FRANCE NEEDS A PUBLIC LABEL FOR THE EVALUATION OF AI USED IN HEALTHCARE

In France today, there is no harmonised public mechanism to certify that AI technologies used in healthcare are safe and trustworthy, despite the call of several national institutions to ensure the effectiveness and safety of such technologies.

Given the inadequacy of the French regulatory arsenal in evaluating AI-enabled medical devices and the proliferation of various private initiatives to label technologies, public authorities should get involved. At Global Health Advocates France, we believe a public label for AI in healthcare would be a perfect tool to harmonise the existing regulatory landscape and protect the public interest.

REGULATION AND EVALUATION OF AI SYSTEMS IN HEALTHCARE: A GUARANTEE OF QUALITY

AI technologies are increasingly used in healthcare, notably to assist medical professionals in remote disease monitoring, writing medical reports, diagnostic assistance, etc. Although these tools are revolutionising certain aspects of medicine, they can be risky if poorly supervised. From errors and biased calculations to discriminatory results for certain groups, the risks of AI in healthcare have potentially serious consequences for people's health and rights.

Yet these risks are avoidable, at every stage of technology design, thanks to particular measures such as data quality control or algorithmic biases training. Because healthcare is a very sensitive domain, it is necessary to ensure that such measures have been taken in AI tools' creation process to guarantee the best quality of care and equal treatment for all. The assessment of AI tools and medical devices is thus central.

SHORTCOMINGS IN THE EVALUATION OF AI SYSTEMS IN HEALTHCARE

In France, however, only a fraction of AI technologies are subject to such evaluation. Only medical devices that are reimbursed are evaluated today. Indeed, all AI technologies used in healthcare must first comply with the European Medical Device Regulation (MDR), which lays down minimum safety and quality requirements. However, at the French level, only digital medical devices for individual use are subject to an in-depth assessment by the Haute Autorité de santé (HAS), as part of their

reimbursement process. Digital medical devices for professional use, on the other hand, are not subject to any structured national assessment. These technologies include diagnostic assistance algorithms, which are becoming increasingly popular among health professionals, and which can have serious consequences for health in the event of errors.

In addition to allowing potentially risky tools to be marketed to certain groups, this situation makes it impossible to guide healthcare professionals towards reliable technologies and leaves the implementation of quality control procedures to the discretion of AI developers. At present, the only resource available to healthcare professionals for guidance is a selection guide produced by the HAS, but this is not sufficient to guarantee product quality.

A PUBLIC LABEL: AN ESSENTIAL TOOL FOR PUBLIC INTEREST

In the absence of a clear regulatory framework, initiatives have proliferated to create labels and certification procedures to provide a framework for technologies and organizations. These labels are often disparate, assessing distinct aspects such as the human guarantee, ethical data processing or diversity within companies. In addition, these mostly private initiatives sometimes lack transparency regarding assessment criteria and offer paid certification, making it difficult to verify their quality.

In this context, public authorities have a crucial role to play in protecting the public interest. As regulators and guarantors of public safety, they can offer an appropriate response by developing a public label. This would be an effective tool for encouraging compliance with rigorous quality and ethical criteria while remaining capable of adapting to rapidly evolving technologies. Complementing existing legislative mechanisms (such as the European AI Act, the Code de la Santé Publique and the Code de la Sécurité Sociale), a public label for AI in healthcare would strengthen the evaluation framework through an incentive mechanism, by making the granting of public funding for research and innovation conditional on criteria of excellence.

FIND OUT MORE

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