Innovations

Liability and Accountability of AI Used in Neuroscience

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Abstract

Artificial intelligence (AI) has played a significant role in the development of neuroscience by aiding in the interpretation of sensitive neuroscientific data from the human brain. This paper initially elaborates on how these tools are potentially paving way for earlier and more accurate detection of brain disorders and how it helps in acquiring a comprehensive grasp of the intricacies of human brain. But what is more important is the convergence of AI and neuroscience to do this brain intervention in an unbiased way and to make sure the sensitive neurological data is not put into use for anything other than in a clinical context. The increase in the availability of such data raises the chance of escape of such uniquely sensitive information into unscrupulous hands that might lead to high ethical concerns. Neurotechnological mindreading, whether voluntary or involuntary, has a potential risk of violation of mental privacy. This paper aims to put an end to the debate of increasing regulations to deal with these concerns, in a way that it does not hamper unlocking new frontiers in cognitive science.

1. Introduction

Artificial Intelligence is a bifurcation under the branch of computer science that aims to create machines that are quick-witted and brilliant that can perform tasks that typically require human intelligence. The development of AI is increasing by the day, and it is widely used in various fields like healthcare, finance, transportation, and more. In healthcare, AI has been used to diagnose diseases[1], predict the likelihood of a patient developing a disease[2], used to make personalized treatment plans[3], used for drug discoveries[4]etc. Healthcare encompasses a wide spectrum of medical treatments addressing every facet of human body, yet an intriguing correlation emerges when we examine the intersection of medicine and AI. Notably, the field of neuroscience stands out as an area intricately intertwined with the evolution of artificial intelligence, playing a pertinent role in its historical development.

There are two ways that neuroscience inspires humans to design AI systems. **One-** that emulates human intelligence, and **two**- to build neural networks that mimic brain structure. The AI advancements are taking the media by storm by performing impressive tasks and solve problems better than us, achieving performance that rivals or even exceeds human capability. The sensory signals, i.e., the visual and auditory nerves arrive at the cortex of the brain. It contains the Ventral (What function), Dorsal (Where function) and Limbic (Emotional function). These are the Object

recognition, Spatial Recognition and the Gut feelings of the human body respectively. Furthermore, much like the intricate network of neurons in the human brain, Artificial Neural Networks (ANNs) consist of interconnected units operating in parallel.[5] This concept led to the development of Multi-Layer Perceptron (MLP), which, resembling the layered structure of the human brain, operates in hierarchical layers. Additionally, the human brain's working memory mechanism served as a source of inspiration for scientists in the creation of recurrent neural networks (RNNs)[6].

2. Ai in Neuroscience

Neuroscience is the systematic examination of the brain's structure andcognitive functions of the brain. Neuroscience and AI are mutually interrelated. These two fields immensely help each other in their advancements. The biological neural network has led to the realization of complex deep neural network architectures that are used in our brain, which is in turn used to develop versatile applications, such as text processing, speech recognition, object detection,[7] etc.

2.1 Reinforcement Learning (Rl)

The exploration of reinforcement learning in both human and animal behaviour has served as a catalyst for computer scientists to devise algorithms tailored for artificial systems. This form of learning proves instrumental in the development of complex applications, including but not limited to robot-assisted surgery, autonomous vehicles, and gaming applications. With its ability to intelligently analyse complex data and extract hidden patterns, AI fits as a perfect choice for analysing neuroscience data that are very complex.[8]

In reinforcement learning, the agent autonomously learns to replicate specific tasks by responding to rewards while refraining from others due to associated penalties.[9] This autonomous learning occurs through continuous feedback, devoid of guidance, adopting a trial-and-error framework.[10]

For example, dogs were trained to have food after hearing a bell which is referred to as Pavlovian conditioning. The key point is that the organisms start learning by the error-called prediction error, between the expected outcome and the actual outcome (i.e., getting food at the ring of bell and whether the dog really received food at the ring of the bell).[11]In the context of learning, organisms acquire knowledge through experiential trial and error, aiming to minimize mistakes and enhance their understanding.

