# Critical appraisal checklists and reporting guidelines

**Doug Altman**

**The EQUATOR Network workshop**

**31 October 2013, WHO, Geneva**

equator network

# Guidelines and Checklists

- **Study conduct**
  - Researchers: How to do it (well)

- **Reporting guidelines**
  - To ensure full information is provided about study methods and findings
  - Researchers: how to report the study
  - Peer reviewers: assess adequacy of reporting

- **Critical appraisal**
  - Reviewers/readers: Assess adequacy of study methods

# Critical appraisal: observational comparative effectiveness studies

grace PRINCIPLES

*A Validated Checklist*

for Evaluating the Quality of Observational Cohort Studies for Decision-Making Support

**D6** Were important covariates that may be known confounders or effect modifiers available and recorded?

*Important covariates depend on the treatment and/or outcome of interest, (e.g., body mass index should be available and recorded for studies of diabetes; race should be available and recorded for studies of hypertension and glaucoma).*

- ☐ **Yes**—most if not all important known confounders and effect modifiers available and recorded, e.g., measures of medication dose and duration.
- ☐ **No**—at least one important known confounder or effect modifier not available and recorded (as noted by authors or as determined by user's clinical knowledge) *or* not enough information in article

Comments:

equator network

# Critical appraisal: systematic review

**Table 2: AMSTAR is a measurement tool created to assess the methodological quality of systematic reviews.**

| | |
|---|---|
| **1. Was an 'a priori' design provided?**<br>The research question and inclusion criteria should be established before the conduct of the review. | ☐ Yes<br>☐ No<br>☐ Can't answer<br>☐ Not applicable |
| **2. Was there duplicate study selection and data extraction?**<br>There should be at least two independent data extractors and a consensus procedure for disagreements should be in place. | ☐ Yes<br>☐ No<br>☐ Can't answer<br>☐ Not applicable |
| **3. Was a comprehensive literature search performed?**<br>At least two electronic sources should be searched. The report must include years and databases used (e.g. Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found. | ☐ Yes<br>☐ No<br>☐ Can't answer<br>☐ Not applicable |
| **4. Was the status of publication (i.e. grey literature) used as an inclusion criterion?**<br>The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc. | ☐ Yes<br>☐ No<br>☐ Can't answer<br>☐ Not applicable |
| **5. Was a list of studies (included and excluded) provided?**<br>A list of included and excluded studies should be provided. | ☐ Yes<br>☐ No<br>☐ Can't answer<br>☐ Not applicable |

# Critical appraisal

- **Cannot assess the methods used if those methods are not described in adequate detail**

- **Good reporting is necessary for judging study methods;**
  - Relevance
  - Reliability
  - etc

