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CONSORT 2010: progress and challenges

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"When authors fail to adequately describe RCT methods ... and results, their data are of limited use to reviewers, and in turn, cannot be used to make the decisions for which they were intended."

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State of the literature

Poor reporting of the medical literature has been recognized as a serious problem for decades [1,2]. This has a multitude of economic, policy and clinical implications [3]. Worldwide, each year over US$100 billion is spent on health research. This research, in turn, is relied on heavily by clinicians and policy-makers alike to make decisions about patient care. Randomized controlled trials (RCTs) have been the focus of particular scrutiny because of their direct impact on health care. For instance, systematic reviews of RCTs, the widely-recommended vessel for determining efficacy for health care interventions, are often severely and frequently hampered in what they conclude because of inadequate reporting of included RCTs [4]. When authors fail to adequately describe RCT methods (i.e., how treatments should be administered or what outcomes were measured, when and how) and results, their data are of limited use to reviewers, and in turn, cannot be used to make the decisions for which they were intended. Ultimately, the money spent on funding such research goes to waste when their reports do not accurately and/or completely reflect what was done. This is not only unfortunate; some argue, it is unethical, immoral and unacceptable [3,5].

In order to implement successful treatments and thereby, replicate successful outcomes in practice, clinicians need to be presented with complete descriptions about treatments, know which outcomes will be affected and have all the information available to help determine whether bias was present that may affect study findings. As obvious as this may seem, particularly in today's age of evidence-based healthcare, the majority of RCTs are still largely incompletely reported. In a sample of 80 RCTs and systematic reviews published over a 1-year period (October 2005–October 2006), Glasziou *et al.* found that only 49% of trials sufficiently described the details of the interventions (i.e., timing, dose, duration and frequency of treatment, route of administration and any monitoring used) [6]. More recently Duff *et al.*, found that the methodological reporting of a sample of RCTs from major oncology journals was inconsistent and deficient in describing at least ten items about cancer therapies deemed essential by oncologists applying them [7]. Only 11% of 262 trials sampled reported all ten items completely. Due to the complex nature of cancer and other treatments, it essential that studies evaluating them provide all the necessary information a clinician might need to implement successful treatments in practice.

Reporting of trial outcomes has also been found to be incomplete and inconsistent. A recent systematic review, based on 16 studies, each comparing a median of 54 RCTs to their available protocols or registry entries, found that up to 50% of trial reports omitted, introduced or changed at least one primary outcome from what was stated in the protocol [8]. The review also identified a number of other common

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discrepancies between trial protocols and reports, including the method of allocation concealment used and who was blinded to the study intervention; reasons for these and other discrepancies are often incomplete or unreported. Many fundamental aspects of RCTs, needed by clinicians in order to implement successful findings in practice, are not reported transparently, if at all.

A major innovation

Over the last decade or more there have been several efforts to improve the quality of reporting of research studies. That work has had considerable success in raising consciousness of the need for complete and transparent reporting and there are encouraging signs of improvement in some areas. The Consolidated Standards of Reporting Trials (CONSORT) statement, the sentinel reporting guideline for two-group parallel randomized trials to appear in the health literature, was originally published in 1996 [9], after a pivotal meeting of two groups of researchers (including clinical trialists, statisticians, epidemiologists and biomedical editors), both campaigning for better reporting standards for RCTs [10,11]. The statement was then revised and accompanied by an explanation and elaboration (E&E) document in 2001 [12,13] and both statement and E&E were updated in 2010 [14,15]. The CONSORT 2010 statement is comprised of a 25-item checklist which authors should address when reporting their trial, and a flow diagram to help authors present the flow of participants throughout a trial. The CONSORT group regards the statement as a living document meant to evolve and be updated in light of new literature and other factors.

Over time, the CONSORT statement has had a wide-reaching and positive impact. Over 600 general and specialty health journals currently endorse the CONSORT statement; such endorsement has been shown to be associated with better reporting of RCTs [16,17]. While it's not a specific intent of CONSORT, some suggest that CONSORT may even impact the way trials are designed [18]. Furthermore, CONSORT has received considerable support from influential groups of editors such as World Association of Medical Editors, the Council of Science Editors and the International Committee of Medical Journal Editors.

CONSORT can also be used by peer reviewers evaluating reports of randomized trials and by editors as part of their decision making process regarding the merits of accepting for publication reports of RCTs.

The CONSORT statement has been 'extended' eight times to address complex issues in the reporting of different trial types, such as for reporting non-inferiority and equivalence trials [19–26]; at least five more extensions are currently in development, such as for reporting crossover trials. Additionally, following publication of the original CONSORT statement, at least 80 more reporting guidelines aimed to improve the quality of reporting of other types of research have been developed, many of which have used the CONSORT model [27,28]: PRISMA for systematic reviews of randomized trials [29,30,101], STROBE for observational studies [31,102], STRICTA for reporting trials using acupuncture [26], STARD for diagnostic accuracy studies [32,33], REMARK for tumor marker prognostic studies [34] and TREND for nonrandomized evaluations of behavioral and public health interventions [35,103].

