Current reporting in published research

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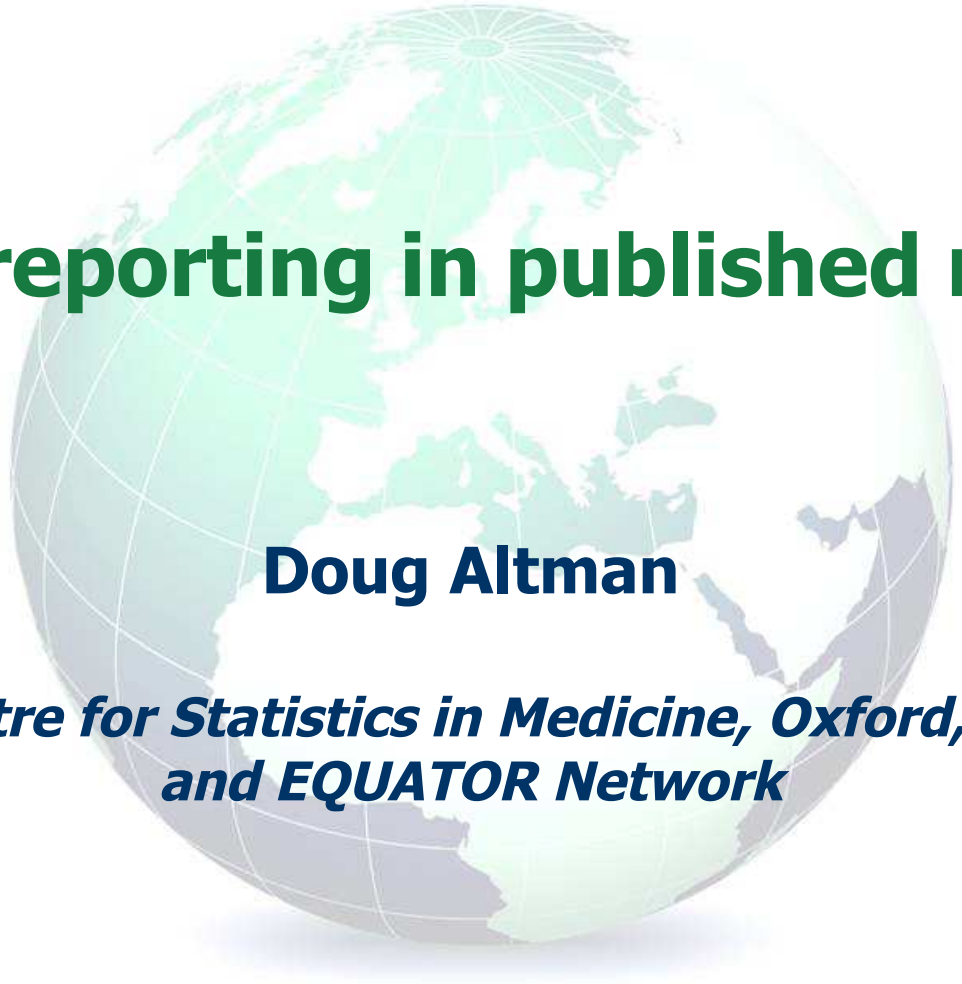


Research article

- **A published research article is a permanent record that will be used by users for many different purposes**
- **Some readers might be satisfied with scanning an article, or a brief summary**
- **Others will study it in detail for possible inclusion in a systematic review or to influence a clinical practice guideline**
  - Only an adequately reported research study can be fully appraised and used appropriately
- **Published research articles should be fit for multiple purposes**
  - New ways of publishing (e.g., with online supplements with methodological information) can help to meet these varying needs