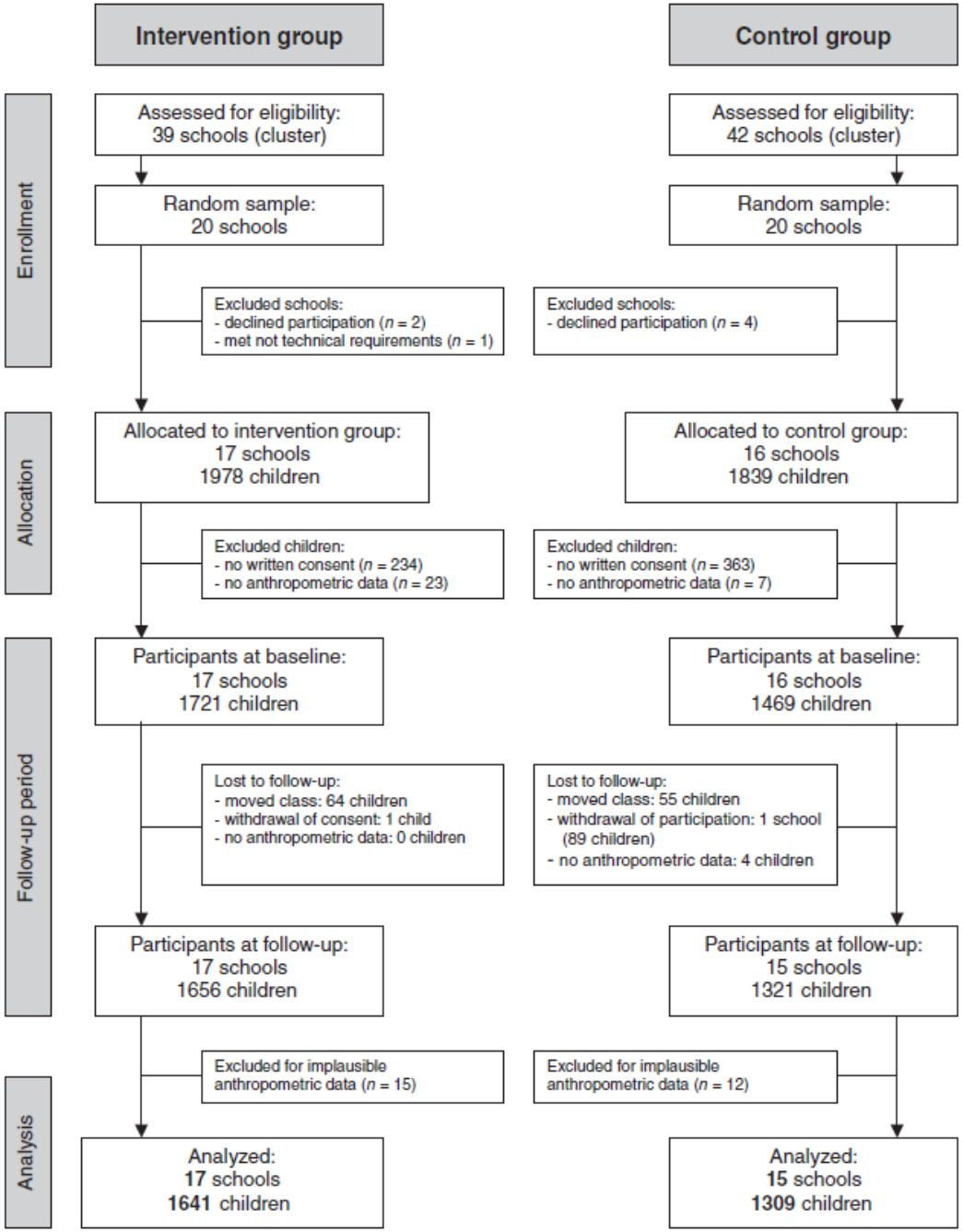
# A cluster randomised trial?

ARTICLE

## Promotion and Provision of Drinking Water in Schools for Overweight Prevention: Randomized, Controlled Cluster Trial

Rebecca Muckelbauer, MSc[a], Lars Libuda, MSc[a], Kerstin Clausen, PhD[a], André Michael Toschke, MD, MSc, MPH[b], Thomas Reinehr, MD[c], Mathilde Kersting, PhD[a]

*Pediatrics* 2009;123;e661-7




The study population comprised children attending the second and third grades of elementary schools in deprived neighborhoods of 2 neighboring cities, namely, Dortmund and Essen, Germany ...

Schools in Dortmund represented the intervention group (IG) and schools in Essen the control group (CG). For each city, 20 schools were selected randomly (Fig 1).

# Good (clear) reporting

**Sequence generation:**

- "Independent pharmacists dispensed either active or placebo inhalers according to a computer generated randomization list."
- ... The randomization code was developed using a computer random number generator to select random permuted blocks. The block lengths were 4, 8, and 10 varied randomly ..."

# Unclear reporting

**"Patients were assigned to either the intervention or control group, by selection of a card from a pile of equal numbers of cards for each group."**

[*Lancet* 2002; 360: 1455–61.]

# Clear reporting but poor methodology

**"Randomization was alternated every 10 patients, such that the first 10 patients were assigned to early atropine and the next 10 to the regular protocol, etc. To avoid possible bias, the last 10 were also assigned to early atropine."**

