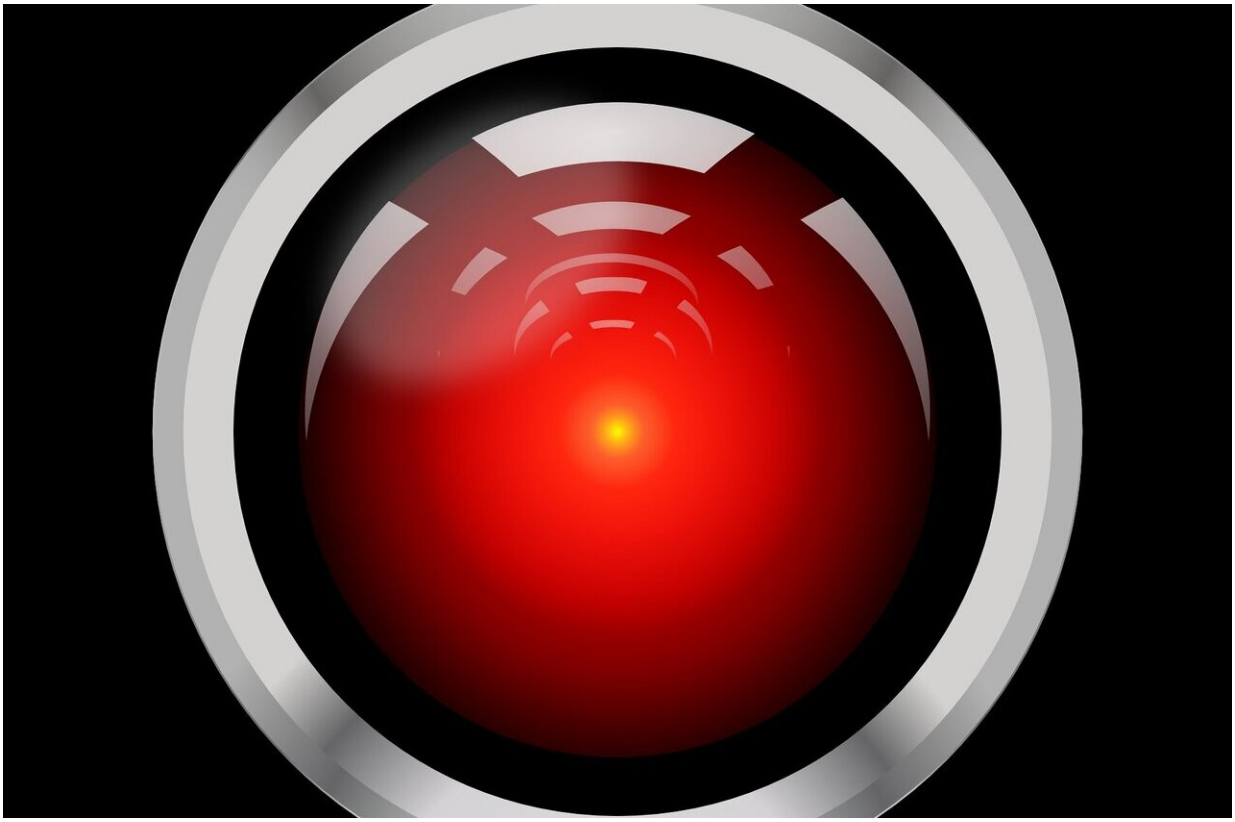
MedicalXpress

Patients set to benefit from new guidelines on artificial intelligence health solutions

September 10 2020



Credit: Pixabay/CC0 Public Domain

Patients could benefit from faster and more effective introduction of artificial intelligence (AI) innovations to diagnose and treat disease—thanks to the first international standards for reporting of

clinical trials for AI.

As evaluation of health interventions involving machine learning or other AI systems moves into clinical trials, an international group has developed guidelines aiming to improve the quality of these studies and ensure that they are reported transparently.

The use of these international guidelines will enable patients, health care professionals and policy-makers to be more confident on whether an AI intervention is safe and effective. This is a key step towards trustworthy AI in health.

