The QUOROM Statement: revised recommendations for improving the quality of reports of systematic reviews

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The QUOROM (QUality Of Reporting Of Meta-analyses) Statement

- a evidence-based guidance to help improve the reporting of meta-analysis of randomized trials
- comprises of a 21 item checklist that parallels the process involved in completing a meta-analysis
- a flow diagram detailing the flow of randomized trials through the meta-analysis process
QUOROM Statement

- Developed in 1996
  - Following CONSORT model
- Published in 1999
- Since 1996 increased evidence base from methodological and empirical research
  - e.g. Cochrane Methodology Register
    - 1000 entries in 1999
    - 8255 entries in 2006
- Some deficiencies in QUOROM have been recognized
Meeting objective

- To revise the QUOROM Statement
  - Take advantage of procedures used when developing reporting guidelines

Meeting preparations

- A SR of studies examining the quality of reporting SRs was completed.
- A comprehensive literature search was undertaken to identify methodological and other articles that might inform the conference.
- International survey was completed of systematic reviewers, consumers, and groups commissioning and/or using SRs:
  - To ascertain their views of QUOROM.
  - The merits of the checklist items.
Revision of QUOROM

- A 3-day meeting was held in Ottawa, Canada, in June 2005
  - 29 participants: systematic reviewers, methodologists, editors and a consumer
  - Important Cochrane contribution – 18 participants
- Meeting preparation activities were presented
- Revised statement consists of
  - 27-item checklist
  - four-phase flow diagram
    - identification, screening, eligibility, inclusion
Conceptual issues affecting the update

- Distinction between articles and studies
- Iterative nature of completing a systematic review
- Need to distinguish between conduct and reporting of primary studies
- Quality assessment
  - Key idea is “risk of bias”
  - Both study level and outcome level assessment
- Need to consider risk of reporting bias (between and within study)
- “Systematic review” or “meta-analysis”?
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(Study) Publication bias

- Selective reporting of randomized trials based on the level of statistical significance
Outcomes reporting bias

- selective reporting of outcomes
  - typically statistically positive
  - selected by investigators (post hoc)
Outcomes reporting bias

**methods**

- compared the contents of 102 trial protocols, approved by the scientific-ethics committees for Copenhagen and Frederiksberg, Denmark, during 1994 and 1995, with 122 subsequent publications.

Some salient results

- nearly two-thirds had a change in at least one primary outcome between the protocol and publication
- statistically significant outcomes had a higher likelihood of being reported compared to non-significant ones

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- “Systematic review” or “meta-analysis”?
What is a systematic review?

Identification of possibly relevant citations

Inclusion of eligible studies

Data extraction, tabulation and synthesis

Data analysis

Meta-analysis
Meta-analysis

“a review in which bias has been reduced by the systematic identification, appraisal, synthesis, and, if relevant, statistical aggregation of all relevant studies on a specific topic according to a predetermined and explicit method”

The issues discussed might also be useful for reporting of systematic reviews (i.e., meta-analysis, as defined above, without statistical aggregation), particularly of RCTs.
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Systematic review

