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Characteristics of funding of clinical trials: cross-sectional survey and proposed guidance

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ABSTRACT

Objectives To provide a detailed and current characterisation of funding of a representative sample clinical trials. We also aimed to develop guidance for standardised reporting of funding information.

Methods We addressed the extent to which clinical trials published in 2015 in any of the 119 Core Clinical Journals included a statement on the funding source (eg, whether a not-for-profit organisation was supported by a private-for-profit organisation), type of funding, amount and role of funder. We used a stepwise approach to develop a guidance and an instrument for standardised reporting of funding information.

Results Of 200 trials, 178 (89%) included a funding statement, of which 171 (96%) reported being funded. Funding statements in the 171 funded trials indicated the source in 100%, amount in 1% and roles of funders in 50%. The most frequent sources were governmental (58%) and private-for-profit (40%). Of 54 funding statements in which the source was a not-for-profit organisation, we found evidence of undisclosed support of those from private-for-profit organisation(s) in 26 (48%). The most frequently reported roles of funders in the 171 funded trials related to study design (42%) and data analysis, interpretation or management (41%). Of 139 randomised controlled trials (RCTs) addressing pharmacological or surgical interventions, 29 (21%) reported information on the supplier of the medication or device. The proposed guidance addresses both the funding information that RCTs should report and the reporting process. Attached to the guidance is a fillable PDF document for use as an instrument for standardised reporting of funding information.

Conclusion Although the majority of RCTs report funding, there is considerable variability in the reporting of funding source, amount and roles of funders. A standardised approach to reporting of funding information would address these limitations. Future research should explore the implications of funding by not-for-profit organisations that are supported by for-profit organisations.

Strengths and limitations of this study

- First cross-sectional survey of a large and representative sample of clinical randomised controlled trials (RCTs) to describe the characteristics of the funding statements in detail.
- Provides a proposed guidance and instrument for standardised reporting of funding information.
- Use of systematic and transparent methods, for example, duplicate and independent processes in screening and data collection.
- Includes trials limited to the clinical field and so our findings may not apply similarly to other fields such as public health research.

BACKGROUND

Funding sources may influence the reporting of research findings and the interpretation of results.[1–6] One study found that 86% of trial protocols documented an industry partner's right to disapprove or review proposed manuscripts.[7] This might also apply to other types of funders, for example, government. Reporting of funding in trials may appropriately influence how physicians interpret and use trial findings in clinical practice.[8 9] The Consolidated Standards of Reporting Trials (CONSORT) checklist recognises this issue by including a section on reporting of funding.[10 11]

Reports in the lay media have documented how for-profit organisations support research through not-for-profit organisations.[12 13] In one example, The Independent recently highlighted a systematic review suggesting that the consumption of low-energy sweeteners in place of sugar reduces energy intake and body weight.[14] The review authors list the International Life Sciences Institute as the study funder. While the Institute describes itself as 'a non-profit, worldwide organisation whose mission is to provide science that improves human health', it receives funding primarily from companies such as the Coca-Cola Company, PepsiCo and Nestlé.[15] Other examples of not-for-profit organisations

funded by industry and supporting research are the Sugar Association[16 17] and the now defunct Global Energy Balance Network.[18]

We conducted a comprehensive review of the literature and found 22 studies that assessed reporting of funding in clinical trials (see online supplementary appendix 1).[5 19–39] The main gap we identified in this literature is a detailed and current characterisation of funding of a representative sample of trials. Indeed, all of the identified studies focused on trials published in specific clinical areas or journals. Most (14, 64%) reported only on funded trials or did not differentiate between non-funded trials and those that do not report on funding. Seventeen studies (77%) did not always distinguish trials with no funding from those funded by the government or by not-for-profit sources. Moreover, these studies seldom assessed reporting on the role of funder (n=4), provision of supplies (n=2) and the amount of funding (n=0). None of the studies explored the relationship between not-for-profit organisations funding trials and for-profit organisations.

