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Is there a solution to publication bias? Researchers call for changes in dissemination of clinical research results

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Abstract

Objectives: To explore opinions of authors of published reports of clinical trials and Cochrane systematic reviews on the causes and methods of preventing publication bias.

Study Design and Setting: An online questionnaire was developed and sent to researchers publishing in high-impact or national general medical journals, authors of Cochrane systematic reviews, and a general population of researchers. Open-ended questions about publication bias were qualitatively analyzed. We also held a focus group with experienced researchers and/or Cochrane reviewers.

Results: Publication bias was common: 48 (36%) respondents had own unpublished trials and 40 (30%) admitted selective outcome reporting; but researchers felt strongly that blame rested also with the system that promotes and augments publication bias practices. Qualitative analysis of both survey responses and focus group discussion identified possible ways of reducing publication bias through increased transparency, improvements to trial registries, search engines and databases, enhancement of the role of institutional review boards, positive encouragement of scientists, and policy changes.

Conclusion: Although well aware of the problem, clinical researchers knowingly contribute to problems of selective reporting and nonpublication of trials. They call for changes in current practices of journal-based communication of trial reporting and for systematic evaluation of measures to decrease publication bias. © 2014 Elsevier Inc. All rights reserved.

Keywords: Publication bias; Clinical trials; Guideline adherence; Questionnaires; Focus groups; Information dissemination

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1. Introduction

Results from clinical trials are necessary to provide unbiased information for making decisions about medical therapies and diagnostic procedures. Yet, despite the need for greater transparency of clinical research and recent strong initiatives to increase this transparency, for example, mandatory registration and posting of results from clinical trials [1,2], there is still a long way to go before 100% of studies are published [3]. Recently updated systematic review on biases in clinical trials [4] confirmed that the extent of publication bias remains unchanged and that studies with significant or positive results are more likely to be published. The blame has been put on investigators as "*almost all failure to publish is due to the failure of investigators to submit reports for publication*" [5]. Even Cochrane Collaboration researchers—experts acutely aware of publication bias—publish only about a third of results presented at annual meetings [6].

Despite a number of studies investigating the prevalence and causes of nonpublication [7−11], investigators have not been asked about possible solutions. To address this knowledge gap and contribute to the discussion on how to achieve full transparency of clinical research [3], we used an online survey to assess how clinical researchers and Cochrane systematic reviewers explain the reasons behind publication bias and propose methods to prevent it. We further explored the themes that emerged in the survey in a focus group discussion held at a research conference on transparency in health research.

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What is new?

- Clinical researchers from 41 countries reported high rates of nonpublication of their own trials (36%) and admitted to selective reporting of trial results (30%), confirming that publication bias remains a serious problem.
- Researchers are aware of being the main culprits for publication bias but feel strongly that the blame rests with the system that allows such practices — from research funders and institutions to journals and trial registries.
- To preserve the integrity and transparency of clinical research, researchers call for radical changes in the process of communicating the trial results to the professional and general public, including legal actions and alternatives to journals.

2. Methods

2.1. Survey development and data collection

A questionnaire (Appendix A at www.jclinepi.com) was developed based on previous surveys on publication bias [7]. The term "clinical trial" used in the survey was defined as "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes." The types of publication bias addressed in the survey were "publication or nonpublication of research findings, depending on the nature and direction of the results; duplicate publications from the same patient data sets; and selective reporting of outcomes."

The questionnaire was piloted for content and face validity among a convenience sample of eight experienced researchers and revised according to comments and suggestions.

The questionnaires were sent out using the SurveyMonkey platform. The survey was performed using the total design method for mailing procedure [12]. No incentives other than information on the results of the surveys and on the OPEN (Overcoming the failure to Publish nEgative fiNdings) project were offered for completing the surveys.

2.2. Survey respondents

Four target groups were identified: (1) researchers who had published their trial(s) in high-impact journals ($n = 452$), (2) researchers who had published in European national medical journals ($n = 331$), (3) authors of Cochrane systematic reviews ($n = 452$), and (4) a general population of researchers. Details of the search strategy by which we obtained e-mail addresses of potential respondents are available in Appendix B at www.jclinepi.com. Of 1,299 collected addresses, 35 bounced back and 45 were set to automatically reject e-mails from the SurveyMonkey platform. General population of researchers had access to the survey at the Web site of the OPEN project (www.open-project.eu).

2.3. Content analysis of survey responses

Each survey included seven open-ended questions where respondents could leave comments and elaborate their answers to the other survey questions. Both authors read all responses independently and grouped them according to the type of suggestion or opinion on publication bias. All discrepancies were discussed and agreed on for final interpretation.

2.4. Focus group

We also organized a focus group during EQUATOR Scientific Symposium 2012, "ACT now: Accuracy, Completeness, and Transparency in health research reporting", held in Freiburg, Germany, 11–12 October 2012 (information on the meeting is available at http://www.equator-network.org/courses-events/equator-scientific-symposium-2012/). At the start of the focus group, participants were given a short anonymous questionnaire, which included a definition of publication bias and questions on sociodemographic factors and publication experience. After a brief introduction, the participants were asked "What could be the reasons for failing to publish results of completed trials?" After no new information could be gained, the interviewers moved to the question "What are the ways to identify, diagnose and prevent publication bias?", and finally to "What do you think about public access to trials, research information, Masters and PhD theses and ethical board reviews?" All respondents' answers were audio recorded and transcribed verbatim. The content analysis followed the same procedure as that of the online survey.

3. Results

3.1. Online survey

The response rate, up to the end of December 2012 when the survey was closed, was 8% (33 of 441) from researchers who had published in high-impact journals, 7% (21 of 310) from authors in national general medical journal, and 14% (64 of 468) for Cochrane reviewers. We also received 64 responses via the OPEN Web site. The main characteristics of the respondents are presented in Table 1. The respondents had experience in conducting clinical trials, which were mostly investigator driven and mostly either publicly funded or not funded (Appendix C at www.jclinepi.com). More than a third (36%) had