Istituti Ortopedici Rizzoli

L'Integrità della Ricerca Biomedica
nell'era dell'Evidence-based Health Care

Bologna, 23 novembre 2001

GIMBE®

Gruppo Italiano per la Medicina Basata sulle Evidenze

Evidence-Based Medicine Italian Group

*Cons*olidated standards *of* *R*eporting *Trial* revised

The *CONSORT* Statement II

Massimo Annicchiarico

Azienda USL Bologna Nord

" Randomized controlled trials are the standard of excellence for scientific studies of effects of treatment ."

Fletcher & Fletcher & Wagner, 1996

"RCT is a very beautiful technique, of wide applicability, but as with everything else there are snags. When humans have to make observations there is always the possibility of bias "

Al. Cochrane

What is "quality" of an RCT ?

- The clinical relevance of the research question.

- The internal validity of the trial (the degree to which the trial design, conduct, analysis, and presentation have minimised or avoided biased comparisons of the interventions under evaluation).

- The external validity (the precision and extent to which it is possible to generalise the results of the trial to other settings).

- The appropriateness of data analysis and presentation.

- The ethical implications of the intervention evaluated. *Jadad, A. 2000*

Reporting RCT : Key quality elements usefulness for interpretation of results

1) *Is the topic interesting to you* ?

Title, introduction objective, (but the information in the title and the abstract could give you a misleading message)

2) *Are the results likely to be unbiased* ?

Research design, participants, interventions, main outcome measures, results, sampling frame, approach by the investigators, criteria used to include prospective participants or to exclude them, interventions, randomisation and blinding metod and implementation, measure of outcomes, metods of analysis

3) *Would you be able to use the results* ?

clinical setting

4) *Are the results important enough for you to remember* ?

How well RCT are reported ?

Statement about sample size: 11,1%
Use of confidence intervals: 13,3 %

Pocock SJ, *N Engl J Med.* 1987;317:426-432.

Information about type of randomization: 40%

Altman DG, *Lancet.* 1990;335:149-153.

How the randomization sequence was generated: 32%
How intervention assignement was concealed. 22,8%

Schulz KF, *JAMA.* 1994;272:125-128.

*S*tandard *o*f *R*eporting *T*rials
SORT
(*JAMA* 1994)

Asilomar Working Group
on Raccomandation for
Reporting of
Clinical Trials in the
Biomedical Literature
(*Ann Intern Med* 1996)


JAMA®
The Journal of the American Medical Association

Special Communication - August 28, 1996

Improving the Quality of Reporting of Randomized Controlled Trials

The CONSORT Statement

Colin Begg, PhD; Mildred Cho, PhD; Susan Eastwood, ELS(D); Richard Horton, MB; David Moher, MSc; Ingram Olkin, PhD; Roy Pitkin, MD; Drummond Rennie, MD; Kenneth F. Schulz, PhD; David Simel, MD; Donna F. Stroup, PhD

