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# Improving the quality and value of research publications: How can we speed up progress?

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# Research article

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- **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 ...

Primary research

Design



Conduct



Publication

# Research article

- Research article is '**end product**' of one process ...

Primary research

Design

Conduct

Publication

- ...and '**raw material**' of other processes

Publication

Informs further research

Systematic review

Clinical practice guideline

Informs health policies and clinical practice

# Research article

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- **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, ...
- **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 (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



# In simple terms...

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- **Non-reporting**
- **Selective reporting**
- **Poor reporting**
- **All are very common**



# Consequences of failure to publish

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- **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**
- **Even if there is no bias the evidence-base is diminished and thus there is extra (and avoidable) imprecision and clinical uncertainty**



# Evidence of poor reporting

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- **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 pharmaceutical companies



# Incomplete reporting of research is very common

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- **Hundreds of published reviews show that key elements of trial methods and findings are commonly missing from journal reports**
- **262 reports of randomized trials from prominent oncology journals** [Duff et al, *JNCI* 2010]
- **Only 11% of articles reported all 10 essential details of the intervention**
  - e.g. drug name, dose, route, ...



# Poor Reporting of Quality of Life Outcomes in Dermatology Randomized Controlled Clinical Trials

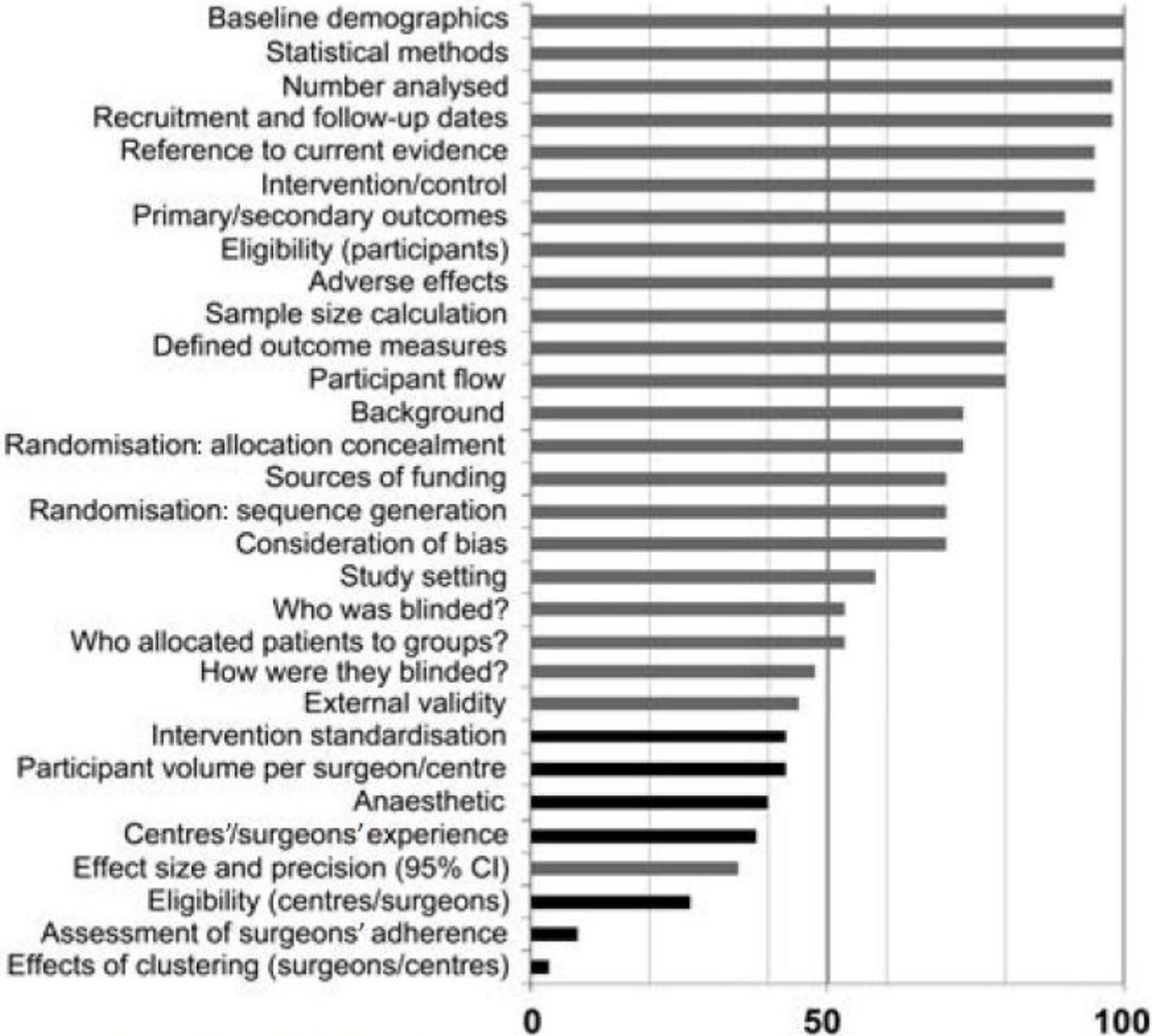
Le Cleach et al, *Dermatology* 2008

Among 67 studies:

- 87% did not adequately describe the questionnaires
- 75% did not address handling of missing data
- 95% did not disclose before-and-after results as means of overall scores and each dimension



CONSORT-NPT items



● specific to CONSORT-NPT statement  
 ● also in original CONSORT statement

Percent reported



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

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**“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.”**

**“... one of the largest trials of the effects of cardiac rehabilitation, which found no beneficial effect, is yet to be published in a peer-reviewed journal over a decade after its completion.”**

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



# Consequences of inadequate reporting

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- **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**



# Reporting guidelines

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- **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



RESEARCH

Open Access

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

Kenneth F Schulz<sup>1\*</sup>, Douglas G Altman<sup>2</sup>, David Moher<sup>3</sup>, the CONSORT Group

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

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



