

Endorsement of the CONSORT statement by high impact medical journals: survey of instructions for authors

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The CONSORT (Consolidated Standards of Reporting Trials) statement of 1996, updated in 2001,^{1,2} gives recommendations for reporting randomised controlled trials and has been endorsed by the World Association of Medical Editors, the International Committee of Medical Journal Editors (ICMJE), and the Council of Science Editors. Studies indicate that it has helped to improve the quality of reporting of trials.³⁻⁵ I sought to determine the extent to which leading medical journals had incorporated the CONSORT recommendations into their instructions for authors.

Methods and results

Using citation impact factors for 2001, I identified the top five journals from each of 33 medical specialties and the top 15 journals for general and internal medicine. I excluded selected journals that did not publish clinical research (based on explicit statement, inspection of journal contents, or PubMed search) and replaced them by the next on the list. The final sample of 167 journals was obtained after examining 232 journals. Thirteen journals represented two specialties.

Between January and May 2003 I examined the instructions for authors on each journal's website and extracted all text mentioning CONSORT or other publications relevant to randomised trials. I also sought any mention of the ICMJE's *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*.

CONSORT was mentioned in the instructions of 36 (22%) journals (see bmj.com), more often in general and internal medicine journals (8/15; 53%) than in specialty journals (28/152; 18%). However, 9/36 journals referred only to the obsolete 1996 statement, whereas the other 27 journals (16% of the sample)

Citations of CONSORT statement and ICMJE guidelines in 167 medical journals' instructions to authors, 2003

Mentioned in instructions to authors	No (%)
CONSORT:	
Any mention	36 (22)
Suitable reference*	27*
Web address	15+1†
2001 journal article	16
2001 explanatory article	3
Obsolete reference (1996 journal article)	9
1996 journal article	8
Other reference based on 1996 article	1
ICMJE:	
Any mention	72 (43)
Suitable reference	27
Web address	23
Other web sites (journals)	4
Obsolete reference (journal publication prior to 2000)	41
No reference given	4

CONSORT=Consolidated Standards of Reporting Trials; ICMJE=International Committee of Medical Journal Editors.

*More than one may have been cited.

†Reference to JAMA website.

What is already known on this topic

The CONSORT statement of 1996, revised in 2001, is a set of reporting recommendations for randomised controlled trials, but there is no reliable estimate of uptake by journals

What this study adds

In 2003, about 20% of high impact medical journals referred to CONSORT in their advice to authors, but many used ambiguous language regarding what was expected or failed to cite CONSORT appropriately

Journals should be more explicit in their expectations of authors and ensure the accuracy of their instructions to authors

referred to the latest version, gave the web address (www.consort-statement.org), or both (table). No journal cited alternative reporting recommendations for randomised controlled trials.

Of the 167 journals, 72 (43%) referred to the ICMJE guidelines. Another incorporated much of the ICMJE text without attribution. Eleven of these journals cited the ICMJE guidelines only for particular issues, mostly reference style or authorship.

Only 24/72 journals gave the address; 4 others referred to versions on the websites of the *CMAJ* or the *Lancet*. Most of the remaining 44 journals cited an obsolete journal publication: one from 1999, 30 from 1997, five from 1991, two from 1988, and two from 1982. Four journals gave no reference. Journals that referred to CONSORT were much more likely to refer to the ICMJE guidelines (26/36; 72%) than those journals that did not (46/131; 35%).

Comment

In 2003, 36/167 (22%) of high impact medical journals referred to CONSORT in their advice to authors. The uptake of CONSORT by leading journals is encouraging, but 11/36 referred only to a superseded version of CONSORT. Also, many used ambiguous language regarding what was expected from authors. Similar problems were seen for the ICMJE guidelines.

This study reviewed electronic resources, which are volatile. One journal (*Annals of Emergency Medicine*) updated its guidelines during the study period.

The CONSORT statement was developed to help improve the quality of reports of randomised controlled trials. Its effectiveness will be influenced by the nature of its implementation; ambiguous statements are likely to be less effective than stronger directions.

 Illustrative examples from journals' instructions to authors are on bmj.com

Journals supporting CONSORT should state unambiguously what they expect from authors.

In 2003, many journals gave out of date citations for both CONSORT and the ICMJE guidelines. This carelessness sets a poor example for authors. Journals should be more vigilant regarding the information in their instructions to authors, should be explicit in their expectations of adherence to specific recommendations, and should cite the web address to ensure that the latest versions are obtained along with any extensions.

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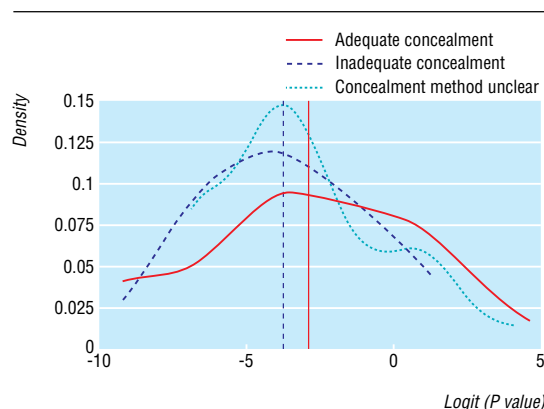
Adequacy and reporting of allocation concealment: review of recent trials published in four general medical journals

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In randomised controlled trials, allocation concealment (separating the process of randomisation from the recruitment of participants) is important for rigorously designed trials.¹⁻⁴ In 1996 many major medical journals adopted the CONSORT statement (whereby researchers have to include a short checklist of essential items and a flow diagram when reporting trials),⁵ and this move encouraged the reporting of allocation concealment. We reviewed the prevalence of adequate allocation concealment and its association with the statistical significance of trial results.

Methods and results

We searched by hand four general medical journals (the *BMJ*, *JAMA*, the *Lancet*, and the *New England Journal of Medicine*) to identify randomised controlled trials published from January 2002 to December 2002. We included articles if the authors reported that participants were randomised and if the trial was published as a full report with the results of the main analyses. We categorised articles according to whether allocation concealment was adequate (the person who executed the allocation sequence was different from the person who recruited participants), inadequate (the person who recruited participants also executed the allocation sequence), or unclear (the article failed to describe how the researchers concealed the allocation). We considered the widely used "sealed envelope" method to be inadequate unless performed by an independent third party. We used a kernel density plot to compare the P values of trials that used adequate concealment methods with those that used inadequate methods; we used P values because these were readily available; across most of the trials, which used different statistical methods and outcome measures. Our statistical analyses adjusted for clustering effects by journal.



Distribution of P values by adequacy of allocation concealment. As the P values were highly positively skewed, the data were transformed using the logit function. The vertical lines represent mean P values for trials using adequate or inadequate concealment

Among the 234 trials that met the inclusion criteria, allocation concealment was adequate in 132 (56%) and inadequate in 41 (18%); in 61 (26%) the concealment method was unclear. Of the trials whose allocation concealment was considered adequate, 118 used independent allocation (which included using a telephone, fax machine, or pager to a randomisation service); five used sealed envelopes opened by a third party; eight used a computer; and one used a combination of adequate methods. Of the 41 trials whose allocation concealment was inadequate, 39 used sealed envelopes, one selected a card from a pile, and one added the name of the next participant to the randomisation list.

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