CONSORT I
Clinical Trialist
methodologists
epidemiologists
statisticians
editors

Controversies

Beyond CONSORT: Need for Improved Reporting Standards for Clinical Trials

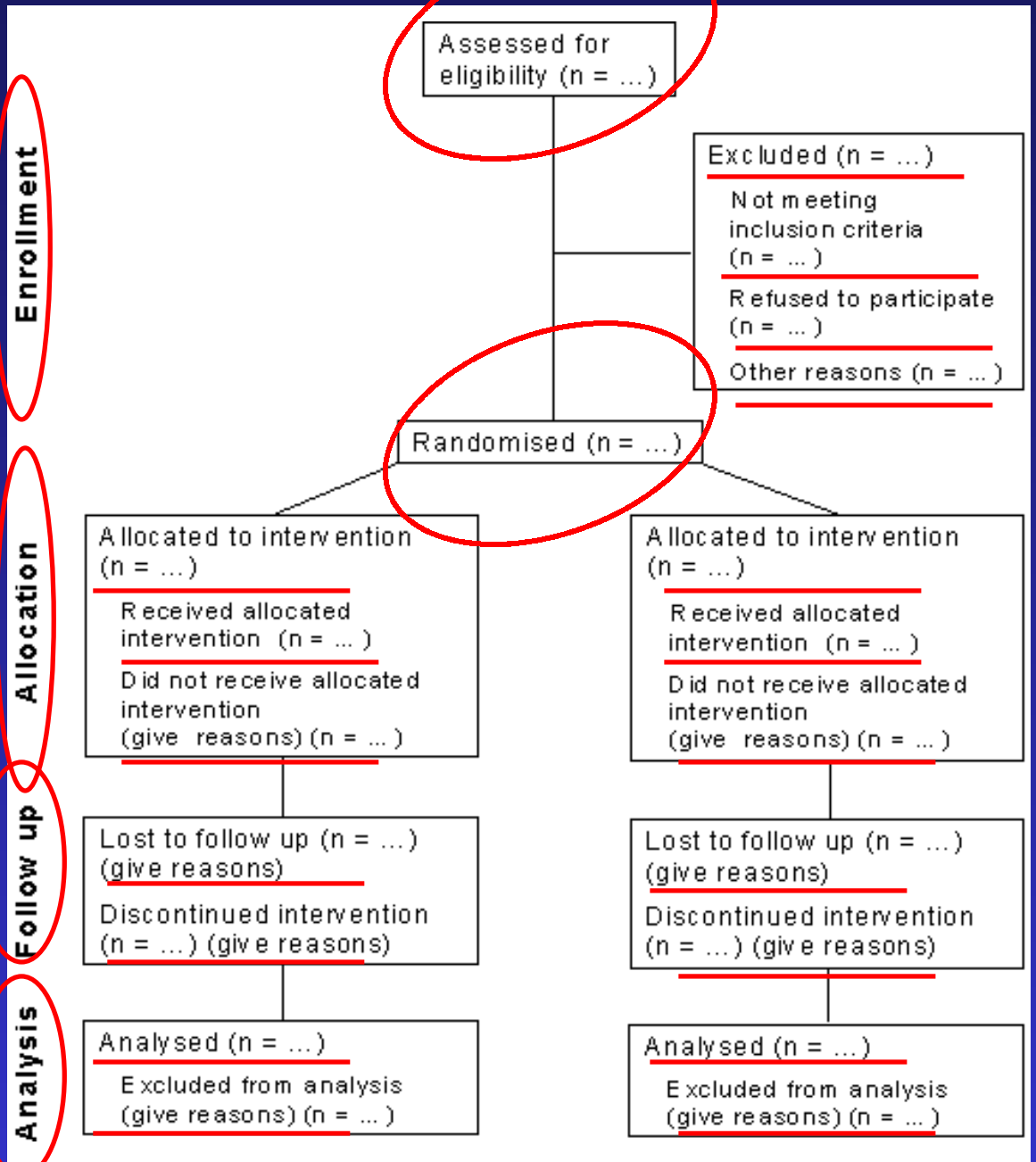
Curtis L. Meinert, PhD

JAMA, May 13, 1998—Vol 279, No. 18

The Revised CONSORT Statement for Reporting Randomized Trials: Explanation and Elaboration

Douglas G. Altman, DSc; Kenneth F. Schulz, PhD; David Moher, MSc; Matthias Egger, MD; Frank Davidoff, MD; Diana Elbourne, PhD; Peter C. Gøtzsche, MD; and Thomas Lang, MA, for the CONSORT Group

17 April 2001 | Annals of Internal Medicine | Volume 134 • Number 8 | 663



CONSORT II flow-chart: showing *all* numbers to prevent bias

The CONSORT II check-list

Items to include when Reporting a randomized trial

- Title and abstract
- Introduction: background
- Methods: partecipants, intervention, objectives, outcomes, sample size
- Randomization: sequence generation, allocation concealement, implementation
- Blinding
- Statistical methods
- Results: partecipant flow, recruitment, baseline data, number analyzed, outcome and estimation, ancillary analyses, adverse events
- Discussion: interpretation, generalizability, overall evidence

The CONSORT II glossary

GLOSSARY

Adjusted analysis: Usually refers to attempts to control (adjust) for baseline imbalances between groups in important patient characteristics. Sometimes used to refer to adjustments of *P* value to take account of multiple testing. See *Multiple comparisons.*

Adverse event: An unwanted effect detected in participants in a trial. The term is used regardless of whether the effect can be attributed to the intervention under evaluation. See also *Side effect.*

Allocation concealment: A technique used to prevent selection bias by concealing the allocation sequence from those assigning participants to intervention groups, until the moment of assignment. Allocation concealment prevents researchers from (unconsciously or otherwise) influencing which participants are assigned to a given intervention group.

Allocation ratio: The ratio of intended numbers of participants in each of the comparison groups. For two-group trials, the allocation ratio is usually 1:1, but unequal allocation (such as 1:2) is sometimes used.

