Brainomix AI-powered Imaging tool, e-Stroke, for diagnosing stroke: An Ethical Review

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Abstract

The integration of Artificial intelligence systems into our daily lives has seen a rapid growth, but the unimaginable happened when these AI systems were introduced into healthcare. However, this fast-paced growth and innovation could mean that ethical boundaries are crossed, privacy policies are breached, and fundamental rights are neglected. As a result of this expansion in AI technologies, there is an urgent need to address, assess, and evaluate AI projects in terms of ethical adherence and risks, and implement sanctions against any form of misconduct.

This report aims to critically evaluate the responsible delivery of the Brainomix e-Stroke system through a series of ethical structures and frameworks. To achieve this, the e-Stroke system has been subjected to some ethical landscapes: the **SUM Values**, **FAST Track principles**, and the **PBG Framework**. This analysis passed through every phase of the development lifecycle. It was observed that the design and implementation process are not as transparent and open to public scrutiny as it should especially regarding ethical conduct even after several attempts to reach out which begs a myriad of questions.

This report strives to ask these difficult but necessary questions and offer some recommendations where necessary.

keywords: *Ethical, Framework, Healthcare, Implementation, lifecycle.*

Contents

1 Introduction

According to *C. Lu et al. 2020*, the field of machine learning **ML** has completely revolutionized healthcare by incorporating deep learning methods such computer vision, large language models and, neural networks. Although, many lives have been saved, and many more will, the relevance of ethical conduct and data privacy during data collection all through to the final stage of the project cannot be under-emphasized. In more recent years, there has been a focus on patient data collection that may directly interface with the clinician to guide further management.

There has been a significant growth in the use of AI for research and development in the medical sector but the ethical challenges faced have called for a holistic and robust government intervention. Firm structures must be put in place to address these concerns. Ethical challenges in the collection and processing of personal data, automation of tasks, and reliance for medical diagnosis have been noticed in the use of AI technologies in healthcare. If proper ethical guidelines and structures that can accommodate a robust architecture are not in place, we risk severe ethical and legal consequences in the coming years.

The Brainomix e-Stroke system is an advanced AI-powered technology specifically designed for the rapid and accurate assessment of stroke patients. This innovative system utilizes sophisticated algorithms to analyze neuroimaging data, including computed tomography **(CT)** and magnetic resonance imaging **(MRI)** scans, enabling healthcare professionals to make swift and well-informed decisions in the diagnosis and treatment of stroke. The purpose of this report is to assess the ethical dimensions of the e-Stroke system using the SUM values, FAST Track Principles, and the PBG Framework across the development lifecycle of the AI project.

This report has been structured in a concise yet detailed manner. The first section gives an in-depth analysis of the technical components and functionalities of the AI-driven e-Stroke system. The second section gives a critical study of the e-Stroke system using the SUM Values, FAST Track Principles, and the PBG Framework across the entirety of the development lifecycle. The third and last sections discuss some ethical implications and recommendations respectively.

2 Background

Stroke is an acute cerebrovascular disease. According to the National Institutes of Health (**NIH**), it is believed to be the second main cause of disability and death in the world. Its effect is a global substantial financial burden of about 34 billion dollars per year says *Cui et al. 2022*. According to a research by *Aguiar de Sousa et al. 2019*, more than 85,000 patients are admitted annually to health centres as a result of new acute stroke, and this number is expected to increase by 44% by 2035 says *Stevens et al. n.d.*. There are two main categories of stroke: Hemorrhagic stroke and Ischemic stroke and the ability to differentiate between these two can be a deciding factor if a person will live or die as getting this right helps in determining the appropriate treatment plan for each patient.

Time is of absolute importance. "The faster the diagnosis is made, and the appropriate therapy is initiated, the better the outcome of patients", *Mokli et al. 2019*. Certainly, artificial intelligence **(AI)** has the ability to detect acute strokes, a crucial achievement in facilitating timely treatment and minimizing the associated health risks. While traditional imaging techniques like Computed Tomography **(CT)** and Magnetic Resonance Imaging **(MRI)** can also detect strokes, their processes are often time-consuming and relatively less accurate when compared with AI. AI algorithms are specifically designed to swiftly process and interpret data, making them well-suited for the rapid decision-making demands involved in managing major vessel occlusive strokes. Leveraging the early insights from CT and MRI scans, AI can effectively aid in the identification of various stroke types, including Ischemic and Hemorrhagic strokes. The synergy between artificial intelligence and deep learning algorithms has enabled clinicians make faster analysis of a patient's brain scan and also get the results quicker.