# Reporting vs conduct: study methods

**METHODS – each aspect of the methods**

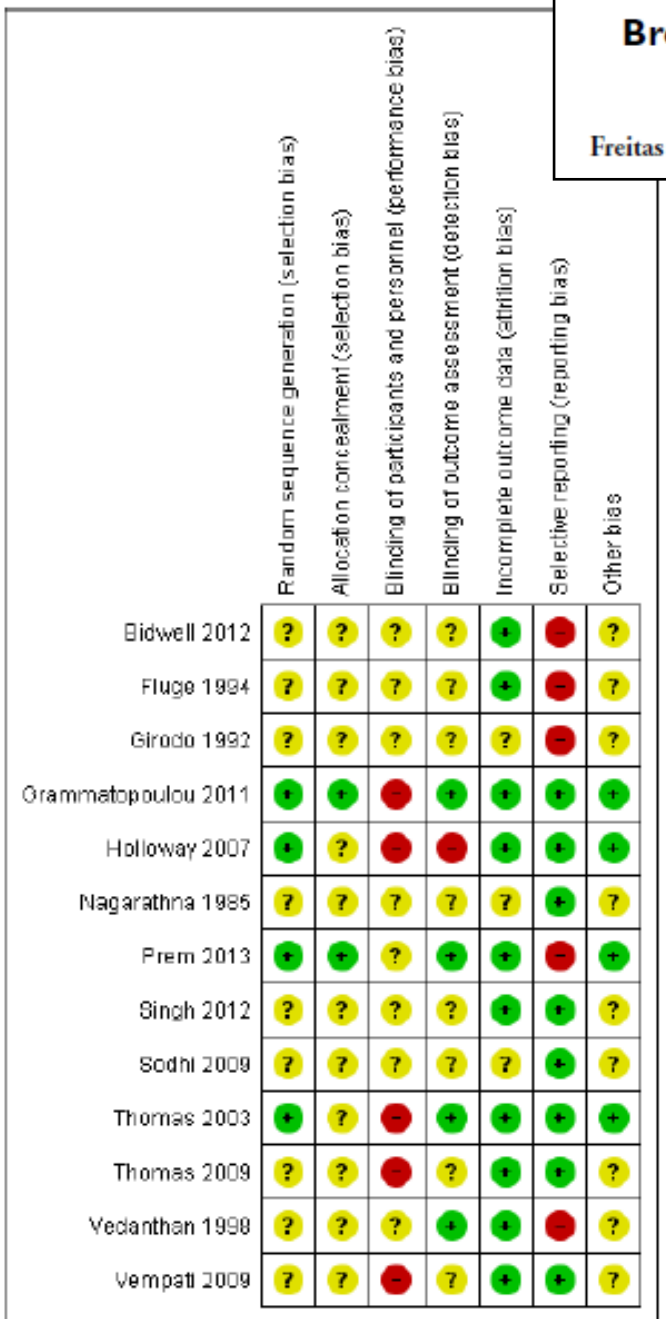
| | Done well | Done poorly | Not done |
|---|---|---|---|
| **Fully reported (=reproducible)** | | | |
| **Ambiguously or incompletely reported** | | | |
| **Not reported** | | | |

