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Global Spotlights

The Artificial Intelligence Act approved by the EU: the difficult dialogue between the black box and the cardiologist

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'We do not have knowledge of a thing until we have grasped its why, that is to say, its cause' (Aristotle)

'The physician must convert or insert wisdom to medicine and medicine to wisdom' (Hippocrates)

Contemporary medicine is evidence-based in its deepest foundations. Empirical philosophy came to existence hand in hand with Greek medicine. Hippocrates' and Galen's imperative was to use experience as an instrument of knowledge.[1] Evidence-based medicine remains the paradigm for rational, ethical, and effective clinical practice. Will this hold true in the era of non-explainable artificial intelligence (AI)? Perhaps yes, since the ability to explain how results are produced may be less important than the ability to produce them and verify their effectiveness. Even nowadays, after centuries of observation and research, medical management is often not fully supported by the fundamental knowledge of pathophysiological mechanisms.

According to Aristotle, 'we do not have knowledge of a thing until we have grasped its why'.[2] Therefore, maybe, we should grasp why AI does what it does and demand that the AI algorithms in medical devices should be explainable and verifiable (and, by the way, these as well as other terms, such as explicability, interpretability, or intelligibility, used in the context of high-risk medical AI, should be explicitly defined).[3] Not everything that is logical and consistent with our pathophysiological reasoning, however, has been shown to be effective as expected when tested in a rigorous way in clinical trials. Thus, perhaps logic is not that important and, as conventional wisdom holds—'whatever heals, is right'. Consequently, in 'the difficult dialogue between the black box of AI and the cardiologist', we may not necessarily demand explainability of AI.[4]

These questions are now more relevant than ever, because in March 2024, the European Parliament voted overwhelmingly in favour of the AI Act, which was followed by the final approval by the Council on May the 21st.[5] The regulation provides a unified framework for AI systems, from development through marketing and use, based on a proportionate risk-based approach. The proposed regulation classifies an AI system as high risk when it is, according to Article 6, 'subject to a conformity assessment before being placed on the market or put into service in accordance with the EU harmonization legislation'. Since all medical devices in risk class IIa or higher (including high-risk software) must undergo conformity assessment by a notified body in order to be placed on the market, under the Medical Device Regulation, then all medical devices utilizing AI algorithms fall into the category of 'high-risk' AI according to the AI Act. It imposes several obligations on clinicians, such as informing patients, verifying input data, or fulfilling vigilance reporting (*Table 1*).

As per Recital 73 of the AI Act, 'High-risk AI systems should be designed and developed in such a way that natural persons can oversee their functioning, ensure that they are used as intended and that their impacts are addressed over the system's lifecycle'. Article 14.2 of the AI Act states that 'Human oversight shall aim to prevent or minimize the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose'. To paraphrase Hippocrates: 'The physician must convert or insert wisdom to AI-driven medicine, and AI-driven medicine to wisdom'. Article 14.3 portends a difficult 'dialogue' between the 'black box' and cardiologists, by stating that 'the oversight measures shall be commensurate to the risks, level of autonomy and context of use of the high-risk AI system'. What does this mean for practising physicians—is it doable and if so, how?

The human oversight requested by the new AI Act puts an undesirable legal responsibility on the human involved in the case of 'black-box' AI systems where the human has no way to verify the outcome of the AI tool, whether it is about making diagnoses, suggesting therapies or choosing follow-up schemes. In those cases, the healthcare provider should refuse to simply 'push the button' and instead should only use or prescribe these AI tools if they have been shown in appropriately designed clinical investigations to provide the desired outcome for the

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Table 1 Obligations for clinicians as users of high-risk artificial intelligence systems (medical devices) in healthcare

Obligations for clinicians as users of high-risk AI systems	
Human oversight	Human oversight is essential to prevent or minimize risks to health and ensure safety when the system is used in accordance with its intended purpose.
Informing patients	Patients should be adequately informed and give consent for the use of medical devices, classified according to the AI Act as high-risk AI systems.
Verifying input data	The users of a high-risk AI system (including AI/ML enabled devices) are responsible to verify whether the input data meet the provider's requirements.
Vigilance reporting	Healthcare professionals using medical devices classified as high-risk AI systems should report incidents to the manufacturers and/or to the respective national competent authorities.

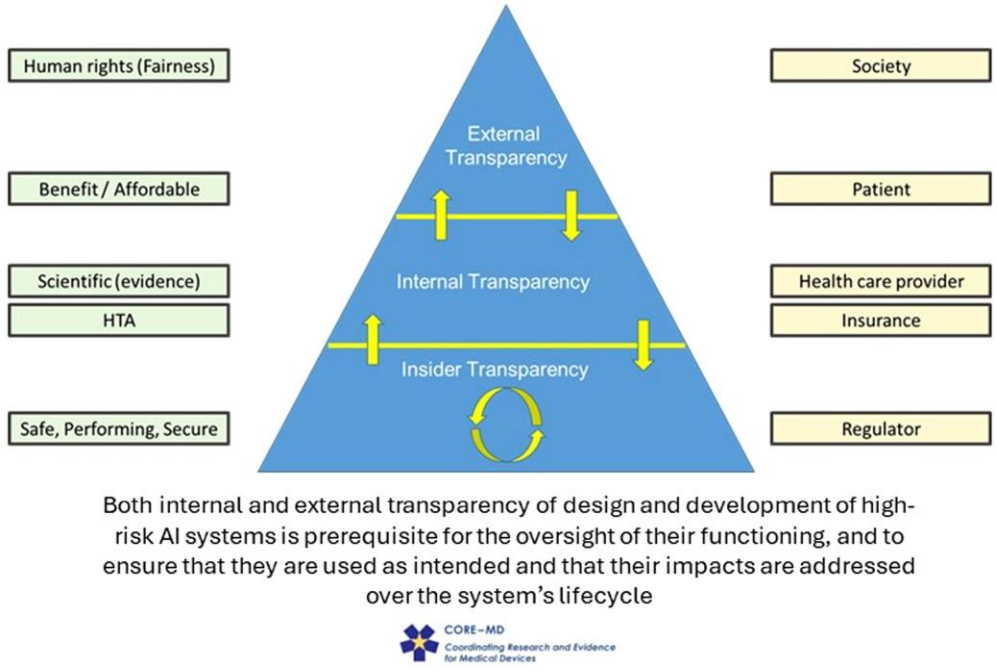

Figure 1 Transparency of the design and development of high–risk AI systems (Adopted from Kiseleva et al.[7])

intended population. Several AI tools are not black but grey boxes, where some of the 'reasoning' of the AI system (or neural network) can be verified and understood—as long as there is full and detailed disclosure of the input data, of the output of the model (for example in terms of diagnostic performance, reproducibility, and probability of any conclusions), and of information about its applicability or generalizability—but they would still need to be tested in real-life clinical settings as humans tend to overrate the accuracy and dependability of such systems and may be wrongly influenced by them.

Artificial intelligence tools do have the benefit of consistency, which is sometimes lacking in human decision-making. Bias can be present, but that is also the case in human decision-making and may be better verifiable and amenable to correction in AI systems.

So simply refusing to use AI tools with a potential benefit to patients is not a good option, but in the clinical community, we have the duty to organize and participate in the appropriate testing of these tools.[6] This will require us to get better acquainted with the intricacies of AI systems, the do's and don'ts of how to test and validate them, and the consistency of refusing to use non-validated tools, however nice and appealing they may seem. Both internal transparency and external transparency of the design and development of high-risk AI systems are prerequisites for the oversight of their functioning (*Figure 1*).[7]

Declarations

Disclosure of Interest

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