



REPORT ON THE STATE OF APPLICATION OF NEW TECHNOLOGIES TO HUMAN LIFE

Disruptive Technologies in
Health: Gene Editing and
Artificial Intelligence (AI)

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Disruptive Technologies in Health: Gene Editing and Artificial Intelligence

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**CNECV ANNUAL REPORT TO THE PORTUGUESE PARLIAMENT ON THE STATE
OF APPLICATION OF NEW TECHNOLOGIES TO HUMAN LIFE 2022
- Disruptive Technologies in Health: Gene Editing and Artificial Intelligence -**

Executive Summary

PRELIMINARY REMARK: DISRUPTIVE TECHNOLOGIES IN HEALTH

The National Ethics Council for Life Sciences (CNECV), in compliance with the provisions of paragraph c) of No. 1 of Article 3 of Law No. 24/2009 of 29 May, which establishes this advisory body, and especially in pursuit of its mission to contribute to the qualification of public policies and the training as well as raising awareness of society in general regarding the ethical implications of scientific-technological progress, presents its Report on the State of Application of New Technologies to Human Life, whose edition for the year 2022 focuses on "disruptive technologies in health".

This report focuses on two technologies - gene editing and artificial intelligence - whose development, despite having been underway for many decades, has more recently acquired exceptional speed, as well as the ability to converge with other technologies in a revolutionary process of reciprocal enhancement. In fact, it is important to stress that this current trend towards the convergence of technologies is also occurring between the two highlighted here, with the application of artificial intelligence to genomic editing, with a view to improving the precision of the identification of genes to be edited, thus reducing potential side effects and increasing its effectiveness.

In this new context, both show a growing impact in the field of life sciences, particularly in research and clinical assistance, triggering new paradigms of relationship and action. It is in this sense that they become truly disruptive, i.e., that they break with defined patterns of structuring of institutions, of organisation of functioning systems, of social interrelations. The continuity of the establishment, in the comfort of the security it often provides, is broken, suddenly interrupted, digging a gap, generating a deep void - frightening for those who prefer the predictable and exciting for those who prefer the unforeseen - that has to be inexorably crossed by a new path, transforming the lived reality.

The simple fact that we are facing a disruption is already, in itself, disturbing from an ethical point of view. Certainly not because of fear of the new, which is part of the history of humanity; and certainly not because of uncritical adherence to the new as if it were synonymous with good. It is disturbing because the inauguration of a new reality, at such an accelerated speed as the present one, generates difficulties of adaptation and



integration, since not everyone will be able to accompany the change, running the serious risk of being left behind, that is, of being ostracised and abandoned by the voracity of progress. Ethics, however, being aware of the unconditional value of each person individually considered, on which the equality of all citizens is also based, requires models adapted to each and every one, not allowing anyone to be left behind. This is our challenge.

The assessment of the two selected domains starts with a brief historical and contextualising note on the technology in question, highlighting the diversity of its applications - both effective at present and potential in the short/medium term - pausing here and there for a developed analysis, according to their greater level of current or foreseeable impact on the health field, then proceeding to the identification and articulation of the different values involved in the technological innovation in question.

The Report on the State of the Application of New Technologies to Human Life concludes with Recommendations for legislators, professionals and citizens in general on ways to develop the targeted technologies to enhance their social benefits and mitigate or eliminate their potential harms.

*Maria do Céu Patrão Neves
President, CNECV*



RECOMMENDATIONS

I. Genomic editing and artificial intelligence raise some cross-cutting ethical considerations that must be taken into account in the course of their development, and which the CNECV sets out as a requirement to:

1. **recognise the actual and potential health benefits of biotechnology and information technology**, through the discovery of innovative and advanced means of diagnosis and therapy, rehabilitation, as well as new processes for disease prevention and health care and promotion;

2. **maintain the centrality of the Human**, in the assumption that only the **Human** is an unconditioned end, and that all and any technology has an instrumental status or a means to fulfil the person, individually and collectively considered. The exploitation of the benefits of new technologies by sectarian and/or particular interests that tend to aggravate existing asymmetries and accentuate social injustice should be avoided;

3. **preserve the identity of the human being**, respecting humanity's common heritage and assuming responsibility for future generations;

4. **respect the core values of the Human Being and their fundamental rights**, forbidding all forms of instrumentalisation and discrimination based either on their intrinsic characteristics, on their identity construction, or on their socio-economic constraints, which are not interchangeable with instrumental performance values such as productivity, efficiency and profitability;

5. **invoke the precautionary principle whenever the future impacts of present initiatives are frankly unknown and unpredictable or potentially harmful** to humans, thus establishing moratoria to allow the necessary knowledge to be deepened.

