THEME EDITORIAL

The age of health-AI and India: Ethics guidance, regulations, governance and beyond

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"…it is the first technology in history that can make decisions and create new ideas by itself. All previous human inventions have empowered humans, because no matter how powerful the new tool was, the decisions about its usage remained in our hands.… AI isn't a tool – it's an agent.…"

— Yuval Noah Harari, *Nexus: A brief history of information networks from the Stone Age to AI.*

To appreciate the ethical issues arising out of the deployment of Artificial Intelligence (AI) and health-AI technologies, we need to understand how they were conceived, what enables their proliferation, and what is driving their use. These questions have shaped the broader contours of the theme section in this issue of the *Indian Journal of Medical Ethics (IJME)*.

Some key features distinguishing AI technology from other branches of computer science are: its algorithmic capability to perform automated tasks without explicit human programming of every step [1, 2], its inaccessibility from human scrutiny [3], and its adaptability. In the case of health-related AI, this technology uses "…advanced statistical algorithm(s) to analyse structured and unstructured medical data, often retrospectively, with the final goal of predicting a future outcome, identifying hidden patterns, and extracting actionable information with clinical and situational relevance" [4]. Health-AI technologies that are categorised as "safety critical AI" (SC-AI) require a higher level of reliability and safety than do other AI systems. Steps to prevent the misuse of the data corpuses which are central to developing health-AI technologies include: requiring valid consent for the re-use of data; taking action to protect data owners' safety and dignity; ensuring data quality to minimise or eliminate instances of false positive or negative outcomes; addressing the potential de-skilling of health professionals with their capacity for critical thinking; and establishing systems of accountability and redress to prevent harm to patients.

The unprecedented pace of growth of AI technology in general, and health-AI technology in particular, is facilitated by the availability today of large-scale heterogeneous datasets combined with advanced computing capabilities. The global health-AI technology market was estimated to be worth USD 39.34 billion in 2025, and is expected to grow from USD 56.01 billion in 2026 to USD 1,033.27 billion by 2034 [5]. In India, the Ayushman Bharat Digital Mission is supporting the implementation of electronic medical record systems, with a current penetration of 35%, mostly in large private hospital chains, and dominated by tech giants like Reliance, Amazon, Microsoft and Google [6]. The range of AI-based health technologies available include screening, osteoporosis prediction models for patients' risk assessment, treatment interventions, and rehabilitation [7].

This combination of the commercial value of AI technology, the dominance of technology giants, and the ability of these tech giants to gain access to existing data corpuses is a formidable challenge. Measures are needed to balance the benefits and risks of these technologies in order to make them human-centred, and consider both fairness-justice and harm principles.

There are a number of guidance documents on the ethics and governance of health-AI technologies. The Indian Council of Medical Research (ICMR) [8] acknowledges many potential ethical challenges, such as the absence of algorithmic transparency and explainability, lack of clarity on liability, accountability and oversight of AI, and the evidence of bias and discrimination when these technologies are deployed. The ICMR document also notes potential ethical concerns relating to data quality, data ownership, and usability. The document also discusses concerns related to the trust placed by the patient-doctor dyad in AI software's effectiveness, and its acceptance of the risks inherent in this technology. The World Health Organization's 2021 [1] guidance lists six principles for consideration by governments, developers, and providers using AI. These are: (i) protecting autonomy; (ii) promoting human well-being, safety and the public interest; (iii) ensuring transparency, explainability and intelligibility; (iv) fostering responsibility and accountability; (v) ensuring inclusiveness and equity; and (vi) promoting AI that is responsive and sustainable.

While guidance documents and legal and regulatory frameworks are helpful, the gap between these frameworks and their implementation remains a global concern. In India, mainstream education in technology and medicine has little on ethics, human rights, and humanities in general, and their application to health and healthcare technologies in particular [9]. The authors' engagement with peers and stakeholders working on big data and digital and AI technologies — public and private — reveals that this sector is inadequately informed by questions of ethics and human rights.

Moreover, there are many challenges in operationalising and implementing ethics-related guidance. Some of these are: the broader socio-cultural contexts; specific vulnerabilities of care receivers in healthcare settings; the healthcare ecosystem in which health-AI operates; the healthcare- and technology-related policy environment; legal dimensions; limited opportunities and work environments for collaborative and multidisciplinary pursuits in AI; and the commercial stakes of health-AI investors-developers.

The five contributions in this theme section engage with some of the issues mentioned above. They look at ethics, regulatory and governance matters through a social sciences and humanities lens to better understand the challenges of health-AI.

Key insights in the theme section

Together, the essays cover a broad spectrum of contexts of health-AI development and deployment. The commentaries by Waitzman and Abramowitz [10] and by Naik and Reddy [11] examine the local settings in which a particular health-AI technology is being developed and deployed. Fontanini [12] and George [13] offer a humanities perspective, employing phenomenological frameworks to take the conversation beyond ethics guidelines and regulatory systems. Khera [14] utilises economic theories to discuss the risks of data privacy becoming a tradable entity, and emphasises the moral imperative to safeguard the right to privacy. These central threads are developed in this theme section, drawing upon real-life examples or hypothetical scenarios that are rapidly becoming real-life challenges.

