**Are CONSORT checklists submitted by authors adequately reflecting what information is actually reported in published papers?**

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**Abstract**

**Background**: Compulsory submission of a checklist from the relevant reporting guideline is one of the most widespread journal requirements aiming to improve completeness of reporting. However, the current suboptimal levels of adherence to reporting guidelines observed in the literature may indicate that this journal policy is not having a significant effect.

**Main body**: We explored whether authors provided the appropriate CONSORT checklist extension for their study and whether there were inconsistencies between what authors claimed on the submitted checklist and what was actually reported in the published paper. We randomly selected twelve randomised trials from three journals that provide the originally submitted checklist and analyzed six core CONSORT items. Only one paper used the appropriate checklist extension and had no inconsistencies between what was claimed in the submitted checklist and reported in the published paper.

**Conclusion**: Journals should take further actions to take full advantage of the requirement for the submission of fulfilled CONSORT checklists, thus ensuring that these checklists reflect what is reported in the manuscript.

**Background**

Completeness of reporting is a critical issue in health research. It enhances the transparency of research methods and findings, thus promoting their credibility and reproducibility. In an attempt to improve completeness of reporting, several reporting guidelines for different study designs and clinical areas were developed in the last two decades (1). The CONsolidated Standards Of Reporting Trials (CONSORT), was created in 1996 to help authors report the methods and findings of randomised trials (2). It has been revised and updated twice (3,4). ‘Endorsement’ of CONSORT by medical journals has been one of the most widespread actions implemented to improve the levels of completeness of reporting of randomised trials. It is defined as any of the following situations: (a) journal editorial statement endorsing CONSORT; (b) requirement or recommendation in journal’s ‘Instructions to Authors’ to follow CONSORT when preparing their manuscript; or (c) requirement for authors to submit a CONSORT checklist with their manuscript (5). Existing evidence shows that, despite modest improvements when CONSORT is endorsed by journals, the completeness of reporting of trials remains sub-optimal (5).

In recent years, dozens of medical journals have opted for policy (c) as described above, as it has the most potential to improve completeness of reporting. In addition, in an effort to make the editorial process more transparent and credible, some journals following this policy, such as PLOS One, BMJ Open, and Trials, also make the original CONSORT checklist submitted by the authors accessible for the readers as supplementary material. However, the current suboptimal levels of adherence to reporting guidelines observed in the literature across different research areas and study designs (6) may indicate that this journal policy is not having the desired effect. To date, there has been no investigation into whether or not there are inconsistencies between what authors claim to have reported in the submitted checklist and what is actually reported in the published paper.

A number of specific study designs (such as cluster designs) or interventions (such as non-pharmacological interventions) have additional specific extensions (7,8). In the journals mentioned above, authors are required to submit the CONSORT extension that applies to their study. Thus, it is essential to assess whether authors actually provide the appropriate extensions for their studies.

In this commentary, we explore 1) whether authors provide the appropriate CONSORT checklist, and 2) whether there are inconsistencies between what authors claim to have reported in the submitted checklist and what they have actually reported in the published paper, for those papers submitted with the appropriate checklist was submitted. Our intention is to illustrate whether CONSORT checklist fulfillment by authors should be considered a guarantee that CONSORT items are effectively satisfied.

**Our findings**

We looked at twelve randomly selected randomised trials published in either Trials, BMJ Open, or Plos ONE published between 1 January 2016 and 30 June 2017 (see Supplementary file 1: Point 1, search strategy and study selection). We chose those journals because they require authors to submit a CONSORT checklist with their manuscript and they make this checklist accessible for the readers as supplementary material.For each paper selected, we retrieved the initial CONSORT checklist and manuscript submitted by the authors. First, we independently determined if the CONSORT checklist originally submitted by the authors was the appropriate extension for the study design. Then, for papers using the appropriate checklist, we compared it with what was actually reported in the published paper to identify any inconsistencies (see Supplementary file 1: Point 2, analysis of inconsistencies). We focused on six core CONSORT items of the “Methods” and “Results” sections: (6a) outcomes; (8a) randomisation/sequence generation; (9) allocation concealment mechanism; (11a) blinding; (13a) flow of participants; and (13b) losses and exclusions. We selected those items because they are essential for systematic reviewers to evaluate the risk of bias. For each item, the CONSORT Explanation and Elaboration document (9) was used to determine what information should be reported.

We graded the consistency between what authors said and what they reported for each item as follows:

* Completely consistent: There was no divergence between what authors claimed to have reported through the originally submitted CONSORT checklist and what they reported in the published paper.
* Partially consistent: This may include any of the following: (a) Partial absence of relevant information that was expected to be reported; or (b) the information corresponding to that item was reported elsewhere in the paper to what was claimed in the checklist.
* Not consistent: Authors claimed to have reported that item through the CONSORT checklist but did not adequately report the information in the published paper.

From the twelve randomly selected randomised trials, the standard CONSORT checklist was appropriate for six papers (four of which were standard parallel trials covered by CONSORT and two were crossover trials, for which there is not an extension yet). The other six required CONSORT extensions (for cluster trials, three; for pragmatic trials, two; and for non-pharmacological interventions, one) but authors did not use them in any case, despite being available at the time of submission. The aforementioned extensions were published between 2008 and 2012 (7,8,10), yet the six papers requiring their uptake were all submitted later than May 2015.