2.2 Ai's Role in Diagonising/ Treating Various Neurological Disorders.

2.2.1 AI in neuro-imaging

Artificial intelligence (AI) proves instrumental in the analysis of neuro-imaging data, offering a means to alleviate the workload on radiologists. For instance, amid the COVID-19 pandemic, AI systems were deployed to automatically identify the presence of the virus, addressing the surge in infection cases.[12]

Moreover, the accuracy of AI-supported analysis of CT scan images matches that of a skilled radiologist.[13] Neuroscience provides insights into the specific areas of the human nervous system susceptible to diseases, disorders, and injuries, facilitating more effective treatment strategies.[14]

2.2.2 AI in Tumours and Neurosurgical OT

The optimal approach for autonomous robotic surgery has been recognized in the ablation of brain tumours. The deployment of AI faces challenges in tasks such as knot tying during suturing.[15] The variability in the shape and precise location of motor cortical areas among individuals presents a challenge, and accurate knowledge of these locations is imperative for planning neurosurgical procedures. Utilizing machine learning algorithms in conjunction with extracting pertinent features from MRI images and MR spectroscopy holds the potential to supplant traditional invasive methods in tumour classification.[16]

2.2.3 AI in Seizure disorders

There is now a machine learning methodology for forecasting the results of epilepsy surgery, utilizing supervised classification and data mining. The prediction of outcomes, relying on specific clinical and neuropsychological features, achieves an accuracy rate of nearly 90%. [17][18]The application of advanced artificial intelligence techniques in tandem with pre-processing, involving filtering and artefact removal, enables automatic seizure detection using scalp electroencephalogram (EEG).[19]

2.2.4 AI in Headaches and facial pain

Artificial intelligence is employed in the identification of migraines. A four-layer XGBoost classifier[20] was utilized to examine and categorize self-reported data from individuals, distinguishing between various headache types such as tension-type headache (TTH), trigeminal autonomic cephalalgia (TAC), migraine, epicranial, and thunderclap headaches.[21]

2.2.5 AI in Neuro-Traumatology

Researchers created computer programs to forecast the chances of motorcycle riders surviving after an accident. They employed Artificial Neural Networks (ANN) to foresee outcomes after head injuries. The ANN showed better results than traditional models and even outperformed human doctors in various assessments.[22]

They believe that this modelling approach could become a valuable tool to help doctors make decisions.[23] Additionally, they utilized fuzzy logic and computer algorithms to examine traumatic brain injuries.[24]

2.2.6 AI in Neurorehabilitation

An emerging generation of brain–machine interfaces, enhanced by AI, is empowering individuals with disabilities to interact with their surroundings. Through AI-facilitated sensory substitution, the need for functioning eyes and hands becomes obsolete. This innovation enables individuals to perceive and experience the world directly through their brains. Consequently, those with significant motor disabilities can leverage brain signals to control devices such as robotic arms or neural prostheses.[25]

3. Ways in Which the Employed Ai Could Go Wrong.

3.1privacy

Considerable personal information can be extracted from individuals' data trails. For instance, a study conducted at the Massachusetts Institute of Technology in 2015 revealed that a detailed analysis of motor behaviour, observed through keyboard typing patterns on personal devices, could facilitate the early diagnosis of Parkinson's disease.[26] Similarly, a 2017 study proposed that mobility patterns, derived from individuals carrying smartphones during their daily activities, could serve as indicators for early cognitive impairment associated with Alzheimer's disease.[27]

The information contained within MRI scans is highly sensitive, and any unauthorized access to this data constitutes a breach of mental privacy. In a conducted experiment, participants were regularly exposed to a collection of 1000 images. Subsequently, MRI scans were performed while instructing participants to mentally envision specific images from the set. Through the utilization of AI to analyze and interpret the MRI data, the technology successfully reconstructed images closely resembling those envisioned by the individuals. This compelling evidence underscores the potential for the deciphering of thoughts, raising concerns about the profound implications for mental privacy if such capabilities are exploited. Individuals may experience apprehension regarding the security of their private thoughts.

The integration of neural devices with the Internet introduces the potential for external entities, such as hackers, corporations, or government agencies, to monitor or even manipulate an individual's mental experiences.

3.2 Ai's Algorithmic Bias

The rise of artificial intelligence (AI) has led to the utilization of aggregated healthcare data for constructing sophisticated models that automate the diagnostic process.

Nonetheless, a significant issue with machine learning algorithms is their tendency to acquire unintended biases from the training data. In the healthcare sector, this can result in inaccurate diagnoses and inappropriate care suggestion. Recently, several stories involving AI algorithmic bias have emerged, where there is a tendency of AI to favour certain groups based on gender, age, and race.
Algorithmic bias in artificial intelligence within the medical domain has the potential to result in life-threatening consequences.

