

ARTIFICIAL INTELLIGENCE, LIFE SCIENCES AND HEALTHCARE

Health regulation

Up to this moment, the Brazilian National Health Surveillance Agency (Anvisa) has not regulated the use of AI for health. However, software that encompasses AI technology can be subject to regularization (health registration and/or notification, being considered as a Software as Medical Device – SaMD), if it has one of the following purposes, pursuant to Section 4, X, of Anvisa Resolution No. 751/2022:

- i. diagnosis, prevention, monitoring, treatment (or relief) of a disease.
- ii. diagnosis, monitoring, treatment or healing of an injury or deficiency.
- iii. investigation, substitution, alteration of anatomy or of a physiological or pathological process or state.
- iv. life support or maintenance.
- v. birth control or support.
- vi. provision of data based on in vitro exams of samples derived from the human body, including donations of organs and tissues.

Most countries do not have an AI legislation per se yet - its development and adoption will challenge several stakeholders in the healthcare industry (such as governments, sanitary authorities, healthcare developers and professionals).

In order to assist in drawing up such regulations and policies, the World Health Organization (WHO) prepared the "[Ethics and Governance of artificial intelligence for health](#)" report, listing six ethical principles related to the use of AI for health:

Protecting human autonomy: it requires that human autonomy be preserved in the processes and application of AI for health. Within the field of health services, for example, this principle requires that the physician necessarily hold decision-making power over the medical conduct. In other words, the use of AI must be a support and an instrument for a possibly more precise and effective medical decision.

Artificial intelligence (AI) is already present in several sectors of economy and may have a direct connection with the improvement of processes and efficiency gain.

The use of AI for health has become more frequent and efficient. AI could, for instance, reach diagnoses more precisely than expert physicians. A study involving physicians in the United States of America and in the United Kingdom, as published in [Nature](#) scientific journal, has concluded that an AI-based technology was able to diagnose breast cancer more precisely than radiologists. AI managed to reduce false positive results by 5.7%, in the USA, and by 1.2% in the United Kingdom; and false negatives by 9.4% in the USA and by 2.7% in the United Kingdom.

Promoting human well-being and safety and the public interest:

it implies that AI technologies should not cause damage and/or loss to humans. To ensure that, such technologies must comply with regulatory requirements on efficacy, safety, and quality before being used for health. Moreover, measures to control and improve the quality of such technologies must be implemented.

Ensuring transparency, explainability and intelligibility:

transparent information assuring healthcare professionals, users, and regulators the correct understanding of AI technology must be guaranteed (for example, functionalities, goals, and use).

Fostering responsibility and accountability:

it aims at holding people accountable for damages caused by AI used for health, thus encouraging appropriate and responsible use of such technologies.

Ensuring inclusiveness and equity:

AI technologies for health must be designed with wide, diverse, and equitable application and use in sight, regardless of age, sexual orientation, income and/or patients' characteristics. In addition, the development of

new technologies must consider that there is a risk that AI technology will create discriminatory biases. In this case, such biases must be identifiable for correction.

Promoting AI that is responsive and sustainable:

AI in health must always be used responsibly so that its purposes are ultimately fulfilled for the benefit of society. Additionally, AI must be developed and operate aiming to minimize any impacts to the environment (for instance, promoting energy efficiency).

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