The introduction of the Brainomix e-Stroke system has marked a significant accomplishment in stroke management. It capitalizes on a state-of-the-art AI technology system to accelerate and enrich the diagnosis and treatment of stroke patients. By harnessing the proficiencies of AI algorithms, the e-Stroke system empowers healthcare practitioners to swiftly make well-informed decisions, thereby facilitating the timely application of suitable treatments like thrombolytic therapy and endovascular procedures within the critical time frame crucial for effective stroke management. By automating and standardizing the analysis of intricate neuroimaging data, the e-Stroke system streamlines the workflow of healthcare professionals, en-

abling them to deliver timely and customized care that meets the specific needs of each individual patient.

Figure 1: e-Stroke software interface.
Source: `https://www.brainomix.com/stroke/`

2.1 Deep Learning Methods

Deep learning is a more recently developed technique of machine learning, which mimics the human brain using multiple layers of Artificial Neural Network **(ANN)**. In relation to *Lee et al. 2017*, there are no clearly defined differences between shallow and deep learning; however, deep learning is characterized by having multiple hidden layers in its configuration. As machine learning is a subset of artificial intelligence, deep learning is likewise a subset of machine learning making it a superset of artificial intelligence. It is credited for its advanced algorithm to identify, capture, and interpret key features embedded in complex data-*Cui et al. 2022*. "Recent advances in deep machine learning **(DL)** offer new strategies for harnessing computational medical image analysis to inform decision-making in acute stroke" *Chavva et al. 2022*.

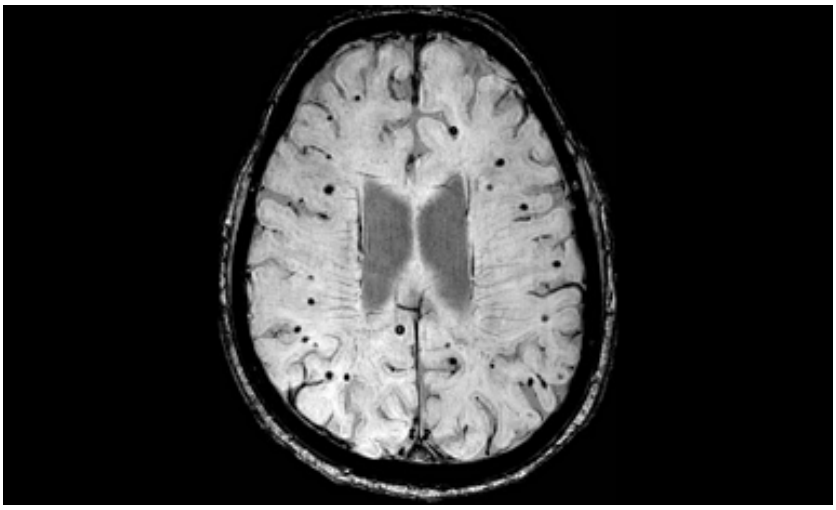

Figure 2: CT scan of the brain.
Source: `https://www.brainomix.com/stroke/`

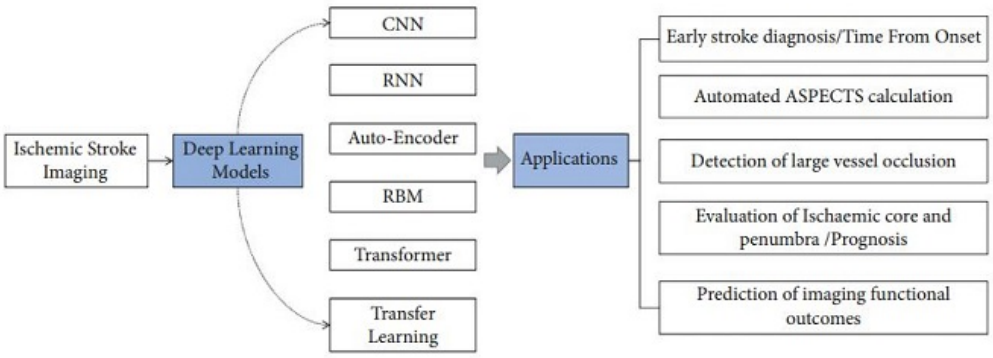

Figure 3: Applications of deep learning in acute ischemic stroke imaging analysis.

