# Enhancing the quality and transparency of health research through the use of reporting guidelines

**Doug Altman**

**The EQUATOR Network**

***Centre for Statistics in Medicine, Oxford, UK***

# Research and publication

- **Medical research should advance scientific knowledge and – directly or indirectly – lead to improvements in treatment or prevention of disease**

- **If research is not published it might as well not have been done**
  - Implications for *access* to research

- **A research report is the only tangible evidence that the study was done**

# The purpose of a research article

- **Articles are written for multiple readerships**
  - Clinicians
  - Researchers
  - Policy makers
  - Patients
  - Media

- **Scientific manuscripts should present sufficient data so that the reader can fully evaluate the information and reach his or her own conclusions about results**
  - Assess reliability and relevance

# The purpose of a research article

- **Clinicians might read it to learn how to treat their patients better**
  - "Editors, reviewers and authors are often tempted to pander to this group, by sexing up the results with unjustified clinical messages – sometimes augmented by an even more unbalanced press release."

    [Buckley *Emerg Med Australas* 2005]

- **Researchers might read it to help plan a similar study or as part of a systematic review**
  - Need a clear understanding of exactly what was done

# We need research we can rely on

- **Assessment of reliability of published articles is a necessary condition for the scientific process**

  [Ziman. *Reliable Knowledge*, 1978]

  – It is seriously impeded by inadequate reporting

- **Good reporting is an essential part of good research**

- **Authors (and journals) have an obligation to ensure that research is reported adequately**

  – i.e. transparently and completely

# Biased reporting is scientific misconduct

**"In return for the altruism and trust that make clinical research possible, the research enterprise has an obligation to conduct research ethically and to report it honestly."**

[International Committee of Medical Journal Editors, 2004]

**"Failure to publish an adequate account of a well-designed clinical trial is a form of scientific misconduct which can lead to those caring for patients to make inappropriate treatment decisions."** [Chalmers, 1990]

# Transparency and reproducibility

## What should be reported?

- **All key aspects of how the study was done**
  - Allow repetition (in principle) if desired
- **"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]
- **Same principle should extend to all study aspects**

- **Key study findings**

# Evidence of poor reporting

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

- **We cannot tell exactly how the research was done**

# 519 Randomised trials published in December 2000

**Failure to report key aspects of trial conduct:**

**73%** **Sample size calculation**
**55%** **Defined primary outcome(s)**
**60%** **Whether blinded**
**79%** **Method of random sequence generation**
**82%** **Method of allocation concealment**

[Chan & Altman *Lancet* 2005]

# 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."**

*(Cochrane Library, accessed on 18 Sept 07)*

# Systematic reviews

**"Despite quality guidelines, the average quality of published [systematic reviews] of antidepressants is barely acceptable. A need exists for adherence to standardized reporting and quality guidelines."**

[Hemels et al. *Curr Med Res Opin* 2004. Systematic reviews of pharmaco-therapy in major depressive disorder]

# 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."**

# Selective reporting

- **In addition, there is accumulating evidence of two major threats to the medical literature**

- **Study publication bias – studies with less interesting findings are less likely to be published**

- **Outcome reporting bias – results included within published reports are selected to favour those with statistically significant results**
  - In 122 RCTs a median of 50% of efficacy and 65% of harm outcomes per trial were incompletely reported and could not be included in a meta-analysis [Chan et al, *JAMA* 2004]

# Impact of poor reporting

- **Cumulative published evidence is misleading**
- **Adverse effects on**
  - Other researchers
  - Clinicians
  - Patients
- **“Failures in the system of reporting clinical trials findings can result in harm to patients”** [Glass 1994]

# Whose fault is poor reporting?

- **Poor reporting indicates a collective failure of authors, peer reviewers, and editors**

  ... on a massive scale

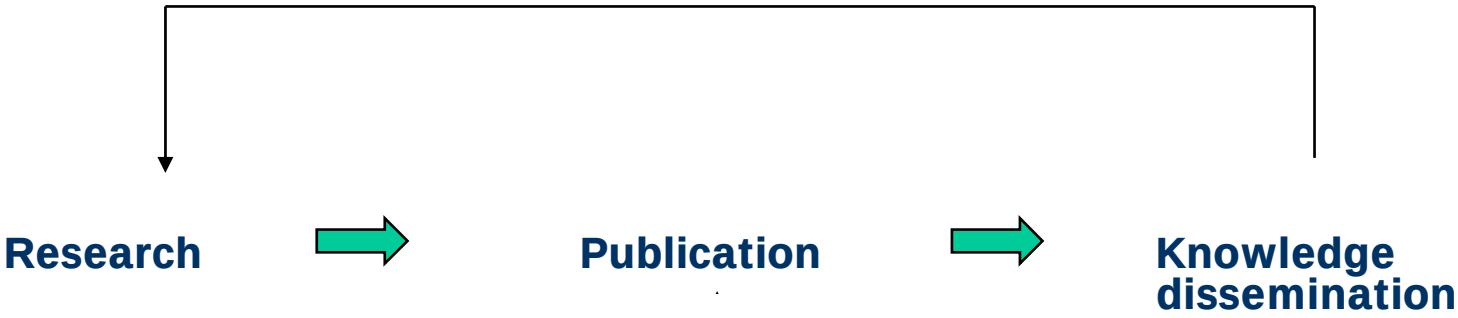
- **Researchers (authors) may not know what information to include in a report of research**