CONSORT is one of the most widely-cited (Web of Science metrics) publications of all time; it has been cited more than 5300-times (excluding any self citations). Since the publication of CONSORT 2010, the CONSORT website has seen a 30% increase in the number of visitors than during the same period in 2009 ([104], tracking by Google Analytics).

Development of a comprehensive library of examples of good reporting is currently underway. To build this database, the CONSORT group has used various mechanisms including and recent editorial [36], social networking [@CONSORTing] and announcements on the CONSORT website [105] to invite and stimulate authors, editors and readers to submit examples of trial reports that describe CONSORT checklist items adequately. The submission system and library (which started off with examples from the CONSORT 2010 E&E) can be found on the CONSORT website [106].

Impact of CONSORT

A systematic review of studies evaluating the impact of CONSORT has shown it to be associated with improvements in the reporting of RCTs [16]. The review examined studies comparing RCT reporting before and after their publishing journals 'endorsed' the CONSORT statement (i.e., recommended its use in its 'Instructions to Authors') and those published in endorsing and non-endorsing journals. For both comparisons, the review found that CONSORT is associated with improved reporting of RCTs; however, included studies were few (n = 8), methodologically weak and methodologically heterogeneous [16]. An update to this review, including more than six times as many studies (n=50), strengthens the findings from the original review, in favour of CONSORT [37]. For example, participant flow diagrams were adequately reported in 25% (risk ratio [RR] = 1.25; 95%CI: 1.01, 1.53) more trials published in CONSORT-endorsing journals than those in non-endorsing journals. Despite such improvements, however, a number of key items were reported

in less than 50% of trials published in both endorsing and non-endorsing journals – how sample size was determined (44.3%), method of sequence generation (44.5%), method of allocation concealment (29.2%), who was blinded (22.9%). Of note, primary outcome definition was clear in only 61.9% of studies. Although these results are disappointing, the CONSORT group have considered this and other data when revising the CONSORT 2010 statement in an effort to improve the reporting of these items.

Improvements with CONSORT 2010

At first glance, the CONSORT 2010 checklist appears to include three additional items than the 2001 checklist, totalling 25 items over the earlier 22 items. Upon closer examination, however, many more thoughtful improvements to the checklist have been made. These changes include: simplified wording of nine items, removal of imperative verbs, separation of items comprised of multiple items into five sub-items, renumbering of two items to accommodate sub-items, and the addition of three new items to the end of the checklist.

A detailed listing of exact changes can be found in the CONSORT 2010 statement [14]. Of particular importance however, is the diffusion of items describing allocation concealment, sequence generation and blinding into multiple items, so as to address the problems identified in Hopewell's 2010 paper which found improvements in key CONSORT items between 2000 and 2006 such as primary outcome description (RR = 1.18, 95% CI: 1.04–1.33), methods of random sequence generation (RR = 1.62, 95% CI: 1.32–1.97) and allocation concealment (RR = 1.40, 95% CI: 1.11–1.76), but not in others – no difference in reporting of who was blinded (RR = 0.91, 95% CI: 0.75–1.10) [17]. Despite improvements, the adequacy of trial reporting for these items remains low. For instance, while 2006 demonstrated improved reporting, still only 52% of trials reported details of primary outcome, 34% adequately described methods of sequence generation, and one quarter properly reported how allocation concealment was achieved. The CONSORT 2010 statement was developed to encourage and enhance clear reporting of these, and all, CONSORT items. As an example, one change in the 2010 statement includes improvements to the description of primary outcomes and whether the reported primary outcome(s) deviates from what was planned, as stated in the trial protocol (items 6a and 6b). The statement also now calls for a declaration of where trial protocols can be accessed, regardless of whether they were published (item 24). This item, along with items 23 (trial registration) and 25 (source of funding), also follow from empirical evidence that access to trial protocols will help in assessing whether planned methods were different from those carried out [8,38] and that source of funding has been shown to influence treatment estimates [39,40]. The increasing importance of trial registration is evidenced by the emergence of numerous international and national clinical trial registries over the last decade.

The CONSORT group also updated the E&E paper at the same time it updated the statement. This document includes an example of good reporting for each checklist item along with a rationale and evidence, whenever available, as to why authors should report the requested information. Many of the examples included in the 2010 E&E paper were also updated.