Algorithmic bias can arise from the input data, particularly when it is sourced from diverse age groups, leading to potential inaccuracies in its applicability. Ethnicity-based bias is another concern; for example, if an AI for diagnosing a specific disease is trained using a dataset predominantly composed of individuals from a particular ethnic group in Asia, deploying this AI in the US may yield inaccurate results due to the inherent bias in the training data.

Research shows clinicians often provided different care to white patients and patients of colour. Those differences in how patients are treated get immortalized in data, which are then used to train algorithms[28]

A landmark 2019 study published in the journal Science found that an algorithm used to predict health care needs for more than 100 million people was biased against Black patients.[29]

3.3 Socioeconomic Inequality

Primary care, while often the initial point of contact for socioeconomically disadvantaged populations with health or social needs, can be inaccessible to certain groups, thereby exacerbating health inequities (HI). Despite relatively equal theoretical access to primary care and clinical management across different groups, health outcomes still vary. More affluent patients of majority ethnicity tend to have better health outcomes.[30]

This disparity is a result of external factors that lead to poorer baseline health status and differences in the effectiveness of the care provided. Factors such as adherence to treatment and advice, economic barriers, and others, collectively known as social determinants of health (SDH), play a significant role.[31]

As the need for care increases with deprivation, more primary care resources are required to provide adequate care in disadvantaged areas and communities.[32] Therefore, the role of primary care in reducing HI is not limited to addressing inequities within primary care itself. It also involves leveraging its unique societal position to mitigate underlying differences in health outcomes.[33]

This is mirrored in how Artificial Intelligence (AI) could influence inequities both within and through primary care.

3.4 Uncontrollable Self-Aware Ai

There is a growing concern about the potential for rapid advancements in artificial intelligence (AI) leading to sentience, posing the risk of AI surpassing human controland potentially behaving in a harmful manner. Reports have emerged, including one from a former Google engineer, claiming that the AI chatbotLaMDA[34] demonstrated signs of sentience by engaging in conversations akin to human interactions. As AI progresses toward achieving artificial general intelligence and, eventually, artificial superintelligence, calls to halt these developments entirely are on the rise

3.5 Lack of Transparency

In areas like healthcare, the requirements of transparency are crucial since the decisions directly affect people's lives. A significant challenge in the field of Artificial Intelligence (AI) is the lack of transparency, often referred to as the "black-box" problem.[35] The opacity of algorithmic decision-making processes is a concern in and of itself, but it becomes particularly critical in healthcare, where people's lives and health are at risk.

In numerous instances, and especially when things go awry, it is imperative to understand the cause in order to prevent similar occurrences in the future. This necessitates tracing how the algorithmic input was transformed into a specific output and identifying the contributing factors. However, this level of traceability is not always feasible with AI, adding to the complexity of the issue.

3.6 Catastrophic Forgetting

Scientists are examining a substantial challenge in machine learning referred to as "catastrophic forgetting," which is the phenomenon of AI systems forgetting information from prior tasks when learning new ones. The study indicates that, similar to humans, AI retains information more effectively when confronted with diverse tasks rather than those that closely resemble each other. Findings from this research may contribute to the enhancement of continuous learning in AI systems, improving their ability to emulate human learning processes and elevate overall performance.

4. Liability of Ai If It Causes Damage, Harm, or Injury While Employed in Neuroscientific Procedures.

The degree of autonomy possessed by the AI system, whether it operates independently or under human supervision, significantly influences the attribution of liability. Informed consent processes emerge as a crucial facet, demanding scrutiny to ensure participants are adequately informed about AI's involvement and associated risks. Aligning with established standards of care within neuroscientific practices is extremely important.

4.1 Liability of Hospitals Who Employ Such Ais

Beyond the direct interaction between physicians/practitioners and patients, health systems, hospitals, and practices bear a responsibility for patient well-being. The concept of negligent credentialing posits that a health system or physician group may be held accountable for **failing** to adequately assess a physician who deviates from **established standards of care**.[36] Legal perspectives suggest a **parallel liability** for health systems that inadequately vet an AI/ML system before its clinical implementation.[37] Health systems are already obligated to ensure safe equipment, facilities, and proper training for their employees in utilizing provided equipment.[3839] Consequently, a claim against a health system could be grounded in evidence of deficient implementation, training, or vetting of an AI/ML system.

