The CONSORT STATEMENT

From the Therapy chapter for the 3rd edition of Clinical Epidemiology, by DL Sackett
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In the mid-1990-s a group of trialists (including me), statisticians, epidemiologists and biomedical journal editors met in Ottawa to discuss our concerns over the deficiencies in the way that RCTs were being reported. Each of us had encountered numerous instances in which trials were called "randomized" when they were not, participating clinicians had advance notice of the treatment to which their next patient would be allocated, definitions of primary events (outcome measures) were changed after "peeking" at them during the progress of a trial, and trial patients unaccountably disappeared or were inappropriately declared "ineligible" for final analyses.

At about that same time, some of us had begun to carry out cohort studies of reports that had avoided and committed these errors[1], and had found that non-randomized trials generated both over- and under-estimates of efficacy, that the failure to conceal a randomization list led to the overestimation of efficacy, and that the return of "ineligible" patients to the final analysis often erased a treatment's apparent benefit.

We decided that both clinicians and patients would benefit if an RCT's strengths and weaknesses were made clear in its report, and set about devising a "checklist" and "patient flow-diagram" that we thought authors ought to employ in writing up their trials. We also considered whether each recommendation was supported by solid evidence that it contributed to the validity of an RCT (see the note accompanying Table 3-09-2). Where possible, the inclusion of an item on the checklist was justified from empirical research (cohort studies of trials that met and failed that item), but other items were included based only on our "expert" opinions (and we acknowledged the deficiencies[2] of that approach). The eventual result was the "Consolidated Standards of Reporting Trials" or CONSORT statement[3].

The CONSORT statement received a huge boost when it was endorsed by editors of the leading clinical journals, culminating with its support by the "Vancouver Group" (The International Committee of Medical Journal Editors). Its use expanded rapidly, and it looks like it has begun to achieve its goal. Some studies comparing the reporting of RCTs before and after the adoption of CONSORT suggested that it has had a positive impact on making trial reports more transparent. For example, unclear statements about whether the destined allocation of the next patient was concealed from their clinician fell from 61% of trials in 1994 to 39% by 1998[4]. Other studies have documented how far we still have to go. For example, a team led by PJ Devereaux found that 6 of 11 methodolocal items in the CONSORT checklist were reported in less than 50% of the papers published in 29 medical journals.[5]

On the other hand, "bad" reporting does not necessarily mean "bad" methods. For example, Heloisa Soares led a team who compared the protocols of 56 radiation oncology trials with their subsequent publications[6]. Although all trials concealed their randomization, only 42% reported doing so. Alpha and beta errors were specified in 74% of the protocols, but appeared in only 10% of the reports. As more journals force authors to follow the CONSORT checklist (and, better yet, provide internet links to their protocols), this disparity should decrease.

The CONSORT group is alive and well. It periodically revises the CONSORT statement based on proposals from its members and the feedback it receives. In addition, a sub-committee has been formed to track down, appraise, and summarize both individual methocological studies and systematic reviews of Evidence Supporting CONSORT On Reporting Trials (ESCORT).

The 2001 version of the CONSORT statement appears in Table 3-09-2 (cohort evidence when it exists) and its accompanying patient flow-diagram is shown in Figure 3-2-N-1. In 2004 the

CONSORT group developed an additional set of items for *cluster randomized trials*, and these appear *in italics* in the table.

Table 3-09-2: Checklist of items to include when reporting a randomized trial
(Author's note: will insert the latest version of this checklist at the last minute)
Cluster items in italics

Section & Topic	#	Descriptor	Sort of Evidence
Title and abstract	1	How participants were allocated to interventions (e.g., "random allocation," "randomized," or "randomly assigned"), *specifying that allocation was based on clusters*.	Cohort study[7]
Introduction Background	2	Scientific background and explanation of rationale, *including the rationale for using a cluster design.*	Expert opinion
		Methods	
Participants	3	Eligibility criteria for participants *and clusters,* and the settings and locations where the data were collected.	Expert Opinion
Interventions	4	Precise details of the interventions intended for each group*, whether they pertain to the individual level, the cluster level, or both,* and how and when they were actually administered.	Expert opinion
Objectives	5	Specific objectives and hypotheses *and whether they pertain to the individual level, the cluster level, or both*. (The question posed by the trial).	Expert Opinion
Outcomes	6	Clearly defined primary and secondary outcome measures, *whether they pertain to the individual level, the cluster level, or both,* and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors).	Expert opinion
Sample size	7	How sample size was determined *(including method of calculation, number of clusters, cluster size, a coefficient of intracluster correlation (intraclass correlation coefficient or k), and an indication of its uncertainty)* and, when applicable, explanation of any interim analyses and stopping rules.	Expert Opinion
Randomization: sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification*, matching*).	Expert opinion
Randomization: Allocation concealment	9	Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), *specifying that allocation was based on clusters rather than individuals, and* clarifying whether the sequence was concealed until interventions were assigned.	Cohort study[8]
Randomization: implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	Expert opinion

Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated.	Cohort study[9]
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s)*, indicating how clustering was taken into account,* methods for additional analyses, such as subgroup analyses and adjusted analyses.	Expert opinion
Results			
Participant flow	13	Flow of *clusters and* participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of *clusters and* participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	Cohort study
Recruitment	14	Dates defining the periods of recruitment and follow-up.	Expert opinion
Baseline data	15	Baseline demographic and clinical characteristics of each group *for the individual and cluster levels as applicable*.	Cohort study
Numbers analyzed	16	Number off *clusters and* participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat." State the results in absolute numbers when feasible (e.g., 10/20, not 50%).	Cohort study
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group *for the individual or cluster level as applicable*, and the estimated effect size and its precision (e.g., 95 percent confidence interval) *and a coefficient of intracluster correlation (intraclass correlation coefficient or k) for each primary outcome*..	Expert opinion
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory.	Cohort study[10]
Adverse events	19	All important adverse or side effects in each intervention group.	Expert opinion
Comment			
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes.	Cohort study
Generalizability	21	Generalizability (external validity) *to individuals and/or clusters (as relevant)* of the trial findings.	Expert opinion

Overall evidence	22	General interpretation of the results in the context of current evidence.	Cohort study

Figure 3-2-N-1: Revised template of the CONSORT diagram showing the flow of participants through each stage of a randomized trial.

(to be added later)

Figure – regular consort flow

Figure –cluster flow – first sort

Figure – c;luster flow, 2nd sort

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