Challenges facing CONSORT

Over 600 journals have endorsed the CONSORT statement. There is variation, however, as to what exactly 'endorsement' means. In a survey of journal editors, 95% said their journal endorses the CONSORT statement [Moher D *et al.* Unpublished Data. 2010]; of those, 85% mentioned CONSORT in their 'instructions to authors'. However, when asked whether authors are required to submit a checklist or whether peer reviewers use CONSORT when assessing RCTs, only 38 and 14%, respectively, said they did. This illustrates a discrepancy between endorsement and adherence to the CONSORT statement. In order to bridge this gap, a dedicated knowledge translation strategy is being developed by the CONSORT group.

Future perspective

Plans for the next revision of the statement are already underway, along with a detailed knowledge translation plan to increase its uptake and implementation among journal editors, peer reviewers, authors as well as other target groups such as funding agencies and educators and trainees at academic institutions.

One way to help improve the uptake of CONSORT is to maximize its usefulness for authors. For example, for authors reporting a cluster pragmatic trial there is no existing checklist. The CONSORT group is hoping to develop personalized checklists that would enable authors to generate a specific checklist incorporating items for both CONSORT checklists into a single checklist.

While the CONSORT group has had a good start in the number of journals endorsing the CONSORT statement, and subsequently asking authors to adhere to it when reporting trials, these journals still only represent a small percentage of those publishing RCTs. There is an immediate and long term need to strengthen the number of journals endorsing CONSORT and improve how these journals adhere to it.

There is growing evidence that use of the CONSORT checklist is associated with improved reporting. While this is the case for many CONSORT checklist items it is not so across all of them. There needs to be a long term commitment for continued evaluation of these items.

While many stakeholder groups, such as editors, recognize the merits of CONSORT to help improve the quality of reporting RCTs, the CONSORT group has found it challenging to obtain continued long term funding. Within the next decade we would like to secure a solid funding base.

Financial & competing interests disclosure

D Moher is one of the developers of the CONSORT Statement (and other reporting guidelines) and an executive member of the Enhanced Quality and Transparency of Reporting (EQUATOR) network. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

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Bibliography

1 Mahon WA, Daniel EE. A method for the assessment of reports of drug trials. *Can. Med. Assoc. J.* 90(9), 565 (1964).

2 Gotzsche PC. Methodology and overt and hidden bias in reports of 196 double-blind trials of nonsteroidal antiinflammatory drugs in rheumatoid arthritis. *Control. Clin. Trials* 10(1), 31–56 (1989).

3 Chalmers I, Glasziou P. Avoidable waste in the production and reporting of research evidence. *Lancet* 374(9683), 86-89 (2009).

4 Moher D, Tetzlaff J, Tricco AC, Sampson M, Altman DG. Epidemiology and reporting characteristics of systematic reviews. *PLoS Med.* 4(3), e78 (2007).

5 Moher D. Reporting research results: a moral obligation for all researchers. *Can. J. Anaesth.* 54(5), 331–335 (2007).

6 Glasziou P, Meats E, Heneghan C, Shepperd S. What is missing from descriptions of treatment in trials and reviews? *Br. Med. J.* 336(7659), 1472 (2008).

7 Duff JM, Leather H, Walden EO, LaPlant KD, George TJ. Adequacy of published oncology randomized controlled trials to provide therapeutic details needed for clinical application. *J. Natl Cancer Inst.* 102(10), 702 (2010).

8 Dwan K, Altman DG, Cresswell L, Blundell M, Gamble CL, Williamson PR. Comparison of protocols and registry entries to published reports for randomised controlled trials. *Cochrane Database Syst. Rev.* 1, MR000031 (2011).

9 Begg C, Cho M, Eastwood S *et al.* Improving the quality of reporting of randomized controlled trials. The CONSORT statement. *JAMA* 276(8), 637–639 (1996).

10 Andrew E, Anis A, Chalmers T *et al.* A proposal for structured reporting of randomized controlled trials. *JAMA* 272(24), 1926 (1994).

11 Working Group on Recommendations for Reporting of Clinical Trials in the Biomedical Literature. Call for comments on a proposal to improve reporting of clinical trials in the biomedical literature: a position paper. *Ann. Intern. Med.* 121, 894–895 (1994).

12 Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel group randomized trials. *Lancet* 357(9263), 1191–1194 (2001).

13 Altman DG, Schulz KF, Moher D *et al.* The revised CONSORT statement for reporting randomized trials: explanation and elaboration. *Ann. Intern. Med.* 134(8), 663 (2001).

14 Schulz K, Altman D, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMC Med.* 8(1), 18 (2010).

15 Moher D, Hopewell S, Schulz KF*et al.* CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ* 340, c869 (2010).

16 Plint AC, Moher D, Morrison A *et al.* Does the CONSORT checklist improve the quality of reports of randomised controlled trials? A systematic review. *Med. J. Aust.* 185(5), 263 (2006).