Therefore, the main objective of this study was to provide a detailed and current characterisation of funding of a representative sample of clinical trials. We also aimed to develop guidance for standardised reporting of funding information.

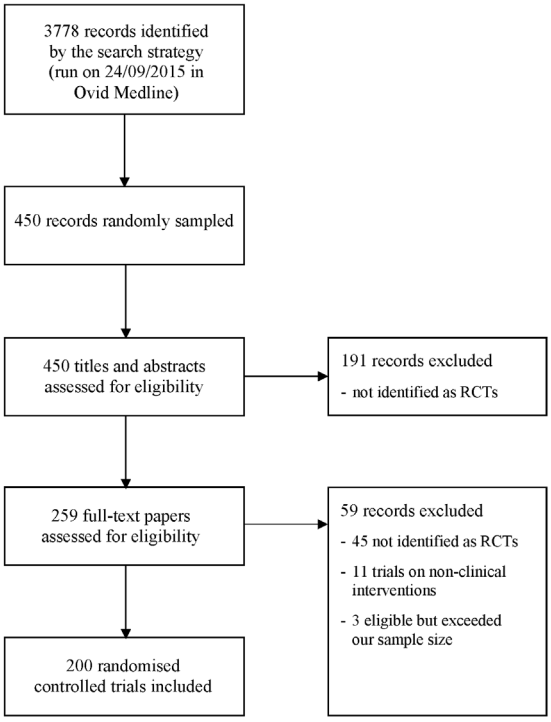

Figure 1 Study flow diagram. RCTs, randomised controlled trials.

METHODS

Design overview and definitions

We followed systematic methodology to conduct a cross-sectional survey of published randomised controlled trials (RCTs). We define funding as any support (eg, monetary support, provision of supplies, assistance in manuscript writing). We considered as funding statement any text in the trial report providing any information regarding the funding of the trial, including a statement of no funding. A funding statement could indicate more than one funding contribution.

Eligibility criteria

We included reports of studies described as RCTs comparing at least two therapeutic interventions of any type in humans and published in English. We included RCTs with cross-over designs and secondary reports of trials (ie, follow-up study, post hoc analysis, interim analysis, prespecified analysis or secondary outcomes or substudy of a trial). We excluded non-randomised trials, trials addressing basic sciences topics and non-clinical interventions, and research letters.

Search strategy

We searched Ovid Medline in September 2015 and limited our search to the year 2015 and the 119 Core Clinical Journals (Abridged Index Medicus).[40] We applied the search filter obtained from the Cochrane handbook to identify RCTs. See online supplementary appendix 2 for the detailed search strategy.

Selection process

We used an online sequence generator (www.random.org/sequences) to randomise the citations captured by the search. We followed the order of the randomisation list to screen citations until we obtained 200 eligible RCTs. Our sample size allows for a narrow 95% CI (±5%) around proportions of studies reporting sources of funding.

Following calibration exercises, three reviewers (MBH, NJ, MK) worked in teams of two (MBH was the reviewer on both) to screen titles and abstracts in duplicate and independently, using EndNote X7.5 software (Thomson Reuters, Philadelphia, Pennsylvania, USA). We obtained the full texts of citations judged as potentially eligible by either reviewer. The two teams of reviewers screened full texts in duplicate and independently. They resolved disagreements by discussion, or with the help of a third reviewer (EAA) as needed. A Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) study flow diagram[41] presents the results of the selection process (figure 1).

Data extraction process

We developed a standardised data extraction form along with specific instructions. After pilot testing the form, we embedded it electronically into Research Electronic Data Capture (REDCap), a secure web-based application designed to support data capture for research studies.[42] After completing calibration exercises, nine authors divided into teams of two extracted data in duplicate and independently (MBH was a reviewer on each of the eight teams). Each team compared results and resolved

disagreements through discussion, or with the help of a third reviewer (EAA) as needed.