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Meta-analysis

Systematic review
Name change

- QUOROM?
  - QUality Of Reporting Of Meta-analyses
- PRISMA?
  - Preferred Reporting Items for Systematic reviews and Meta-Analyses
- A new name would avoid ‘quality’ and recognize “Systematic review” as a concept
<table>
<thead>
<tr>
<th>Section/topic</th>
<th>#</th>
<th>Checklist item</th>
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<tbody>
<tr>
<td>TITLE</td>
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<tr>
<td>ABSTRACT</td>
<td></td>
<td>Provide a structured summary, including the following information, as applicable: background, objective, data sources, study eligibility criteria, participants and interventions, study appraisal and synthesis methods, results, limitations, conclusions and implications of key findings; registration number.</td>
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<tr>
<td>INTRODUCTION</td>
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<td>Rationale</td>
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<td>Provide the rationale for the review in the context of what is already known.</td>
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<td>Objectives</td>
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<td>Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes and study design (PICOS).</td>
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<td>METHODS</td>
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<td>Protocol and registration</td>
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<td>Indicate if a review protocol exists, if not where it can be accessed (e.g., web address) and, if available, provide registration information including registration number.</td>
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<td>Eligibility criteria</td>
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<td>Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.</td>
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<td>Information sources</td>
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<td>Describe all information sources (e.g., databases with dates of coverage, study authors to identify additional studies) in the search and date last searched.</td>
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<td>Search</td>
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<td>Present full electronic search strategy for at least one database (e.g. Medline), including any limits used, such that it could be replicated.</td>
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<td>Study selection</td>
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<td>State the process for selecting studies (i.e., screening, eligibility, included in systematic review and, if applicable, included in the quantitative synthesis).</td>
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<td>Data collection process</td>
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<td>Describe methods of data extraction from reports (e.g., piloted forms, independently, in duplicate, blinded) and any processes for obtaining and confirming data from investigators.</td>
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<td>Data items</td>
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<td>List and define all variables for which data were sought (e.g., PICOS, funding sources), indicate which were pre-specified and any assumptions and simplifications made.</td>
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<td>Assessment of risk of bias in included studies</td>
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<td>Describe methods used for assessing risk of bias of included studies, and how this information is to be used in the data synthesis.</td>
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<td>Summary measures</td>
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<td>State the principal summary measures (e.g., risk ratio, difference in means).</td>
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<td>Synthesis</td>
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<td>Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I²) for each quantitative contrast.</td>
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<td>Assessment of bias across studies</td>
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<td>Specify any assessment of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).</td>
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<td>Additional analyses</td>
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<td>Describe methods of additional analyses (e.g., sensitivity analyses, subgroup analysis, meta-regression), if done, indicating which were pre-specified.</td>
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<td>RESULTS</td>
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<td>Results of the study selection</td>
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<td>Give numbers of studies selected, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.</td>
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<td>Study characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide an example.</td>
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<td>Risk of bias</td>
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<td>Present data on risk of bias of each included study (see item 12).</td>
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<td>Results of individual studies</td>
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<td>For all outcomes considered (benefits or harms) present, for each study: (a) simple summary data for each intervention group (e.g., the basic effect estimate and variance), (b) effect estimates (e.g., risk ratio, difference in means) and confidence intervals, ideally with a forest plot.</td>
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<td>Synthesis</td>
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<td>Describe studies and their results. Present results of each quantitative synthesis item, including confidence intervals, and a table of results.</td>
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<td>Assessment of bias across studies</td>
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<td>Present results of any assessment of bias (see item 15).</td>
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<td>DISCUSSION</td>
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<td>Summary of evidence</td>
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<td>Summarize the main findings including the strength of evidence for each main outcome, including their relevance to key groups (e.g., healthcare providers and users, policy makers).</td>
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<td>Limitations</td>
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<td>Discuss study level limitations (e.g., study design and review level limitations (e.g., incomplete retrieval of identified research, reporting bias)).</td>
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<td>Conclusions</td>
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<td>Provide a general interpretation of the results in the context of other evidence, and implications for future research.</td>
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Methods

- **Protocol, item 5**
  - indicate if a review protocol exists, if and where it can be accessed (e.g. web address)
Methods

- **data collection process**, item 10
  - describe method of data extraction from reports (e.g. piloted forms, independently, in duplicate, blinded) and any processes for obtaining and confirming data from investigators
Results

• results of the study, item 17
  • give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram
Funding, item 27

- sources of funding and other support (e.g. data analysis); role of funders
Not specific

- The checklist is not specific to RCTs
  - “Recommendations for reporting systematic reviews of healthcare interventions: the PRISMA Statement”
Dissemination strategy

- Short PRISMA Statement
- Explanatory and elaboration document
  - Modeled after CONSORT and STARD
- For each checklist item
  - Example of good reporting
  - Rationale for inclusion
  - Supporting evidence