The CONSORT II web site

www.consort-statement.org

Use of the CONSORT Statement and Quality of Reports of Randomized Trials

A Comparative Before-and-After Evaluation

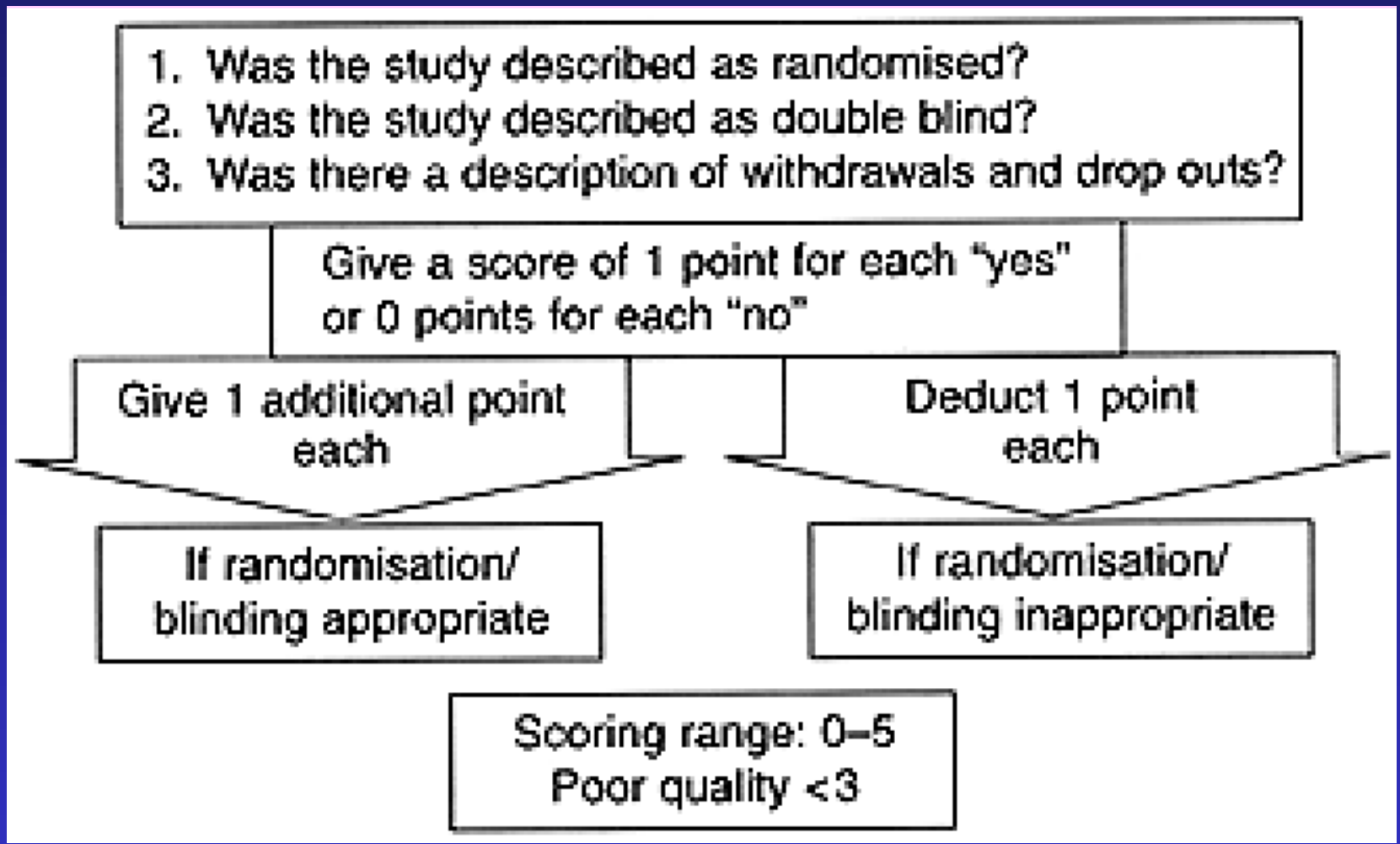
David Moher, MSc
Alison Jones, BA
Leah Lepage, PhD
for the CONSORT Group

Context The Consolidated Standards for Reporting of Trials (CONSORT) statement was developed to help improve the quality of reports of randomized controlled trials (RCTs). To date, a paucity of data exists regarding whether it has achieved this goal.

Objective To determine whether use of the CONSORT statement is associated with improvement in the quality of reports of RCTs.

1992 JAMA, April 18, 2001—Vol 285, No. 15

Jadad quality scale



CONSORT Checklist of 40 Criteria Included in Reports of Randomized Trials for Articles Published in *BMJ*, *JAMA*, *The Lancet*, and *NEJM* during the First Half of 1994 and 1998

	BMJ	*JAMA*	*Lancet*	Total Adopters	*NEJM* (Comparator)
Total (n = 40)					
1994, Mean (SD)	21.1 (4.2)	26.0 (4.6)	21.8 (4.8)	23.4 (5.1)	22.0 (3.0)
1998, Change (95% CI)	6.4 (2.9 to 9.9)‡	1.6 (–0.8 to 4.0)	4.9 (2.5 to 7.3)‡	3.7 (2.1 to 5.3)‡	0.8 (–1.1 to 2.7)

*CONSORT indicates Consolidated Standards for Reporting of Trials; CI, confidence interval.
†$P<.05$ (2-sided).
‡$P<.001$ (2-sided).