Data extracted

We extracted the following characteristics of the RCTs:

- number of trial authors;
- whether it is the first full-text report of the trial findings;
- classification of the income level of the country in which the first author's institution is located (as high, upper-middle, lower-middle or low-income country according to the July 2015 World Bank list of economies);
- type of intervention and type of control;
- number of trial sites;
- number of randomised participants;
- level of risk of bias associated with allocation concealment, a methodological feature as an indicator of risk of bias (based on the Cochrane Collaboration's tool for assessing risk of bias);[43]
- whether authors reported conflicts of interest;
- whether the report included a funding statement.

We then focused on trials that included funding information. We extracted the following funding characteristics reported in the paper:

- whether it reported funding versus no funding;
- the type of source(s) of funding (see online supplementary appendix 3). These included internal funding (when it is an academic or hospital affiliation) and external funding, categorised into government, private-for-profit, private not-for-profit with evidence of support by private-for-profit that is a health industry, private not-for-profit with evidence of support by private-for-profit that is not a health industry and private not-for-profit with no evidence of support by private-for-profit. As needed, we performed an online search to accurately assign the type of the funding source. When a funding source was identified as a not-for-profit organisation, we searched the organisation's website for any information on partnership with or support from a for-profit organisation (see online supplementary appendix 4 for details);
- amount of funding;
- whether the paper reported to be sponsored by a source different than the source of funding/support;
- whether information was reported (across the paper) on supplies in trials on pharmacological or surgical interventions (ie, drugs, devices, equipment, samples or placebos) and whether the supplier is a funding source. We looked for that information in the funding statements, acknowledgement statements and the methods section.

Finally, and in trials that reported being funded, we assessed whether the role of funder was explicitly reported for any funder as involved or not involved in the process of the research study.

Data analysis

We assessed agreement between reviewers of each team for inclusion of RCTs at the full-text screening stage using chance-corrected agreement (kappa statistic). We conducted descriptive analyses of the general characteristics of the RCT, as well as the characteristics of the funding statement. We present summary data for categorical variables as frequencies and percentages and for continuous variables as median and IQR. All calculations used SPSS, V. 21.0 for Windows (SPSS, Chicago, Illinois, USA).

Candidate independent variables for multivariable logistic regression analyses to assess the predictors of reported funding and the role of funder included characteristics of the RCT and variables related to Journal policy for reporting funding (ie, journal requirement for reporting of funding, journal requirement for reporting on the role of funder). For variables related to journal policy for reporting funding information, we used unpublished data we had collected in mid-2014 for another cross-sectional survey.[44]

Development of the guidance

We used the following approach for developing the proposed guidance for standardised reporting of funding information. First, our classification of funding sources was based on one we had used in a previous study (governmental, private not-for-profit and private-for-profit)[45] that we modified after a review of relevant literature[5 22 27] and of journals' policies on reporting of funding information (unpublished data from another cross-sectional survey).[44] Second, we refined the classification through an iterative process of discussion and revisions based on funding statements reported in this sample of RCTs, as well as in a sample of systematic reviews.[46] Finally, we used Adobe Acrobat XI software to develop a fillable PDF document for use as an instrument for standardised reporting of funding information.

The process included both in-person and email discussions among the authors of this article and feedback from external experts. The individuals involved have the following profiles: author EAA is a clinical epidemiologist and was an associate journal editor for Health and Quality of Life Outcomes journal; author GG is a clinical epidemiologist and has been a member of editorial boards of eight journals. The external experts we consulted include Dr Elie Al-Chaer (health researcher with a law degree and editor-in-chief of International Journal of Women's Health and Dove Press), Dr Joerg Meerpohl (associate editor of Health and Quality of Life Outcomes journal) and Dr Peter Tugwell (co-editor of the Journal of Clinical Epidemiology).

RESULTS

Figure 1 presents the study flow diagram. Agreement proved substantial (kappa=0.78) and near perfect (kappa=0.86) respectively for each of the two teams at the full-text screening stage.