Liability extends to health systems, physician groups, and physician-employers for the actions of their employees or affiliates.[40]**Vicarious liability**, distinct from other forms of negligence, entails being held accountable for someone else's actions. In negligent credentialing, the hospital itself is deemed negligent, while vicarious liability holds the physician as negligent, with the hospital assuming responsibility. The rationale behind vicarious liability includes the equitable distribution of costs for injuries among hospitals and groups to compensate victims.[41]
Establishing vicarious liability is most straightforward for an employee. For instance, a hospital could face legal action for the actions of its physician employees in cases involving the unsafe deployment of an AI/ML algorithm.[42]

To demonstrate the potential application of vicarious liability in a scenario involving AI/ML clinical tools, consider a hospital procuring a cancer prediction algorithm for use in the emergency department (ED) or intensive care unit (ICU).[43]In such a case, a court might attribute vicarious liability to the hospital for the negligence of an emergency medicine physician who misinterprets the output from the AI/ML system. The justification for this legal decision lies in the fact that patients at risk for cancer, seeking care in the ED or admitted to the ICU, typically do not choose their individual ED physician; rather, these physicians are closely associated with the hospital.[44]

As healthcare grapples with the dynamic landscape of AI integration, hospitals are urged to implement a comprehensive strategy encompassing legal compliance, ethical considerations, and an unwavering commitment to safeguarding patient well-being.

4.2 Liability of Physicians or Medical Practitioners Who Use Such Ai

Medical malpractice is contingent upon an injury caused by a physician deviating from the established standard of care, determined by the collective practices of their professional peers in accordance with local or national standards. Even when a physician relies in good faith on an AI/ML system for recommendations, they may still be held liable if their **actions fall below the standard of care**, meeting the criteria for medical malpractice. Physicians are duty-bound to

independently apply the standard of care in their field, irrespective of the output from an AI/ML algorithm.[45] Although legal precedents regarding physician use of AI/ML are not fully developed, existing cases suggest that physicians bear responsibility for errors arising from AI/ML output.

Physicians may incur **liability based on their degree of control over the AI's functionality** or their ability to modify the algorithm. This control can be categorized as translucent if they have influence or opaque if control is lacking. Emphasizing informed consent is crucial, necessitating transparent communication by physicians about the role of AI in patient care to mitigate potential liability arising from patient dissatisfaction or unforeseen consequences.

The responsibility for adequate training and maintaining proficiency in AI use falls squarely on physicians, and deficiencies in training may contribute to errors, potentially leading to liability. Addressing data security and privacy, documenting AI use, and engaging in continuous professional development are essential components of physicians' responsibility to mitigate potential liabilities associated with the integration of AI into medical practice.

Navigating this evolving landscape requires physicians to strike a balance between leveraging the benefits of AI and upholding their professional duties to ensure patient safety, informed consent, and adherence to ethical standards.

4.3 Liability of Creators

The focal point shifts to manufacturer liability, questioning the accountability of AI creators in instances of harm during neuroscientific procedures and the applicability of traditional product liability laws to AI systems, particularly in the realm of medical AI/ML products.

The legal landscape concerning **products liability** for medical AI/ML products remains unsettled. On one hand, developers of medical algorithms, akin to manufacturers of tangible products, could potentially be held liable for injuries resulting from issues such as poor design, failure to provide adequate warnings about risks, or manufacturing defects.[46]In cases where an AI/ML system utilized by healthcare practitioners leads to patient injury, liability for a design defect may revolve around concerns related to the process of inputting data, software code, or output display.

Conversely, patients encountering harm from medical AI/ML may face challenges in pursuing claims. In many jurisdictions, patients might be required to demonstrate the existence of a viable and potentially cost-effective alternative design.[47] Furthermore, the intangible nature of software, distinct from traditional items or combinations of software and hardware, complicates its integration into the conventional liability framework.[48] Courts and legislatures, motivated by a desire to foster innovation, have been hesitant to extend liability to software developers.[49]

As a consequence, the legal precedents in healthcare software products liability exhibit inconsistency and at times lack clarity. For example, a court dismissed a patient's claims against a surgical robot manufacturer on the grounds that the patient couldn't establish a direct link between the robot's error messages and failure and his specific injuries. In contrast, another court, with relatively limited discussion, approved a jury award against a developer whose software caused a catheter to continuously ablate heart tissue.[50] This legal ambiguity may lead injured patients to pursue avenues of redress against parties other than software developers, such as clinicians and health systems.