17 Hopewell S, Dutton S, Yu LM, Chan AW, Altman DG. The quality of reports of randomised trials in 2000 and 2006: comparative study of articles indexed in PubMed. *BMJ* 340, c723 (2010).

18 Williams HC. Cars, CONSORT 2010, and clinical practice. *Trials* 11(33) (2010).

19 Ioannidis J, Evans SJW, Gøtzsche PC *et al.* Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann. Intern. Med.* 141(10), 781 (2004).

20 Campbell MK, Elbourne DR, Altman DG. CONSORT statement: extension to cluster randomised trials. *BMJ* 328(7441), 702 (2004).

21 Piaggio G, Elbourne DR, Altman DG, Pocock SJ, Evans SJW. Reporting of noninferiority and equivalence randomized trials: an extension of the CONSORT statement. *JAMA* 295(10), 1152 (2006).

22 Gagnier JJ, Boon H, Rochon P, Moher D, Barnes J, Bombardier C. Reporting randomized, controlled trials of herbal interventions: an elaborated CONSORT statement. *Ann. Intern. Med.* 144(5), 364 (2006).

23 Zwarenstein M, Treweek S, Gagnier JJ *et al.* Improving the reporting of pragmatic trials: an extension of the CONSORT statement. *BMJ* 337, a2390 (2008).

24 Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Ann. Intern. Med.* 148(4), 295 (2008).

25 Hopewell S, Eisinga A, Clarke M. Better reporting of randomized trials in biomedical journal and conference abstracts. *J. Inf. Sci.* 34(2), 162 (2008).

26 MacPherson H, Altman D, Hammerschlag R *et al.* STRICTA Revision Group. Revised standards for reporting interventions in clinical trials of acupuncture (STRICTA): extending the CONSORT statement [J]. *PLoS Med.* 7(6), e1000261 (2010).

27 Moher D, Weeks L, Ocampo M *et al.* Describing reporting guidelines for health research: a systematic review. *J. Clin. Epidemiol.* 64(7), 718–742 (2011).

28 Simera I, Moher D, Hoey J, Schulz K, Altman D. A catalogue of reporting guidelines for health research. *Eur. J. Clin. Invest.* 40(1), 35–53 (2010).

29 Liberati A, Altman DG, Tetzlaff J *et al.* The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *PLoS Med* 6(7), e1000100 (2009).

30 Moher D, Liberati A, Tetzlaff J, Altman DG, PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *BMJ* 339, b2535 (2009).

31 Elm E, Altman DG, Egger M *et al.* Strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. *Br. Med. J.* 335(7624), 806 (2007).

32 Bossuyt PM, Reitsma JB, Bruns DE *et al.* Towards complete and accurate reporting of studies of diagnostic accuracy: the STARD initiative. *Clin. Chem.* 49(1), 1 (2003).

33 Bossuyt PM, Reitsma JB, Bruns DE *et al.* The STARD statement for reporting studies of diagnostic accuracy: explanation and elaboration. *Clin. Chem.* 49(1), 7 (2003)

34 McShane LM, Altman DG, Sauerbrei W, Taube SE, Gion M, Clark GM. Reporting recommendations for tumor marker prognostic studies (REMARK). *J. Natl Cancer Inst.* 97(16), 1180 (2005).

35 Des Jarlais DC, Lyles C, Crepaz N. Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: the TREND statement. *Am. J. Public Health* 94(3), 361 (2004).

36 Moher D, Hopewell S, Schulz KF, Altman DG. Resources for authors of reports of randomized trials: harnessing the wisdom of authors, editors, and readers. *Trials* 12, 98 (2011).

37 Turner L, Moher D, Shamseer L, Weeks L, Peters J. The Influence of CONSORT on the quality of RCTs: an updated review. Presented at: *The 9th Annual Cochrane Canada Symposium*. Vancouver, Canada, 16–17 February 2011.

38 Chan AW, Hróbjartsson A, Haahr MT, Gøtzsche PC, Altman DG. Empirical evidence for selective reporting of outcomes in randomized trials. *JAMA* 291(20), 2457 (2004).

39 Sun X, Briel M, Busse JW *et al.* The influence of study characteristics on reporting of subgroup analyses in randomised controlled trials: systematic review. *BMJ* 342, d1569 (2011).

40 Lexchin J, Bero LA, Djulbegovic B, Clark O. Pharmaceutical industry sponsorship and research outcome and quality: systematic review. *BMJ* 326(7400), 1167 (2003).

Websites

101 PRISMA
www.prisma-statement.org

102 STROBE Statement
www.strobe-statement.org

103 Centers for Disease Control and Prevention. Transparent reporting of evaluations with nonrandomized designs (TREND) statement
www.cdc.gov/trendstatement

104 CONSORT statement
www.consort-statement.org

105 CONSORT news
www.consort-statement.org/news

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