## EQUATOR Network: promises and results of reporting guidelines

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# Key principles of research publications



- A published research article should not mislead
- It should provide enough information on methods to allow replication (in principle)
- It should present the **methods** and **results** in a form to allow the study to be included in a subsequent systematic review and meta-analysis

### $\rightarrow$ Accuracy, completeness and transparency

(Declaration of Helsinki)

# **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

## A few recent examples of poor reporting of RCTs



39% of 137 non-pharmacological interventions were adequately described

[Hoffmann et al, BMJ 2013]

319 RCTs in top-ranked anaesthesiology journals in 2011 satisfied a median of 60% of the CONSORT criteria [Münter et al, *Eur J Anaesthesiol* 2014]

## **109 RCTs in haematology**



- 118 major discrepancies in outcomes between publication and registry (629 total discrepancies)
- 30 (25%) primary outcomes were demoted
- 47 (40%) primary outcomes were omitted
- 30 (25%) primary outcomes were added
- 8 (7%) changed the timing of assessment for a primary outcome

[Wayant et al, PLoS One 2017]

# Reporting vs conduct: study methods



#### **METHODS** – each aspect of the methods

	Done well	Done poorly	Not done
Fully reported (=reproducible)			
Ambiguously or incompletely reported			
Not reported			

# Reporting vs conduct: study methods



#### **METHODS** – each aspect of the methods

	Done well	Done poorly	Not done
Fully reported (=reproducible)			
Ambiguously or incompletely reported	?	?	?
Not reported	?	?	?

## Reporting vs conduct: results



#### **RESULTS** – for each analysis

	Exactly as pre- specified	Explicitly not pre- specified	Post hoc but not declared as such
Fully reported (= can be included in meta-analysis)			
Ambiguously or incompletely reported			
Not reported			

## What should be reported?



### Methods

- All key aspects of how the study was done
  - Ideally as pre-specified in protocol differences explained

### Results

- Main findings
  - corresponding to protocol

### Underlying principles

- "Tell the reader what you did"
- Provide enough information on methods to allow replication (in principle)

## **Reporting guidelines**



- A minimum set of items required for a clear and transparent account of what was done and what was found in a research study
  - Include 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





### Enhancing the QUAlity and Transparency Of health Research

- The EQUATOR Network is an international initiative set up to improve reliability and value of medical research literature by promoting good research reporting
  - Accurate
  - Complete
  - Transparent
- Set up in 2006, officially launched in June 2008

## Why was EQUATOR set up?



- Widespread deficiencies in research reporting
- Several reporting guidelines existed, but were
  - difficult to find
  - rarely used

## EQUATOR core programme



### Raise awareness

- Problems resulting from inadequate reporting
- Existence of helpful resources / tools
- Provide resources
  - Ensure people have easy access to reliable, up-to-date resources
- Develop an education and training programme





## Reporting guidelines for main study types



Randomised trials	<u>CONSORT</u>	Extensions	<u>Other</u>
Observational studies	STROBE	Extensions	<u>Other</u>
Systematic reviews	PRISMA	Extensions	<u>Other</u>
Case reports	CARE	Extensions	<u>Other</u>
Qualitative research	SRQR	COREQ	<u>Other</u>
Diagnostic / prognostic	STARD	TRIPOD	<u>Other</u>
studies			
Quality improvement studies	SQUIRE		<u>Other</u>
Economic evaluations	CHEERS		<u>Other</u>
Animal pre-clinical studies	ARRIVE		Other
Study protocols	<u>SPIRIT</u>	PRISMA-P	<u>Other</u>
Clinical practice guidelines	AGREE	<u>RIGHT</u>	<u>Other</u>

See all 385 reporting guidelines

# What has been the impact of reporting guidelines?



- The ideal time to influence quality of reporting is when paper is being written
  - Challenging!
- Passive interventions
  - Instructions to authors (NB language varies)
  - Editorials
- Active interventions
  - Enhanced editorial oversight or peer review
- Experiments



**Figure 2. Quality scores, reporting of allocation concealment, and inclusion of trial flow diagram significantly improved over time.** doi:10.1371/journal.pone.0084779.g002

### 456 cohort, case-control, and cross-sectional studies published between 2004 and 2010 in four dermatological journals



#### Bastuji-Garin et al. PLoS ONE 2013.

Time series of six-monthly mean STROBE scores and values predicted from the segmented and simple linear regression models.





RESEARCH ARTICLE

Did the reporting of prognostic studies of tumour markers improve since the introduction of REMARK guideline? A comparison of reporting in published articles

Peggy Sekula<sup>1</sup>\*, Susan Mallett<sup>2</sup>, Douglas G. Altman<sup>3</sup>, Willi Sauerbrei<sup>1</sup>

### No!

### REPORTS

### Elevating the Quality of Disability and Rehabilitation Research: Mandatory Use of the Reporting Guidelines

Leighton Chan, Allen W. Heinemann, Jason Roberts

AJOT has now joined 28 other major rehabilitation and disability journals in a collaborative initiative to enhance clinical research reporting as standards through adoption of the EQUATOR Network reporting cal guidelines, described below. Authors will now be required to use nd lz, these guidelines in the preparation of manuscripts that will be bsubmitted to AJOT. Reviewers will also use these guidelines to evaluate brk on the quality and rigor of all AJOT submissions. By adopting these ity standards we hope to further enhance the quality and clinical nd applicability of articles to our readers.

