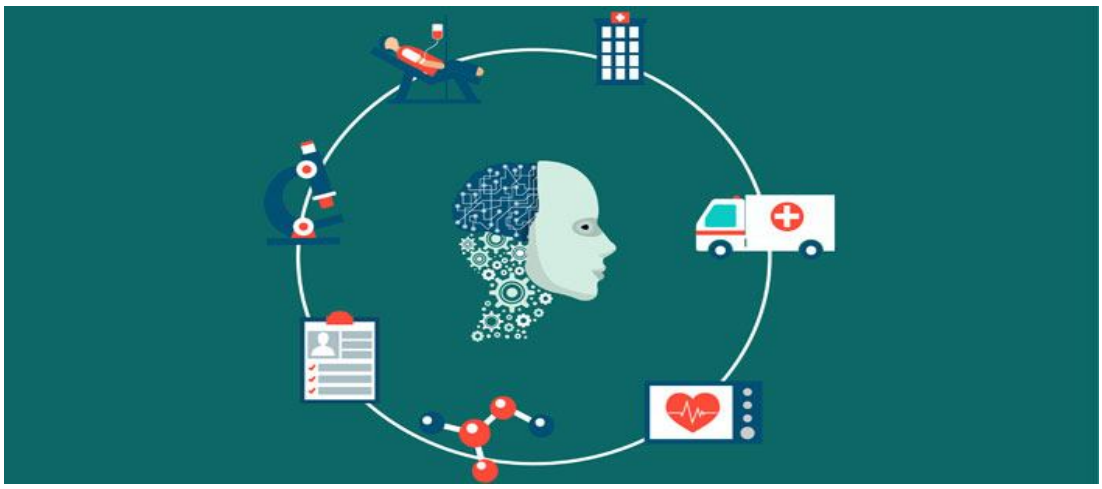
### *H. Identification*

If the patient's social security number is available, it must be used as a unique identifier, in the absence of which two government ID cards can be used instead.



## V. INTERNATIONAL EXPERIENCES

There is a strong case for the introduction of new standards, regulations, and governance frameworks, for AI in health. The law as it operates today is not dynamic, and therefore cannot provide adequate guidance and remedy to innovators or consumers of AI in the healthcare sphere. One of the foremost questions to be answered is whether AI is capable of providing correct medical advice, and to what extent can reliance be placed on such advice.

Any discussion of data privacy and security in Europe (and, increasingly, beyond Europe) must begin with the General Data Protection Regulation (GDPR). The GDPR has set a high standard in the EU – and has emerged as a benchmark for third countries – for the protection of personal data, including health data.

German law allows for the use of health data (without consent) for scientific research following a balancing of interest test and subject to safeguards, such as encryption, training, and the appointment of a Data Protection Officer.

In Belgium, the national law was updated to lift (subject to safeguards) certain rights of individuals in their personal data in order to better balance the interests of individuals with the specific needs of scientific research.

These developments are promising. More remains to be done at national level to improve the framework for secondary use of health data to promote public health.

### *A. Electronic Health Records Standards, 2016*

The EHR Standards, 2016 are an attempt to regulate data ownership and privacy standards around the storage of health data collected from patients. This includes data from medical establishments as well as data from medical devices and self-care devices and systems. The government bodies have recognised the need for standardisation of such data, and has accordingly laid down standards relating to information capture, storage, retrieval, exchange and analytics, including images, clinical codes and data. These include ISO and other national standards to be used for EHRs.

## VI. WAY FORWARD AND CONCLUSIONS

There is need to focus on regulating, deploying and developing digital healthcare across the globe. Broadly, the policy includes setting up of health information exchange platforms, creation of health registries, tele-consultation, use of smart phones/tablets to capture real time information, etc. Some other actions to be taken by the government over the years include the introduction of the electronic health record standards for creation and maintenance of electronic health records by healthcare providers and the setting-up of a task force on AI, which has identified healthcare as one of the focus sectors.

There is need for active efforts to find solutions, including WHO/EU/World Bank funding to support research and innovation in digital health solutions and improved infrastructure to enable the cross-border exchange of health information; the eHealth network to advance the interoperability of eHealth solutions; and public-private partnerships to promote innovation and strengthen interoperability.