- **Editors may not know what information should be included**

**What help can be given to authors?**

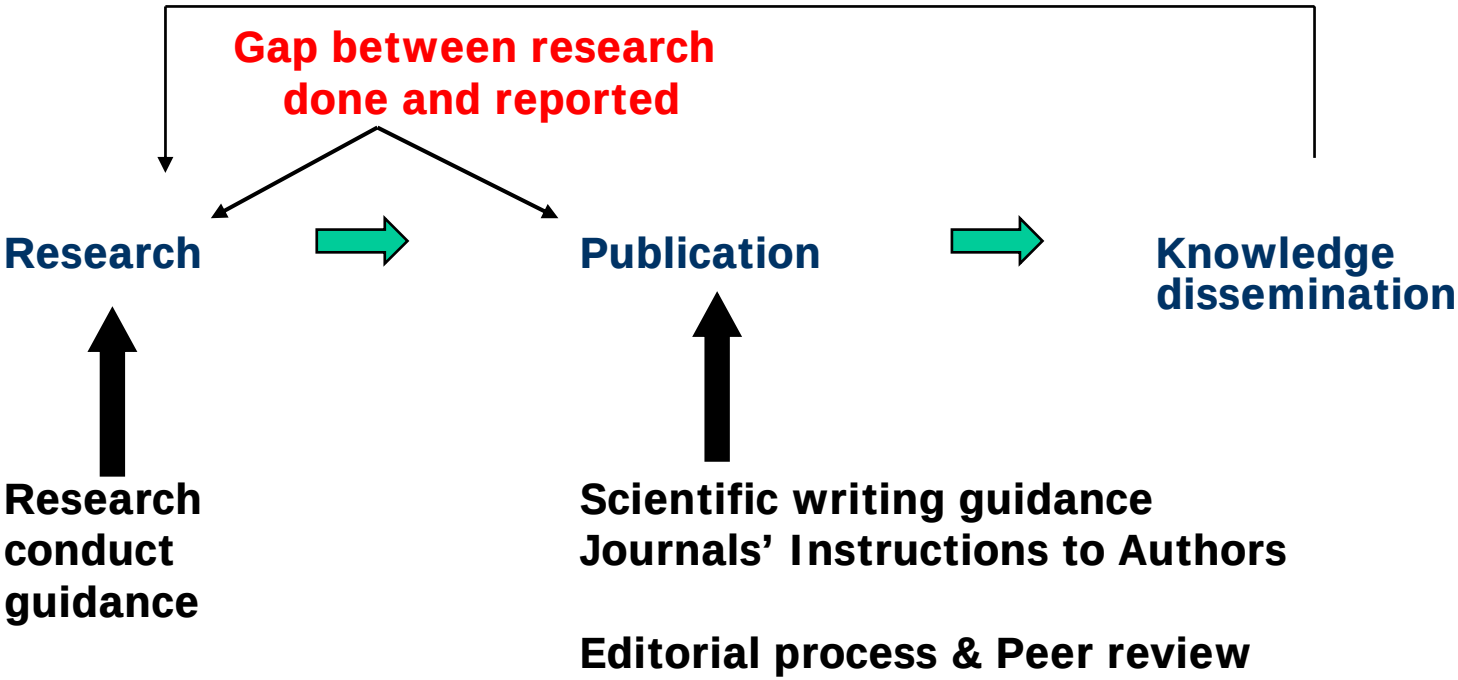
**What help can be given to editors?**

# Knowledge creation cycle

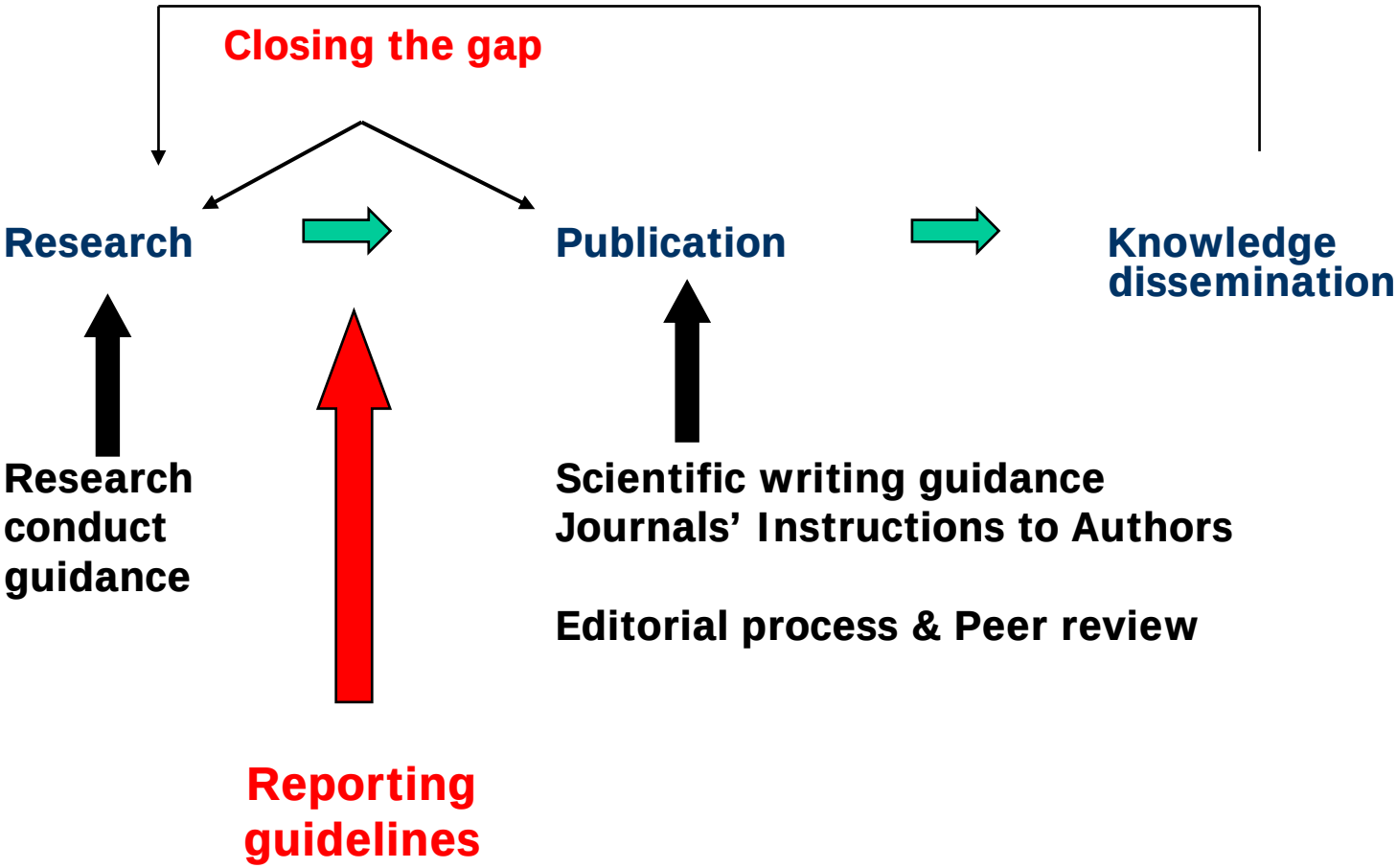


# Knowledge creation cycle

# What can be done to improve research reports?



# What can be done to improve research reports?



# Rationale for checklist items

- **Minimum set of essential items**
  - Necessary to evaluate the study
  - Evidence-based, whenever possible

- **The information is critical to assessing the reliability of a study**
  - perhaps combined with evidence that this key information is often omitted

  or

  - There is evidence that not reporting it is associated with bias

# Reporting guidelines

- **CONSORT (RCTs)**
  - and extensions
- **QUOROM (meta-analyses of RCTs) (→ PRISMA)**
- **STARD (diagnostic studies)**
- **STROBE (observational studies)**
- **REMARK (tumour marker prognostic studies)**
- **…**

# Key aspects of reporting guidelines

- **Items critical to assessing the reliability of a study**
  - For authors, editors, and readers
- **Guidance not requirements**
  - Journals may enforce adherence
- **<u>Not</u> methodological quality**

  "Accurate and transparent reporting is like turning the light on before you clean up a room: It doesn't clean it for you but does tell you where the problems are."

  [Frank Davidoff, *Ann Intern Med* 2000]
- **Adherence does not guarantee a high quality study!**

**Good reporting is not an optional extra: it is an essential component of doing good research**

www.equator-network.org