5. Regulatory Frameworks Available to Govern Ai in India.

India currently lacks a dedicated regulatory framework specifically designed to oversee the operations of artificial intelligence (AI) and impose penalties for any adverse consequences that may arise. Although comprehensive, AI-specific regulations are still in the process of evolution, several initiatives and guidelines have been established to steer the responsible development and deployment of AI technologies within the country.

5.1 Principles Responsible for Ai

Formulated in February 2021, the Principles for Responsible AI constitute the initial segment of an approach document crafted by NITI Aayog as a continuation of the national strategy.It serves as India's roadmap for the creation of an ethical, responsible AI ecosystem across sectors.[51]

5.2 Operationalising Principles Responsible for Ai

In August 2021, NITI Aayog published the follow-up segment of its approach document, focusing on putting into practice the principles established from the ethical considerations in AI governance explored in the initial part. .[52] The document underscores the importance of regulatory and policy interventions, capacity development, and promoting ethics by design to instill a responsible mindset within the private sector regarding AI.

5.3 Draft National Data Governance Framework Policy

On 26 May 2022, the Ministry of Electronics and Information Technology released the draft National Data Governance Framework Policy (NDGFP).[53] The primary objective of this policy is to modernise and revamp government data collection and management procedures and foster an ecosystem for AI and data-driven research and start-ups in India.[54]

5.4 Draft Indian Standard: It – Ai Guidance on Risk Management

The Bureau of Indian Standards (BIS) has a committee on AI that is proposing draft Indian Standards equivalent to ISO Standards.[55] There are currently three draft Indian standards related to AI that correspond to International Standards, with the latest one focusing on Guidance on Risk Management and having recently been open for public consultation.[56]

5.5 Recommendations on Leveraging Ai and Big Data in Telecommunication Sector

After a consultation in the latter half of 2022, the Telecom Regulatory Authority of India (TRAI) released its recommendations on "Leveraging Artificial Intelligence and Big Data in the Telecommunication Sector" on 20 July 2023.[57] The recommendation paper calls for the immediate establishment of a common regulatory framework covering AI across all sectors i.e., the Artificial Intelligence and Data Authority of India (AIDAI). The central responsibility of AIDAI would involve formulating regulations and guidelines to ensure the responsible application of AI across diverse sectors.

5.6 Global Partnership On Ai [GPAI]

India has become a member of the Global Partnership on Artificial Intelligence (GPAI), joining other prominent economies like
The GPAI is a global initiative engaging various stakeholders, with its goal being the guidance of ethical advancement and application of AI. It underscores principles such as human rights, inclusion, diversity, innovation, and economic growth.

5.7 Other Legislations

Out of several legislations present to govern disputes arising out of the Internet or disputes arising in the healthcare sector, there are certain ones that deal with matters intersecting the both. Some of them are:

a. The Information Technology (IT) Act, 2000[58]

While the Information Technology Act does not explicitly reference artificial intelligence (AI), its legal framework for electronic governance encompasses elements such as digital signatures and electronic records. Given the inherently digital nature of AI, one could reasonably interpret that it falls within the ambit of this Act to a certain extent[59].

b. **The IT Data Protection Rules, 2011[60]**

These rules, notified under the IT Act, structured framework for intermediaries—entities engaged in the storage or transmission of data on behalf of others—and digital media. While they do not explicitly mention AI, they could apply to AI systems that function as intermediaries or are involved in digital media.

c. **IT Intermediary Guidelines Rules, 2011[61]**

These rules, also under the IT Act, deal with the protection of "sensitive personal data or information"[62]. They could apply to AI systems that process such data. However, they do not specifically address AI.

d. Drugs and Cosmetics Act and Rules, 1945[63]

Under Section 3(b) of the Act, software used for diagnosis or treatment is included, thereby covering AI as well[64]. However, the Act does not provide detailed regulations for AI.

e. Medical Device Rules, 2017[65]

These rules recognize 'software' as a medical device, thereby bringing AI within their ambit, especially if the AI is used in healthcare applications[66].

