Ethics of AI in global health research

Cape Town, 29&30 November 2022

Global Forum on Bioethics in Research

Governance paper
The 'proverbial' black box that is ethics of AI in global health research: are Kenyan RECs well equipped?

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Brief description of the context

The lack of adequate regulatory and policy frameworks for integrating artificial intelligence (AI) in research in low and middle-income countries (LMICs) raises ethical and legal issues. These issues include discrimination caused by algorithmic bias[1], lack of transparency when seeking informed consent[2] and emerging high risks that may cause harm to participants[3]. This is coupled with the inadequate capacity of research ethics committees (RECs) to review research protocols involving AI in health and the lack of knowledge from researched communities. The lack of legal and ethical frameworks in regulating the use of AI in health leads to the need for accountability not by the machine, but by the people who built it and the protection of those who use it[4].

In Kenya, the Data Protection Act (DPA)[5] makes provision for a regulatory framework for data collectors, processors, and data participants. This is supported by the National Guidelines for Ethical Conduct of Biomedical Research Involving Human Participants in Kenya (NGEBMR) (2020)[6], which offers some ethical guidelines on how to handle data while protecting participants. The existing guidance on the application of digital innovation by the National Commission for Science, Technology, and Innovation (NACOSTI) (2021), demonstrates significant optimism in regulating the use of digital technology, including AI in science, technology, and innovation in Kenya. However, all these regulations and guidelines give minimal attention directly to the use of AI in research. Simultaneously, some researchers in Kenya have been using AI for health in diagnosis, storage of electronic medical records, disease outbreaks, surveillance, health policy and planning[7]. Furthermore, the role of ethical review in AI research is poorly examined or explained in the DPA. This paper examines the gaps in the DPA and NGEBMR as a resource for reviewing AI in global health research in Kenya. It assesses the challenges RECs face when reviewing AI-based health research protocols and offers recommendations on how traditional research ethics procedures may be adapted to respond to AI-based health research.

Commentary

In terms of readiness to uptake AI, Kenya ranks third in Sub-Sahara Africa with a score of 45.5% according to the Government Artificial Intelligence Readiness Index 2021 by Oxford Insights. The index was defined by three pillars: government, technology, data and infrastructure. The government pillar incorporates governance and ethics, digital capacity, and technological adaptability. Governance and ethics are understood to include indicators related to data protection and privacy legislation, cyber security, the national ethics framework, legal frameworks, and business models. Under this domain, the Readiness Index sought to answer the question, are there regulations and ethical frameworks in place to implement AI in a way that builds trust and legitimacy?

NACOSTI, the body that accredits and offers training to all RECs in Kenya, has not adopted the mandatory inclusion of members with expertise in AI[8]. Hence there is very little knowledge in the review of ethics in AI.

Traditional research ethics procedures may apply in sections 28–30[5] of the DPA on the collection of data. This section permits the collection of personal data through consent by the data participant only. However, there is a need to specify in what context the data is being collected from the data participant and how it is being used and stored. Whether it is for marketing, healthcare, or business. This is because some data are more sensitive than others, especially in the health sector. Section 35 states that a data participant should always offer consent on any automation of their data being processed or profiled. Additionally, section (35) (3) (a) (b) states that the data controller/processor should notify the data participant of the use of any data collected. Unfortunately, it is not explicit how informed consent from the data participants before data automation, profiling and general collection of data will be sought during research in AI.

Furthermore, the focus on the prevention of ethics dumping in Kenya is solely based on biological samples in health research isolating regulation of potential ethical dumping of AI health data. There are no clear indications or procedures in sections (48), and (49) that allow personal data transfer and safeguards outside Kenya. There is no clear indication of continuous respect for the data participant on what would happen to their data if it was continuously used, and it may be discarded. An adequate regulatory and policy framework would ensure the ethical soundness of research involving AI. Moreover, it would increase the capacity of RECs to review such research and, ultimately, create awareness in communities under research in Kenya.

Recommendations

Effective AI research models should be built on law, policy, and ethical guidelines. This model will incorporate ethical guidelines and review processes to discover, assess, or track the impact of AI health research. We propose the adoption of the Emanuel *et al*. framework[9] and some insights into the traditional Kenya National ethical guidelines for biomedical research in interpreting and reviewing AI-based health research. This is as follows:

Community engagement

While there is a need to consider and commend AI's attention around and positivity in global health research, most of its adoption is centred around the European context. This excludes the African context, causing exclusion and discrimination in the communities' use of AI in healthcare. AI research needs to incorporate Africa's communitarian philosophies of making decisions together and a sense of inclusion in the changes we face. Community consultations to gather feedback and offer public access to the understanding of Algorithmic Impact Assessment (AIA) procedures will offer accountability and build trust in the community[10]. Such assessment is done to assess the possible societal impacts of the AI system before it is used. RECs should ensure that a human-centred technology design for AI health research is incorporated that includes the community's desires and public concerns. This form of engagement should be done early and continued throughout the study.