The opening contribution by Waitzman and Abramowitz [10] reports on the introduction of AI to the rapidly evolving field of pre-hospital emergency medicine (PHEM). The authors describe issues arising from PHEM's deployment in Israel, offering normative and theoretical analyses grounded in real-world developments. They argue that AI deployment in PHEM demonstrates, "… AI's potential to improve triage, dispatch, and emergency preparedness. Yet, this accelerated adoption has outpaced ethical, legal, and institutional safeguards." [10]. The authors identify gaps in the fragmented Israeli regulatory system, and highlight the need for a comprehensive national framework to oversee health-AI use.

At the heart of AI use and algorithmic functioning is the question of "authenticity". Fontanini [12] raises critical questions on the role and motives of grief bots — AI-based simulations enabling interaction with the deceased's simulated persona. The grief bot is presented by industry as a compassionate tool to help deal with loss. Can the identity and memory of a person be reduced to a curated dataset? Who benefits from digital "immortality", and at whose expense? Who owns the data stored, used and reused, and with whose consent? Fontanini brings in philosophical concepts from Plato to Locke, and Heidegger to Ricoeur to address these questions.

Drawing upon Heidegger's critique of technology, George [13] describes the current technological advances in AI and health-AI as a "mega-cultural technological transformation", with its pervasive nature "…affecting all aspects of human existence and people everywhere". He argues that "We cannot change these trends but there can be thoughtful ways of responding to them." Technology disrupts and destabilises current practices, leading to previously unexperienced dilemmas and ambivalences. George calls for an examination of the medical ethical dilemmas and complex scenarios brought about by health-AI. He develops his argument using two examples: the use and amassing of electronic health records for non-medical purposes; and the use of health-AI for drug development.

Khera [14] offers a detailed analysis of how our personal data are increasingly being commodified, breaching our right to privacy. Drawing upon the thinking of economists and philosophers, the author argues that markets for personal data privacy are "noxious markets", that is, markets which are toxic to human values; and that we must draw moral limits in such cases, similar to the ban on child labour and on the organ trade. It is worrisome, Khera notes, that governments and corporations hold vast personal data repositories and, with rapidly advancing technology, individuals using digital platforms have little power to prevent violations of their privacy. She provides several Indian examples of the disturbing consequences of the digital economy for individuals and society at large, and concludes with an appeal to place democracy and human rights above markets. She proposes steps towards this objective.

Naik and Reddy [11], in the last essay of the theme section, focus on the need to set up AI governance systems, given that AI is embedded in the healthcare system. The authors propose a governance model based on their analysis of three healthcare use cases. Each AI-based task in a healthcare scenario is analysed for its short-, medium-, and long-term impact, and assessed as to whether it would replace human capacity, augment it, or create new capabilities.

Some takeaways

The five contributions offer a multi-disciplinary approach to the ethical challenges of AI in healthcare and health research, and also put forward some broad guiding principles:

First, we need public engagement to address these challenges. We need a discerning public — medical doctors, health professionals, field workers, journalists, and health advocates as well as the general public. As users of AI, all of us need to raise our voices against injustices such as inequitable access, human rights violations such as stigma and bias, economic exploitation of vulnerabilities, and de-skilling of humans. These papers help to equip us with the ethical reasoning and frameworks to back our arguments.

Second, as underlined by Waitzman and colleagues [10] as well as by Naik and Reddy [11], it is imperative that guidance documents and legal frameworks for health-AI are ethically sound and enable proper regulation. There is a need to set up governance structures informed by local healthcare ecosystems within the broader context shaping healthcare needs and health-seeking behaviour.

Third, the humanities and social sciences are essential to this project. Fontanini [12] and George [13] engage with phenomenological approaches to analyse health-AI technologies from a risks and benefits perspective, and Khera [14] offers a perspective on data privacy as a non-tradable right using theories from economics. Such analyses make the human being central to advances in science and technology.

In India, where health-AI technologies are being developed and deployed at a rapid pace, there is a need for more in-depth discussion on policy, ethics, regulation, and human rights. As a country, we represent a massive source of data, but have little or no commitment to people-centred healthcare. We have a long way to go in terms of protecting the interests of users of health-AI, and safeguarding data corpuses from misuse by commercial interests.

These contributions are a starting point to generate debate on matters relevant to health-AI, in terms of both improving these technologies as well as reducing health inequities in society. We need such analyses if we want advances in health-AI to be truly meaningful and safe for users, for societies at large, and for the planet. AI must respond to widening health inequity, and redress injustices that are rooted in the structural, historical, and social realities of people today and those of generations to come.

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Conflict of Interest: SSB is a Working Editor, *IJME,* and MV is on the Editorial Board of *IJME.*

Funding: None

To cite: Bandewar SS, Vaz M. The age of health-AI and India: Ethics guidance, regulations, governance and beyond. *Indian J Med Ethics.* 2026 Oct-Dec; 11(4) NS: 265-268. DOI:10.20529/IJME.2026.066

Submission received: October 23, 2026

Submission accepted: November 2, 2026

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