# 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)
- GRIPS (genetic risk prediction studies)
- ...

**See EQUATOR website**

- **Most guidelines are not yet widely supported by medical journals or adhered to by researchers**

- Their potential impact is blunted



# **Responsible research publication: international standards for authors**

A position statement developed at the 2<sup>nd</sup> World Conference on Research Integrity,  
Singapore, July 22-24, 2010

Elizabeth Wager & Sabine Kleinert



# State of play

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- **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**



# How can we speed up progress?

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- **No easy answers to behaviour change**
- **All parties should play a role:**
  - authors
  - peer reviewers
  - editors
  - research funders
  - medical educators
  - ethics committees
  - ...
- **It's time to end the persistent widespread failure of major bodies to recognise the waste and harm associated with bad reporting of research**



# What should authors do?

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- **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?

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- **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?

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- **Research funders should have explicit policies**
  - 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**
- **More research is needed into how to improve the value of research articles (knowledge translation)**



## RESEARCH

### **Effect of using reporting guidelines during peer review on quality of final manuscripts submitted to a biomedical journal: masked randomised trial**

“Additional reviews based on reporting guidelines improve manuscript quality, although the observed effect was smaller than hypothesised and not definitively demonstrated.”





## Results of a longitudinal study of rigorous manuscript submission guidelines designed to improve the quality of clinical research reporting in a peer-reviewed surgical journal

Kathryn E. Wynne<sup>a</sup>, B. Joyce Simpson<sup>a</sup>, Loren Berman<sup>a</sup>, Shawn J. Rangel<sup>b</sup>, Jay L. Grosfeld<sup>c</sup>, R. Lawrence Moss<sup>a,\*</sup>

The *Journal of Pediatric Surgery* instituted specific reporting guidelines for authors in June 2006  
73 articles before implementation and 147 articles after implementation were independently assessed by 2 reviewers (observational studies)  
Mean global composite scores increased from 72.2 to 80.1 post-Guidelines (P<0.0001).



# Maximising the value of research

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- **Research is done to generate new knowledge**
- **A research article is for communicating that new knowledge**
- **Published research articles should be fit for multiple readerships with multiple purposes**
- **There are ethical, moral, scientific and financial reasons for maximising the value of research**



Editorial

# An Unbiased Scientific Record Should Be Everyone's Agenda

The PLoS Medicine Editors

## Editorials

### Reporting research results: a moral obligation for all researchers

David Moher PhD

Epidemiology:  
May 2000 - Volume 11 - Issue 3 - pp 361-363  
Epidemiology and Society

### **Failure to Publish Results of Epidemiologic Studies Is Unethical**

Savitz, David A.

# **ACT now: Accuracy, Completeness, and Transparency in health research**



# ACT now