Table 1 General characteristics of the included randomised controlled trials (n=200)

	Overall n (%)*
Number of trial authors; median (IQR)	9 (6–14)†
Paper is the first full-text report of the trial findings	171 (86%)
Classification of the income level of the country in which the first author's institution is located:	
High income	179 (90%)
Upper middle income	15 (8%)
Lower middle income	4 (2%)
Low income	2 (1%)
Type of intervention	
Pharmacological	97 (49%)
Surgical/invasive procedure	42 (21%)
Non-invasive procedure	11 (6%)
Lifestyle intervention	15 (8%)
Screening/diagnostic intervention	9 (5%)
Psycho-therapeutic intervention	4 (2%)
Rehabilitation	6 (3%)
Other	16 (8%)
Type of control	
Active control (as opposed to non-active)	82 (41%)
Number of trial sites; median (IQR)	2 (1–17)
Number of randomised participants; median (IQR)	160 (60–485)
Level of risk of bias associated with allocation concealment	
High risk	4 (2%)
Low risk	59 (30%)
Unclear	137 (69%)
Reporting of conflicts of interest	
Not reported	12 (6%)
Reported with no conflicts of interest disclosed	80 (40%)
Reported with conflicts of interest disclosed	108 (54%)
Inclusion of a funding statement	
Included (as opposed to not included)	178 (89%)

*For continuous variables, numbers refer to median (IQR), indicated in the relevant row.
†The number of trial authors per trial ranged between 1 and 91.

Table 2 Characteristics of the funding statements included in the randomised controlled trials (n=178 trials)

	Overall n (%)
Funding statement reported being:	
Funded (as opposed to not funded)	171 (96)
Source(s) of funding (when reported as funded, n=171)*	
Internally funded	26 (15)
Externally funded by:	
Government	99 (58)
Private-for-profit	68 (40)
Private not-for-profit with evidence of support by private-for-profit that is a health industry	14 (8)
Private not-for-profit with evidence of support by private-for-profit that is not a health industry	15 (9)
Private not-for-profit with no evidence of support by private-for-profit	25 (15)
Statement included amount of funding received	2 (1)
Paper reported to be sponsored by a source different than the source of funding/support	2 (1)
Paper reported information on supplies (ie, drugs, devices, equipment, samples or placebos)†	
Yes, supplied by manufacturer same as funder	12 (9)
Yes, supplied by manufacturer different than funder	17 (12)
Not reported	110 (79)

*More than one type could apply for trials reporting more than one source of funding.
†Calculated using the number of trials on pharmacological interventions and surgical/invasive procedures (n=139).

Characteristics of the RCT

The first authors of most trials (90%) had affiliations in high-income countries and almost half (49%) assessed pharmacological interventions (table 1). About half the trials (54%) were multicentre, and had two as the median number of sites. Most trials (94%) reported on conflicts of interest and 54% disclosed presence of conflicts of interest. Almost all (178, 89%) included a funding statement.

Characteristics of the reported funding

Table 2 presents the characteristics of the reported funding of the 178 trials with a funding statement, of which 171 (96%) reported being funded. The median number (IQR) of funding sources for each funded trial was 1 (1–3), with a range of 1 to 12 sources per trial. The top most frequent sources of funding were governmental (58%) and private-for-profit (40%). Of the 54 funding contribution statements in which the source was identified as being a not-for-profit organisation, we found evidence of support of those organisations from private-for-profit entity(ies) in 29 (54%), of which 26 (48%) did not disclose this support in the study report. Twenty-one trials (12%) reported funding from private-for-profit

Table 3 Reporting on the roles of funders in the randomised controlled trials that reported being funded (n=171)