# Assessing risk of bias

**A critical element of a systematic review**

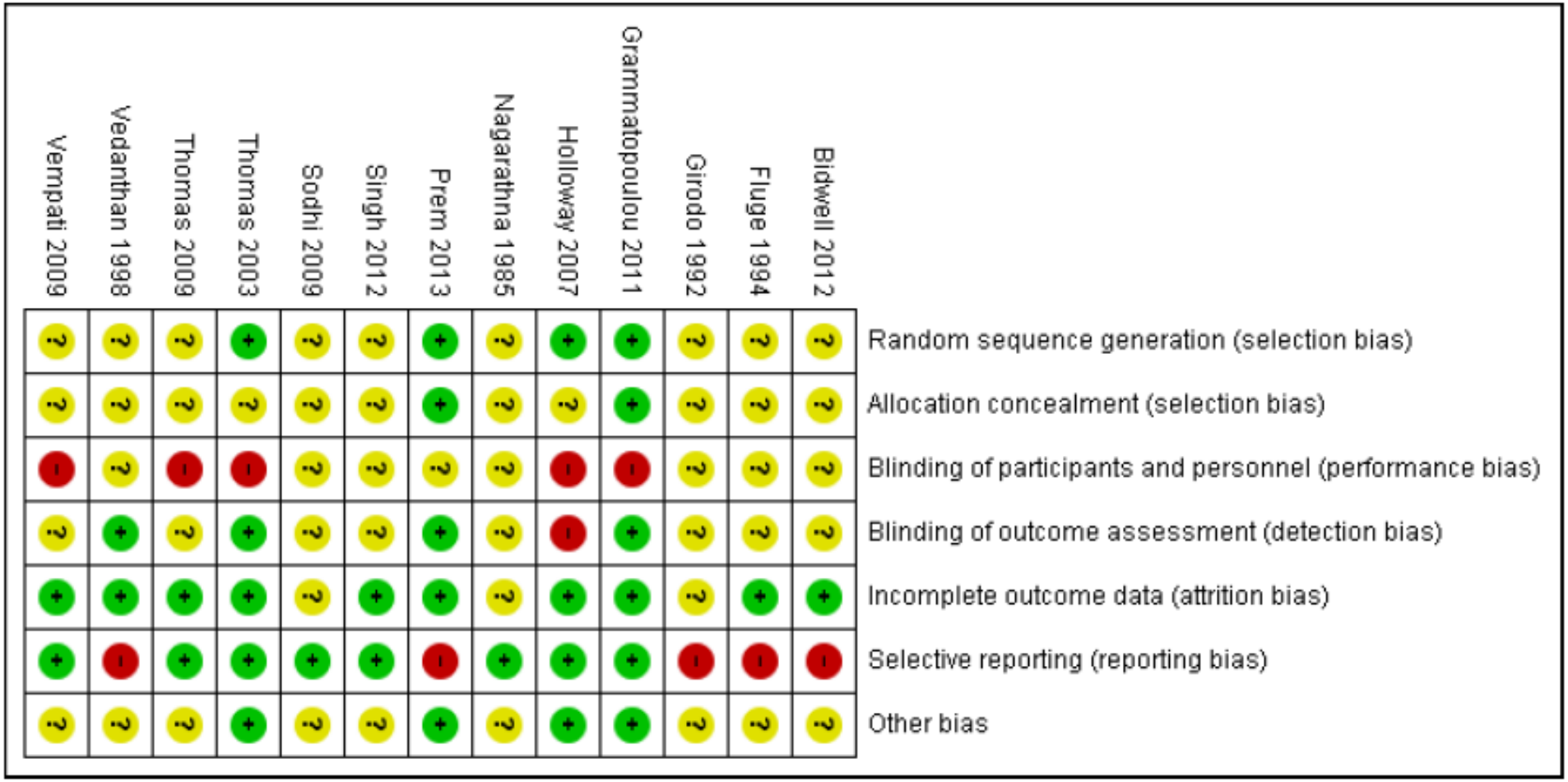
- **Risk of bias results from suboptimal methods**
- **Methods need to be reported well to allow assessment of risk of bias**

**Figure 1. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.**




## Breathing exercises for adults with asthma (Review)

Freitas DA, Holloway EA, Bruno SS, Chaves GSS, Fregonezi GAF, Mendonça KMPP




**Citation:** Freitas DA, Holloway EA, Bruno SS, Chaves GSS, Fregonezi GAF, Mendonça KMPP. Breathing exercises for adults with asthma. *Cochrane Database of Systematic Reviews* 2013, Issue 10. Art. No.: CD001277. DOI: 10.1002/14651858.CD001277.pub3.

# 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** | | | |

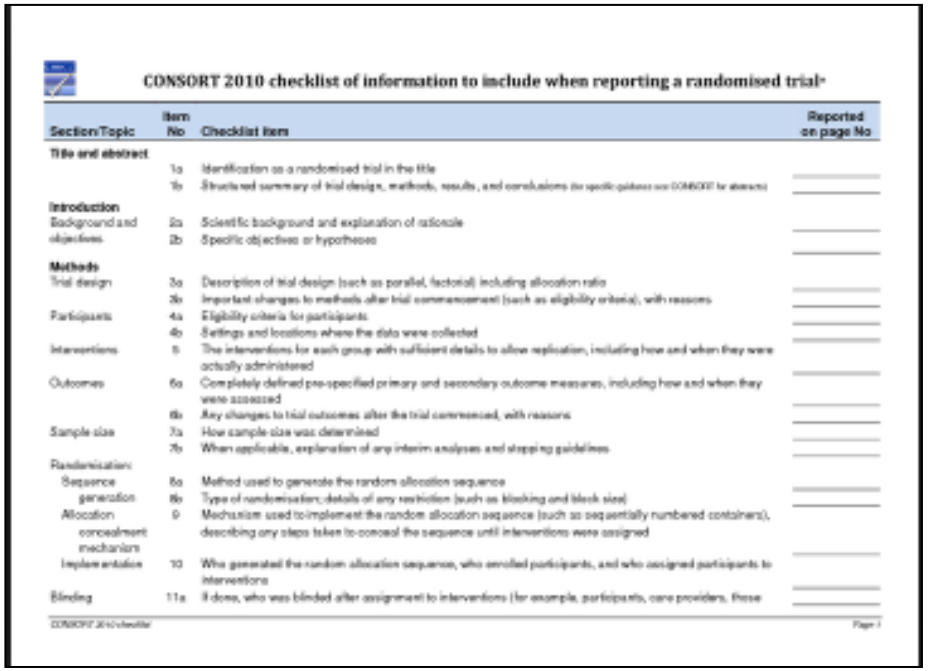
# Good reporting is essential

- **Quality of reporting is a key factor in determining the value of a research publication**
- **It is impossible to appraise a study if the report lacks key information**
- **Full reporting of results is essential to allow a study to be included in a meta-analysis**

