

Ethics of AI in global health research

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Adaptability of India's Health Data Regulations

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Globally, regulatory policies in general are developed using one-time decision-making processes, using limited ex-ante assessments and ad-hoc reviews or revisions. However, in the real world, changes are constantly occurring across different domains - social, economic, technological, political, and cultural. To be meaningful and effective, the regulations need to keep pace with these changes. Adaptive regulations offer an array of mechanisms where decision-making is not a one-time process, instead, it is iterative and planned, based on new information and changing circumstances.

The complexity and rise of health data have resulted in increasing applications of artificial intelligence (AI) in healthcare, patient engagement, and administrative activities. While there are numerous benefits of electronic access and exchange of health data, there are increasing risks of privacy and security breaches. Further, with the advent of big data and advanced analytics, a lot of non-health data is being collected and traded online. This non-health data could be a better predictor of an individual's health than his/her health records. Thus, new and emerging technologies are changing the nature of privacy and how it could be protected. In India, laws and policies regarding AI and health data are still evolving. Therefore, there is an opportunity to apply theoretical principles of adaptive regulation to India's AI and health data policies and propose recommendations to design adaptive policies and laws.

Based on the review of literature, 6 broad features of adaptive regulation are synthesized from the perspective of a learning-oriented decision-making process. These are: (i) assessing risk and uncertainties, (ii) broader and fuller impact assessment, (iii) monitoring and evaluation, (iv) iterative decision-making and policy adjustment, (v) public participation, and (vi) adaptive governance structures. These six features are embedded in the form of an adaptive regulatory cycle with three stages of pre-implementation, implementation, and post-implementation. In this context, India's four health data policies and one legislative bill are analyzed and 10 key stakeholders interviewed. The analysis is anchored on the application of the adaptive regulatory cycle with six adaptive features.

In the health data sector, India's regulatory cycle in the pre-implementation stage (assessing risks and uncertainties, and broader impact assessments) indicates low adaptiveness on the books and moderate adaptiveness in practice. In the implementation stage (monitoring and evaluation), it indicates high adaptiveness on the books and moderate adaptiveness in practice. And in the post-implementation stage (iterative decision-making), it indicates high adaptiveness both on the books as well as in practice. Regarding the two overarching adaptive features of public participation and adaptive governance structures, the former shows high presence both on the books and in practice while the latter shows low presence both on the books and in practice.

Combined document and interview analysis indicate a gap in monitoring and evaluation (M&E) in practice whereas it indicates high prevalence of iterative decision-making in both theory and practice. However, the interview analysis also suggests that these iterations and policy revisions are not informed by formal policy evaluations. Therefore, this finding connects with the limited effectiveness of M&E in practice. To address these gaps in India's health data sector, it is recommended to introduce structured decision-making processes (e.g. risk assessment, regulatory impact assessment, etc., using simplified and flexible methodologies), focus on formal policy evaluations, and strengthen inter-agency coordination. Further, considering this sector is

dynamic and nascent in law and policymaking, more built-in provisions of periodic reviews are recommended.

Overall, most of India's analyzed health data policies are still evolving. Therefore, before India begins to use AI in health research, it should create a more 'adaptive framework' for health policy so that it can best learn and improve how AI is working, and address any ethical issues that arise with using AI.

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