The Lancet REWARD (Reduce research Waste And Reward Diligence) Campaign

Measures to increase value: editors

Joan Marsh
Deputy Editor
The Lancet Psychiatry
Past President, European Association of Science Editors
"A lancet can be an arched window to let in the light or it can be a sharp surgical instrument to cut out the dross and I intend to use it in both senses".
A family of print and online journals

2015 Impact Factor: 44.0

Impact Factors:
- The Lancet Oncology: 26.5
- The Lancet Neurology: 23.4
- The Lancet Infectious Diseases: 21.3
- The Lancet Respiratory Medicine: 15.3
- The Lancet Diabetes & Endocrinology: 16.3
- The Lancet Psychiatry: 5.7
- The Lancet Haematology: 4.9
- The Lancet HIV: 8.3
- The Lancet Global Health: 14.7
- The Lancet Public Health: 14.7
Cascade

Before or after peer review

Transfer by editorial office
Research in Context panel

• Evidence before this study, i.e. results of literature search

A description of all the evidence that the authors considered before undertaking this study.
• the sources (databases, journal or book reference lists, etc) searched;
• the criteria used to include or exclude studies (including the exact start and end dates of the search),
• any language restrictions imposed;
• the search terms used;
• the quality (risk of bias) of that evidence;
• and the pooled estimate derived from meta-analysis of the evidence, if appropriate.
Research in Context panel

- Evidence before this study, i.e. results of literature search

We ask for
Databases searched
Search terms used
Exact start and end dates, e.g. searched from inception of the database to 31st May 2017
Any language restrictions imposed

If not done recently, we ask them to update.
Research in Context panel

Added value of this study

Authors should describe how their findings add value to the existing evidence.

Implications of all the available evidence

Authors should state the implications for practice or policy and future research of their study combined with existing evidence.
Lancet editors : study protocol check

We require the registration of all interventional trials in a primary register that participates in WHO's International Clinical Trial Registry Platform.

We encourage full public disclosure of the minimum 20-item trial registration dataset at the time of registration and before recruitment of the first participant.

Reports of trials must conform to CONSORT 2010 guidelines, and should be submitted with their protocols.

Reports of trials should include all prespecified primary and secondary outcomes unless the protocol states that some will be published separately.
Lancet editors : study protocol check

Protocol published in journal

Protocol available online, include link

Publish in appendix so always available with the paper
Statistical review

Panel of statisticians who work in psychiatry departments

Check all statistical aspects and usually comment on other aspects of the manuscript

Review within 3-5 working days

Re-review if any changes are made to statistics
Clinical peer review

At least two positive, constructive clinical reviews

At least one that is not an author recommendation

At least one from the country where the study was performed, if appropriate

As fast as possible: reviewers asked to return comments within 5 days (usually takes longer)
Peer review - example

Efficacy and cost-effectiveness of antidepressants vs psychotherapy in elderly people in China

We would need:
Expert on antidepressants
Expert on psychotherapy for depression
Expert on depression who is working in China
Economics reviewer

One person might cover more than one of these or we might need 4 reviewers + statistician
International Committee of Medical Journal Editors

Lancet is a member

ICMJE Guidelines include CONSORT and standard form for declaration of conflict of interest

www.icmje.org
Recommendations

Read the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals.

Conflicts of Interest

Use the ICMJE Form for Disclosure of Potential Conflicts of Interest to generate a disclosure statement for your manuscript.
Reporting guidelines

• **CONSORT**  Randomized clinical trials
• **STROBE**  Observational studies in epidemiology
• **PRISMA**  Systematic reviews and meta-analyses
• **STARD**  Diagnostic accuracy
• **COREQ**  Qualitative research: interviews and focus groups
• **ENTREQ**  Synthesis of qualitative research
• **SQUIRE**  Quality improvement in healthcare
• **CARE**  Clinical cases
• **SAMPL**  Basic statistical reporting
• **SPIRIT**  Standard protocol items for clinical trials

www.equator-network.org
Clinical trial reports are often missing essential methods

Chen & Altman, 
Lancet 2005

Hopewell BMJ 2010
CONSORT requirements for abstracts

a) Background: A sentence indicating the aim of this study.
b) Methods: A brief summary of the main patient characteristics (ie, main entry criteria)
c) Methods: Details of the regimens used.
d) Methods: Details of how randomisation was done (eg, allocation concealment; nature of blinding, if any; how sequence was generated; stratification factors.
e) Methods: An explicit description of the actual primary endpoint.
f) Methods: The nature by which analyses were done (eg, intention to treat, per protocol).
g) Methods: The trial registration number.
h) Methods: The status of the trial – is it ongoing/still enrolling/is this an interim analysis, etc?
CONSORT requirements for abstracts

i) Findings: Efficacy data for the primary endpoint only.

j) Findings: The most common (grade 3-4) adverse events (include actual numbers of patients affected); any serious adverse events.

k) Interpretation: please do not just restate your findings. What do they mean, clinically? What are their implications?

l) A line at the end of the abstract stating who funded the research.
CONSORT trial profile

XXX patients assessed for eligibility

XXX enrolled

XXX randomised

XXX assigned treatment A

XX discontinued treatment
  XX [reason 1]
  XX [reason 2]
  XX [reason 3]
  XX other

XXX treatment ongoing

XXX included in intention-to-treat analysis

XXX assigned treatment B

XX discontinued treatment
  XX [reason 1]
  XX [reason 2]
  XX [reason 3]
  XX other

XXX treatment ongoing

XXX included in intention-to-treat analysis
Reporting of studies with disappointing results

Negative studies
Lancet will publish ‘the last word’

Lancet Psychiatry
Negative studies
Pilot studies
  Poor recruitment
  High drop out

Ask for as many data as possible, especially for failed studies, as these can inform meta-analyses
Replication studies?

Independent validation  Yes

Replication in a different population or setting  Yes, probably in specialist Lancet journal, not The Lancet

Replication in the same population and setting  Unlikely in a Lancet journal
Data availability

Increasing calls for data from published studies to be made available

How feasible is this for clinical studies until we can guarantee anonymity and data protection?

Is blockchain technology a solution?

Lancet journals encourage but do not insist.
European Association of Science Editors

Sex and Gender Equity in Research

The SAGER Guidelines

A comprehensive procedure for reporting of sex and gender information in study design, data analysis, results and interpretation of findings.
Ensure correct use of the terms sex (biological factors) and gender (identity, psychosocial or cultural factors)

Report the sex and/or gender of study participants, the sex of animals or cells, and describe the methods used to determine sex and gender

Discuss the influence or association of variables, such as sex and/or gender, on your findings, where appropriate

EASE Sex And Gender Equity in Research (SAGER) guidelines
http://www.ease.org.uk/about-us/gender-policy-committee/
Questions?

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