	Reported role as:		Did not report role
	Not involved	Involved	
	n (%)	n (%)	n (%)
Any role of the below	41 (24)	44 (26)	86 (50)
Protocol/design of the study	41 (24)	30 (18)	100 (58)
Data collection	31 (18)	16 (9)	124 (73)
Verifying data accuracy/fact checking	0 (0)	3 (2)	168 (98)
Outcome adjudication	0 (0)	1 (1)	170 (99)
Data analysis/interpretation/management	40 (23)	31 (19)	100 (58)
Funded a medical writer	1 (1)	19 (11)	151 (88)
Preparation of the manuscript	34 (20)	20 (12)	117 (68)
Review of the manuscript	17 (10)	7 (4)	147 (86)
Approval of the manuscript	17 (10)	8 (5)	146 (85)
Decision to submit the manuscript	18 (10)	6 (4)	147 (86)
Appointed an independent data and safety monitoring board	0 (0)	1 (1)	170 (99)
Auditing of study conduct	0 (0)	3 (2)	168 (98)
Management	0 (0)	3 (2)	168 (98)
Team assembly	0 (0)	2 (1)	169 (99)
Conduct of study	13 (8)	12 (7)	146 (85)
Generated randomisation list	0 (0)	3 (2)	168 (98)
Enrolment of participants	0 (0)	1 (1)	170 (99)
Logistical support	0 (0)	3 (2)	168 (98)
Holding study data	0 (0)	1 (1)	170 (99)
Study oversight	0 (0)	2 (1)	169 (99)
Steering committee	0 (0)	1 (1)	170 (99)
Measurement of study variable	0 (0)	5 (3)	166 (97)

in addition to another source. Two trials reported the amount of funding received. Of the 139 RCTs assessing pharmacological or surgical interventions, 29 (21%) reported information on the supplier of the medication or device.

The reported roles of funders

Table 3 presents the reported roles of funders in the 171 trials that reported being funded. Eighty-five trials (50%) indicated the role of funders and provided descriptions of 22 different roles. The most frequent roles indicated in these 85 trials were participation in the design of the study (42%), data collection (27%), data analysis, interpretation or management (41%), manuscript preparation (32%), decision to submit the manuscript (15%) and conduct of the study (15%).

Results of the regression analyses

Online supplementary appendix 5 presents the details of the multivariable logistic regression analyses. Reporting being funded was positively associated with two variables (table 4), based on data from all included trials (n=200). Explicit reporting on the role of funder was positively associated with three variables (table 4), based on data from trials reporting being funded (n=171).

Proposed guidance

The proposed guidance provides suggestions for both funding information and the reporting process. Box 1 lists the funding information that relates to the phases of the research study for which the funding was received, the funding sources and the involvement of the funders in the process of the research study.

As for the process of reporting funding information, we suggest that the corresponding author plays the role of the guarantor of this information (given his/her primary responsibility of communicating with both the journal and the readers) and take responsibility for

- Collecting funding information and filling a standardised form
- Sending the form to all coauthors for approval and verification of accuracy and completeness of the information
- Submitting the up-to-date form at the time of submission of the manuscript for consideration for publication

Table 4 Results of the multivariable regression analysis

Dependent variables	Independent variables	Adjusted OR (95% CI)	p Value
'Reporting being funded' model (n=200)	Journal impact factor	1.44 (1.09 to 1.90)	0.011
	Affiliation with an institution from a high-income country (reference category being middle or low-income countries)	0.09 (0.02 to 0.37)	0.001
'Explicit reporting on the role of funder' model (n=171)	Journal impact factor	1.07 (1.04 to 1.10)	<0.0001
	Journal requirement for reporting on the role of funder	3.76 (1.64 to 8.62)	0.002
	Funding from private-for-profit source(s) (reference category being all other types of funding sources)	5.7 (2.37 to 13.85)	<0.0001

- Updating and re-submitting the form at the time of acceptance of the manuscript for final publication

Online supplementary appendix 6 provides a fillable PDF document for use as an instrument for standardised reporting of funding information.