Development of new reporting guidelines which expand on the current SPIRIT 2013 and CONSORT 2010 reporting frameworks will boost transparency and robustness for clinical trials evaluating AI health solutions.

Future clinical trials evaluating an AI intervention will be expected—and often required—to report their publications to the new standards. The guidelines will also help medical professionals, regulators, funders and other decision-makers assess the quality of planned clinical trials and assess whether the algorithm is safe and likely to bring about patient benefit.

Researchers from the University of Birmingham and University Hospitals Birmingham NHS Foundation Trust (UHB) worked with leading insttitutions from across the world—including the United States and Canada—and have published their findings and the new guidelines today in *Nature Medicine*, the *BMJ* and *The Lancet Digital Health*.

Researchers developed the additional guidance to tackle concerns that many studies of AI are of insufficient quality and are not transparent. This was highlighted in research published last September, led by several

of the same researchers which highlighted that less than one percent of 20,500 analyzed studies relating to health AI were of sufficient quality that independent viewers could have confidence in their results.

Professor Alastair Denniston, Lead for AI at Birmingham Health Partners Center for Regulatory Science and Innovation, and Consultant Ophthalmologist at UHB, commented: "Patients could benefit hugely from the use of AI in medical settings, but before we introduce these technologies into everyday practice we need to know that they have been robustly evaluated and proven to be effective and safe. Our previous work showed just how big a problem this can be and that we needed a way to cut through the hype surrounding AI in healthcare. These new reporting guidelines—SPIRIT-AI and CONSORT-AI—provide a solution to the 'hype' problem. They provide a clear, transparent framework to support the design and reporting of AI trials that will help to improve quality and transparency. These extended guidelines will help to reduce wasted effort and deliver effective AI-led medical interventions to patients quicker."

SPIRIT-AI extension is a new guideline for clinical trials protocols and CONSORT-AI extension is a new reporting guideline for clinical trial reports, for evaluating interventions with AI components.

Professor Melanie Calvert, NIHR Senior Investigator and Director of Birmingham Health Partners Center for Regulatory Science and Innovation commented: "There is growing recognition that interventions involving AI need rigorous evaluation to demonstrate their impact on health outcomes. Without this, we risk not generating sufficiently robust evidence to decide whether AI interventions should be commissioned in the real world. These new guidelines will help to identify and overcome research challenges associated with AI-led health innovation, but we could not have got to this exciting point without the help of patients involved in research."

Elaine Manna, from London, has been living with age-related macular degeneration for 20 years and was one of a number of patient partners who helped to develop the new guidelines. She was asked to provide a patient perspective on developing the guidelines after taking part in an AI research study involving Moorfields Eye Hospital NHS Foundation Trust, in London, and British technology company DeepMind.

Elaine commented: "A super-fast algorithm was tested on my eye—diagnosing my condition as well as an expert ophthalmologist or optometrist. This was a development with significant implications for saving sight and reducing waiting times for appointments. It's vital for patients to be equally involved in their healthcare—understanding how decisions are made, being informed and involved in decision making. Helping to develop the SPIRIT-AI and CONSORT-AI guidelines, I went from thinking of myself as someone with a degenerative eye disease to someone who felt empowered."

The SPIRIT-AI extension includes 15 new items and the CONSORT-AI extension includes 14 new items—all considered sufficiently important for clinical trial protocols of AI interventions to be routinely reported in addition to core items.

More information: Reporting guidelines for clinical-trial reports for interventions involving artificial intelligence: the CONSORT-AI extension. *Nature Medicine*. doi.org/10.1038/s41591-020-1034-x (2020)

Guidelines for clinical-trial protocols for interventions involving artificial intelligence: the SPIRIT-AI extension. *Nature Medicine*. doi.org/10.1038/s41591-020-1037-7

Provided by University of Birmingham

Citation: Patients set to benefit from new guidelines on artificial intelligence health solutions (2020, September 10) retrieved 20 April 2024 from https://medicalxpress.com/news/2020-09-patients-benefit-guidelines-artificial-intelligence.html

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.