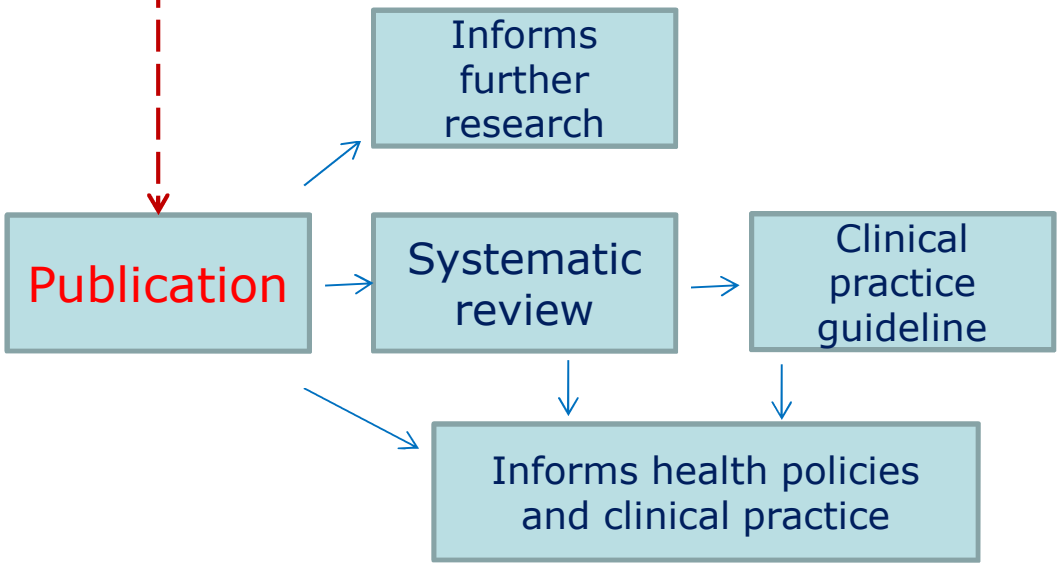
Research article

- Research article is 'end product' of one process …

Research article

- Research article is 'end product' of one process …

- …and 'raw material' of other processes



Research article

- **Readers need a clear understanding of exactly what was done**
  - Clinicians, Researchers, Systematic reviewers, Policy makers, …
- **The goal should be transparency**
  - Should not mislead
  - Should allow replication (in principle)
  - Can be included in systematic review and meta-analysis

Taxonomy of poor reporting

- **Non-reporting**
  Failure to publish a report of a completed study (even if was presented at a conference)
- **Selective reporting**
  Biased reporting of data within published report
- **Incomplete reporting**
  Key information is missing
- **Misleading presentation**
  e.g. claiming study is an RCT when it isn't; post hoc change of focus (spin)
- **Inconsistencies between sources**
  e.g. publication conflicts with protocol