5 Regulatory Frameworks Available to Govern Ai Globally.

The European Commission has introduced the Artificial Intelligence Act, a proposed regulation aiming to establish a unified regulatory and legal framework for artificial intelligence within the European Union. By doing so, Europe seeks to position itself as a global centre for reliable artificial intelligence**.** The Act is designed to safeguard the safety and fundamental rights of individuals and businesses**,** while simultaneously promoting AI adoption, investment, and innovation across the EU.[67]

The proposals identify and categorize four levels of AI risk: unacceptable risk, high risk, limited risk and minimal risk.[68]Healthcare applications of artificial intelligence typically belong to the high-risk category and must satisfy specific criteria to obtain regulatory approval:

1. Adequate risk assessment and mitigation systems
2. High quality of the datasets feeding the system to reduce risks and discriminatory outcomes
3. Recording actions to guarantee the traceability of outcomes.
4. Detailed documentation providing all information necessary on the system and its purpose, for authorities to assess its compliance
5. Providing the user with transparent and sufficient information.
6. Appropriate human oversight measures to reduce risk
7. A high degree of resilience, security, and precision.

The European Commission's proposed Artificial Intelligence Act outlines the role of an independent notified body in ensuring AI products adhere to general requirements. These

requirements include specifying the AI's intended purpose, ensuring accuracy, and assessing the reliability and representativeness of training data. The proposed regulation strikes a balance between ethics, transparency, and the imperative to foster innovation. To achieve this, anonymized, pseudonymized, or encrypted patient data would be used, allowing AI applications access to validated information while safeguarding patient privacy.[69]

6 Regulatory Frameworks Adopted Based on the Eu's Ai Act

7.1 FDA's SaMD

The U.S. Food and Drug Administration (FDA) have introduced the Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan**.** This plan, released in January 2021, outlines a comprehensive approach to enhance the FDA's oversight of AI/ML-based medical software. The primary goal is to ensure both safety and effectiveness while harnessing the iterative potential of AI and machine learning in medical devices. By embracing this framework, the FDA aims to strike a balance between innovation and patient well-being.[70]

The action plan outlines five key areas of emphasis, each accompanied by specific measures the FDA plans to implement:

1. Enhancing the proposed regulatory framework, which includes issuing draft guidance on a pre-established change control plan for software that learns over time.
2. Assisting in the cultivation of good practices for machine learning to assess and enhance machine learning algorithms.Fostering a patient-centered approach, including device transparency to users
3. Developing methods to evaluate and improve machine learning algorithms
4. Advancing real-world performance monitoring pilots

Although not as extensive as the European Commission's proposals, the FDA's action plan aligns with key principles central to AI regulation. Arguably, one of the crucial areas to concentrate on involves mitigating the potential for inherent bias in AI.

Guidelines by IMCoR

The Indian Medical Council of Research is trying to match the requirements of the EU's AI Act by providing Ethical Principles for AI in Healthcare, Guiding Principles for Stakeholders involved in development, validation and deployment, Ethical Review Procedures in Medical AI and Informed Consent Process, Governance of AI Technology use for Healthcare and Research in its Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare.[71]

While existing frameworks provide some guidance, they fall short in several critical areas. The current regulations in India miss adaptability and they often struggle to keep pace with the dynamic AI landscape. The existing frameworks lack comprehensive guidelines for ensuring fairness, transparency, and accountability in AI development and deployment. High-risk AI applications, such as healthcare diagnostics which is the primary objective of our research, require specialized oversight. The current frameworks struggle to adequately assess and manage these risks. Striking a balance between regulation and innovation is crucial. While we need safeguards, overly restrictive frameworks may stifle creativity and hinder AI progress. Thus, the policymakers must urgently collaborate to design a forward-looking legislative framework that fosters innovation, protects fundamental rights, and ensures the responsible development and

deployment of AI technologies. Only through such concerted efforts can we harness AI's potential while safeguarding societal well-being.

