EQUATOR Network - promoting transparent and accurate reporting of research studies

Can you trust your research literature?

Doug Altman

Centre for Statistics in Medicine
University of Oxford
“Can you trust the research published in medical journals? Mostly I believe you can. But not always … some of the most newsworthy reports published by our leading journals spontaneously combust under the gentlest of scrutiny.”

Guardian 16 Sept 2004
Liver Transplant for Hepatitis C Virus

Effect of Using Older Donor Grafts on Short- and Medium-Term Survival

M. B. Majella Doyle, MD; Christopher D. Anderson, MD; Neeta Vachharajani, MD; Jeffrey A. Lowell, MD; Surendra Shenoy, MD; Mauricio Lisker-Melman, MD; Kevin Korenblat, MD; Jeffrey S. Crippin, MD; William C. Chapman, MD

Arch Surg. 2008;143(7):679-685
**Results:** At 1, 3, and 5 years, overall patient survival was 88.1%, 78.3%, and 69.2%, respectively, and graft survival was 85.6%, 75.6%, and 65.6%, respectively, in patients with HCV. There was no significant difference in patient or graft survival between patients with and those without HCV. Recurrent HCV with clinically significant disease was 20% at 1 year and 62% at 10 years. Seventy-two patients received transplants from donors 60 years or older (24 of 187 [12.8%] with HCV and 48 of 302 [15.9%] without HCV). No difference was demonstrated in short- or medium-term patient or graft survival in recipients of grafts from older donors.

**Conclusion:** The increasing use of marginal donors, including carefully selected older donors, does not seem to adversely affect short- or medium-term results and may be a source of additional organs for expanding liver transplant waiting lists.

“Patients who undergo liver transplantation at age 60 or above have 1-year and 5-year survival rates similar to those of younger patients ...”

NEW YORK (Reuters Health) - Advanced donor age, per se, does not adversely affect the transplant recipient or the survival of the organ after liver transplantation, according to a report in the Journal of the American College of Surgeons.
Doyle et al
Effect of age of donor

- Age > 60 was not statistically significant in the multivariate analysis
  
  HR = 3.03 (95% CI: 0.70-12.20)
  
  P = 0.12

- However:
  
  “There are at least 25 other studies that have demonstrated that older donors are associated with worse outcomes in recipients with hepatitis C ...”
A randomised trial

ARTICLE

Promotion and Provision of Drinking Water in Schools for Overweight Prevention: Randomized, Controlled Cluster Trial

Rebecca Muckelbauer, MSc, Lars Libuda, MSc, Kerstin Clausen, PhD, André Michael Toschke, MD, MSc, MPH, Thomas Reinehr, MD, Mathilde Kersting, PhD

*Pediatrics* 2009;123;e661-7
The study population comprised children attending the second and third grades of elementary schools in deprived neighborhoods of 2 neighboring cities, namely, Dortmund and Essen, Germany ... Schools in Dortmund represented the intervention group (IG) and schools in Essen the control group (CG). For each city, 20 schools were selected randomly (Fig 1).
Importance of good research reporting

- Complete, accurate and transparent reporting is an integral part of responsible research conduct

  ... All scientists have a responsibility to ensure that they conduct their work with honesty and integrity; to ensure that methods and results are reported in an accurate, orderly, timely and open fashion. ...


- **Scientific article**
  - often the only tangible evidence that the study was done
  - should present sufficient information to allow a full evaluation of the presented data and further use of these findings
Importance of good research reporting

- Research should be reported fully and accurately
- There is much evidence that this does not happen
- Assessment of reliability of published articles is seriously impeded by inadequate reporting
- Many journal articles are not fit for purpose
What should be reported?

“Describe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results.”

[International Committee of Medical Journal Editors]

- A similar principle should extend to all study aspects
  - Selection of participants
  - Interventions
  - Outcome measures
  - etc

- The goal should be to allow replication (in principle)
What do we mean by poor reporting?

