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Increasing the Reporting Quality of Clinical Trials—No Easy Solutions?

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Speich and colleagues[1] report the results of 2 randomized studies that aimed to assess a method to increase the reporting quality of randomized trial protocols and reports. Submissions of protocols and result reports to 7 journals were randomized so that peer reviewers of manuscripts in the intervention arm received additional guidance asking them to assess the study report against a curated list of 10 "important and poorly reported items" from the Consolidated Standards of Reporting Trials (CONSORT) or Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklists as part of their review. Neither study produced evidence that the intervention was successful in raising the quality of reporting compared with the controls who received no additional guidance. As the authors note, prior trials[2,3] of simple editorial interventions have similarly failed to yield any notable improvement in reporting quality. With the continued ineffectiveness of what would be relatively simple and low-cost interventions to improve the quality of trial reports, it may be time to reconsider the editorial processes around the publication of these studies.

The authors speculate that one reason this, and similar, interventions may have failed is that "peer reviewers already have a high workload (for which they do not receive compensation) and might therefore not be willing to conduct more tasks or follow further instructions," which rings true but also calls into question what, fundamentally, reviewers of trial manuscripts are being asked to do. CONSORT purports, based on expert opinion, to contain "a checklist of essential items that should be included in reports of RCTs [randomized clinical trials]" so that others can adequately assess the trial's methods and findings.[4] The SPIRIT checklist serves a similar purpose for trial protocols. Dozens of journals have endorsed both checklists, apparently agreeing that this set of information is "essential." However, if those tasked with reviewing clinical trial results and protocols fail to check for these "essential" elements during their appraisals, even when specifically prompted, are they fully performing their duty as a reviewer? Although reviewing a trial write-up certainly requires evaluations beyond simply ensuring adherence to a checklist such as CONSORT, it is difficult to imagine how one could reach an informed decision on the design, findings, and risks of bias for a given trial if these fundamental facets of the research are not being interrogated.

The continued use and development of reporting checklists like CONSORT and SPIRIT do not, however, appear to be in vain. A Cochrane Review found that journals endorsing CONSORT have seen improvements in reporting quality.[5] However, the authors of that review specifically note that overall reporting remains suboptimal, falling short of the ideal imagined by the development of these guidelines. Endorsement of a relevant reporting checklist must mean more than simply being made to attach a document to a submission that is never scrutinized during the editorial or peer review process.

An intervention that has been shown across 2 trials to improve reporting quality is dedicating expert reviewers to focus solely on reporting quality.[6,7] Implementing this type of additional review would require resources from journals and could further tax an already strained editorial and peer reviewer workforce. If editors and peer reviewers were forced to adopt every additional responsibility and check proposed in the literature, nothing would ever get published. However, if the community of journals agrees, through their endorsement of CONSORT and similar initiatives, that "the whole of medicine depends on the transparent reporting of clinical trials,"[4] then perhaps this should be seen as a worthwhile investment alongside concerted efforts to assess ways of accomplishing these reviews efficiently and cost-effectively.

Research that explores ways to ensure more complete and transparent reporting for randomized trials should continue, and more journals throughout the clinical literature should be willing to open their editorial processes to experimentation. Failure to attract a more diverse array of journals into these meta-studies makes conducting these types of studies difficult and can temper the generalizability of the findings; for instance, Speich and colleagues[1] assessed few industry-sponsored trials in this study likely because of their sample of journals. Still, we are fortunate that these authors, and others, have shared their findings about what does not work. A simple informational resource that improves reporting quality through minimal editorial effort would likely see widespread adoption and be a major boon to the biomedical literature. Unfortunately, we have yet to come across this panacea. What does appear to work would require hard work, investment, and a rethinking of how journals design, implement, and staff their editorial and peer review procedures. However, the payoff for this investment could be a more transparent, complete, and higher-quality evidence base for medicine.

ARTICLE INFORMATION

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