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How Journals Use CONSORT: Experiences at PLoS

EQUATOR Reporting your RCT 2010

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There are many different types of journals out there – and as many different peer review systems
Why are journals important in moving towards better reporting?

- Once, journals were (pretty much) the only mechanism for publishing results of trials and other studies.

- Now - increasing focus on web registries – eg clinicaltrials.gov, company websites.

- But journals still provide the main method of disseminating full details of trial design and results.

- Investigators still want peer-reviewed journal publication as credit for what has been done.

- Peer review and editorial process provides an important opportunity for achieving good quality reporting.
The life cycle of a research article

Research → Submission → Peer review → Publication

- Rejection:
  - 2-3 Experts
  - Is it rigorous?
  - Good enough?
  - Right audience?
  - Takes months/years

Journal name is key
What goes on in the black box called “peer review”? 

At *PLoS Medicine*:

- Papers handled by in-house editor
- Additional advice from external academic editor (researcher / clinician)
- Around 90% papers rejected *before* peer review based on scope, quality, importance
- Typically 2-3 subject reviewers (eg in the clinical specialty)
- 1 statistical reviewer
- Around 50% papers rejected *after* peer review – eg prove not to be methodologically robust
How *PLoS Medicine* uses CONSORT during the editorial process

- RCT submissions **must** include CONSORT flowchart and checklist to get through to editorial assessment
- These items also made available to academic editor, peer reviewers (including statistician)
- We encourage authors reporting non-randomized trials (eg single-arm) to use applicable parts of CONSORT guidance
- Editors and peer reviewers consider how well specific items in CONSORT have been reported
- Editors give further guidance / advice to authors on improving writeup if a revision is invited

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PLoS journals – additional standards for trials reporting

- Trial registration: require prospective registration in WHO ICTRP approved registry
- Authors must also provide a copy of the original trial protocol
- Editors and peer reviewers check protocol, registry record, for key items
- Encourage authors to be more upfront in describing changes from protocol in their paper
What do editors look for in research papers?

- Does the study ask an important question?
- Is the design appropriate, and sufficiently robust, to answer that question?
- Are the findings relevant to practice or policy?
- If YES, YES, YES – consider further
- Even if the outcomes are “negative” or “disappointing”!
Caution: ways in which journals can introduce bias

- Journals want to publish new and interesting papers
- May be a tendency for editors / reviewers to suggest emphasis on the “positive” parts of a study, shift focus away from disappointing outcomes
- This can give rise to outcome reporting bias
- Lack of space may mean some editors can’t include fully detailed methods – eg protocol deviations etc
- Lack of time may mean editors can’t always help authors use CONSORT to apply it to their study
Specific examples – applying CONSORT guidance to real papers

- Many researchers think that once they have ticked the boxes in the checklist and filled out the numbers in the flowchart, salvation is theirs – they are “CONSORT compliant”

- I hope CONSORT group would agree: this is not true

- For editor (and reader) the devil is in the details!
What is outcome reporting bias ("ORB")?

- An area addressed by CONSORT that’s receiving greater attention from journals and researchers
- ORB is a form of publication bias
- Occurs when statistically significant findings are more likely to be reported in published papers
- Authors, reviewers and editors can all contribute to the problem (and help address it)
- Some journals – including PLoS journals – now ask for full protocols for submitted RCTs
- On PLoS Medicine – check outcomes reported in the paper against those in the protocol
- Frequently ask authors to add results for these outcomes to the paper and / or add explanations about outcome changes

Using CONSORT guidance in peer review: specific examples

• **Item 6a.** Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed

• “All outcome measures, whether primary or secondary, should be identified and completely defined. The principle here is that the information provided should be sufficient to allow others to use the same outcomes. When outcomes are assessed at several time points after randomisation, authors should also indicate the pre-specified time point of primary interest.”
Results reporting – outcome definition and analysis

Example of paper submitted to PLoS journal with a fully completed CONSORT flowchart and checklist

This feedback was sent from editor to authors:

“In the objective, method, results and discussion sections, the authors should clearly indicate and separate the following:

a. the primary objective of this trial: i.e., assessment of beneficial effect at 6 months on the [redacted],

b. the secondary objectives of the study: i.e., assessment of secondary outcomes and safety...

c. the ancillary exploratory analyses...

2) The analyses performed should be a true ITT analyses with data for all patients randomised analysed.

3) The authors report the results on a subgroup of patients divided according to age. Was the randomisation stratified on age?

4) The reporting of the results should follow the CONSORT recommendations by reporting the number of patients with data, summary statistics in each arm (mean [SD] or median [IQR] but also between group differences such as difference in means with 95% CI”
Using CONSORT guidance in peer review: specific examples

- **Item 18.** Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory

- “Multiple analyses of the same data create a risk for false positive findings. Authors should resist the temptation to perform many subgroup analyses. Analyses that were prespecified in the trial protocol are much more reliable than those suggested by the data, and therefore authors should report which analyses were prespecified. If subgroup analyses were undertaken, authors should report which subgroups were examined, why, if they were prespecified, and how many were prespecified. Selective reporting of subgroup analyses could lead to bias”
Using CONSORT guidance in peer review: specific examples

• **Item 18.** Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory

• Example
  • “We performed a double-blind randomised placebo-controlled trial of pralidoxime chloride (2 g loading dose over 20 min, followed by a constant infusion of 0.5 g/h for up to 7 d) versus saline in patients with organophosphorus insecticide self-poisoning. Mortality was the primary outcome; secondary outcomes included intubation, duration of intubation, and time to death.”
  • “An exploratory analysis using Cox’s regression investigated the effects of potentially important prognostic factors such as percentage of aged acetylcholinesterase on admission and OP concentration on admission”

Using CONSORT in publication

- Optional template for authors, using CONSORT items as headings for structured writeup of the paper

- Available for authors on all PLoS journals but most heavily used on *PLoS Medicine, PLoS ONE*

- Sent to authors when a revision is invited

- Authors can use components that work for them – in addition to the CONSORT checklist and flowchart

- Works best for primary papers (ie reporting main results of RCT); less so for exploratory / ancillary papers

- For published papers, CONSORT flowchart, checklist and protocol all included alongside as figures / supporting information

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Where are CONSORT items reported?

- Trial registration (item 23)
- Funding (item 25)
Where are CONSORT items reported?

- Study setting (item 4b)
- Participants (item 4a)
- Interventions (item 5)
- Outcomes (item 6a)
Journal experiences of CONSORT

- *PLoS Medicine* is a CONSORT endorser (and we try hard to be an implementer!)

- But making sure that every paper we publish fully adheres to CONSORT is another matter

- Despite the simplicity and usability of CONSORT, substantial editorial input is often needed to help authors understand and use the guidance for their particular study

- CONSORT instruments (checklist, flowchart) now well accepted and used by authors

- Most authors not yet ready to try template-based reporting

- We tried enforcing this for a while but it did not take off
What are the barriers?

• Lack of awareness of appropriate standards for reporting
• Language?
• Lack of time – for authors, editors, reviewers
• Authors need to get the paper published as quickly as possible
• Reluctance among researchers to admit that not all went as planned – eg outcome changes during the trial
Using CONSORT: what are the advantages and opportunities?

For authors:

- Adhering to CONSORT upfront means your paper will go straight through to the editor’s desk
- Clearly reported papers go through peer review faster and with fewer revisions. Quicker, easier trip through copyediting
- We can’t guarantee the decision will be different (as this may well hinge on the importance of the question and quality of the study)

For editors / guideline developers:

- Look at guidance for exploratory or ancillary papers?
- Look at reporting standards for non randomized trials?

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