Mainly
- Key information is missing, incomplete or ambiguous
  - Methods
  - Results

Also
- Misleading interpretation
- Selective reporting
- etc
Vasopressin vs epinephrine for out-of-hospital cardiopulmonary resuscitation

- Primary outcome: hospital admission (alive)

- The overall comparison gives
  OR = 0.8 (95% CI: 0.6 to 1.00) [P=0.06]
<table>
<thead>
<tr>
<th></th>
<th>Vasopressin (N=589)</th>
<th>Epinephrine (N=597)</th>
<th>P Value</th>
<th>Odds Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients Hospital admission</td>
<td>214/589 (36.3)</td>
<td>186/597 (31.2)</td>
<td>0.06</td>
<td>0.8 (0.6–1.0)</td>
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<td>Vasopressin (N=589)</td>
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<td>186/597 (31.2)</td>
<td>0.06</td>
<td>0.8 (0.6–1.0)</td>
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<td><strong>Ventricular fibrillation Hospital admission</strong></td>
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<td></td>
<td>103/223 (46.2)</td>
<td>107/249 (43.0)</td>
<td>0.48</td>
<td>0.9 (0.6–1.3)</td>
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<tr>
<td><strong>Pulseless electrical activity Hospital admission</strong></td>
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<td></td>
<td>35/104 (33.7)</td>
<td>25/82 (30.5)</td>
<td>0.65</td>
<td>0.8 (0.5–1.6)</td>
</tr>
<tr>
<td><strong>Asystole Hospital admission</strong></td>
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<tr>
<td></td>
<td>76/262 (29.0)</td>
<td>54/266 (20.3)</td>
<td>0.02</td>
<td>0.6 (0.4–0.9)</td>
</tr>
</tbody>
</table>
Vasopressin vs epinephrine for out-of-hospital cardiopulmonary resuscitation

- Methods section has no mention of planning to look at the subgroups
- Overall result for the primary outcome shown only in a table
- Results, Discussion and Abstract focus on subgroup analyses
  - Significant effect in one of 3 clinical subgroups
- Comparison of P values is wrong
- No significant difference between subgroups (interaction test)
Reporting of research

73 articles in 13 chiropractic journals
- 21% lacked description of the study design
- 77% did not provide a sample size justification
- 26% reported inappropriate descriptive statistics
- 26% reported conclusions not supported by the results

- Hundreds of similar studies
Reporting of adverse events in RCTs of HAART: systematic review.
[Chowers et al. *J Antimicrob Chemother* 2009]

- Only 16/49 trials reported AEs with no pre-selection
- 67% reported only some AEs
  - e.g. the most frequent, if P<0.05, or ‘selected’ AEs

- “These facts obstruct our ability to choose HAART based on currently published data.”
- “Authors and editors should ensure that reporting of AEs in HAART trials follows the CONSORT guidelines for reporting on harms in randomized trials.”
Post hoc specification

- **Choosing the analysis after looking at the data**
  - Many other analyses are implied but not reported

- **Data-derived choice of analyses will be misleading**
  - Results can be seriously biased
Reporting of sample size calculations and data analyses in publications compared with protocols

Chan et al, BMJ 2008
Growing evidence of poor reporting

- **Unethical reporting practices with serious adverse consequences**
  - Non-reporting or delayed reporting of whole studies
  - Selective reporting of only certain outcomes
  - Omission of crucial information in the description of research methods and interventions
  - Presenting data (graphs) in confusing or misleading ways (particularly important for presenting benefits and harms)
  - Inadequate statistical reporting
  - Omissions or misinterpretation of results in abstracts
Example of poor reporting: details of treatment

- **Glasziou et al. (BMJ 2008)**
  - assessed descriptions of treatments in 80 published articles (55 randomised trials & 25 systematic reviews)
  - crucial elements of the interventions were missing in 41 of those studies (of 25 SR only 3 provided intervention description sufficient for implementation)
Selective reporting

- **Dwan et al. (PLoS ONE 2008)**
  - Reviewed 16 cohort studies that assessed *study publication bias* and *outcome reporting bias* in randomised controlled trials
  - Strong evidence that studies reporting positive or significant results were more likely to be published and outcomes that were statistically significant were more likely to be fully reported
  - Discrepancies between publications and original trial protocols: 40–62% of studies had at least one primary outcome changed, newly introduced or omitted
Neurology trial
Surgical intervention

Protocol

Primary outcome:
% with Score<3 at 1 yr

P ≥ 0.05

Publication

Primary outcome:
% dead/dependent at 1 year

P < 0.05
Delays in publishing the results of clinical trials harm patients, and public health

Kameshwar Prasad
The FISS (Fraxiparine in Ischemic Stroke Study) trial involved 312 patients with acute ischaemic stroke, the results were in favour of fraxiparine, and it was published in the *New England Journal of Medicine*. A larger trial, FISS bis, failed to confirm the findings, but unfortunately has been published only in an abstract form in 1998; not surprisingly it has received little publicity—certainly very little compared with the publication of FISS in a prestigious medical journal. Hence, thousands of patients with acute ischaemic stroke continue to incur the risks and costs associated with the use of this drug without any certainty at all that it improves their outcome.
Comparison of Registered and Published Primary Outcomes in Randomized Controlled Trials

Sylvain Mathieu, MD

Context As of 2005, the International Committee of Medical Journal Editors recommended that study authors include detailed participant information about the study prior to participant enrollment. Registration usually involves reporting information on the 20 items proposed by the World Health Organization registration advisory group in April 2004. The research community has embraced this policy, as seen by a marked increase in trial registration.