II. In relation to genomic editing and artificial intelligence, it is also urgent to:

1. **support advanced research carried out in Portugal and/or integrated in international projects**, by making available the necessary means and appropriate legislation for the development of scientific knowledge and technological innovation;

2. **accompany** this progress with an **investment also in the field of social and human sciences, particularly in Ethics, Psychology, Sociology and Science Communication**;

3. **recognise that** nowadays **all fundamental research results in some form of practical application**, so the distinction between the two levels is no longer ethically significant;



4. **encourage translational research** (TR), in the transfer of advances validated in the laboratory to clinical practice, stimulating scientific research with the involvement of health professionals, in order to better respond to clinical needs and obtain better health outcomes;

5. **strengthen the mechanisms for promoting and supervising the scientific integrity of researchers and the social responsibility of** both research and funding institutions;

6. **promote scientific and health literacy in society**, as well as public debate on the ethical aspects and societal impact of disruptive technologies applied to health and biomedical research;

7. strictly **observe** the ethical-legal requirements of **respect for privacy and the informed consent process** and re-examine them in the light of the challenges posed by new technologies;

8. **invest in the health professional/researcher relation and people**, strengthening the means of communication and its quality, in recognition of its therapeutic impact on a physical and psychological level.

III. In specific terms, and considering separately the technologies covered in this report, the CNECV recommends,

A. in the context of **genome editing**:

1. **to make the interest and well-being of each person**, considered in their diversity and **irreducible to their genetic characteristics, prevail** over the sole interest of society or science;

2. **to carefully assess and exercise caution with regard to potentially irreversible and long-lasting effects of genome editing**, with consequences that cannot always be foreseen, calling for responsible and prudent use of these techniques;

3. **to adequately address the different concepts, applications and consequences related to genome editing** and its applications;

4. **to distinguish the purposes of prevention, therapy and breeding**, contexts in which the use of genome editing techniques may correspond to different ethical evaluations;

5. **to observe the highest ethical standards and legal norms in research using human biological material**, especially embryos, and ensure the fair distribution of benefits;

6. **to assess the risks of genome editing therapies against the potential benefits in an** appropriate, prudent, objective and transparent manner, taking as



indispensable criterion the protection of recipients of therapy and their descendants;

7. **to penalise the use of genome editing in the reproductive line** particularly in conditions considered clinically less severe or for which proven alternative techniques exist;

8. **to prohibit the use of genome editing to improve human characteristics and capabilities**, other than those conducive to good health, due to the risk of determinism, both individually, in the reduction of a person to their genetic characteristics, stigmatisation and discrimination, and collectively, in the introduction or exacerbation of social inequalities in access to scarce and expensive technologies;

9. **to provide genome editing with appropriate regulations**, regularly revised, taking into account the evolution of scientific knowledge and technological innovation, aspects of reasonableness of risks in the light of potential benefits, respect for autonomy, for the identity of the person, in his/her right to difference, and for his/her genomic privacy, valuing information and literacy as promoters of free and informed consent;

10. **to provide for mechanisms to mitigate unforeseen and harmful effects** and to supervise unauthorised or premature applications, both in research and in clinical application;

11. **to guarantee the privacy and protection of genomic information**, considered as particularly sensitive due to its intrusive and discriminatory, being ethically relevant the preservation of the right not to know (or the right not to be informed) and the right to forget;

12. **to involve the public in the debate on genome editing technologies**, with reliable information and the use of appropriate media and communication materials, with the results being analysed by experts - scientists, ethicists, social researchers - to demystify unrealistic expectations or unfounded fears;

13. **to encourage broad and participatory public debates regarding the regulation of clinical trials involving somatic cell genome editing** for indications beyond the treatment or prevention of serious genetic diseases or conditions. Such discussions should also be transparent and inclusive.

