Ethical and Regulatory Challenges for AI-Biosensors in Healthcare

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Abstract:

AI-biosensors are devices that can detect and measure biological or chemical signals of interest, such as glucose, DNA, hormones, toxins, pathogens, etc. They have many applications in various fields, such as healthcare, environmental monitoring, food safety, biodefense, and bioengineering. However, AI-biosensors also pose some regulatory and ethical challenges that need to be addressed before they can be widely used and accepted by the society. Some of these challenges are safety and reliability, privacy and data protection, social and cultural implications, innovation and regulation. AI-biosensors are constantly evolving and innovating with new technologies, materials, methods, or applications. This may pose challenges for the existing regulatory frameworks and authorities that may not be able to keep up with the pace and scope of innovation. AI-biosensors should balance between innovation and regulation, and ensure that they are developed and used in a responsible and sustainable manner. AI-biosensors should also engage with various stakeholders, such as researchers, regulators, policy makers, industry partners, civil society groups, and end-users to foster dialogue, collaboration, and public trust. Proposed in April 2021 and expected to enter into force in 2025, the European Union Artificial Intelligence Act (EU AI Act) will be the first EU regulatory framework for AI and could serve as a law model for the regulation of AI-biosensors. There are some scattered international instruments and frameworks that address some of the ethical, legal, and social issues related to biosensors. States and the World Health Organization (WHO) with its constitutional mandate to deal with global public health should regulate the use of AI-biosensors and adopt legally binding rules and international standards in this sensitive field.

Keywords: AI; biosensors; data collection; healthcare; privacy; regulations.

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