323 randomised trials
- 46% adequately registered
- 28% not registered
- 14% registered after the completion of the study
- 11% registered with no/unclear description of primary outcome

147 adequately registered trials
- 31% had evidence of discrepancies between the outcomes registered and the outcomes published.

When it could be assessed, statistically significant results were favoured in 83% (19 of 23)

Conclusion Comparison of the primary outcomes of RCTs registered with their subsequent publication indicated that selective outcome reporting is prevalent.

JAMA. 2009;302(9):977-984
“The idea of [a] drug’s use being based on the selective reporting of favourable research should be unimaginable ... Changes are required at every level of the global health-care infrastructure.”
Reporting and Interpretation of Randomized Controlled Trials With Statistically Nonsignificant Results for Primary Outcomes

Isabelle Boutron, MD, PhD
Susan Dutton, MSc
Philippe Ravaud, MD, PhD
Douglas G. Altman, DSc

A ccurate presentation of results of a randomized controlled trial (RCT) is the cornerstone of the dissemination of evidence-based medicine. However, studies indicate that authors may present results in a way that could lead to a biased interpretation. This phenomenon is sometimes referred to as "spin." The authors aimed to identify the nature and frequency of such presentation. They conducted a systematic review of all RCTs published in 2006 and found that 40% of the articles were rated as showing spin. The authors suggest that more education and research are needed to address this issue.

Context Previous studies indicate that the interpretation of trial results can be distorted by authors of published reports.

Objective To identify the nature and frequency of distorted presentation or "spin" (ie, specific reporting strategies, whatever their motive, to highlight that the experimental treatment is beneficial, despite a statistically nonsignificant difference for the primary outcome, or to distract the reader from statistically nonsignificant results) in published reports of randomized controlled trials (RCTs) with statistically nonsignificant results for primary outcomes.

Data Sources March 2007 search of MEDLINE via PubMed using the Cochrane Highly Sensitive Search Strategy to identify reports of RCTs published in December 2006.

JAMA. 2010;303(20):2058-2064
Spin in a representative sample of 72 reports of randomised trials

**Title**
- 18% Text of title

**Abstract**
- 38% Results section of abstract
- 58% Conclusions section of abstract

**Main text**
- 29% Results
- 41% Discussion
- 50% Conclusions

>40% had spin in at least 2 sections of main text
“The most familiar and common approach was to focus on statistically significant results for other analyses, such as within-group comparisons, secondary outcomes, or subgroup analyses”
Poor reporting is a serious problem for systematic reviews and clinical guidelines

- “The biggest problem was the quality of reporting, which did not allow us to judge the important methodological items ...”

- “Data reporting was poor. 15 trials met the inclusion criteria for this review but only 4 could be included as data were impossible to use in the other 11.”
  
  (Reviews on Cochrane Library, accessed on 18 Sept 07)

- “In my work as a systematic reviewer, it is such a joy to come across a clearly reported trial when abstracting data.”

  Yeung CA. BMJ Rapid Response, 12 April 2010
The impact of poor reporting

- **Cannot assess reliability of individual studies**
  - Methods may not be adequately described
  - Methodological weaknesses may not be apparent

- **Cannot assess a body of evidence**

- **Adverse effects on**
  - Other researchers
  - Clinicians
  - Patients
What does the poor quality of published studies tell us about peer review?

- Peer review is difficult and only partly successful
- Reviewers (and editorial staff) are unable to eliminate errors in methodology and interpretation
- Readers should not assume that papers published in peer reviewed journals are scientifically sound
  - But, many readers (including other researchers) DO assume that papers published in peer reviewed journals are scientifically sound

⇒ Important that misleading papers are identified
⇒ Good reporting is critical
What can be done to improve the reliability of research reports?

- **Research**
  - Research conduct guidance

- **Publication**
  - Scientific writing guidance
  - Journals’ I to A

- **Knowledge dissemination & translation**
What can be done to improve the reliability of research reports?