B. in the field of **artificial intelligence (AI) applied to health**:

1. **to recognise that AI**, albeit a determining factor of scientific and technological progress in the field of biomedicine - through the evolution of its proficiency in performing mechanical tasks and its capacity to carry out some



demanding cognitive activities – **should remain as a tool, of instrumental value, to be used at an operational level**, assisting and collaborating with human aims and contributing to their individual and social fulfilment, pursuant to the principles of human dignity and social justice;

2. **to state that**, despite the fact that AI is gradually reproducing different human functions more quickly, more accurately and more cheaply, its superior **efficiency is a utilitarian value** and not a value in itself, which only humans play a leading role in;

3. **to require** that the development of **AI respects the core values of human beings and their fundamental rights**, rejecting the reinvention of ethical values shaped by the conveniences of digital dynamics, **and focuses on the promotion of the human** (*human-centered design*), rejecting the pragmatism of exploitation by sectarian and/or particular interests;

4. **to take into account the transformations that the AI originates in institutional and social organisation systems, as well as in the modalities of individual action and interpersonal relationships**, timely identifying and preventing the negative impacts of digitalisation on human activities, such as the reduction of freedom and the worsening of dependencies and vulnerabilities, by eliminating alternatives and subtracting skills;

5. **to invest in new technological and legislative resources to strengthen individual privacy and the protection of sensitive personal data**, exponentially produced by the application of AI;

6. Specifically in the field of **biomedical research**, it is important to

a) **ensure** that the **possibility of formulating scientific doubts and hypotheses, implementing different explainable methodologies and replicating the studies** is maintained;

b) **promote the originality** of the analyses and interpretations of the realities under study;

c) **review the criteria for intellectual property** at various levels, establishing clear and transparent requirements for a rigorous determination of authorship and contribution, reflected at all stages of research;

d) **contribute**, possibly within the World Intellectual Property Organization (WIPO), to **the revision of the current patent law** that the progress of AI threatens to make obsolete;

7. Specifically in the area of **clinical assistance**, it is important to



- a) **promote the digitalisation of health services into an integrated network**, in terms of the diversity of services and **extending to the whole of the national territory**, also seeking to link not only public and private health institutions, but also health institutions and social support institutions;
 - b) **attend to the potential impact of technological mediation on the distancing of person-to-person relationships**, indispensable for a link of trust between partners in the therapeutic project, valuing the close and dialoguing relationship between patients, users and families and health professionals, in the practice of a personalised clinic in relation to the more standardised AI interventions; to make alternative ways of communication available to citizens without easy access to digital tools;
 - c) **assume** that, especially through AI applications, **both the autonomy and the responsibility of the person in managing their health are strengthened**;
 - d) **prevent** the apparent infallibility of **algorithmic decision making from restricting the freedom and creativity of health professionals** in their procedures and decisions **or the rights of patients**, in particular to a second opinion and alternative clinical interventions; to **provide for the civil liability of AI**;
 - e) **study the impacts** on patients and their families of **the vulgarisation of humanoid robots in healthcare provision**, especially in the long term;
 - (f) **develop systems for evaluating the quality and scientific evidence of digital and mHealth applications** that help individuals and health professionals to make informed and responsible choices and promote their usefulness;
8. Specifically in the area of **hospital management**, it is important to
- a) **promote telehealth as an enabler of equity in access to health and in its provision of new means of communication** with health professionals, **new services**, as well as in the **continuous monitoring of patients**, decongesting facilities and freeing up professionals for other functions;
 - b) **streamline the flow of information for the benefit of patients, the qualification of care and the optimisation of services**, protecting access, through **strict data coding**;



- c) **ensure that**, in the programming of AI systems, **the human factor remains present** (*in the loop*) as a fundamental element in all decision-making processes.
9. Specifically in the field of **public health administration**, it is important to
- a) **invest in** internationally recognised classification systems, **in the development of a global harmonised standard for coding**, respecting human rights, **together with a common governance framework**, contributing to a European Health Data Space and **monetising personal health data for the benefit of public health**;
 - b) **develop AI's predictive capacity** in anticipation and/or preparation for future health crises, preventing any type of biases that could lead to discrimination against population groups;
 - c) **counter the colonisation of data** and the deepening of the asymmetries of power it establishes.
10. Specifically in the field of **public health education and teaching**, it is important to
- a) **make teaching and continuing vocational training methodologies assisted by AI widely accessible**, provided they are validated in scientific evidence;
 - b) **favour access and a competent use of AI systems to promote health education**, in an informed and critical attitude on the part of the citizen, understanding how the AI works and becoming aware of the associated risks.

Approved unanimously at the 275th Plenary Meeting of the CNECV on 21 April 2023.