Impact of poor reporting on the development of systematic reviews

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The impact of a research article

- Scientific manuscripts should present sufficient data so that the reader can fully evaluate the information and reach his or her own conclusions about results
  - to assess reliability and relevance
- Readers need a clear understanding of exactly what was done
  - Clinicians
  - Researchers
  - Systematic reviewers
  - Policy makers
  - ...
Transparency and value

- Research only has value if
  - Study methods have validity
  - Research findings are published in a usable form

Avoidable waste in the production and reporting of research evidence

Iain Chalmers, Paul Glasziou

Without accessible and usable reports, research cannot help patients and their clinicians. In a published research involving patients have been disincentives for those who might otherwise
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, Outcomes etc

- The goal should be transparency
  - Should not mislead
  - Should allow replication (in principle)
  - Can be included in systematic review and meta-analysis
What do we mean by poor reporting?

Mainly

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

Also

- **Selective reporting**
  - Whole or part of study
- **Misleading interpretation**
- **etc**
Evidence of poor reporting

- There is considerable evidence that many published articles omit vital information
  - Hundreds of reviews of published research articles

- We often cannot tell exactly how the research was done
# Reports of RCTs indexed on PubMed

<table>
<thead>
<tr>
<th></th>
<th>Dec 2000 (N=519)</th>
<th>Dec 2006 (N=616)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Defined primary outcome(s)</td>
<td>45%</td>
<td>53%</td>
</tr>
<tr>
<td>Sample size calculation</td>
<td>27%</td>
<td>45%</td>
</tr>
<tr>
<td>Method of random sequence generation</td>
<td>21%</td>
<td>34%</td>
</tr>
<tr>
<td>Method of allocation concealment</td>
<td>18%</td>
<td>25%</td>
</tr>
<tr>
<td>Whether blinded</td>
<td>40%</td>
<td>41%</td>
</tr>
</tbody>
</table>

“In 37% of papers patient numbers were inadequately reported; 20% of papers introduced new statistical methods in the 'results' section not previously reported in the 'methods' section, and 23% of papers reported no measurement of error with the main outcome measure.”

Case-control studies

Bias in psychiatric case-control studies: literature survey. [Lee et al, Br J Psychiatry 2007]

- **RESULTS**
  “The reporting of methods in the 408 identified papers was generally poor, with basic information about recruitment of participants often absent …”

- **CONCLUSIONS**
  “Poor reporting of recruitment strategies threatens the validity of reported results and reduces the generalisability of studies.”
Poor reporting is a serious problem for systematic reviews and clinical guidelines

“Risk of bias assessment was hampered by poor reporting of trial methods.”

“Poor reporting of interventions impeded replication”

“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.”
[Nolte et al. Amphetamines for schizophrenia. CDSR 2004]

“Poor reporting of data meant that individual effect size could not be calculated for any of these studies.”
Bleakley et al. Some conservative strategies are effective when added to controlled mobilisation with external support after acute ankle sprain: a systematic review. Aust J Physiother 2008.
Impact of poor reporting

- Cumulative published evidence is misleading
  - Methodological weaknesses may not be apparent
  - Results may be biased

- Assessing the reliability of published articles is seriously impeded by inadequate reporting
  - Data cannot be included in a systematic review
Taxonomy of poor reporting

- **Non-reporting (or delayed reporting) of whole studies**
  (even when some results have been presented in public)

- **Misrepresentation of study design**
  - e.g. study claiming is an RCT when is not

- **Selective reporting**
  - patient outcomes
  - analyses, e.g. subgroups, alternative analyses

- **Incomplete publication**
  - Omission of crucial aspects of research methods, e.g. interventions
  - Incomplete results: data cannot be included in meta-analysis

- **Misleading interpretation (spin)**
  - e.g. post hoc change of focus,

- **Inconsistencies between sources**
  - e.g. publication conflicts with protocol

*NB outright dishonesty is excluded!*
Turner et al, *NEJM* 2008
“There is strong evidence of an association between significant results and publication; studies that report positive or significant results are more likely to be published and outcomes that are statistically significant have higher odds of being fully reported. Publications have been found to be inconsistent with their protocols.”
Selective reporting is very common

Almost all articles on cancer prognostic markers report statistically significant results

Panayiotis A. Kyzas\textsuperscript{a}, Despina Denaxa-Kyza\textsuperscript{a}, John P.A. Ioannidis\textsuperscript{a,b,c,*}
Figure 3. Funnel plot with contours showing different levels of study significance.
doi:10.1371/journal.pmed.1000286.g003

C-Reactive Protein in stable coronary artery disease
Impact of poor reporting on systematic reviews

- **Failure to publish a report of a completed study**
  - Leads to **bias** (overestimation of effects)
    - Limited scope for detection
    - Selective (or delayed) publication on basis of results

- **Selective reporting**
  - Leads to **bias** (overestimation of effects)
    - Very hard to detect – need protocol
    - Similar effect to missing studies

- **Incomplete reporting of methods**
  - May not be able to assess risk of bias
  - May not be able to tell if a study is eligible for inclusion

- **Incomplete reporting of results**
  - Cannot include a study in meta-analysis
  - Leads to **bias** if style of reporting linked to findings
Impact of poor reporting

- Poor reporting may have a profound effect on published evidence
- Systematic reviews may be misleading
  - Tendency towards overestimating treatment effects
- Problems likely to be worse for observational studies