Closing the gap

Research

Research conduct guidance

Publication

Scientific writing guidance
Journals’ I to A

Knowledge dissemination & translation

Editorial process & Peer review

Reporting guidelines
Reporting guidelines (RG)

- RG specify a minimum set of items required for a clear and transparent account of what was done and what was found in a research study, reflecting in particular issues that might introduce bias into the research

- Evidence-based & reflect consensus opinion

- Benefits of using RG:
  - Improved accuracy and transparency of publications
  - Easier appraisal of reports for research quality and relevance
  - Improved efficiency of literature searching
Examples of reporting guidelines – CONSORT Statement

- **22 items that should be reported in a paper**
  - Based on empirical evidence where possible

- **Also a flow diagram describing patient progress through the trial**

- **Main objective**
  - To facilitate critical appraisal and interpretation of RCTs by providing guidance to authors about how to improve the reporting of their trials

- **Secondary objective**
  - To encourage and provide incentives for researchers to conduct high-quality, unbiased randomized trials

- **www.consort-statement.org**
# CONSORT STATEMENT

<table>
<thead>
<tr>
<th>Item number</th>
<th>Description</th>
<th>Reported on page number</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title and abstract</strong></td>
<td></td>
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</tr>
<tr>
<td>1</td>
<td>How participants were allocated to interventions (e.g., “random allocation”, “randomised”, or “randomly assigned”).</td>
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<tr>
<td><strong>Introduction</strong></td>
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<tr>
<td>2</td>
<td>Scientific background and explanation of rationale.</td>
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<tr>
<td><strong>Methods</strong></td>
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<td>3</td>
<td>Eligibility criteria for participants and the settings and locations where the data were collected.</td>
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<tr>
<td>4</td>
<td>Precise details of the interventions intended for each group and how and when they were actually administered.</td>
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<tr>
<td>5</td>
<td>Specific objectives and hypotheses.</td>
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<tr>
<td>6</td>
<td>Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors, &amp;c.).</td>
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<tr>
<td>7</td>
<td>How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.</td>
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<tr>
<td><strong>Randomisation</strong></td>
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<td>8</td>
<td>Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification).</td>
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<tr>
<td>9</td>
<td>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.</td>
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<tr>
<td><strong>Implementation</strong></td>
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<tr>
<td>10</td>
<td>Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.</td>
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<tr>
<td><strong>Blinding (masking)</strong></td>
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<td>11</td>
<td>Whether or not participants, those administering the interventions, and those assessing the outcomes were aware of group assignment. If not, how the success of masking was assessed.</td>
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<tr>
<td><strong>Statistical methods</strong></td>
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<tr>
<td>12</td>
<td>Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses.</td>
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<tr>
<td><strong>Results</strong></td>
<td></td>
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<tr>
<td>13</td>
<td>Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analysed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.</td>
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<tr>
<td><strong>Recruitment</strong></td>
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<td>14</td>
<td>Dates defining the periods of recruitment and follow-up.</td>
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<tr>
<td><strong>Baseline data</strong></td>
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<td>15</td>
<td>Baseline demographic and clinical characteristics of each group.</td>
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<tr>
<td><strong>Numbers analysed</strong></td>
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<tr>
<td>16</td>
<td>Number of 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%).</td>
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<tr>
<td><strong>Outcomes and estimation</strong></td>
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<tr>
<td>17</td>
<td>For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (e.g., 56K CI).</td>
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<tr>
<td><strong>Ancillary analyses</strong></td>
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<tr>
<td>18</td>
<td>Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory.</td>
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<tr>
<td><strong>Adverse events</strong></td>
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<tr>
<td>19</td>
<td>All important adverse events or side-effects in each intervention group.</td>
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<tr>
<td><strong>Discussion</strong></td>
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<td>20</td>
<td>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.</td>
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<tr>
<td><strong>Generalisability</strong></td>
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<tr>
<td>21</td>
<td>Generalisability (external validity) of the trial findings.</td>
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<tr>
<td><strong>Overall evidence</strong></td>
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<tr>
<td>22</td>
<td>General interpretation of the results in the context of current evidence.</td>
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</tbody>
</table>

**Checklist of items to include when reporting a randomised trial**
CONSORT STATEMENT

Flow diagram of the progress through the phases of a randomised trial
Other reporting guidelines

- PRISMA  (SR/meta-analyses of RCTs)
- STARD   (diagnostic studies)
- STROBE  (observational studies)
  ... and many others

- As yet most guidelines have had limited impact
  - Passive dissemination through publication only - not widely known
  - Compliance not required by journals
EQUATOR Network

