Outcome reporting bias in government-funded RCTs

An-Wen Chan and associates,1 in their evaluation of outcome reporting bias in 48 randomized controlled trials funded by the Canadian Institutes of Health Research (CIHR), found that a high number (median 26) of outcomes were declared in each protocol, but not all of these outcomes were reported in the published papers; in addition, statistically significant efficacy outcomes had a higher likelihood of being reported than nonsignificant ones.

Twenty of the 48 studies were jointly funded by industry and CIHR. It would be of interest to know whether the results were consistent between the 2 subgroups of studies, those funded by government only and those cofunded by industry.

This work shows that research promoted through public funding is not free from bias. The explanation of outcome reporting bias is challenging. In particular, further investigation is needed to identify the factors that affect selection of outcomes between a study’s protocol and the published report of the study.

[The authors respond:]

In response to Pasquale Moja and associates, we would first like to clarify 2 points in their letter. First, it would be more accurate to state that a median of 26 outcomes was declared in both the protocols and the publications, rather than in the protocols alone. Also, with regard to the assertion that “research promoted through public funding is not free from bias,” we would clarify that it is not the research itself that is biased, but rather the reporting of the research.1

Moja and associates ask about the consistency of results across sources of funding. We would not expect significantly greater deficiencies among trials that were jointly funded by government and industry sources, as these studies were investigator-driven rather than fully controlled by the industry sponsor. Furthermore, formal subgroup analyses would be underpowered to detect any differences.

However, we do agree that stratifying the data by funding source would provide valuable preliminary insight into factors that might affect selective outcome reporting. Exploratory post hoc analyses for efficacy outcomes revealed consistent results across funding subgroups. The odds ratios for outcome reporting bias were 3.4 (95% confidence interval [CI] 1.3–9.3) for trials funded jointly by industry and CIHR (n = 11 trials) and 2.3 (95% CI 1.1–5.1) for trials funded by CIHR alone (n = 19 trials). The prevalence of major discrepancies in the specification of primary outcomes also did not differ significantly between jointly funded (7/20, 35%) or CIHR-funded (12/28, 43%) trials.

An-Wen Chan
Karmela Krlëša-Jerić
Isabelle Schmid
Randomized Controlled Trials Unit
Canadian Institutes of Health Research
Ottawa, Ont.

Douglas G. Altman
Centre for Statistics in Medicine
Oxford, UK

Reference

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Medical education and chronic disease

Anton Miller and associates,1 in their commentary on the need to improve health care services for children with chronic health conditions, reveal one of the weaknesses of the medical profession. We have difficulty adapting to new situations, such as that presented by the increasing prevalence of chronic disease in our society.

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