DISCUSSION

Summary of findings

The objective of this study was to describe the characteristics of the funding statements in reports of clinical trials. About nine in ten trial reports included a funding statement and 96% of those statements indicated that funding existed. The latter statements specified the source, amount and role of funders in 100%, 1% and 50% of cases, respectively. The most commonly reported sources of funding were government and private-for-profit sources. Of all funding contribution statements in which the source was identified as being a not-for-profit organisation, about half related to not-for-profit organisations for which we found evidence of support by private-for-profit entity(ies). Only three of those statements disclosed the support by the private-for-profit entities. For trials of pharmacological or surgical interventions, only a fifth reported information on the supplier of the medication or device. We identified descriptions of a total of 22 different roles for the funders. Trials most frequently reported on roles related to the design of the study, data collection, data analysis and manuscript preparation. We also propose a guidance and instrument for standardised reporting of funding information.

Box 1 Suggestions for what funding information to report

Funding sources (and grant ID if applicable)

- All types of funding sources, including the following with specifications:
  - Internal funding (specifying institution)
  - Government(s) (specifying granting agency, level of government)
  - Intergovernment (two or more government agencies such as the European Union)
  - Private-for-profit (listing companies/entities)
  - Private not-for-profit (listing organisations/philanthropies)
- Research phases for which funding was received: planning, conduct and/or reporting of the research study under consideration. When funding relates to provision of supplies, the appropriate answer is 'conduct'.
- Type of funding received including monetary support, provision of supplies, and so on.
- Value of monetary support and value of other supports.
- Whether the funding provided by any of the funding sources is supported by an entity other than/external to the funding source.

Involvement (role) of funding sources

- Involvement (role) of each funder in the process of the research study, including:
  - Study planning and conduct: design and protocol drafting, study management, participant recruitment, data collection, data management, data analysis, quality control.
  - Study reporting (manuscript): preparation, review, approval, decision to submit.
  - Authorship: authors employed by the funder.

Reporting of funding

The high percentage of trials that reported being funded may be explained by the fact that conducting an RCT typically requires a large number of resources.[47–49] Also, we found a positive association between reporting being funded and affiliation with an institution from a high-income country. This may reflect better opportunities for, and higher ability of, institutions from high-income countries to obtain funding.

Explicit reporting on the role of funder was associated with journal requirement for reporting on the role of funder. This might explain the relatively low percentage of trials that reported on the roles of funders given that only 31% of clinical journals require authors to state the role of funder (unpublished data from another cross-sectional survey[44]). Explicit reporting on the role of funder was positively associated with trial funding from private-for-profit sources. This may be due to the adherence of the industry to higher standards of reporting. Indeed, several studies found that industry-funded trials had higher quality scores as compared with trials funded by other sources.[24 50–53]

Both reporting being funded and explicit reporting on the role of funder were associated with higher journal impact factor. This is consistent with our previous findings that better reporting of authors' conflicts of interest is associated with higher journal impact factor for both systematic reviews and trials published in Core Clinical Journals.[46 54]

We found that half of not-for-profit organisations included in funding contribution statements were supported by private-for-profit entity(ies). This is probably an underestimate due to lack of reporting of such support by authors. This also suggests that these types of relationships are prevalent. Indeed, one recent study found that 96 national health organisations accepted money from the Coca-Cola Company, PepsiCo or both,[55] with a number of these organisations known to fund research (eg, Juvenile Diabetes Research Foundation). This is very concerning given that the appearance of support by a not-for-profit may portray confidence in the study findings, in spite of the fact that the indirect for-profit support may have biased those findings. Indeed, while we explored whether private not-for-profit organisations were supported by private-for-profit entity(ies), this may also apply to other types of funding sources.

Strengths and limitations

This is the first cross-sectional survey of a large and representative sample of clinical RCTs to describe the characteristics of the funding statements in detail. Our proposed guidance and instrument for standardised reporting of funding information may serve researchers from different fields of health. Moreover, they may be used for other types of research studies and manuscripts and not only trials (eg, systematic reviews). In addition, we used systematic and transparent methods for screening and data collection.

