Ethics of AI in global health research

Cape Town, 29&30 November 2022

Global Forum on Bioethics in Research

Who minds the machines? Developing a governance framework for pre-market authorisation of responsible AI applications in healthcare in South Africa

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Artificial intelligence (AI) is a rapidly evolving set of technologies that are set to radically transform the healthcare system. AI will considerably improve workflow efficiency, and diagnostic accuracy, reduce health costs and help with the alleviation of staff shortages in low-resource settings. However, AI design, development, and deployment within the high-risk healthcare sector are fraught with ethical, legal, and human rights constraints. The constraints have imperative value within the South African context considering its history of economic inequalities, exploitation, and racial disparities. Immature regulation and governance frameworks in LMIC including South Africa further compound the constraints of AI.

This paper proposes enforceable governance reforms of the regulatory authorisation (by SAHPRA in South Africa) for the manufacture, wholesale, or marketing of AI software as a medical device (SaMD). The two key recommendations are 1) to develop ethical and human rights impact assessment tools that aim to mitigate against derogation of ethical principles and human rights and can guide researchers, AI developers, regulators, and clinicians in decisions about the design, development, and deployment of AI; and 2) the reform of the current single-stage regulatory oversight mechanism to provide for total product lifecycle regulatory oversight of AI SaMD. A key element of local regulatory approval must be satisfactory evidence (through impact assessments and post-deployment audits) that the training and validation of the AI algorithms were performed on local population data, and if this is not the case, that measures are in place to detect biased and inaccurate algorithmic outputs. Statutory established national and provincial health research ethics committees (RECs) set standards of practice, review the research protocol for patient safety, and provide guidance on human rights and ethical issues that may affect research at the design and development phase[1]. The implementation of ethical and human rights impact assessment broadly aligns with the core responsibility of the RECs during clinical trials and health research involving AI SaMD. Regulatory approval pathways, data protection laws, and REC approval processes comprise distinct legal and regulatory compliance measures. Multi-stakeholder pluralistic participation will aspire to align these frameworks and provide for total product lifecycle coverage of AI in health care through ethical and human rights impact assessment, audits, and post-deployment surveillance mechanisms. The governance reforms will be valuable to local legislators, regulatory agencies, AI developers, health researchers, research ethics committees, healthcare personnel, and ultimately patients, as the end-user, of the need for responsible human-centric AI within the healthcare system.

Reference

1. National Health Act 61 of 2003 Chapter 9; Department of Health (DOH). *South African Good Clinical Practice: Clinical Trial Guidelines* (2020) and DOH *Ethics in Health Research Principles, Processes and Structures* (2ed.)(2015)

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