Collaborative partnerships

It would be commendable to establish *ad hoc* Committees on AI to conduct inclusive multi-stakeholder consultations to determine the feasibility and potential elements of a legal framework for the design and application of AI according to Kenyan law[11]. RECs in Kenya must intensively engage research communities, the government, experts and other stakeholders in digital innovations in the policy review process. RECs should also ensure that all stakeholders submit data-sharing agreements for review to ensure that data rights are understood and respected.

Social value

RECs should ensure that all research involving AI in health fits into the Kenyan context while identifying who the beneficiaries are. This is because different counties in Kenya have different health needs and finite resources. It could also ensure that if a vulnerable population is included, there should be justification in the study. RECs should ensure that researchers clearly state how they will disseminate and share potential benefits with the community. This can be done through an algorithmic impact evaluation report where researchers give monthly progress reports on the impact of the use of AI in healthcare can be looked up when in use.

Scientific validity
Data is the nourishment that AI algorithms should survive and thrive[12]. However, there needs to be justification and considerations as to why AI is required for a study. The choice of study design and procedures must be rigorously reviewed to yield valid and reliable data. The REC must ensure that research participants' healthcare interventions align with the scientific objectives in the proposal. This is because sometimes the interventions to which the research participants are entitled may go beyond what is sustainable or feasible for the study objectives.

Fair selection of study population
To ensure the interests of research participants are defended, RECs can offer a checklist of non-bias and non-discriminatory guidelines. This would entail selection based on scientific importance and not convenience. RECs looking at the research on AI systems in the Kenyan context should review the inclusivity and diversity of the data to be collected. By and large existent research AI models are predominantly designed using western epistemologies and worldviews, which can limit their applicability to African contexts[13]. Moreover, the use of western languages, graphics, and aesthetics inherent in AI designs may contradict the Kenyan reality[14,15] especially in clinical research.

Favourable risk-benefit ratio
There is a need for Kenyan RECs to observe potential harms that may stem from inadequate benefits or high risks of AI in the community. The REC should weigh whether an AI-led study's risks, burdens, or benefits are needed. This is because research participants in the Kenyan context have a higher chance of facing algorithmic bias, stigma, and physical or psychological harm.

Independent review
When reviewing AI health research proposals, an ad hoc AI consultancy expert should always be brought in. For independent oversight to occur, training should be done, and national guidelines dedicated to AI health research should be created. Reviews by RECs should be independent of public or private deployers of AI, equipped with interdisciplinary expertise and training. This also includes monitoring and evaluation of risk assessment and non-infringement of human rights[16]. There need to be adequate standard operating procedures that clearly show the impact assessment procedure adapted to respond to AI-based health research and its impact on the community before it is approved. Lastly, the NGEBMR should ensure basic training in AI for all ethics review members.

Informed consent
The goal of informed consent is to generally respect the participants' and communities' decision-making interests. As suggested above, working with various stakeholders, especially the research community, could reveal new aspects and levels of effective consenting, risks, and privacy issues in research involving AI. RECs should draft transparency requirements for AI health-based research proposals. Consent on all AI systems should not be a 'terms and conditions' jargon document. A short, simple write-up to aid the understanding of the participant should be required for review by RECs[17]. We recommend that RECs informed consent forms for AI use in global health research closely resemble user agreements where necessary[10].

Ongoing respect of participants and communities
To ensure health equity while still ensuring ongoing respect for the community, when using AI, monitoring and evaluation are required. Every research relating to AI in global health should have a framework for publishing and sharing with the public. This will allow an effective monitoring and evaluation system and reduce research fatigue of the same study in a community. Here, we recommend RECs create an AIA model template that focuses on the impacts of AI and whether they will be ongoing, reversible, short-term, or perpetual[18].

Conclusion
In Kenya, AI readiness is at its peak, but its regulation unfortunately is lacking. The recommendations made above may inform RECs' ethics review of AI-based global health research. We hope that these recommendations may be used to inform law and policy in the future.

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This paper was prepared for GFBR 2022. Further details on the meeting are available at www.gfbr.global.