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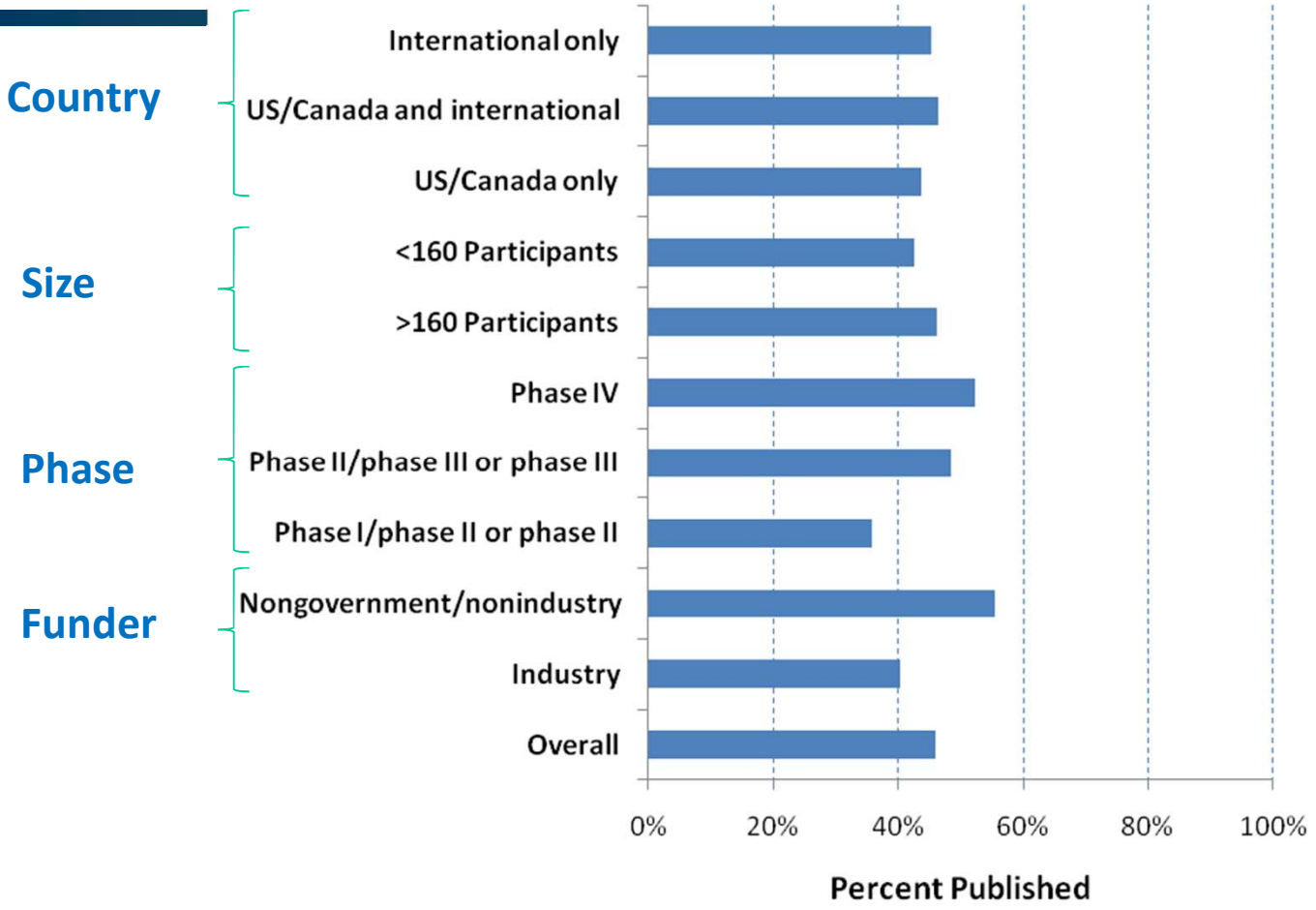
All the above are very common

Of 635 clinical trials completed by Dec 2008, 294 (46%) were published in a peer reviewed biomedical journal, indexed by Medline, within 30 months of trial completion.



Ross JS, Mulvey GK, Hines EM, Nissen SE, Krumholz HM. Trial publication after registration in ClinicalTrials.gov: a cross-sectional analysis. *PLoS Med* 2009.

Consequences of failure to publish

- **Non-publication of research findings always leads to a reduced evidence-base**
- **Main concern is that inadequate publication *distorts* the evidence-base – if choices are driven by results**
  - Literature is biased
- **Even if there is no bias the evidence-base is diminished and thus there is extra (and avoidable) imprecision and clinical uncertainty**

Some types of selective reporting in RCTs

For a specific outcome

- **Adjusted or unadjusted results**
- **Intention to treat or per protocol or …**
- **Missing outcome data:**
  - Available cases vs LOCF vs other methods
- **Subgroup analyses**

For the set of outcomes

- **Selective outcome reporting**

All of these practices are common

Studies of outcome reporting bias in reports of randomised trials

Comparison of protocols and publications

- **Several studies have found clear evidence of selective reporting of outcomes**
  - Non-significant findings are less likely to be published
- **Also discrepancies are common between the primary outcomes in protocol and publication**
  - 62% and 40% in 2 cohorts

59 RCTs of anti-arrhythmic agents (2002–2011) [Camm et al, *Int J Cardiol* 2013]

4b **Settings** and locations where the data were collected	**69%**
6a Completely defined pre-specified primary and secondary **outcome measures**, including how and when they were assessed	**86%**
8a Method used to generate the random allocation **sequence**	**25%**
8b **Type of randomization**; details of any restriction	**19%**
9 Mechanism used to **implement** the random allocation sequence, describing any steps taken to conceal the sequence until interventions were assigned	**14%**
12a **Statistical methods** used to compare groups for primary and secondary outcomes	**51%**
17a For each primary and secondary outcome, **results** for each group, and the estimated effect size and its precision	**46%**
19 All important **harms** or unintended effects in each group	**36%**

Poor description of non-pharmacological interventions in RCTs

- **Hoffmann *et al, BMJ* 2013**
  - Of 137 interventions, only 53 (39%) were adequately described;
  - this was increased to 81 (59%) by using 63 responses from 88 contacted authors.