- **EQUATOR: Enhancing the QUAlity and Transparency Of health Research**
- **Project initiated in 2006, launched in June 2008**
- **Why we initiated the project:**
  - Reporting of much health research is not adequate
  - There are good consensus reporting guidelines which are not being widely used
  - There are many other reporting guidelines where it is not very clear how they were developed and again not used
- **Aim:**
  - To improve reliability of health research literature by promoting transparent and accurate reporting of health research
- **Key stakeholders:**
  - Developers of reporting guidelines, editors & peer reviewers, researchers (authors), medical writers, research funders, ... everyone interested in improving the quality of research publications and of research itself
EQUATOR – five major goals

- Develop and maintain a comprehensive internet-based resource centre providing up-to-date information, tools and other materials related to health research reporting
- Assist in the development, dissemination and implementation of robust reporting guidelines
- Actively promote the use of reporting guidelines and good research reporting practices through an education and training programme
- Conduct regular assessment of reporting guidelines implementation
- Conduct regular audits of reporting quality across the health research literature
Welcome to the EQUATOR Network website – the resource centre for good reporting of health research studies

Too often, good research evidence is undermined by poor quality reporting.

The EQUATOR Network is an international initiative that seeks to improve reliability and value of medical research literature by promoting transparent and accurate reporting of research studies.

Highlights

EQUATOR Spanish website
New site launched on 16 July 2010 in collaboration with the Pan American Health Organization (PAHO). Find out more and visit the site.

Promote good reporting
Print and display EQUATOR leaflets

EQUATOR Newsletter
New reporting guidelines, events, and other news. Subscribe now

The EQUATOR Network is funded by:

[NHS National Institute for Health Research]
[MRC Medical Research Council]
[CIHR IRSC]
[CHEST Scientist Office]
[Pan American Health Organization]
Library for health research reporting

The EQUATOR Network library currently contains:

- An introduction to reporting guidelines
- Comprehensive lists of the available reporting guidelines, listed by study type:
  - Experimental studies
  - Observational studies
  - Diagnostic accuracy studies
  - Systematic reviews
  - Qualitative research
  - Economic evaluations
  - Quality improvement studies
  - Other reporting guidelines
  - Sections of research reports
  - Specific conditions or procedures.

- Reporting guidelines under development
- Guidance on scientific writing
- Guidance developed by editorial groups
- Medical writers – additional resources
- Research ethics, publication ethics and good practice guidelines
- Development and maintenance of reporting guidelines
- Examples of guidelines for peer reviewers
- Editorials introducing RGs
- Resources related to development and maintenance of reporting guidelines
- Examples of editorials introducing reporting guidelines
- Examples of guidelines for peer reviewers
- Examples of good research reporting
- Useful and interesting presentations

Download the most frequently-used reporting guidelines (PDF files):

- CONSORT checklist
- CONSORT flowchart
- CONSORT extensions
- STARD checklist & flowchart
- STROBE
- QUOROM checklist & flowchart
- MOOSE
How to shift the ‘reporting culture’

- Collaboration of all parties involved in research publishing needed
  - Scientists, research organisations, funders and regulators
  - Journals (editors, peer reviewers, publishers)
  - Other organisations (higher education, REC, ..)

- Working towards:
  - … accurate, complete and transparent reporting of research studies is considered a ‘norm’ (not something extra)

- How to achieve this?
  - Clearly defined policies, requirements and expectations
  - Provision of tools and other resources
  - Education and training
  - Motivation and incentives
  - Application of safeguards and checks
Clear instructions to authors (and peer reviewers)
  - What it is expected

Specify relevant reporting guidelines, link to them and EQUATOR from I to A
  - Make it easy

Motivation and incentive
  - ‘major incentive for authors to report their research in a complete, transparent, and accurate manner will be to make the peer reviewer’s work easier, which may in turn make publication more likely and, perhaps, hasten the process’
    *(Developmental Medicine and Child Neurology)*

Otherwise promote good research reporting
  - *PLoS Medicine, BMJ* – new journal sections for guidelines, etc.
  - *Lancet* journals – publishing links to the original protocols
Research organisations and funders

- Clear guidelines on research reporting

- Provision of relevant training and education to research students and all researchers
  - Principles of good research reporting
  - Awareness of available resources
EQUATOR contribution

- Freely available, up-to-date online resources (EQUATOR ‘Library for Health Research Reporting’)

- Education programme development
  - Courses for editors and peer reviewers
  - Young research professionals and research students

- Motivation and incentives
  - Working with journals (funders)

- Other safeguards and checks complementing RG
  - e.g. SPIRIT initiative (Standard Protocol Items for Randomized Trials)
  - Mandatory trials registration, public availability of research protocols

- Promotion – important EQUATOR role
Write with attention to the readership
(Take advantage of available resources)

Read published articles with great caution!