EDITORIAL

'Consort 2010: A Standard for Reporting Clinical Trials Revised Anew?

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CONSORT or the CONsolidated Standards Of Reporting Trials is a statement used worldwide for reporting of randomized controlled trials (RCTs). It is intended to improve the reporting of an RCT, enabling readers to understand a trial's design, conduct, analysis and interpretation, and to assess the validity of its results. It emphasizes that this can only be achieved through complete transparency from authors.[1] David Moher and Drummond Rennie organized the first statement in 1996 which was revised in 2001 following further methodological research, and now more than 700 studies comprise the CONSORT database providing the empirical evidence to underpin the initiative. Three years ago in January, 2007, a group of 31 experts in trial design gathered in Montebello, Canada, to discuss what revisions were needed to the CONSORT guidelines. Two and a half days later, these statisticians, trial methodologists, researchers, and journal editors established the principles for what was then called CONSORT III. Then began the long refinement and consultation process, culminating in what is now published as CONSORT 2010.[2]

They only looked at those items considered absolutely necessary for reporting an RCT. Some items are fundamental but may not have been included, e.g., approval by an institutional ethics review board, because, in their opinion, funding bodies strictly enforce ethical review and medical journals usually address reporting ethical review in their instructions for authors. Also, some items may be desirable, e.g., whether on-site monitoring was done, but a lack of empirical evidence or any consensus on their value made them preclude its inclusion at this point in time. The 2010 statement thus addresses minimum criteria but authors are welcome to add other information as they deem fit.[3]

It does not include recommendations for designing, conducting, and analyzing trials but it does indirectly affect design and conduct since transparent reporting may reveal deficiencies in research if they exist. It is a 25 item checklist with a lucid explanation and elaboration of each item, with examples, that one needs to consider while writing such reports. The checklist items pertain to the content of the Title, Abstract, Introduction, Methods, Results, Discussion, and Other information. For example, in the discussion section one should state specific interpretations of study findings, including sources of bias and imprecision (internal validity) and discussion of extrapolation or external validity.[1]

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The CONSORT Statement is accompanied by the CONSORT Explanation and Elaboration Document. This document is intended to enhance the use, understanding and dissemination of the CONSORT Statement. Through examples and explanations, the meaning and rationale for each checklist item are presented.[1]

A flow diagram is intended to depict the passage of participants through an RCT. The revised flow diagram depicts information from four stages of a trial (enrollment, intervention allocation, follow-up, and analysis). The diagram explicitly shows the number of participants, for each intervention group, included in the primary data analysis. Inclusion of these numbers allows the reader to judge whether the authors have done an intention-to-treat analysis.[1]

In short, it is good to follow CONSORT if we wish to have a realistic chance of getting our manuscript accepted for publication by any of the more than 400 medical journals who support this statement. The statement has also been endorsed by the International Committee of Medical Journal Editors (ICMJE) and the World Association of Medical Editors (WAME). It has been translated into 10 languages.[4]

The 2010 update of the statement is accompanied by a comparative study by Hopewell S et al which assesses whether the quality of reporting of randomized trials has improved since publication of the CONSORT statement in 2001. Improvements occurred in the reporting of several items that are crucial for the assessment of trial quality. Essential items like sample size estimation, description of the randomization procedure, or description of the concealment of treatment allocation are described in an unacceptably low number of reports.[4,5] I would suggest that reviewers pay more attention to these, thus helping lower their incidence. Efforts to improve the reporting of randomized controlled trials accelerated in the mid-1990s, spurred partly by methodological research. Researchers had shown for many years that authors reported such trials poorly, and empirical evidence began to accumulate that some poorly conducted or poorly reported aspects of trials were associated with bias.[5]

Randomized controlled trials represent the gold standard in evaluating healthcare interventions but the gilt edge is only when they are appropriately designed, conducted, and reported. To assess the results the reader needs to have complete, clear and transparent information on its methodology and findings. In fact, completeness, clarity, and transparency seem to be the watchwords, repeated quite often in the CONSORT-related articles published in the March 27th BMJ issue.

Only randomized trials allow valid inferences of cause and effect and have the potential to directly affect patient care, occasionally as single trials but more often as the body

of evidence from several trials, whether or not combined formally by meta-analysis. It is thus entirely reasonable to require higher standards for papers reporting randomized trials than those describing other types of study. Like all studies, randomized trials are open to bias if done badly. It is thus essential that randomized trials are done well and reported adequately. Readers should not have to infer what was probably done, they should be told explicitly. Proper methodology should be used and be seen to have been used. Yet reviews of published trials have consistently found major deficiencies in reporting.[6-11]

These included no/inadequate information on method used to assign participants to comparison groups (generation of unpredictable allocation sequence and concealment of the allocation), definition of primary end point, no sample size calculation, analysis of data on all participants, improper randomization, and recently new concerns such as selective outcome reporting.[12]

Apparently the revision process resulted in "evolutionary, not revolutionary, changes to the check-list" and the flow diagram was not modified except for one word. Some renumbering of items 2 to 5 happened. The website contains a side by side comparison of the 2001 and 2010 versions and the noteworthy general (wording has been simplified to make it clear, consistency of style has improved across items, imperative verbs have been removed, etc) and specific changes are encapsulated in two boxes appropriately captioned. Among the latter, four important additions relate to mentioning why a trial ended or was stopped, need for trial registration, where can the protocol be accessed, and disclosing funding source since empirical evidence points to association between funding (source) and finding.[12]

New in CONSORT 2010 are three new checklist items such as item 24, sub-items or full items to clarify trial design, any changes to the methods or outcome measures after the trial began, encouragement to present both relative and absolute effect sizes, and registration, funding, and protocol information, and mention of how the success of masking might have been evaluated is no longer required.[3]

For example, items to include in an abstract are: contact details of corresponding author, description of trial design, eligibility criteria and setting, interventions, specific objective or hypothesis, clearly defined primary outcome, method of allocation of participants, blinding of participants, care-givers and assessors, number randomized to and analyzed in each group, trial status, a result for each group, estimated effect size and its precision, important adverse events or side effects, general interpretation of results, registration number and name of trial register, and source of funding. This elaborateness is important since many times decisions are taken by healthcare professionals only on reading abstracts.[12]

CONSORT group members continually monitor the literature and are open to any feedback on the revised statement. Importantly they also provide feed forward or back-feed so that we know that our comments do not go into a black hole never to return. They also invite new members to contribute and strive for a balance of established and emerging researchers. They do not wish to standardize or produce a rigid structure but want authors to simply address checklist items somewhere in their article, with ample detail and lucidity. It is not intended as a tool to evaluate quality of a trial, nor is it appropriate to use the checklist to construct a quality score.[3]

What will it mean for India?

As it is Indians do not like to be strait-jacketed and so may view this statement as even more rigorous than the 1996 and 2001 versions, that is if they are aware of the earlier versions. The 25 item checklist may be the only con of CONSORT. Balancing completeness, conciseness, and readability is a challenge for authors. Although this is not the principal aim of the CONSORT statement, it would behoove authors to try for this so that reading of research reports becomes both educative and enjoyable. The Indian Journal of Pharmacology has a link to CONSORT and it is hoped that all Indian journals will follow this good reporting practice.

I would like to end by suggesting that we begin a trial with the end publication in mind, come right up to the beginning, and then start, being clear about our destination so that we have a fair chance of reaching it. CONSORT will help us do it but provided we have the patience and the right bent of mind. When we write (a) report, we need to report right.

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