As our study focused on clinical trials, our findings may not apply similarly to other fields, for example, health policy and systems research. While we did not conduct a formal and extensive validation of the guidance (and instrument), we believe that it has both face and content validity given that we based it on a thorough review of the related literature, on the cross-sectional survey of trials, and we revised it based on feedback from journal editors and a lawyer.

Comparison to similar studies

We identified 22 studies on the reporting of funding information in clinical trials (see online supplementary appendix 1).[5 19–39] While all 22 studies focused on trials published in specific clinical areas or journals, our study assessed a wide sample of clinical trials published in any of the Core Clinical Journals. None of the 22 studies looked at whether the amount of funding was reported. In fact, we found that two trials in our sample reported amount. Two out of the 22 studies assessed reporting of provision of supplies in trials published between 1987 and 1994.[34 39] To our knowledge, our study is the first one to survey a recent sample of trials for reporting of amount of funding and information on supplies.

Only 4 out of the 22 studies assessed reporting on the roles of funders.[20 22 28 36] Whereas these studies assessed this in industry-funded or partially industry-funded trials, we assessed this across all types of funders. For example, we found that 44% of trials funded solely by governmental sources reported on the role of funder. Example statements from those that reported involvement of the government as a funder include 'appointed an independent data and safety monitoring board', 'had input into the study design and data interpretation' and 'reviewed and approved the report'.

Our previous study on clinical systematic reviews found that a third of systematic reviews did not report on funding or reported no funding in comparison to 15% of trials in this study.[46] When the included systematic reviews reported being funded, the most commonly reported sources of funding were internal funding and government (52% and 67%, respectively). While only 2% of clinical systematic reviews reported funding from private-for-profit sources, we found that 40% of clinical trials reported such funding. Moreover, trials were twice more likely than systematic reviews to report on not-for-profit as their funding source (32% and 16%, respectively). While half of funded trials reported on the role of the funder, a quarter of funded systematic reviews did so.

In comparison to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)[56 57] and the CONSORT checklist sections on funding,[10 11] our guidance provides more detailed and specific recommendations for the reporting of funding information and includes detailed definitions and examples of types of funders. It also includes a clear classification of roles in which funders may be involved in the process of the trial. Whereas the International Committee of Medical Journal Editors conflict of interest disclosure form includes a section for the reporting of 'financial support', the questions and options that follow imply types of financial conflicts of interest for each individual author rather than the study's funding.[58]

Implications for practice

Our proposed guidance may help with clearer and more detailed reporting of the characteristics of funding in trials. This may in turn help readers and systematic reviewers better assess the significance of the funding and how it might affect the credibility of findings.[8 59] Specifically, we recommend that trial authors explicitly report more details on the funders, whether they are supported by for-profit organisations, the provision of drugs and equipment,[11] and on the role of funders.[20 22 28 36] We suggest that authors do not to report funding information (ie, grants received for the conduct of the study) in both the funding section and the conflict of interest section of the manuscript, but only in the former one. Also, our findings have implications for reporting statements (such as SPIRIT and CONSORT) for improving the reporting of funding information.

Implications for future research

Future research should further explore the issue of funding of not-for profit organisations by for-profit organisations and the role of the latter in the planning, conduct and reporting of research studies. Future research could also assess for the accuracy and completeness of reporting of trial funding and roles of funders. Moreover, it would be interesting to explore reporting of funding in primary studies of other research fields (eg, health policy and systems), especially that roles of funders may vary from those described in clinical trials. Finally, our proposed guidance and instrument for the standardised reporting of funding information would benefit from formal and extensive validation.

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Contributors MBH, GG and EAA conceived and designed the study. MBH coordinated the study throughout. EAA had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. MBH, NJ and MK screened papers for inclusion. MBH, NJ, EAA-J, DJH, EAA-J, LCL, MZH, MA-G and SA extracted the data. MBH and EAA analysed and interpreted the data. MBH wrote the first draft of the manuscript with EAA. MBH and EAA developed the first draft of the fillable PDF document. All authors critically revised the manuscript and approved the final version.

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