LEGAL IMPLICATION OF APPLICATION OF GENERATIVE AI -LARGE MULTI-MODAL MODELS (LMMS) IN HEALTHCARE INDUSTRY

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ABSTRACT

The ongoing development of a new paradigm of GenAI-centric applications (LMMs) in the healthcare industry, holds immense promise to improve diagnostics, patient care, and overall healthcare delivery. However, it also brings forth multifaceted challenges, that needs to be addressed. This Article highlights the intended use of LMMs in the healthcare industry and explores the complex legal landscape surrounding its development. This Article also addresses the paramount issues relating to informed patient consent, data privacy, algorithmic biases, and other ethical issues that demands careful navigation. The Article proposes solutions to mitigate those risks and calls for adoption of a holistic approach that could strike a balance between different stakeholders in the healthcare sector.

INTRODUCTION

The advent of Generative AI (GenAI) has transformed the healthcare sector by bringing forth unparalleled opportunities, revolutionizing the medical diagnostics, optimizing treatment outcomes, drug discovery and overall patient care management. Large Multi-Modal AI Models that can harness and integrate vast amount of complex data are at the forefront of this revolution. However, the rapid integration of AI is fraught with challenges. Issues pertaining to patient's data privacy, autonomy, and informed consent in context of AI-driven healthcare pose significant impediments necessitating legal oversight.

What are LMMs?

Large multi-modal models (LMMs) are advanced artificial intelligence models that can process and comprehend data from multiple modalities or sources. Modalities, in the context of AI, refers to different types of data or information, such as - text, image, audio and video. It is a new AI paradigm which integrates or combines multiple modalities (text, image, audio and video) to offer a cutting-edge performance.

LMMs combines –

- **Natural Language Processing (NLP)**- is a branch of AI that gives the machines the ability to read, comprehend, and derive or interpret meaning from human languages. It can mimic the verbal patterns of human linguistic behaviour. Autocorrect, we use it every day, right? And the most impressive of all, Chat GPT, which is open to the general public. NLP is capable of translating text from one language to another; converting voice data into text data; it can intelligently respond to spoken commands or instructions and can easily summarise large volume of data in real time. In healthcare industry, NLP would be helpful in extracting valuable information from medical texts or patient records, assisting with medical research and diagnosis.

- **Computer Vision-** is a rapidly advancing field of artificial intelligence, that enables machines to achieve human-like perception and understanding. It can perform variety of tasks such as – capturing visual data, pre-processing operations like noise-cancellation, image enhancement, detection of visual primitives to improve data quality for analysis; automating data arrangement through convolutional layers, 3D reconstruction; facial

recognition, object detection and avoidance (enabling driverless cars to steer safely through intersections); or could be utilised in assembly lines to detect defects or inconsistencies in products.

- **Audio processing-** enables LMMs to transcribe and interpret auditory information. It can interpretate semantics of speech inputs, handle dialogue management; generate accurate responses;

Integration of all these AI domains can lead to more sophisticated systems that can interact with human naturally.

How are LMMs different from previous AI models?

The most striking difference is that LMMs are built on more advanced complex modal structure; they are embedded with a diverse range of applications, which allows them to process vast amounts of data beyond text, which in the healthcare sector promises to flag early diagnosis of diseases like cancer, providing with improved clinical decisions, whereas prior models were structured on a single modality structure, which was designed to perform narrow tasks, for e.g. medical imaging, testing or detecting diabetes, and is inflexible in adopting other functions.

Benefits

- Analysis large amount of patient's data including genetic information and medical history.
- Helps in diagnosing diseases with greater accuracy. For example – diagnosis of Alzheimer disease which traditionally relied upon combinations of cognitive assessments and neuroimaging, caried considerable risk of late or incorrect diagnosis, has now been made possible by AI, employed to analyse MRI and PET scans more precisely than was possible with traditional methods.
- AI powered system supports medical imaging, which can help radiologists and pathologists to identify critical cases.
- Generate personalised treatment plans catering unique needs of patients, thereby optimizing therapeutic outcomes and minimizing adverse effects.

- Streamline data collection and administrative tasks such as managing patient's medical records, scheduling appointments and billing process , easing workload of medical professionals, freeing up their time, so they can concentrate more on patient care.

- Reduce overall cost of healthcare organisation

- Natural Language Process (NLP) can assist healthcare professional to extract relevant information from unstructured clinical notes.