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."

Incomplete reporting of research is very common

- **Hundreds of published reviews show that key elements of trial methods and findings are commonly missing from journal reports**

- **Consistently show serious amount of inadequate reporting of methods and findings**
  - Numerous medical specialties
  - Nutrition?

Am J Clin Nutr 2010;92:203–10.

Nutrition-related health effects of organic foods: a systematic review

Alan D Dangour, Karen Lock, Arabella Hayter, Andrea Aikenhead, Elizabeth Allen, and Ricardo Uauy

- **"… poor reporting in some articles made it impossible to elucidate specific study methods … and there was rarely any rationale provided for the quantity and duration of exposure to foodstuffs in clinical trials."**

Cite this article as: BMJ, doi:10.1136/bmj.38399.495648.8F (published 31 March 2005)

Papers

Role of multivitamins and mineral supplements in preventing infections in elderly people: systematic review and meta-analysis of randomised controlled trials

Alia El-Kadiki, Alexander J Sutton

"The evidence for the effectiveness of the routine use of multivitamins in an elderly population to reduce infections is of poor to moderate quality, heterogeneous, and conflicting. We found little evidence of adverse events due to the intervention, but this may be due to poor reporting."

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**
- **These problems are generic**
  - not specific to randomised trials
  - not specific to studies of medicines
  - not specific to research by industry

Poor reporting is a serious problem for systematic reviews and clinical guidelines

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

[Meuffels et al. Computer assisted surgery for knee ligament reconstruction, *CDSR* 2011]

"Poor reporting of interventions impeded replication"

[Gordon and Findlay. Educational interventions to improve handover in health care: a systematic review. *Med Educ* 2011]

"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 duration of follow-up was a problem, making it hard to calculate numbers needed to treat to benefit."

[Casas et al. Commentary on Inglis et al. Telemonitoring for chronic heart failure. *CDSR* 2010]

Poor reporting is a serious problem

[Shamseer et al, *Can J Anesth* 2013]

- **>$200 billion spent globally on biomedical research every year, yielding about 1m publications**
- **>85% of investment is wasted** (Chalmers & Glasziou, 2009)
  - one contribution is the production of unusable and biased reports
- **Many studies fail to inform readers about methods and findings of research in a clear and transparent manner**
  - they obscure the true methodological quality of a study
- **Poor reporting is unacceptable and unethical, particularly for patients participating in research**
  - The public expects and assumes that research, especially if publicly funded, is conducted and reported to the highest possible standards
- **Unfortunately, there are serious systemic problems regarding how research is reported**

Consequences of inadequate reporting

- **Assessing the reliability of published articles is seriously impeded by inadequate reporting**
  - Clinicians cannot judge whether to use a treatment
  - Data cannot be included in a systematic review

- **Serious consequences for clinical practice, research, policy making, and ultimately for patients**

- **What can be done?**

"… editors could greatly improve the reporting of clinical trials by providing authors with a list of items that they expected to be strictly reported."

[DerSimonian R et al, *NEJM* 1982]

Reporting guidelines

- **Checklist, flow diagram, text**

- **A minimum set of items required for a clear and transparent account of what was done and what was found in a research study**
  - Reflect in particular issues that might introduce bias into the research
  - Evidence-based & reflect consensus opinion

- **Benefits of using reporting guidelines**
  - Improved accuracy and transparency of publications
  - Easier appraisal of reports for research quality and relevance
  - Improved efficiency of literature searching

Schulz *et al. Trials* 2010, **11**:32
http://www.trialsjournal.com/content/11/1/32

RESEARCH Open Access

CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials

Kenneth F Schulz[1*], Douglas G Altman[2], David Moher[3], the CONSORT Group

CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials

David Moher,[1] Sally Hopewell,[2] Kenneth F Schulz,[3] Victor Montori,[4] Peter C Gøtzsche,[5] P J Devereaux,[6] Diana Elbourne,[7] Matthias Egger,[8] Douglas G Altman[2]

