

Standardized reporting guidelines: The helping hands

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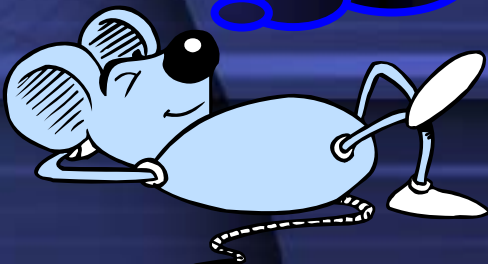


What are they?



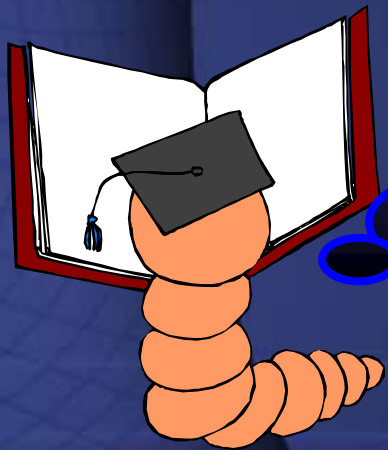
- ❖ Standardized research reporting frameworks
- ❖ Check-list of items which must be referred when reporting a study
- ❖ Different guidelines for different studies

Saves time
and makes
life simpler



Why were they introduced?

to help ensure that essential research information, needed to assess quality, is included in journal articles



"inadequate reporting borders on unethical practice when biased results receive false credibility."

Moher D, Schulz KF, Altman DG. *The Lancet* 2001;357:1191-4.

Some features...

- ❖ More comprehensive than the basic IMRAD
- ❖ Checklists vary by methodology and specific research designs.
- ❖ There are several standardized formats for general and specific research designs
- ❖ Satisfy the reporting requirements of journals



A few of them...

- ❖ **CHERRIES** (**C**hecklist for **R**eporting **R**esults of Internet **E**-Surveys)
- ❖ 30-item checklist
- ❖ for reporting Web-based surveys
- ❖ Journal of Medical Internet Research (Gunther, 2004). Available at <http://www.jmir.org/2004/3/e34/>

A few of them...

- ❖ CONSORT (Consolidated Standards for Reporting Trials):
 - ❖ a 22-item checklist
 - ❖ for reporting simple two group, parallel, randomized controlled trials. Available at <http://www.consort-statement.org/Downloads/Checklist.doc> or <http://www.consort-statement.org/Downloads/checklist.pdf>

A few of them...



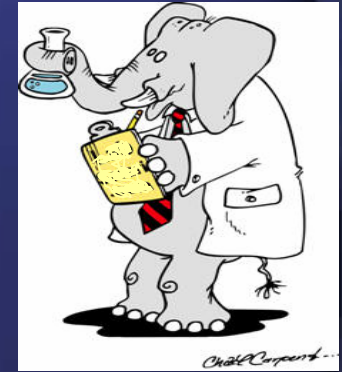
- ❖ MOOSE (Meta-Analysis Of Observational Studies in Epidemiology)
- ❖ a 35-item checklist for reporting observational studies (Stroup et al., 2000). Available at <http://www.greenjournal.org/misc/moose.pdf> or <http://jama.ama-assn.org/cgi/content/full/283/15/2008>.

A few of them...

- ❖ QUOROM (Quality of Reporting of Meta-Analyses)
- ❖ a 17-item checklist for reporting systematic reviews (Moher et al., 1999).
- ❖ Available at <http://www.consort-statement.org/QUOROM.pdf>.

A few of them...

- ❖ STARD (Standards for Reporting of Diagnostic Accuracy)
- ❖ a 25-item checklist (STARD, 2001).
- ❖ for diagnostic test accuracy



<http://www.clinchem.org/cgi/reprint/49/1/7.pdf>

or

[http://www.clinchem.org/cgi/content/full/49/1/7/.](http://www.clinchem.org/cgi/content/full/49/1/7/)

A few of them...



- ❖ STROBE (Strengthening the Reporting of Observational Studies in Epidemiology)
- ❖ Checklist for case-control, cohort, and cross-sectional studies (STROBE Group, 2005).
<http://www.strobe-statement.org>

A few of them...

- ❖ Reporting of Observational Longitudinal Research
- ❖ A 33-item checklist patterned after CONSORT.
- ❖ The checklist criteria focus on threats to the internal and external validity of observational longitudinal studies.
- ❖ Additional items concern recruitment, data collection, biases, data analysis, descriptive issues and generalizability (Tooth et al., 2005).

<http://aje.oxfordjournals.org/cgi/content/abstract/161/3/280>

A few of them...

- ❖ **TREND** (Transparent Reporting of Evaluations with Nonrandomized Designs): a 22-item checklist for nonrandomized designs (Des Jarlais et al., 2004).

<http://www.ajph.org/cgi/content/full/94/3/361/>

OR <http://www.trend->

[statement.org/asp/documents/statements/AJP](http://www.trend-statement.org/asp/documents/statements/AJP)

[H_Mar2004_Trendstatement.pdf](http://www.trend-statement.org/asp/documents/statements/AJP_H_Mar2004_Trendstatement.pdf)

In addition...