Quality of Reports of Randomized Trials, Using an Assessment Tool, for Articles Published in *BMJ*, *JAMA*, *The Lancet*, and *NEJM* during the First Half of 1994 and 1998

Journal	Total No. of Items 1994	Total No. of Items 1998	Randomization 1994, Mean (SD)	Randomization 1998, Change (95% CI)	Double-blinding 1994, Mean (SD)	Double-blinding 1998, Change (95% CI)	Dropouts/ Withdrawals 1994, %	Dropouts/ Withdrawals 1998, % Change (95% CI)	Total 1994, Mean (SD)	Total 1998, Change (95% CI)	Unclear Allocation Concealment 1994, %	Unclear Allocation Concealment 1998, % Change (95% CI)
BMJ	14	20	1.1 (0.4)	0.4 (0.04 to 0.8)†	0.2 (0.6)	0.1 (–0.4 to 0.5)	71	–6 (–40 to 28)	2.1 (0.9)	0.4 (–0.3 to 1.2)	79	–29 (–62 to 4)
JAMA	29	20	1.3 (0.6)	0.1 (–0.3 to 0.4)	0.9 (0.8)	0.2 (–0.3 to 0.8)	76	4 (–21 to 29)	3.0 (1.0)	0.4 (–0.3 to 1.0)	59	–14 (–43 to 16)
Lancet	28	37	1.2 (0.4)	0.4 (0.1 to 0.6)†	0.6 (0.8)	0.3 (–0.2 to 0.7)	96	1 (–8 to 10)	2.8 (0.9)	0.7 (0.1 to 1.2)‡	54	–24 (–48 to 1)
Total Adopters	**71**	**77**	1.2 (0.5)	0.3 (0.1 to 0.4)†	0.6 (0.8)	0.2 (–0.1 to 0.4)	83	1 (–11 to 13)	2.7 (1.0)	0.4 (0.1 to 0.8)§	61	–22 (–38 to –6)‖
NEJM comparator	26	37	1.4 (0.5)	0.02 (–0.2 to 0.3)	0.8 (1.0)	0.3 (–0.4 to 0.5)	92	–6 (–21 to 10)	3.1 (1.0)	–0.01 (–0.6 to 0.5)	69	–8 (–33 to 17)

*CI indicates confidence interval.
†$P<.05$ (2-sided).
‡$P = .01$ (2-sided).
§$P = .02$ (2-sided).
‖$P = .008$ (2-sided).

What is "quality" of an RCT ?

- The clinical relevance of the research question.
- The internal validity of the trial (the degree to which the trial design, conduct, analysis, and presentation have minimised or avoided biased comparisons of the interventions under evaluation).
- The external validity (the precision and extent to which it is possible to generalise the results of the trial to other settings).
- The appropriateness of data analysis and presentation.
- The ethical implications of the intervention evaluated.

The CONSORT Statement: original objectives & hopeful results - 1

Objective

- To improve the standard of written reports of RCTs (*for writers*)

Results - 1

- To lead an improvement in the quality of RCTs as result of authors being aware of the requirements for submission of trial reports

The CONSORT Statement: original objectives & hopeful results - 2

Results - 2

- To facilitate critical appraisal and interpretation of RCTs by providing guidance:
  - To *author* about how to improve the reporting of their trials
  - To *peer-rewievers and editors* to identify reports that are difficult to interpret and those with potentialy biased results
  - To *clincian* to judge whether the results of a trial are credible
  - To *reviewer* to decide how much each trial should influence the overall analysis of all evidence available on a particular topic
  - to *administrator* to deciding whether to purchase a service or a new intervention

Which Journals completely endorse *CONSORT* and how ?

JOURNAL	*ENDORSING HOW*	
Annals of Emergency Medicine	instructions to authors	completed checklist required
Annals of Internal Medicine	instructions to authors	completed checklist required
Archives of Dermatology	instructions to authors	completed checklist required
Archives of Family Medicine	instructions to authors	completed checklist required
British Medical Journal	instructions to authors	completed checklist required
Journal of the American Medical Association		completed checklist required
Obstetrics and Gynecology	instructions to authors	completed checklist required
Scandinavian Journal of Gastroenterology	instructions to authors	completed checklist required

"I numeri possono essere torturati fino a che non confessano"

Anonimo

" ...Ma una bugia ne rende necessarie molte altre"

Anonimo