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Urgent Need for Developing a Framework for the Governance of AI in Healthcare

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Abstract. Lately, the application or integration of Artificial Intelligence in various areas of the Healthcare domain has been a prime attraction; this includes diagnostics, medicine/drugs, medical devices, interventions/procedures, imaging, therapies as well as treatment regimes, and these areas are in direct relation with the patient care, which is the core subject of the improvements envisioned through the implementation of AI. Although carrying this practice with a focused objective of improvisation in providing quality care, the overall concept of such implementations misses the governance path which can comply with any available regulatory environment, which unfortunately at this stage does not exist**.** As these implementations would have a direct impact on patients care, there is an urgent need to institute a robust governance and compliance framework in order to ensure the efficacy, safety, privacy, and ethical considerations. The onus of pioneering this initiative of building a governance framework for the implementation of healthcare artificial intelligence primarily rests with the Food and Drug Authority of the respective country, it is also important for this authority to further organizing the governance framework in agreement or collaboration with other international authorities.

Keywords. Healthcare AI, Data Science, Ethics, Governance

1. Introduction

As per the hype that AI has created, its implementation holds no boundaries. Applications of Artificial intelligence are limitless, starting from simple reporting to enhanced diagnosis, for report writing and decision making without human intervention, trust needs to be built up between man and machine, as a small flaw in the algorithm may lead to a fatal action or incorrect interpretation. Those implementations have a direct impact on the patient with or without the knowledge of the attending physician. In such cases, who shares the responsibility? Machines will not be responsible for their action as their behavior is just programmed. Taking into account the above argument, a proper AI governance framework needs to be designed and defined. This can be done by

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categorizing the areas of applications, the stakeholders and their responsibilities, ethical guidelines, policies and procedures for health care authorities and providers, and finally, a registry maintaining an inventory of all AI based healthcare projects and products. International arbitration and a unanimous agreement are the utmost necessity for technology transfer and AI based products to be traded across the globe.

2. Method

The paper is based on the interaction/interviews with the IT leads for various hospitals with regard to their IT infrastructure and capabilities during the implementation of CIMDR [1], and the experience gained along with the interactions with various stakeholders during the implementation of the research management system [4] and organizing research.

3. Current governance trends

Based on empirical studies, bioethics forms the core of any healthcare-related governance modality for all the advancements in medicine. As far as Big Data and AI-based biomedicine are concerned, sound and effective governance remains crucial to all endeavors that involve understanding and responding to all posed and anticipated challenges [2]. The initial effort from the FDA treating software as a medical device [SaMD] in any healthcare setting was a breakthrough [3], can be considered as a reference point in the construction of the desired framework. However, SaMD grossly deals only with third party medical device manufacturers or commercial clinical software vendors, which covers only a narrow spectrum of clinical areas, complexities, and stakeholders.

4. Considerations in building a governance framework

The most important fact to be taken into account is the mix of stakeholders involved in building or developing AI based solutions for healthcare. As a matter of fact, some of the stakeholders involved, cannot practice or follow a sound research methodology in the absence of an established IRB (Institutional review board) unlike the situation in health care institutions which abide by an established IRB. Hence a centralized IRB for AI based products, drug discovery, diagnostic methods, methods complementing clinical trials, and many other, would be ideal in this situation. Also, instituting a central product review board in order to approve and authorize the use of AI based products, methods, or services in real-time patient care is recommended.

5. Ideal elements of an AI governance framework

Stakeholders: By definition, a stakeholder corresponds to any person, department, or organization who has an interest in and is involved or affected directly or indirectly by a venture. So, when it comes to AI based healthcare solutions, the primary stakeholders

would generally include the healthcare authorities, healthcare providers/hospitals, chief information officers, or chief data officers, commercial companies providing AI based products and services, the local FDA, and also the end-user / Patient.

Centralized Review Board: This centralized authority would carry out both the pre-development and post-development review for the proposed as well as developed output. Further, the review would ideally cover both the research as well as the technical aspect of the project; hence the review board should comprise of two different teams, one dealing with the ethics, informed consents, data, documentation and research aspect ensuring good clinical practice [6] and the other covering the technical aspects dealing with the accuracy, effectiveness, and functioning of the embedded algorithms. An ethics & scientific review process for an AI application is somewhat complicated as it needs a review based on:

- Data used as a training dataset and test dataset
- The output data and output elements
- Data Processing (Clinical data, Sample, Image)
- Primary Methodology and Implementation
- The background research-based evidence
- Informed consents / waivers etc.

Secondly, the algorithm applied would also need a review; for this purpose, documenting the machine learning process, model architecture, and the methodology used for predictions and interpretation is necessary for review purposes. The post-development review would precisely cover the algorithm testing and the efficacy of the AI element within the output. In general, the technical review should include:

- Studying, analyzing and reviewing the input and output data elements
- Actual and staging data repositories(Data after the ETL process to be used)
- Data ETL (Extract load and transfer) process
- Data interpretation methodologies
- Studying the efficiency and efficacy of the algorithm
- Studying and analyzing the prediction models

Progress reports and post-implementation review reports are the essential documents to be mandatorily submitted to the authority in the defined format.

Institutional Review Boards (IRBs): Established Healthcare IRBs are the organizational representatives for all research carried out at the institution level. In the current proposed framework, these IRBs would act as an interface by the central review board, and this would speed up the review process at the authority's end. [4] The IRBs would review the proposed AI application in advance in a systematic manner in sync with the requirements of the central review board, this institutional entity would mostly deal with the ethical and research aspect of the project.

Institutional Command Center or Data Science Hub: Most of the advanced healthcare institutions have established a Command center or a Data Science hub [5] to carry out AI / Machine learning-based activities along with a well-defined testing and internal certification mechanism. Within the governance framework, these entities would interface with the centralized review board technical group.

6. Framework Implementation Methodology

Any patient care related Healthcare AI implementation should nationally be mandated to go through the regulatory guidelines, where any such development proposal needs to be submitted to the central review board authority under the FDA following the necessary documentation guidelines defined by the authority. The two-step review (Clinical and technical) would be carried out by the authority, and necessary recommendations/modifications (if necessary) would be carried out by the entity proposing the solution, followed by the approval to carry out the development. Also the mandatory progress reports should be submitted to the authority during this phase. The proposing institution/company will start then the certification process, by submitting all the necessary post-development documents to the authority, and may also need to be capable of demonstrating the output (if required). The final output would go through a scientific and technical review that estimates the accuracy and effectiveness of the AI techniques and its effects on patient care, based on which the AI product is certified to be used in practice. A periodic review report needs to be submitted to the authority for a specified time duration until the product is well established as an effective solution.

7. Conclusions

It is of utmost importance for all national healthcare authorities to build a dynamic framework to carry out the development of the regulatory guidelines for all AI implementations in the healthcare products and services, ensuring effectiveness and patient safety.

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