

EDITORIAL

AI AND CLINICAL CARE

Applying Clinical Licensure Principles to Artificial Intelligence

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In this issue of *JAMA Internal Medicine*, Bressman et al¹ propose a clever thought experiment: what if medical tools incorporating artificial intelligence (AI) were licensed as advanced practitioners, rather than solely regulated by the



Viewpoint

US Food and Drug Administration (FDA)? This strategy seeks to provide an alternative or complement to FDA clearance in regulation of medical software incorporating AI. The authors suggest this may allow the necessary flexibility to keep up with the pace of change in AI, the breadth of applications for a given model, and the need to ensure that such tools demonstrate clinical utility.²

Many instances of more specific, single-purpose AI applications can be adequately regulated within existing frameworks. However, generative AI may be deployed in a wide range of contexts, and models may continue to develop over time. Because these models are probabilistic rather than deterministic, they may make errors that are analogous to human errors, for example, mistakes due to inadequate knowledge or lapses in judgment. Bressman et al¹ argue that an appropriately flexible framework for certification already exists in the form of licensing oversight of advanced practitioners.

With this approach, the extent of supervision depends on the particular activity, with some tasks requiring more oversight than others.

The proposal leaves a number of critical details to be resolved. Any AI licensing system will need to be able to evaluate and address a model's specific potentials for harm before deployment; thus, some central regulation likely will continue to be required. In addition, determining who will take on the responsibility and oversight for decisions and treatment pathways generated by AI, as well as assume the liability for errors or adverse events, remains a thorny question. These considerations are again analogous to those of clinician licensing, but although medical boards are well positioned for licensing, the extent to which a similar approach could be developed with the necessary expertise for AI in medicine remains to be seen.

A licensure system for medical AI akin to the one used for clinicians offers a more flexible alternative to current regulatory processes and allows continuous evaluation and updating. The enormous breadth of these new technologies could spur those charged with ensuring their safety and efficacy to adopt equally broad thinking in response.

ARTICLE INFORMATION

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