# What is a reporting guideline?

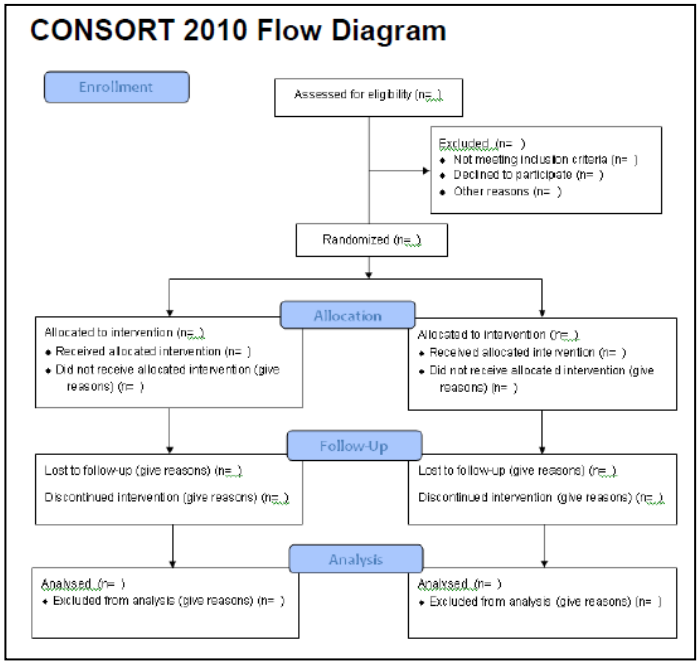
- **Specify a minimum set of items required for a clear and transparent account of what was done and what was found in a research study**
- **Reflect in particular issues that might introduce bias into the research**
- **Format: Checklist, flow diagram, text**

# Example of a reporting guideline



**CONSORT 2010 checklist of information to include when reporting a randomised trial***

| Section/Topic | Item No | Checklist item | Reported on page No |
|---|---|---|---|
| **Title and abstract** | | | |
| | 1a | Identification as a randomised trial in the title | |
| | 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) | |
| **Introduction** | | | |
| Background and objectives | 2a | Scientific background and explanation of rationale | |
| | 2b | Specific objectives or hypotheses | |
| **Methods** | | | |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | |
| | 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | |
| Participants | 4a | Eligibility criteria for participants | |
| | 4b | Settings and locations where the data were collected | |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons | |
| Sample size | 7a | How sample size was determined | |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | |
| Randomisation: | | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence | |
| | 8b | Type of randomisation; details of any restriction (such as blocking and block size) | |
| Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those | |




- Most internationally accepted RGs
  - Based on evidence
  - Consensus of relevant stakeholders (multidisciplinary group)

equator network

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

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

**"Moreover, the CONSORT 2010 statement does not include recommendations for designing and conducting randomized trials. The items should elicit clear pronouncements of how and what the authors did, but do not contain any judgments on how and what the authors should have done. Thus, CONSORT 2010 is not intended as an instrument to evaluate the quality of a trial. Nor is it appropriate to use the checklist to construct a "quality score." "**

# Why not to calculate a score

- **Items on checklist are there for various reasons**
  - Internal validity
  - external validity
  - Indexing/retrieval
  - Reproducibility of methods

**"By itself, accurate, transparent reporting doesn't make good science. Knowing that editors expect a high standard of accuracy and transparency in reports of finished research can, however, encourage researchers do a better job in planning and carrying out the research in the first place. Accurate, 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."**

[Davidoff, *Ann Intern Med* 2000]

# Summary

- **Guidelines for reporting and for critical appraisal are quite distinct**

- **Several checklists are relevant to systematic reviews**
  - for assessing methods of the primary studies
  - for reporting the review
  - for assessing methods of the review

- **Good reporting is essential**
  - to enable the methodology to be understood and appraised
  - to enable the findings to be included in a future meta-analysis