

Reporting guideline for the early-stage clinical evaluation of decision support systems driven by artificial intelligence: DECIDE-AI.

Title: Reporting guideline for the early-stage clinical evaluation of decision support systems driven by artificial intelligence: DECIDE-AI.

Publication year: 2022

Journal: Nature medicine

Authors: Nuffield Department of Surgical Sciences, University of Oxford, Oxford, UK.
baptiste.vasey@gmail.com.

Society: European Respiratory Society

Origin country: International (Europe)

Target countries: Europe

DOI: 10.1038/s41591-022-01772-9

PMID: 35585198

Source: <https://pubmed.ncbi.nlm.nih.gov/35585198/>

A growing number of artificial intelligence (AI)-based clinical decision support systems are showing promising performance in preclinical, in silico evaluation, but few have yet demonstrated real benefit to patient care. Early-stage clinical evaluation is important to assess an AI system's actual clinical performance at small scale, ensure its safety, evaluate the human factors surrounding its use and pave the way to further large-scale trials. However, the reporting of these early studies remains inadequate. The present statement provides a multi-stakeholder, consensus-based reporting guideline for the Developmental and Exploratory Clinical Investigations of DEcision support systems driven by Artificial Intelligence (DECIDE-AI). We conducted a two-round, modified Delphi process to collect and analyze expert opinion on the reporting of early clinical evaluation of AI systems. Experts were recruited from 20 pre-defined stakeholder categories. The final composition and wording of the guideline was determined at a virtual consensus meeting. The checklist and the Explanation & Elaboration (E&E) sections were refined based on feedback from a qualitative evaluation process. In total, 123 experts participated in the first round of Delphi, 138 in the second round, 16 in the consensus meeting and 16 in the qualitative evaluation. The DECIDE-AI reporting guideline comprises 17 AI-specific reporting items (made of 28 subitems) and ten generic reporting items, with an E&E paragraph provided for each. Through consultation and consensus with a range of stakeholders, we developed a guideline comprising key items that should be reported in early-stage clinical studies of AI-based decision support systems in healthcare. By providing an actionable checklist of minimal reporting items, the DECIDE-AI guideline will facilitate the appraisal of these studies and replicability of their findings.