

DIGITAL RIGHTS AND HEALTH ALLIANCE

MANIFESTO TO GUIDE RIGHTS-BASED REGULATION OF NEW TECHNOLOGIES FOR HEALTH

OUR MISSION

The Digital Rights and Health Alliance is a group of European non-profit organisations, institutes, and individuals committed to the protection, promotion, and realisation of fundamental rights. Our collaboration is based on shared concerns about the impact of new technologies, and in particular artificial intelligence (AI), on the protection of human health and fundamental rights. We work together to promote rights-based digital health technology regulation, policy and practices in Europe.

OUR CONCERNS

We are concerned about the impact of digital health technologies in the field of health and on the fundamental rights of people living in Europe in particular. Such health technologies are gradually being implemented across European healthcare systems. Increasingly, they use AI, big data, and automated decision-making and often change care pathways and healthcare delivery processes. Examples are mobile health technologies, AI-based diagnostics and treatments, assistive robotics, and smart sensor technologies. We see that digital health technologies create challenges in three key areas: (1) Health Equity, (2) Power Relations, and (3) Fundamental Rights. Regulation must address all three challenges to fully protect people living in Europe against the risks of digital technologies in healthcare. However, it is currently failing to do so, as existing regulation primarily centres on the functioning of the internal market and its effects on individuals.

Health Equity

Digital health technologies threaten health equity. Health equity is the absence of unfair, avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically or geographically, or by other dimensions of inequality (e.g., sex, gender, ethnicity, disability, age, or sexual orientation)¹. While *the right to health* is an internationally recognised human right, health inequity is still ubiquitous: social, economic, demographic, and geographic circumstances, determine one's health. The increasing use of disruptive, data-driven technology—such as AI for health(care) purposes carries the risk of worsening the situation. This can be explained by the *AI cycle of health inequity*: existing inequities and practices of discrimination in healthcare are ingrained in AI systems that replicate these unfair biases in their output. The accuracy and completeness of health data is often problematic, which can lead to flawed outputs. This means that these systems will create lower-quality or discriminatory results for specific population groups. A reinforcing loop is created resulting in exacerbated health inequity.

¹ [WHO definition](#)

Shifting Power Relations

Digital health technologies impact existing power relations and push the boundaries of social justice. While traditionally, safeguarding the health of its citizens is a core task of the government, and health professionals abide by professional standards and medical-ethical principles, big tech companies are now entering the sphere of healthcare. Consequently, healthcare is becoming increasingly commercialised and commodified. The business model of big tech companies does not fit current public values. Treating patients and their personal data as a 'product' for financial gain puts individuals in a vulnerable position and creates new power asymmetries. Furthermore, it can lead to commercial exploitation, which results in potential loss of individual control and ownership of health data, unethical prioritisation of financial gains over public interest, and consequential impact on trust in and safety of healthcare. Furthermore, governments and healthcare institutions can be enticed to deploy health technology based on unsupported claims of cost-saving and 'efficiency gains', influenced by overly positive narratives and hype on AI in healthcare. However, comprehensive evidence on cost and risk/benefit, impact on quality of care, quality of life, and fundamental rights is often lacking. Health professionals and patients should have more control over the direction of innovation and the deployment of AI in healthcare.

Fundamental Rights

The protection of the fundamental rights of individuals confronted with digital health technologies is at risk. The risk of biases threatens the right to non-discrimination, which can in turn affect the right to adequate access to appropriate care. This is the case when technology does not function equally for everyone, or when specific digital competences are required to access healthcare. The enormous reliance on personal data also affects the fundamental rights to privacy and data protection.

The sharing of large-scale datasets of personal health data across Europe further increases vulnerability to unauthorised access and potential cybersecurity breaches. Moreover, the opaque and complex nature of such technologies forms a threat to patient autonomy and the right to informed consent in relation to medical treatment. At the same time, the right to effective remedies in case of harm caused by health technology is at risk.

KEY PRINCIPLES

Through the Charter of Fundamental Rights of the European Union, states are under the legal obligation to fulfil the fundamental rights of their citizens. In the context of digital health technology this means that they must abide by the following principles:

1. **Ensure equal access to healthcare:** the use of technology may not exacerbate a 'digital divide' in access to healthcare, and should safeguard the right to non-discrimination. In particular, community-specific interventions should be implemented to address unique challenges faced by different groups. This will ensure that technologies are fit for purpose and context-specific, reflecting end-users' realities and lived experience.

2. **Safeguard the use of high-quality digital health technology:** health tech must only be deployed if it is proven safe, effective, and upholds quality of life in the context of use.
3. **Guarantee privacy by design and default:** privacy protection should be at the core of every digital health application and patients' control over their health data is secured.
4. **Safeguard the right to informed consent for medical care, treatment and services:** patient-centred healthcare means putting the autonomy of patients at the forefront, ensuring transparency and improving understanding of digital health technology for every patient to the greatest possible extent.
5. **Enhancing access to digital health:** this includes promoting digital health literacy as well as other determinants of access. A proportionate universalism approach is recommended, focusing on improving access for all while paying particular attention to the needs of disadvantaged groups.
6. **Ensure fair public health surveillance:** If governments use technology for public health, fundamental rights and public health interests must be central—not the controlling of people.
7. **Protect public interest against commercialisation:** Importantly, what constitutes public value should be defined through an evidence-based definition of the expected benefits for citizens and society, and safeguards must be instated to avoid non-legitimate use of health data for commercial purposes.

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