Source: `https://www.google.com`

There are currently no studies assessing the Brainomix e-Stroke system using the ethical structures highlighted above across every stage of the implementation lifecycle. This study characterizes the current literature as well as the novel approach to ethical analysis of the AI project. References and citations have only been drawn from state-of-the-art research works that assess the ethical frameworks in healthcare only as a whole.

3 AI Assessment

As earlier stated, the contributions of AI technology in healthcare have been immense, and these will continue to grow as long as human research and inquisitiveness remain. This however, has been coupled with rising concerns about the ethical implications of these technologies and an array of ethical guidelines for the use of AI and data in healthcare has arisen *Smallman 2022*. The rising need for ethical structures to be put in place to do the necessary checks and balances has brought about several debates. This report wishes to join in this debate by examining the Brainomix e-Stroke system through the lens of the ethical landscapes of the **SUM** values, **FAST Track** Principles, and the **PBG Framework**.

3.1 Support, Underwrite and Motivate (SUM Values)

The SUM assessment focuses majorly on respecting the dignity of stakeholders, Connecting with each other sincerely, Caring for the well-being of each and all, and protecting the priorities of social values, justice, and the public interest.

The ethical analysis using the SUM values of the e-Stroke system according to the above focus was an evaluation of the societal impact of the Brainomix e-Stroke system in terms of improved healthcare delivery and patient outcomes. Brainomix's e-Stroke imaging technology employs AI for the automated analysis of CT and MRI scans. It swiftly notifies clinicians in real-time about patients who could derive significant benefits from mechanical thrombectomy **(MT)**.

"AI has the potential to improve patient outcomes, increase the efficiency of healthcare diagnosis and treatment, and lower the cost of care",*Lehmann 2021*. Swift identification of such strokes and timely referral to specialized facilities for treatment are crucial to securing the most favorable results for patients. According to digitalhealth.net in August 2023, treatment rates rose to 5.7% from 3.6% at hospitals that have employed the e-Stroke system. This is an increase of about 2%.

According to NHS, "Preliminary evaluation of the technology, funded through the initial phase of the government's AI in Health and Care Awards, indicates a potential reduction of over 60 minutes in the interval between stroke presentation and treatment". In a further statement from NHS, the technology has been directly linked to about a threefold increase in the num-

ber of stroke patients who recover with either no or minor disability, meaning they achieve clinical independence, rising from 15% to 50%.

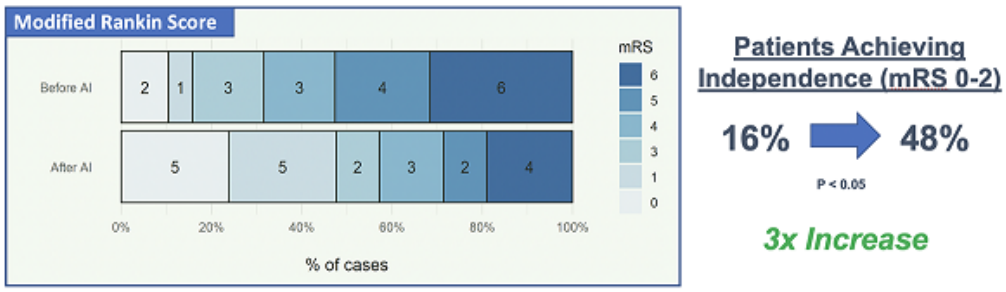

Figure 4: More patients achieving mobility with the e-Stroke System
Source: `https://www.brainomix.com/stroke/`

3.2 FAST Track Principles

The issues of fairness, accountability, sustainability, and transparency cut across every section of the AI project workflow. It demands the cooperation and deliberate involvement of those with adequate knowledge, expertise, and competence. "The use of AI in healthcare takes advantage of the exceptional volume of health data and computing potential to inform evidence-based decision-making" *Prakash et al. 2022*. This activates new ethical problems as regards the confidentiality of the data collected, data privacy, the transparency of data use, accountability of data governance, and probable inequities in AI deployment, *Prakash et al. 2022*.

