Ensuring quality in AI healthcare technologies

Clinical trials are routinely used in health research to test the safety and efficacy of new treatments and products. A growing number of these medical interventions have an AI component, such as AI-assisted diagnostic tests, smart wearable devices, and personalised apps. Until now, however, there had been no universally agreed set of standards for assessing the quality of trials involving AI, making it difficult for the interventions to be compared with each other.

In September 2020, the first international guidelines for the design and reporting of clinical trials involving AI were published in *Nature Medicine*, *The BMJ* and *The Lancet Digital Health*. The work was funded by the Turing, along with the Wellcome Trust, Research England and Health Data Research UK.

The two sets of guidelines, called SPIRIT-AI and CONSORT-AI, provide checklists for researchers to follow to improve the quality and transparency of their trials involving AI. Recommendations include providing clear details of the skills required to operate the AI system, the process for acquiring and selecting the input data, and how the output data will be used, such as whether they will feed into clinical decision-making.

The guidelines will help researchers, peer reviewers, funders, journal editors and regulators to ensure that AI technologies in healthcare are supported by the best possible evidence.

“There is a lot of hype around the use of AI in healthcare. These guidelines will help to cut through that by providing clear standards for AI clinical trials, with the ultimate aim of speeding up the delivery of safe and effective AI innovations to patients.”

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