BMJ 2010;340:c869

Other reporting guidelines

- **Other study types – CONSORT as a model**
  - PRISMA (Systematic reviews of RCTs)
  - STARD (diagnostic accuracy studies)
  - STROBE (observational studies)
  - REMARK (tumour marker prognostic studies)
  - ARRIVE (animal research)
  - REFLECT (RCTs for livestock and food safety)
  - GRIPS (genetic risk prediction studies)
  - …

- **Most guidelines are not yet widely supported by medical journals or adhered to by researchers**
  - Their potential impact is blunted

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The resource centre for good reporting of health research studies

Library for health research reporting

The Library contains a comprehensive searchable database of reporting guidelines and also links to other resources relevant to research reporting.

Search for reporting guidelines

Visit the library for more resources

Key reporting guidelines

CONSORT	Full Record | Checklist | Flow Diagram
STROBE	Full Record | Checklist
PRISMA	Full Record | Checklist | Flow Diagram
STARD	Full Record | Checklist | Flow Diagram
COREQ	Full Record
ENTREQ	Full Record
SQUIRE	Full Record | Checklist
CHEERS	Full Record | Checklist
CARE	Full Record | Checklist
SAMPL	Full Record

Toolkits

The EQUATOR Network works to improve the reliability and value of medical research literature by promoting transparent and accurate reporting of research studies.

Our Toolkits support different user groups, including:

Authors
Information and resources authors

EQUATOR highlights

23/10/2013 - Updated Declaration of Helsinki

The World Medical Association just released an update of the "Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects". Paragraphs 35 and 36 on RESEARCH REGISTRATION AND PUBLICATION AND DISSEMINATION OF RESULTS state: 35. Every research study involving ... Read More

10/10/2013 - Declaration of transparency

A BMJ editorial published today proposes that authors of research papers

3/10/2013 - OPEN: To overcome failure to publish negative

News

Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations
14/11/2013

The latest PAHO research newsletter highlights EQUATOR plans to engage librarians
8/11/2013

A new repository of ongoing training opportunities for authors, reviewers and editors
2013

ATOR workshop for WHO staff in Geneva
5/11/2013

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State of play

- Not all research is published
- Research reports are seriously inadequate
- Improvement over time is very slow
- Reporting guidelines exist for most research types
- Also several statements on responsible research conduct and reporting
- It's much easier to continue to document the problems than to change behaviour

"It is the responsibility of everyone involved to ensure that the published record is an unbiased, accurate representation of research."

[*PLoS Medicine* Editors 2009]

So what should be done?

What should authors do?

- **Be aware of ethical/moral responsibility to publish their findings**
  - Honestly and transparently
- **Be aware of the needs of readers**
  - Principle of reproducibility
  - Should be includable in a future systematic review
- **Be aware of, and follow, major reporting guidelines**

What should editors do?

- **Be aware of the needs of readers**
- **Be aware of, and make authors follow, major reporting guidelines**
- **Train peer reviewers**
- **Support registration of studies and publication of protocols**
  - Ask to see protocol

What should others do?

- **Research funders should have explicit policies**
  - Reporting research, publishing protocols, data sharing
  - Failure to comply would compromise further funding
- **Ethics committees should monitor publications**
  - Clarify what they expect from researchers
- **Responsible reporting of research should be taught as an essential component of research training**
- **All organisations should encourage or require adequate reporting of research**

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Editorial

Better Reporting of Scientific Studies: Why It Matters

The *PLOS Medicine* Editors*

"Transparency in research reporting should be integral to the dissemination of scientific research. The peer review process is a critical part of research and reporting guidelines provide a mechanism to help this process. While following reporting guidelines does not necessarily make the study better, this process does give readers the information to better judge the quality, and therefore the usefulness, of research. As online publication removes the space constraints of print, reporting should be complete and transparent, and reporting guidelines aid that process."

PLoS Med 2013; 10: e1001504.

Importance of good research reporting

Research reports should present sufficient information to allow a full evaluation of the presented data and further use of these findings

Good reporting is an essential part of doing good research

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