What were the fairness challenges faced during the problem formulation stage? Were there any negative impacts of the specification of outcome variables and if these specifications are reasonable and justifiable? Were there mitigating factors that became sensitive and required attention during the modeling and testing phase? More importantly, what was the Fairness Position Statement **(FPS)** where the fairness criteria being used in the e-Stroke system were made explicit and explained in clear and unambiguous language?

1. **Fairness:** Fairness in AI according to *Ueda et al. 2023* refers to the development and deployment of unbiased AI that provides accurate diagnoses and treatments for all patients regardless of their social status or ethnic differences. *MacDonald, Steven, and Trzaskowski 2022* explains that healthcare services aided by AI oftentimes lack transparency and accountability when it becomes difficult to interpret the dependency or reasoning of the AI model involved with decision-making. One of the fairness problems that might have been faced during the data acquisition stage is data bias, which happens during the collection or sorting of data in training the AI model and may have harmful effects on the fairness and accuracy of the model. Another one is the algorithmic bias. This would come during the development and implementation phase of the project. Automation bias might be a big problem when clinicians overly rely on AI for diagnosis which may result in inaccurate predictions. According to a quote from a study done by *Ueda et al. 2023*, it was discovered that wrong AI advice had a negative impact on radiologists' mammogram reading performance across all expertise levels.

   A statement from Brainomix says, Patient selection is crucial for the

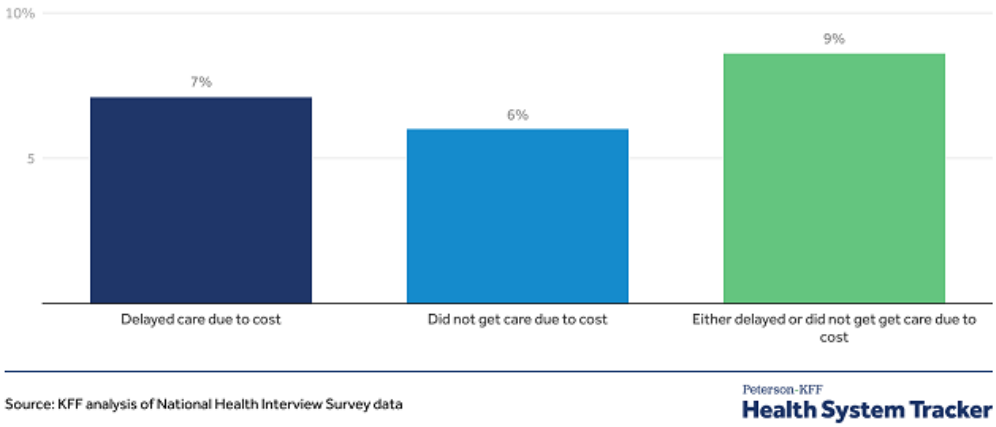

Figure 5: Percentage of adults who reported delayed or going without medical care due to cost

adoption of this procedure because it costs up to £23,000 per patient. This outrageous amount poses a fairness and discriminatory issue against those who need the service most but cannot afford it. This report therefore asks, "Who are those been looked after by this technology?"

2. **Accountability:** Accountability in AI technologies cannot be overemphasized. *Habli, Lawton, and Porter 2020* says, "The prospect of patient harm caused by the decisions made by an artificial intelligence-based clinical tool is something to which current practices of accountability and safety worldwide have not yet adjusted". The question of accountability of the e-Stroke system must answer two main questions: Is it auditable? And who is the technology answerable to? The latter is delicately non-negotiable.

   Answerability of the project is crucial to not just the sustainability of the AI project but also to building trust and ensuring openness. The individual or group of people who must take up this responsibility of checking and asking questions must step outside the project to have an unequivocal look and make the tough decisions without being encumbered or biased.