- Accelerate drug development, by generating new chemical structure with desired properties which has immense potential to revolutionise pharmaceutical industry, bringing new drugs to the market much faster. AI models can also predict how patients will respond to certain medications, uncovering new therapeutic targets.

Ethical and Potential risks

1. **Privacy Concerns** – LMMs heavily relies on large data-sets to improve, in context of healthcare, it will include confidential and sensitive patient information. Disclosure of patient's health histories to third parties could be dangerous. Unauthorised access or breaches can have severe consequence for patients.

2. **Biases –** LMMs can unintentionally learn and perpetuate bias if the existing training data is not diverse. If there exists a historical bias against certain races and ethnicity, it may be challenging to eliminate such bias embedded in the algorithms. For example, facial recognition technologies have shown higher error rates for individuals with darker skinned tones, which indicates that AI models may not have adequately captured the nuances of different populations, and are underrepresenting certain racial and ethnic groups, which may lead to negative social and legal ramifications.

3. **Adoption and Trust factor –** People may not feel conformable with the idea of machine, potentially making major life and death decisions about their healthcare. This mistrust may hinder the adoption of AI technologies in the healthcare sector, because patients prefer to rely on the interaction with more experienced doctors.

4. **Skill Degradation –** Rapid advancement of AI, and delegation of tasks to machines/ computers in the field of healthcare practice, will eventually undermine physicians

competency as medical professionals. Doctors may feel less confident/ insecure in their abilities to override or reject an algorithm's judgement/ decision.

5. **Unreliable Information/ Data Quality** - google is a great place to find false and untrustworthy information about medical terms, symptoms and consequences. This raises questions of whether or not LMMs developers, who are required to provide evidencebased information to end users, will rely on the information available on the internet.

6. **Information synthesis** – dramatic increase in the amount of medically relevant data generated each year, there is simply too much information to be handled without computational help.

7. **Cybersecurity Risks** – Since LMMs is still in its early stages of development , it is susceptible to viruses or technical failures, that could eventually compromise patient privacy or result in severe damage.

8. **Unemployment –** No job is safe from automation. AI is expected to eliminate and replace wide range of professionals from customer representatives to accountants and creative writers and poets. Reason been high exposure to automation, tasks performed by machines is likely to affect manual work. In the field of healthcare, AI can slightly outperform healthcare professionals in terms of efficiency, accuracy and delivering highquality patient care.

9. **Data Poisoning –** Unintended software bugs and malicious manipulation of the data may tamper patients records, which may compromise accuracy and reliability of the model's capacity to learn patterns and will ultimately impact the predictions made. This could lead to serious repercussions including misdiagnosis and inappropriate treatment.

Responsibility & Liability of Developers

AI developers should aim at ensuring transparency at every step so that the end user can make informed choices about sharing their data. Ongoing operational disclosures – sufficient technical documentation should be available to the government.

Developers must strictly adhere to data protection laws, and avoid collection of data from third

party sources such as data brokers, whose data may be incorrect or biased, or else be held liable for damages in failure to meet the reasonable safety standards.

Developers should have appropriate mechanisms to maintain the robustness of the system, exhibiting high resilience against adversarial attacks or system failures. And establish feedback loops facilitating continuous improvement and refinement.

Responsibility of AI developers also extend towards mitigating the impact of AI on labour market. They must consider wider societal consequences which encompass evaluation of jobcreation, re-skilling and socio-economic disparities.

Issues concerning Liability

Owing to the inherently complex and rapidly evolving nature of AI, it has become challenging to adopt a static regulatory framework addressing its governance, liability, enforcement and infringement related issues. It is difficult to attribute responsibility and liability, when there are multiple stakeholders across the AI value chain, which includes- developers, service providers, regulatory body and the end-users, each having distinct roles and responsibilities in development and deployment of LMMs.

Problem- It is apparent that the algorithms are evolving at a faster pace, operating autonomously, which cannot be controlled. This makes it difficult to manage and impose controls as well as to decide who is liable or at fault, if something goes wrong?. In such situations developers may argue that once LMMs are approved by the regulatory authority, they should no longer be held liable/ accountable for any harm resulting in its development, and that the downstream entities (i.e. providers and deployers) - should bear the liability, whereas downstream entities may blame upstream entities for their poor data selection and algorithm design.

A clear criteria needs to be established, assigning defined roles and obligations between the developers, providers and users. Policymakers must strike a balance between regulatory oversight and accountability to ensure fair compensation to those affected by AI.