> Chan, L., Heinemann, A. W., & Roberts, J. (2014). Elevating the quality of disability and rehabilitation research: Mandatory use of the reporting guidelines. American Journal of Occupational Therapy, 68, 127-129. http://dx. doi.org/10.5014/ajot.2014.682004

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Barnes et al. BMC Medicine (2015) 13:221 DOI 10.1186/s12916-015-0460-y

#### **RESEARCH ARTICLE**





Medicine

Impact of an online writing aid tool for writing a randomized trial report: the COBWEB (Consort-based WEB tool) randomized controlled trial

Caroline Barnes<sup>2,3</sup>, Isabelle Boutron<sup>1,2,3\*</sup>, Bruno Giraudeau<sup>3,4</sup>, Raphael Porcher<sup>1,2,3</sup>, Douglas G Altman<sup>5</sup> and Philippe Ravaud<sup>1,2,3,6</sup>

Aim was to evaluate the impact of a writing aid tool (WAT) based on the CONSORT statement and its extension for non-pharmacologic treatments on the completeness of reporting of randomized controlled trials (RCTs). Completeness of reporting was higher with than without

Completeness of reporting was higher with than without use of the WAT: 7.1 (SD 1.2) vs 5.0 (SD 1.6), mean difference 2.1 (1.5–2.7).

### Unreadable "text"

#### Calvet et al. *Am J Gastroenterol* 2005

## This paper has no tables!

#### Cure Rates

Forty-six patients—23 (10%) in the 7-day group and 23 (11.7%) in the 10-day group—did not return for follow-up. A CONSORT flow diagram is shown in Figure 1. Intention to treat cure rates were 73.8% (95% CI: 67-79%) for 7-day and 79.6% (95% CI: 74–85%) for 10-day therapy (p = 0.09). NNT was 17 and the D and its 95% confidence interval were 5.8% (95% CI: -2-14%). In the per-protocol analysis, 175 of 214—81.8% (95% CI: 76–86%)—patients in the 7-day group *versus* 176 of 197—(89.3% [95%CI: 84–93%, p = 0.02; NNT: 13; D 7.5%, 95% CI: 1–14%])—were cured at the 2month follow-up test. Both Intention to treat (77.6% vs 81%, p = 0.28, NNT: 29, D: 3.4%, 95% CI: -1-13%) and perprotocol cure rates (86.2% vs 88.5%, p = 0.35, NNT: 43, D: 2.3%, 95% CI: -610%) were fairly similar in both treatment arms for peptic ulcer patients. Additionally, there were no differences between duodenal and gastric ulcers. Cure rates, however, were clearly lower for 7-day therapy in nonulcer individuals: (65.8% vs 77.2%, p = 0.08, NNT: 9; D: 11.4%, 95% CI: -3-26%) by intention to treat analysis, and 72.5% vs 91%, p = 0.004, NNT: 5, D: 18.5%, 95% CI: 6–31%); in the per-protocol analysis (Fig. 2).





Altman Trials (2015) 16:53 DOI 10.1186/s13063-015-0575-7



#### **EDITORIAL**

**Open Access** 

# Making research articles fit for purpose: structured reporting of key methods and findings

Douglas G Altman





Contents lists available at ScienceDirect

#### Journal of Dentistry

journal homepage: www.elsevier.com/locate/jdent

Full Length Article

The use of tailored subheadings was successful in enhancing compliance with CONSORT in a dental journal

Despina Koletsi<sup>a,\*</sup>, Padhraig S. Fleming<sup>b,c</sup>, Rolf G. Behrents<sup>c</sup>, Christopher D. Lynch<sup>d</sup>, Nikolaos Pandis<sup>c,e</sup>

- Journal (AJODO) adopted a publication template incorporating 20 subheadings corresponding to the 27 CONSORT items
- CONSORT compliance among submissions
  - 87% using the subheading system (n=49)
  - 72% not using subheading system (n=22)

# How to improve research publications



- Collaboration is needed from all parties involved in research publishing
  - Scientists, research organisations, funders and regulators
  - Journals (editors, peer reviewers, publishers)
  - Other organisations (higher education, REC, ...)
- Working towards ...
  - Accurate, complete and transparent reporting of research studies is considered the norm

## Who should do what?



- Some entities have more resources and opportunities notably <u>Research Funders</u> and <u>Journals</u> (publishers)
  - They should fund efforts to raise the value of the research they fund and publish
  - With power come responsibilities
- Journals (editors) should investigate ways to ensure research is well-reported
- Universities and research organisations should ensure better training in research methods and principles
- What can we do as individuals?
- The real problem is the research culture
  - Pressure to publish



"... when researchers are rewarded primarily for publishing, then habits which promote publication are naturally selected. Unfortunately, such habits can directly undermine scientific progress."

"Improving the quality of research requires change at the institutional level."

### **Impact of reporting guidelines**



- No, probably not much impact when it's left to authors
  - Instructions for authors
  - Other approaches could work e.g. templates
- Yes, when effort is made at a journal
  - Specific system implemented (needs resources)
- Structured reporting shows promise
- Web tools on the way

### More research is needed!