3. **Sustainability:** There is an expanding effort to tackle the sustain-

ability issues of AI technologies across every aspects according to the Sustainable Development Goals **(SDG)** but according to *Van Wynsberghe 2021*, it is time to move beyond merely discussing how to consciously address the sustainability of developing AI systems particularly in healthcare. To comprehensively ascertain the sustainability position of the e-Stroke system, it has to go through a Stakeholders Impact Assessment **(SIA)**. This will not only help build public confidence but also strengthen the accountability framework, show unseen risks that might affect stakeholders, and also bring out practices that enhance decision-making.

When speaking about how sustainable an AI technology is and in this case, the e-Stroke system, we are referring to how safe it is, how accurate it is, how reliable and secure is to use, and finally, how robust it is. The issue of safety was ruled out as there are no apparent safety risks that we know of, except for those that have to do with data safety and privacy which we spoke about on fairness. However, the issues of accuracy and reliability cannot be blindly ruled out. According to a research paper written 2 years ago *Seker et al. 2022*, the performance of e-CTA in detecting any large vessel occlusions is comparable to less experienced physicians but is similar to experienced physicians for detecting proximal large vessel occlusions. If the e-Stroke system is just as good as an experienced physician, then its accuracy is supposed to be questioned and the money being spent could be used for something more robust.

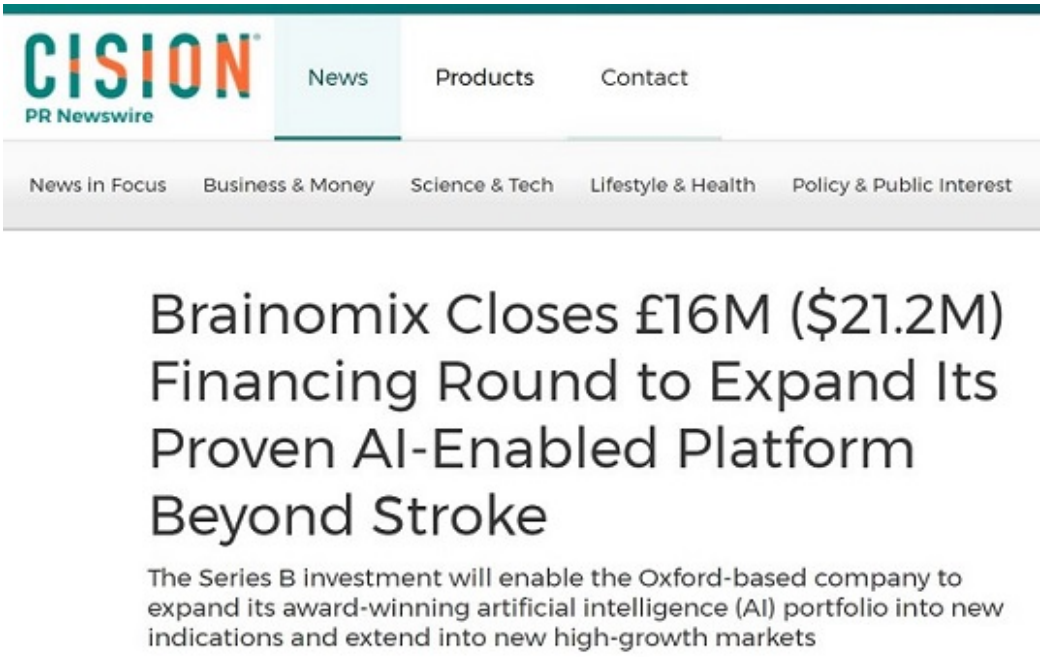

Figure 6: In 2021, Brainomix received a grant to expand their frontiers of research

Source: `https://www.prnewswire.com/`

4. **Transparency:** "Transparency in AI refers to algorithms that are expressive enough to be humanly intelligible on their own or when used in conjunction with external tools, says *Bernal and Mazo 2022*. It includes the justifiability of both the process that goes into the design of the e-Stroke system, its implementation and its results. When there is a big gap in understanding, interpreting and explaining biomedical data and outcomes, it results in ethical issues arising in transparency and accountability which ultimately leads to suboptimal care and unfair health policies *Shaban-Nejad et al. 2021*.