For the six papers which submitted the appropriate CONSORT checklist, only one paper had complete consistency between the checklist and the published paper. The most concerning problems centered around items 8 and 9 (see Figure 9). For example, a possible inconsistency identified regarding CONSORT Item 9 (Allocation concealment mechanism - Mechanism used to implement the random allocation sequence, describing any steps taken to conceal the sequence until interventions were assigned) is the following: authors claim through the checklist that they have reported the item, however we found the paper cites “The sequence of the test conditions was randomized for each participant by LB and KDK. A card was made for each possible sequence and a card was picked blindly for each participant”. This statement does not make clear how the authors implemented the random allocation sequence nor how they kept the assignment concealed. Picking a card does not guarantee that allocation used in the analysis has preceded treatment, neither allows readers to reproduce the mechanism used to implement the random allocation sequence.

A full summary of the evaluations for all six items across all six papers is shown in Supplementary file 2. The level of reporting inconsistencies found for every item among the six papers considered in the analysis is provided in Figure 1. Illustrative examples of inconsistencies found for each item are shown in Supplementary file 3.

**Figure 1:** Reporting inconsistencies found for the six papers that used the appropriate CONSORT checklist.

**Why could reporting inconsistencies occur?**

Among the numerous potential reasons for the presence of reporting inconsistencies, we underline two explanations. Firstly, it is possible that authors are not attentive to the requirements of CONSORT or, despite their efforts to be compliant with the requirements, they are struggling to interpret certain items or the level of detail that is required. Examples include:

* Item 8a, “Method used to generate the random allocation sequence”. This item was adequately reported in just one of the papers screened.Within this item there were various reasons for the inconsistencies, including: lack of thorough and complete reporting from the authors (see example for this item in Supplementary file 2) and the non-technical use of the term “random” (“The study nurse randomly opened a preformed envelope containing the allocated treatment regimen”).
* Item 11a, “If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how”. The initial “If done” may have caused confusion about whether or not the authors have to report what groups of individuals involved in the trial were unblinded. To avoid authors not disclosing the lack of blinding if the trial was unmasked, we suggest future versions of the CONSORT checklist to delete “if done”.

The misinterpretation of CONSORT is a major concern as it means that essential information regarding study conduct is miscommunicated. This is particularly relevant for Item 11a, as according to PRISMA Item 19 (11), when assessing the risk of bias of a study it is necessary to know whether patients, health care providers, data collectors, and outcome assessors are blinded or not.

Secondly, the issues described in this study might also lie with the reviewers and editors. It is possible that they are falsely reassured with regard to the reporting quality of the manuscripts, merely by the presence of a completed checklist. Moreover, the fact that the reporting inconsistencies persist throughout the editorial process might mean that editors and reviewers are not using reporting guidelines as a method to review manuscripts (12) although the CONSORT Explanation and Elaboration document suggests that: “Readers, peer reviewers, and editors can also use CONSORT to help them critically appraise and interpret reports of RCTs”.

**Possible solutions**

In an effort to take full advantage of requiring the submission of checklists, journals should consider clarifying their stance on whether the full checklists, or at least the core items of them, should be examined by editors or reviewers, or even by trained editorial assistants (13).

As the page numbers reported by authors in the checklist are not updated after the peer review process and the typesetting process, they do not correspond to the page where the information is placed in the published paper. Having to update the page numbers in the checklist from original submission to published paper could act as checkpoint for editors or reviewers to remind them to verify whether authors are appropriately reporting the key information in the latest version of the manuscript. An alternative solution could be to ask authors to address the section and the paragraph where the information corresponding to each item is reported. This would reduce the risk of overburdening the authors and could potentially help deter the misconception that these checklists are merely bureaucratic. Furthermore, making available the updated checklist could help systematic reviewers easily and quickly find the relevant information to assess the risk of bias of the studies included in the reviews (11).

**Conclusions**

Poor quality reporting in health research critically affects the credibility, reproducibility, and generalisability of the methods and findings of randomised trials. For these reasons, further exploration of methods that will obligate authors to consistently and accurately fulfill and submit CONSORT checklists is required. Moreover, journals should consider making clear whether the checklists should be examined by editors, peer reviewers, or by a trained editorial assistant.

**Ethics approval:** Not required.

**Consent for publication:** Not required.

**Availability of data and materials:** All data generated or analysed during this study are included in this published paper [and its supplementary information files].

**Competing interests:** EC is Senior editor of Trials. Two members of the MiRoR Network involved in this commentary also play a role in Trials: Isabelle Boutron is Senior Editor and Douglas Altman is Editor in Chief.

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**Authors’ contributions:** DB, AB, IB, JK, and EC contributed to conceptualizing and designing the study. DB, AB, and EC carried out the study, while LB, EG, KG, CO, MO, and CS acted as second reviewers of the included papers. DB drafted the manuscript and AB and EC carried out several major revisions. DA, LB, EG, KG, CO, MO, and CS performed minor revisions. All authors read and approved the final version of the manuscript.

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