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There should be further deliberation to develop standards for deploy ethically and regulatory comply artificial intelligence technologies in healthcare sector. It is pertinent that for protecting people and maintain trust in technology, the development of AI should be rooted in a commitment to ***six key principles of fairness, reliability and safety, privacy and security, inclusiveness, transparency, and accountability***, which further requires codification on the basis of certain key principles broadly on following framework:

*1)* Efforts for building trust directly into the technology.
*2)* Aim for reliable and safe AI Technologies in health sector.
*3)* AI technology must be introduced in healthcare with codified protections for data privacy, and data security.
*4)* Recommendations or decision-making by artificial intelligence should be transparent to those relying on them for health decisions.
*5)* AI Technology for Heath should be all inclusive and respectful to everyone.
*6)* Finally, since these are new technologies, AI based health devices must be designed to detect new threats and introduce appropriate protections as AI evolve in healthcare.

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Dr Mandeep Singh is a Post Graduate in Commerce, Economics, Law and Financial Management. Author was awarded Junior Research Fellowship by UGC, New Delhi for completing his Doctorate in the area of Financial Derivatives.

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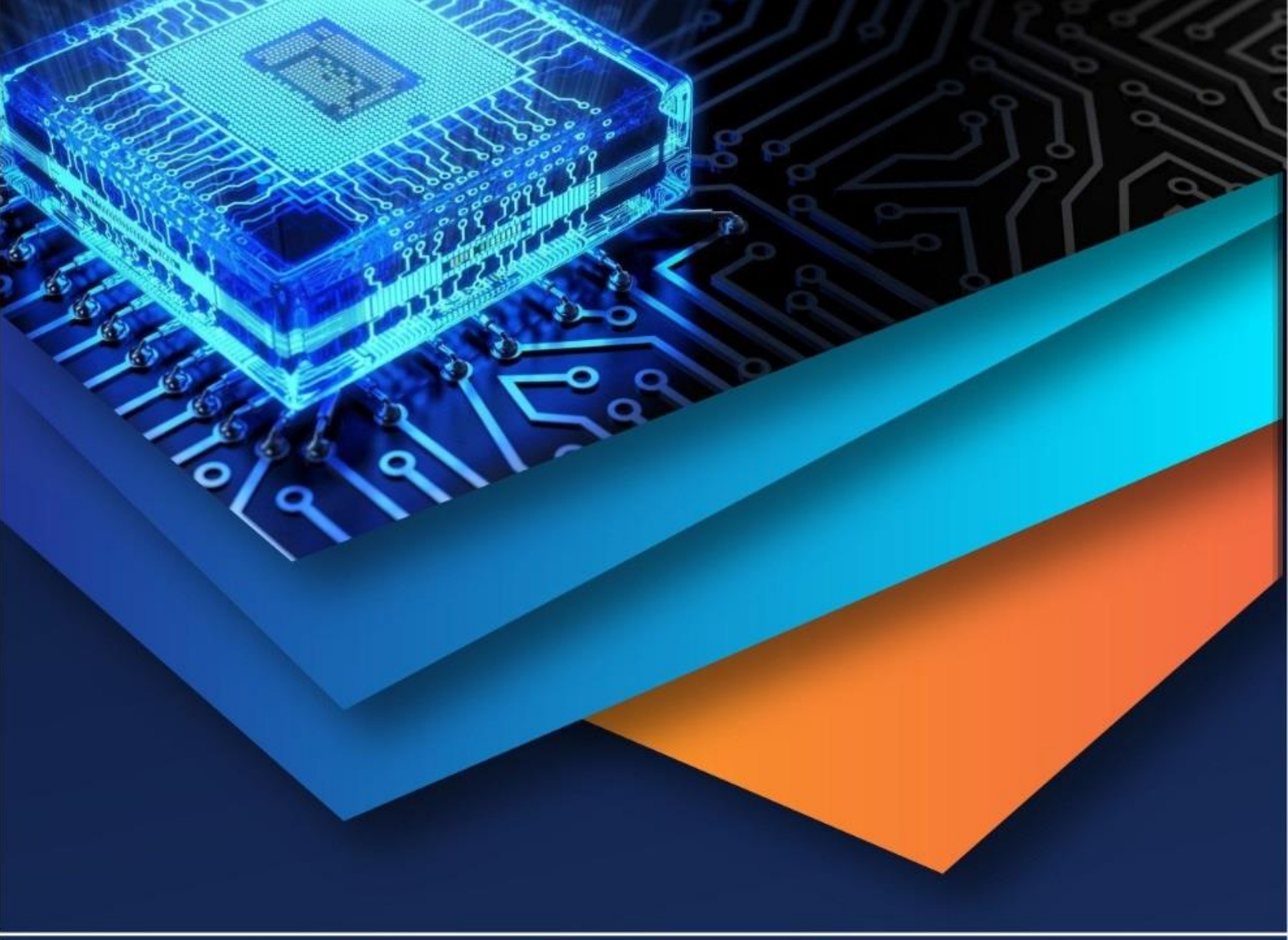

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