Governance

- Development process of LMMs must undergo proper regulatory scrutiny before getting

commercialised.

- Mandatory post-development impact assessment should be done to evaluate the performance of LMMs on clinical endpoints.
- Implement best ethical practices for data collection that prioritize privacy, consent and transparency.
- Incorporate data encryption methods to secure sensitive information.
- Foster collaboration between developers, researchers, professionals and domain experts to ensure that LMMs aligns with the clinical needs and to optimise workflow.
- Prioritize user experience, solicit feedback from healthcare professionals and end-users, to improve upon the usability issues and overall user interface and functionality.

WHO Recommendations

1. WHO recommends developers to consider 'licensing and certifications' in the field of scientific research or medicine, in order to align themselves with clinical relevance and ethical commitments, which will ultimately help them to establish trustworthiness of their product, fostering collaboration with healthcare professionals and leading to better possible solutions in practice.
2. LMMs raises concerns of carbon and water-footprints since they require vast amount of data for training and powerful computational infrastructure, both of which consumes substantial amount of energy. In order to minimise this environmental impact and to promote sustainable innovation, developers must adopt data minimization/ reduction strategies or use energy-efficient hardware or smaller data-sets, that does not consume much of the energy.
3. WHO emphasises on 'Design for value' approach, which calls for participation of all the stakeholders and potential end-users in initial stages of development to ensure informed and best practices.
4. Developers should submit latest research findings and insights via publications and conferences.

Policies and Regulations in India

India has not developed a comprehensive AI-specific legalisation. The Indian Government has catalysed some efforts to harness AI into the healthcare sector. Government of India set up National e-Health Authority (NeHA) in 2015, for overseeing the digitalization of health information/ records to ensure its interoperability across the country. Its primary goal is to develop an integrated healthcare information system in India, building a roadmap, guiding all the stakeholders how to efficiently adopt health informatics standards. It also envisions to develop policies and guidelines for ethical use of AI to meet the clinical standards.

Government of India under the Ministry of Commerce and Industry established AI Task Force in 2017 to kickstart the use of AI across various sectors including healthcare, agriculture, defence and national security. Task Force recommended for creation of robust AI framework to work closely with industry and startups, to foster innovation.

Digital Information Security in Healthcare Act (DISHA), 2018 is one such step aiming to secure the privacy and confidentiality of the patient's data.

Key Provisions:

1. The Act broadly defines 'digital health data' under section 2(e)- which "means electronic record of health-related information relating to physical or mental health, any donation (of body part), information collected while testing or in course of healthcare services.

2. Sec 2(o) defines 'sensitive health-related information' - refers to personal health data, if lost or disclosed could cause substantial harm, inconvenience, violence, embarrassment, or discrimination to an individual, this information includes a person's physical or mental condition, sexual orientation and substance use.

3. The Act affirms that the individual to whom the data relates is the owner of such data. Section 28 confers on the owner of the digital health data, rights over its consent and privacy regarding the collection, storage, and transmission of the data.

    - The right to give, refuse, or withdraw consent for the collection, storage, and transmission of their data.

- They have the right to know which clinical establishment or entities have access to their data and recipients to whom it is shared.
- Regarding the accuracy of the data, the owners can rectify any inaccurate or incomplete data.
- They are required to give explicit permission for each instance of their identifiable data being transmitted or utilized.
- They should be notified every time their data is accessed by a clinical establishment.
- In cases of health emergency, their data may be shared with family members.
- The owner has the right to prevent any transmission or disclosure of sensitive health data that might cause harm or distress.
- They cannot be denied health services if they refuse to consent to data generation, collection, storage, transmission or disclosure. • They can seek compensation in case of breach

4. The Act provides for establishment of National Digital Health Authority and State Electronic Health Authority to ensure privacy of digital health data.
5. The Act stipulates stringent penalty provisions against authorised access and misuse of digital health data.

The Medical Device Rules, 2017 and its amendment in 2020 have expanded the definition of 'medical device' to include software or an accessory intended to be used for a medical purpose.[1]

India lacked a thorough legislation on data protection until the enactment of Digital Personal Data Protection Act, 2023. Before DPDP, India's approach to data protection was fragmented, and lacked enforcement mechanisms to tackle modern data related challenges. This absence of comprehensive law highlighted significant gaps in privacy protection, trust and global

[1] Notification by Ministry of Health and Family Welfare (MoHFW), GOI G.S.R. 102(E), Gazette of India, 2020

compliance. It often led to trust deficit between the consumers and service providers. Users were skeptical about sharing their private information.

