



Editorial

Prestige and Quality Control of Medical Journals[☆]

Prestigio y control de calidad de las revistas médicas

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Although there are several ways to assess the quality of journals that publish peer-reviewed articles, readers expect prestigious journals to only publish clinical trials (and other types of studies) in which the design, methodology, conduct (including ethical, regulatory and logistic aspects) and data analysis are of the highest quality. Evidence that reporting clinical trials outcomes leaves much to be desired has meant that many journals require compliance with CONSORT Statement (<http://www.consort-statement.org/>) in order to publish trial results. This, however, does not prevent the publication of studies with defects such as, for example, outcome reporting bias. This can lead clinicians to make erroneous decisions after reading the article, and moreover, the errors can be transferred to systematic reviews and meta-analyses, which are key in the development of clinical practice guidelines. In one study, bias was detected in the primary efficacy outcomes and safety outcomes in 31%¹ and 47%–76%² of trials included in systematic reviews, respectively.

As investigators are legally required to register clinical trials with medicinal products before start the reports eventually published can be checked against the protocol initially entered in the registry. It is disturbing to observe that in 4%–50% of the articles, at least one of the primary outcomes was omitted, added or changed after the trials were registered or submitted for evaluation to the relevant research ethics committee.³ The issue is that the reader has no way to know when a report is biased, unless the information in the article is compared with registry data (something that very few clinicians have time to do) or with the protocol (to which they rarely have access).

Although most leading journals, those with the highest impact factors (e.g. *Lancet*, *JAMA*, *BMJ*, *PLoS Med*), request that authors submit the trial protocol together with the manuscript reporting the results, this has been shown to be ineffective in preventing outcome reporting bias. Thus, 30% of articles published in 2011–2012 in the *BMJ* and *JAMA* on 76 clinical trials showed discrepancies (omission, introduction; change in timing of the primary outcome assessment) between the primary outcomes published and those declared in the registries.⁴

The biopharmaceutical industry published the results of 86% phase 3 trials of novel therapeutic agents approved between 2005 and 2011 in the United States.⁵ However, if some of those articles convey biased results, erroneous information will be transmitted that will have more or less impact depending on the nature and extent of the bias. This can affect various facets of the trial, such as one or more of the primary or secondary outcomes, sub-group analysis, and reporting of serious adverse reactions and/or deaths.⁶ The fact that regulatory agencies have all the information from all trials should assure clinicians and patients that information provided in the Summary of Product Characteristics has taken into account all the results obtained in all trials. Nevertheless, this does not occasionally prevent companies from publishing articles with major bias. Thus, a review of 96 articles published between 2010 and 2011 in leading journals (all with impact factor >10; 55% of the articles published in *N Engl J Med*, *Lancet* and *JAMA*) found that in 6%, primary efficacy endpoints had been changed with respect to the information included in the registry, and that this affected the interpretation of the results.⁷ Four of these trials were sponsored by the pharmaceutical industry. Biased information, therefore, sometimes reaches the clinician via the most prestigious journals, and the fact that the sponsor has provided the regulatory agencies with all the study data has little impact on it. It is important to note that this practice is not exclusive to industry: in the aforementioned study, 2 trials were sponsored by hospitals.⁷

Article quality (meaning the absence of outcome reporting bias) could be assured by comparing the information in the manuscript with that of a reliable source (the registry or protocol). However, very few journals request the trial protocol for the purpose of evaluating the manuscript (a method which, as mentioned above, is of little help in preventing this type of bias), and 93% of reviewers consider that comparing the information in the manuscript with that included in the registry is a job for the journal's editorial team.⁸ This suggests to journals must introduce quality control mechanisms in the manuscript review process to prevent bias in the publication of clinical trial outcomes.

Two alternatives have been proposed so far to prevent this type of bias: one is based on a statement of integrity, in the form of a "Declaration of transparency" signed by the authors when submitting the manuscript to the journal⁹; the second is a process by which authors must report and explain to the editorial team any inconsistency between the information included in the manuscript and that reported in the trial registry.¹⁰ The former cannot be

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considered a quality control mechanism, since only the manuscript authors are involved. The second, in contrast, could be considered as such if the editorial team check the information submitted by the authors. In any case, other alternatives may also be found.

Implementing quality control measures will be the only way to guaranteeing readers that published outcomes reflect the investigators' original aims, and to show that the prestige of a journal can be measured by the absence of outcome reporting bias in published clinical trials results.

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Conflict of Interests

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