# Comment on "Artificial intelligence and machine learning in pediatrics and neonatology healthcare"

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#### Dear Editor,

We read with interest the article entitled "Artificial intelligence and machine learning in pediatrics and neonatology healthcare" by Matsushita et al.<sup>1</sup>. We agree with the authors on the huge potential of artificial intelligence/deep learning (AI/DL) systems in improving healthcare, especially on the management of chronic diseases. Many countries and multilateral forums are currently developing strategies for AI/DL legal regulation, involving system's design, validation, implementation, and postmarketing monitoring<sup>2</sup>, while taking steps to avoid biased data sets that will negatively impact the system's performance and potentially increase health inequalities<sup>3</sup>. Due to their theoretically unlimited scalability, the risk of such systems should be dimensioned accordingly<sup>3</sup>. Safety and efficacy evaluation demands well-designed studies with a rigorous methodology that is proportional to the sensitivity of data and the risk of patient damage; for risk stratification, regulatory policies could be inspired, for example, on the existing legislation on data protection and the biosecurity classification for laboratories<sup>4</sup>. The adoption of such technologies will also demand societal decisions which involve local conditions such as the availability of healthcare personnel and economic factors. An example is the screening of diabetic retinopathy, a major cause of preventable blindness: how should one health system calibrate the trade-off between sensitivity and specificity? Cost-effectiveness, constrained workforces, and current workflows are some of the variables of this equation<sup>5</sup>.

Regulation should balance safety guarantees and the support for innovations and should engage all the stakeholders,

### REFERENCES

 Matsushita FY, Krebs VLJ, Carvalho WB. Artificial intelligence and machine learning in pediatrics and neonatology healthcare. Rev Assoc Med Bras. 2022;68(6):745-50. https://doi.org/10.1590/1806-9282.20220177 including medical and scientific societies, the academia, and the final user, in order to increase public confidence<sup>3</sup>. Given the expected overwhelming demand in the near future, centralized regulation is unlikely to adequately ensure the safety, efficacy, and equity of implemented systems; possible answers to such challenges may involve a decentralized approach with local evaluation, as well as the proposed creation of the new medical specialty of clinical AI<sup>6</sup>.

The cooperation among developers, ethic experts, physicians, patients, and regulatory agencies is essential for the rapid adoption and successful implementation of AI/DL in health, with an enormous potential of improving healthcare, increasing access, reducing costs, and promoting equity. Scientific and medical societies should participate actively in the formulation of best practices and in the prospective validation of AI systems.

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