Key Features of the Act: -

1. Data processing is restricted to specific legitimate purposes.

2. Data so collected must not be used for any other purpose that is incompatible with the original intent.

3. Individuals are referred to as "Data Principal" under section 2 (j), are granted certain rights, including right to access, correct and erase their data once its purpose has been met.

4. Act imposes strict guidelines and obligations on Data Fiduciaries to obtain explicit consent from Data Principals and to make reasonable efforts to ensure accuracy and completeness of data.

5. The Act establishes grievance redressal mechanism and Data Protection Board to oversee regulation and compliances.

6. Act imposes stringent penalties for non-compliance.

7. Government agencies are exempted from the application of provision of Act in the interest of specified grounds such as security of the state, public order and prevention of offences.

Fast paced evolution of AI calls for re-evaluation of IP laws. Complex issues relating to inventorship as to whether AI can be considered an inventor? , novelty, non-obviousness of AI generated inventions, reluctancy of developers to make comprehensive disclosures, scope of patent claims, accountability of developers and ethical consideration needs to be addressed to better accommodate AI innovations.

Current AI technologies used in healthcare

Viz AI software, is a clinically certified AI technology which can detect large-vessel occlusion strokes (LVOs) using computed tomography imaging and alerts healthcare professionals to

make prompt decisions. Professionals can access these vital images directly on their phones, accelerating diagnoses and significantly/ greatly reducing the time required to initiate lifesaving actions.[2]

In the sphere of healthcare management, Microsoft has recently unveiled an advanced AIpowered analytic platform/ application called Microsoft Fabric to assist healthcare organizations in realizing the full potential of their data. It is designed to unify the unstructured data, allowing/ enabling healthcare professionals to incorporate data from various sources including electronic health records, medical imaging, lab systems, medical devices and claims systems and extract insights from it, by using a common interface. It provides organisations with a safe and controlled means to access, analyse and visualize data-driven insights across their organisation. It has been reviewed by organisations like Northwestern Medicine, Arthur Health and SingHealth.

In India

SigTuple, an Indian-based AI startup company, has developed an in-vitro diagnostic device, Ai 100, a groundbreaking AI-powered digital microscopy solution that aims to automate the microscopic examination of urine and blood samples, extracting and classifying every cell into digital imaging, reducing the chances of errors, delays, or misdiagnosis. This automation has significantly enhanced the efficiency of pathologists and eased the cumbersome task of manually reviewing large volumes of samples. SigTuple has already deployed its device across three states: Punjab, Maharashtra, and Himachal Pradesh.

Niramai Health Analytix is a health tech company that has developed a novel method of detecting early-stage breast cancer using Thermalytix, i.e., a non-invasive, radiation-free, highly accurate screening tool that uses AI to analyse the captured the temperature variation and distribution through a high-resolution thermal sensing device.

Can AI replace healthcare professionals?

Despite the great potential that AI promises to offer, it can hardly replace the years of education and expertise that a medical professional possess. AI lacks the ability to communicate and

[2] Ameer E. Hassan, Victor M. Ringheanu, Laurie Preston et al., "Artificial Intelligence- Parallel Stroke Workflow Rool Improves Reperfusion Rates and Door-In to Puncture Interval," American Heart Association, Vol 2, Issue 5, (2022)

extend emotional support to patients. Though AI can assist in diagnosis and treatment recommendations, the final call still rests on the doctor to make, as automated captured observation cannot surpass a clinical judgement. Human intelligence and intuition will continue to be important in making complex medical decisions.

Conclusion

With the increasing advancement of Generative artificial intelligence (AI) and the burgeoning investment in new AI models – (LMMs), they could have the potential to revolutionize the healthcare sector and many other industries in years to come. It has also raised significant ethical and legal implications, which requires a careful examination. It has become highly crucial for governments to keep up the pace with the ongoing developments in AI technology. It is imperative to develop legal frameworks that could strike balance between innovation, protection and ethical responsibility surrounding AI and could mitigate its potential risks. Another significant concern is "whether India is ready for adoption of generative AI into its healthcare system?" It will not only be challenging to draft a comprehensive legislation but also to navigate cultural perspectives and social attitudes that may impede acceptance of AI.