7 Suggestive Ways to Deal with the Liability

The conventional liability system serves as an incentive for practitioners and stakeholders to invest in activities that enhance care and promote the development of safer products.[7273] The specific allocation of liability varies based on factors such as specialty, practice type, locality, and time. Within the traditional liability framework, physicians face mixed signals regarding how the integration of clinical AI/ML systems may impact their liability. On one hand, existing liability structures may motivate physicians to embrace AI/ML to enhance diagnosis or prediction, thereby reducing the risk of misdiagnoses in clinical care. On the other hand, physicians might hesitate to adopt opaque AI/ML systems that could expose them to liability in the event of injuries.[74]

Proposed Model 1:

The suggested model does not aim to represent empirical liability, which is contingent on various factors such as specialty, practice type, and locality. Instead, it proposes an arbitrary division of liability, allowing stakeholders to engage in contractual agreements for the transfer and redistribution of liability. These agreements may involve indemnification, where one party assumes some or all of another party's liability, or insurance, which spreads risk among policyholders.[75] Additionally, indemnification agreements can be insured, although this is not explicitly depicted.

Proposed Model 2:

In this model, a legislature has the option to partially or fully exempt AI/ML from the traditional liability system, with the government assuming some or all of the associated risk. These systems often rely on taxes or fees imposed on relevant stakeholders. It is important to note that these modifications do not operate in isolation. For example, if a legislature enacts a program to shield stakeholders from the majority of liability risk, as suggested in Model 2, stakeholders may still opt to purchase insurance to cover their residual risk, similar to the approach outlined in Model 1.[76]

The legislative exemption process can be facilitated through the establishment of specialized adjudication systems. While implementing such changes poses challenges as they necessitate coordinated political efforts, there are existing examples of this approach. For instance, Florida and Virginia have instituted neonatal injury compensation programs that gather revenue from a broad base, offering relief to specific groups, streamlining adjudication processes, and compensating more individuals than traditional litigation.[77] An illustration of this is the Florida Birth-Related Neurological Injury Compensation Program, which levies fees on physicians and taxes each birth to create a specialized adjudication system.[78]This system aims to reduce practice costs for obstetricians while compensating patients for injuries.[79] However, it's worth noting that such specialized adjudication systems may yield unintended consequences, as seen in Florida where jurisdictional intricacies have led to duplicative litigation or placed liability on hospitals for physician errors.[80]

These specialized adjudication systems have the potential to develop the expertise needed to address AI/ML liability among stakeholders. Alternatively, legislatures could institute a compensation program that operates on a no-fault basis, disregarding liability considerations. Such programs might assess fees on stakeholders, such as a fee per patient affected by an algorithm or a fee on physicians/practitioners. In the context of black-box scenarios, these no-

fault systems offer the advantage of sidestepping the challenging question of precisely identifying the cause of an error. Policymakers could tailor these programs based on the goal of promoting AI/ML, ensuring safety through manageable personal liability, allocating responsibility among stakeholders, and achieving other public policy objectives.[81]The feasibility of these liability modifications in a political landscape where tort reform is contentious remains an open question.

8 Conclusion

A nuanced approach to liability in AI-driven neuroscience research is imperative, especially for policymakers and researchers who advocate for a balanced integration of legal, ethical, and technological considerations. Striking the right balance between technological advancements and legal accountability is of utmost importance. The analysis outlined above proposes specific measures to hold various entities accountable in different scenarios, highlighting the urgent need for structured legislation to govern AI and associated disputes, thereby bringing order to the current state of uncertainty.

Furthermore, the research underscores the significance of informed consent, transparency, and the protection of participant autonomy within the realm of AI-driven studies in neuroscience. With the continuous advancement of AI, the issue of liability in neuroscience research remains dynamic, necessitating collaborative efforts among policymakers, researchers, and legal experts to establish comprehensive frameworks that align innovation with ethical and legal obligations.

AI/ML systems carry the potential to significantly revolutionize clinical care. While the legal system tends to progress at a slower rate, it cannot remain stagnant in the face of this innovation. The dynamic nature of AI/ML and the associated liability issues present a chance to construct a fresh liability model that aligns with medical advancements, guiding stakeholders on optimal responses to disruptive innovation. Achieving the full advantages of AI/ML requires the legal system to strike a balance in liability, fostering innovation, ensuring safety, and facilitating the swift adoption of these impactful algorithms.

To summarize, this research makes a substantial contribution to the ongoing discourse surrounding the ethical and legal aspects of AI in neuroscience research. It not only lays the groundwork for further exploration but also provides practical recommendations for navigating the evolving landscape of AI-related liabilities in this field.

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