

Publication

A systematic survey identified 36 criteria for assessing effect modification claims in randomized trials or meta-analyses

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Keywords Clinical trials as topic (MeSH); Epidemiologic methods (MeSH); Health care evaluation mechanisms (MeSH); Meta-analysis as topic (MeSH); Precision medicine (MeSH); Subgroup analysis The objective of the study was to systematically survey the methodological literature and collect suggested criteria for assessing the credibility of effect modification and associated rationales.; We searched MEDLINE, Embase, and WorldCat up to March 2018 for publications providing guidance for assessing the credibility of effect modification identified in randomized trials or meta-analyses. Teams of two investigators independently identified eligible publications and extracted credibility criteria and authors' rationale, reaching consensus through discussion. We created a taxonomy of criteria that we iteratively refined during data abstraction.; We identified 150 eligible publications that provided 36 criteria and associated rationales. Frequent criteria included significant test for interaction (nă=ă54), a priori hypothesis (nă=ă49), providing a causal explanation (nă=ă47), accounting for multiplicity (nă=ă45), testing a small number of effect modifiers (nă=ă38), and prespecification of analytic details (nă=ă39). For some criteria, we found more than one rationale; some criteria were connected through a common rationale. For some criteria, experts disagreed regarding their suitability (e.g., added value of stratified randomization; trustworthiness of biologic rationales).; Methodologists have expended substantial intellectual energy providing criteria for critical appraisal of apparent effect modification. Our survey highlights popular criteria, expert agreement and disagreement, and where more work is needed, including testing criteria in practice.

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