   The transparency assessment of the e-Stroke system identifies problems in process transparency and outcome transparency. Nothing about the processes involved in the design and development lifecycle of the e-stroke system was transparent. The only thing we know is that the Brainomix e-Stroke system is a spin-out from the University of Ox-

ford. "Transparent algorithms or explanatory approaches can make the adoption of AI systems less risky for clinical practitioners", *Reddy 2022*.

3.3 PBG Framework

The Process-Based Governance (**PBG**) Framework is a governance architecture to enforce the structures laid out by the SUM Values and the FAST Track principles. The PBG framework for the e-Stroke system has been designed as a template to accommodate the ethics and values towards responsible AI design, innovation, and delivery. It is paramount to analyze this technology according to strict ethical values and landscapes to build trust, discourage discrimination and bias, and build a better society, *Boldt and Orrù 2022*. The framework is analysed in details below:

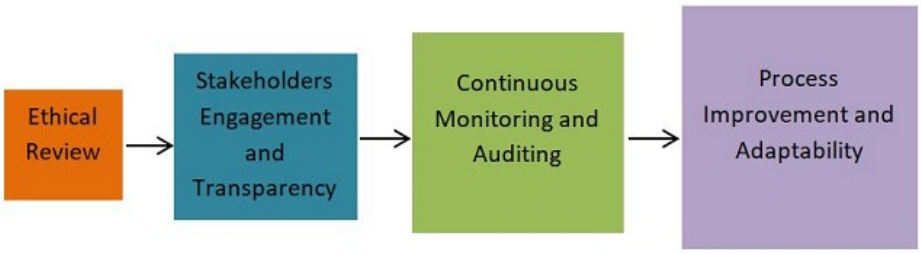

Figure 7: PBG Framework for the e-Stroke system

1. **Ethical Review:** The framework designed suggests a periodic ethical review of the e-Stroke system. This must include but is not limited to regular assessment of the functionalities of the system in terms of fairness and discriminatory non-harm, ethical checks, and assessment of the technical team involved in the project. There must be a continuous evaluation to ensure ethical guidelines and protocols and being followed. A method to achieve this seamlessly is the Ethics-Based Auditing which is an assessment of past or present actions of the technology to check for consistency with ethical guidelines.

2. **Stakeholders Engagement and Transparency:** This is an integral part of the framework. There must be an avenue for open discussion and communication between stakeholders, professionals, administrative bodies, and the development team. Patients must be aware of the

limitations of the technology, how their data is being used and processed, and finally, the accuracy and precision of the technology. This encourages trust and helps make decisions on possible risks and ethical implications of the e-Stroke system.

3. **Continuous Monitoring and Auditing:** The next stage of the framework is monitoring and auditing. In this stage, the e-Stroke system's performance must be checked, data handling procedures must be scrutinized and algorithm performance must be reported and thoroughly evaluated. This is to identify any ethical discrepancy in the system, bias, or system error to enable swift corrective measures and adjustments.

4. **Process Improvement and Adaptability:** The last step of this framework is to adequately provide structures for improvement, growth, and learning. A feedback mechanism must be established that assesses every input and output log, system efficiency, performance, and iterative testing. All these are towards the ethical compliance of a responsible AI architecture.

4 Conclusion

The Brainomix e-Stroke system has significantly contributed positively to healthcare through the diagnosis and treatment of stroke. Using advanced deep neural networks for detection and classification, many people have been given a second chance at life. However, serious concerns still remain as regards data privacy, fairness, accountability, and transparency all through from the problem formulation phase to deployment. These issues must be addressed as they form the bedrock of a responsible AI project.

4.1 Recommendation

The first step towards fairness, openness, and transparency is to make training data available for public scrutiny. Fairness Position Statement (FPS) should be made available to stakeholders. Consent must be received before patient data of any kind or sort is assessed and processed toward unbiased algorithm training. Government structures and guidelines are in place to foster a healthy synergy between AI and the people. These structures should be strictly adhered to and implemented at every stage of a responsible AI delivery workflow.

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