- ❖ **Qualitative Checklist(s):** Several checklists and evaluative guides have been developed for empirical research using qualitative methods or designs.
- ❖ **Criteria for evaluating qualitative studies** (Bromely, et al., 2002). Available at <http://www.liv.ac.uk/lstm/download/guidelines.pdf>

Qualitative data

- ❖ Guides for authors using research that reports qualitative data

Greenhalgh T, Taylor R. How to read a paper: Papers that go beyond numbers (qualitative research). *British Medical Journal* 1997;315:740-3.

Patton MQ (2003). *Qualitative evaluation checklist*.
<http://www.wmich.edu/evalctr/checklists/>

Instruments for specific subspecialties



- ❖ Acupuncture (STRICTA: **S**tandards for **R**eporting **I**nterventions in **C**ontrolled **T**rials of **A**cupuncture)
- ❖ Acute ischemic stroke*
- ❖ They include key appraisal points for assessing quality that are specific to the research design - intended to facilitate review

**Higashida et al.; Trial design and reporting standards for intra-arterial cerebral thrombolysis for acute ischemic stroke. Stroke 2003;34(8);109-37.*

What are the uses?



- ❖ Reporting
- ❖ Designing the protocol
- ❖ Reviewing papers
- ❖ Teaching tool

use has been associated with improved reporting quality

What are the limitations?



- ❖ It is only a guide, not a substitute for training
- ❖ Not instruments of evaluation
- ❖ Following them does not necessarily mean that the paper will be accepted
- ❖ Checklists for research designed to generate qualitative data - overly prescriptive*

*Barbour R. Checklists for improving rigour in qualitative research: A case of the tail wagging the dog? *British Medical Journal* 2001;322:1115-7.

CONSORT (Consolidated Standards for Reporting Trials):

- ❖ A 22-item checklist for reporting simple two group, parallel, randomized controlled trials.*

Available at

<http://www.consort-statement.org/Downloads/Checklist.doc>

<http://www.consort-statement.org/Downloads/checklist.pdf>

* Moher D, Schulz KF, Altman DG. *The CONSORT statement: Revised recommendations for improving the quality of reports of parallel-group randomised trials. The Lancet* 2001;357;1191-4.

PAPER SECTION And topic	Item	Description	Reported on Page #
<i>TITLE & ABSTRACT</i>	1	<u>How participants were allocated to interventions</u> (e.g., "random allocation", "randomized", or "randomly assigned").	
<i>INTRODUCTION</i> Background	2	<u>Scientific background and explanation of rationale.</u>	

PAPER SECTION And topic	Item	Description	Reported on Page #
<i>METHODS</i> Participants	3	<u>Eligibility criteria for participants and the settings and locations where the data were collected.</u>	
Interventions	4	<u>Precise details of the interventions intended for each group and how and when they were actually administered.</u>	
Objectives	5	<u>Specific objectives and hypotheses.</u>	
Outcomes	6	<u>Clearly defined primary and secondary outcome measures</u> and, when applicable, any <u>methods used to enhance the quality of measurements</u> (e.g., multiple observations, training of assessors).	
Sample size	7	<u>How sample size was determined</u> and, when applicable, <u>explanation of any interim analyses and stopping rules.</u>	

PAPER SECTION And topic	Item	Description	Report ed on Page #
Randomization -- Sequence generation	8	<u>Method used to generate the random allocation sequence, including details of any restrictions (e.g., blocking, stratification)</u>	
Randomization -- Allocation concealment	9	<u>Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.</u>	
Randomization -- Implementation	10	<u>Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.</u>	

PAPER SECTION And topic	Item	Description	Reported on Page #
Blinding (masking)	11	<u>Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. When relevant, how the success of blinding was evaluated.</u>	
Statistical methods	12	<u>Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.</u>	

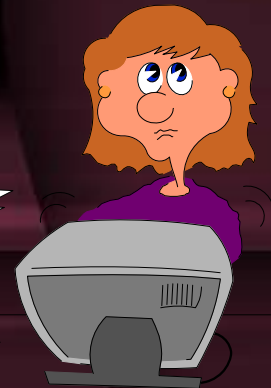
<p>RESULTS Participant flow</p>	<p>13</p>	<p><u>Flow of participants through each stage</u> (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. <u>Describe protocol deviations from study as planned, together with reasons.</u></p>	
<p>Recruitment</p>	<p>14</p>	<p><u>Dates defining the periods of recruitment and follow-up.</u></p>	
<p>Baseline data</p>	<p>15</p>	<p><u>Baseline demographic and clinical characteristics of each group.</u></p>	
<p>Numbers analyzed</p>	<p>16</p>	<p><u>Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat".</u> State the results in absolute numbers when feasible (e.g., 10/20, not 50%).</p>	

Outcomes and estimation	17	<u>For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (e.g., 95% confidence interval).</u>
Ancillary analyses	18	<u>Address multiplicity by reporting any other analyses performed</u> , including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.
Adverse events	19	<u>All important adverse events or side effects in each intervention group.</u>

DISCUSSION Interpretation	20	<u>Interpretation of the results</u> , taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.
Generalizability	21	<u>Generalizability (external validity) of the trial findings.</u>
Overall evidence	22	<u>General interpretation of the results in the context of current evidence.</u>

To conclude...

- Standardized Reporting guidelines are indeed helping hands for authors
- Can be used as a teaching-learning tool
- Improves quality of reporting
- Authors must be familiar with the guidelines specific for their area of research or study design



Thank you

Standardized Research Reporting

<http://researchutilization.org/sqr/standreport.html>

