Review

A systematic review finds underreporting of ethics approval, informed consent, and incentives in clinical trials

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Abstract

Objectives

In this study, we aim to review researchers' reporting practices of the ethics statement, financial incentives, and local ethical committees' profile in their clinical trials.

Study Design and Setting

A systematic search was done through top-ranked 50 medical journals (Scimago Ranking) to retrieve 2,000 latest publications. Only primary clinical trials were included with no restriction to language or participants.

Results

Among the 927 included trials, 14 trials (1.5%) did not report an ethical statement and two-third (63%) did not completely report the investigated components (Institutional Review eBoard approval, Helsinki Declaration, and informed consent). Moreover, 21 trials (2.26%) reported motivational incentives with the method and amount of payment for participants. Of them, 15 trials offered monetary incentives to participants in different forms. In the remaining six trials, the incentives were mainly medical benefits. Only one trial reported the profile or quality of local Institutional Review Board.

Conclusion

A potential gap in the reporting practices of ethics statement and financial incentives was addressed in this review. Authors are urged to fully report all ethical components related to their study, including incentives and compensations plan. Medical journals are also recommended to implement further publication requirements concerning ethics reporting.

Introduction

Health care–related research is bound by several ethical standards that preserve human subjects' well-being and beneficence [1]. Authors are expected to include an ethics statement in all research studies that involve human subjects. This includes stating an Institutional Review Board (IRB) approval, informed consent procedures, and a declaration that the study was conducted in accordance to the global ethical standard [2], [3]. Underreporting of these ethical components in clinical trials is a problem that raises concerns regarding authors' reporting integrity and patients' rights [4], [5], [6].

Another ethical aspect that authors may also miss is describing the process of recruiting subjects [7], [8]. Humans engagement in clinical experiments can be voluntarily or driven by financial incentives. However, voluntary participation is unlikely to be sufficient to cover the needs of some research projects, especially when specific demographic characteristics of participants are required [9], [10]. Using money as motivation to enhance subjects' participation has raised some ethical issues related to patients' autonomy, attitudes during the trial and their benefit and harm [11], [12], [13]. Several studies indicated that researchers occasionally miss important ethical dimensions in their manuscripts, including informed consent procedures, ethics committee approval [14], [15], and conflict of interest [16].

In response to these issues, all ethics-related details including the method and amount of payment to the trial's subjects are now required to be included in the informed consent and protocol and to be reviewed by the Institutional Review Board/Independent Ethics Committee (IRB/IEC) [17]. Transparency and reproducibility are among the essential pillars of medical research. Failing to provide a thorough report of the methodology and ethical components of a trial might, directly or indirectly, hinder the global efforts to tackle credibility issues and irreproducibility, and the efforts to protect research human subjects.

Several aspects of underreporting of medical publications have been addressed before [18], [19], [20]. However, to our knowledge, the guidelines of incentives reporting in publication and the quality of local IRB/IEC have not been previously considered. We believe that high-quality reporting of the ethics statement, method, and amount of payment to participants, and all the changes that take place after registering the protocol provide clear and transparent information for journal editors, reviewers, and readers to assess the integrity and quality of a certain study. In this review, we aim to investigate researchers' reporting practices of the ethics components, financial incentives, and local IRB/IEC's profile in their clinical trials' manuscripts.

Section snippets

Guidelines of ethics statement in the top 50 medicine journals ranked by Scimago

The guidelines for authors from the top 50 searched journals included in our study were screened by two independent coauthors (A.E. and M.E.M.) to check how many of the following ethical components (IRB/IEC approval, Helsinki Declaration, and informed consent) and incentives are required in the manuscript. Any discrepancy was solved by discussion and consensus with senior authors (N.T.H. and L.Q.T.).

Search strategy

We retrieved the latest 2,000 publications (full-text, primary clinical trials, with no

Search result

We retrieved a total of 2,000 citations from the top 50 Medical Journals ranked by Scimago, after applying the inclusion and exclusion criteria, 927 randomized controlled trials were included in the final analysis. Excluded articles were mostly secondary analysis or not randomized controlled trials. There were no non-English articles among our finally included papers. (see PRISMA flow diagram and reasons for exclusion; Fig. 1). Upon scanning the countries where the included trials were

Discussion

This systematic review indicates that 1.6% of clinical trials did not report ethics statement and nearly two-third (63%) did not completely document the investigated ethical statement components despite the intensive peer review process and the strict guidelines of most medical journals. Given that all the included papers in our study are published in high-impact factor journals, this may reflect a similar-to-higher percentage of poor reporting in the medical literature.

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