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

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The QUOROM (*QU*ality Of *R*eporting Of *M*eta-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[1]

[1]Altman DG, Moher D. Developing guidelines for reporting healthcare research: scientific rationale and procedures. Medicina Clinica, 2005;125 (Suppl 1): 8-13

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

Chan AW, Hrobjartsson A, Haahr MT, Gøtzsche PC, Altman DG. Empirical evidence for selective reporting of outcomes in randomized trials: comparison of protocols to published articles. JAMA 2004;291:2457-2465

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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

Chan AW, Hrobjartsson A, Haahr MT, Gøtzsche PC, Altman DG. Empirical evidence for selective reporting of outcomes in randomized trials: comparison of protocols to published articles. JAMA 2004;291:2457-2465

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What is a systematic review?

Identification of possibly relevant citations

Inclusion of eligible studies

Data extraction, tabulation and synthesis

Data 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 (ie, meta-analysis, as defined above, without statistical aggregation), particularly of RCTs

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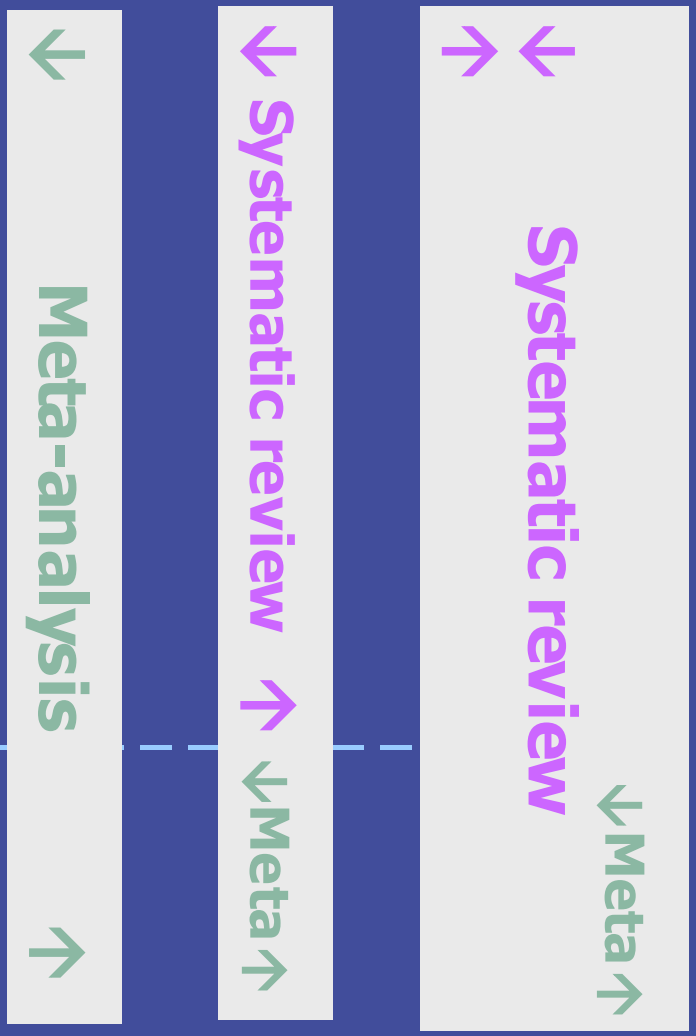



ABSENCE OF EVIDENCE
IS NOT
EVIDENCE OF ABSENCE

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

PRISMA checklist

Section/topic	#	Checklist item
TITLE		
Title	1	Identify the report as a systematic review or meta-analysis.
ABSTRACT		
Structured summary	2	Provide a structured summary including the following information, as applicable: background; objectives; data sources; study eligibility criteria, participants and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; registration number.
INTRODUCTION		
Rationale	3	Describe the rationale for the review in the context of what is already known.
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes and study design (PICOS).
METHODS		
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g. web address) and, if available, provide registration information including registration number.
Eligibility criteria	6	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.
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, study authors to identify additional studies) in the search and date last searched.
Search	8	Present full electronic search strategy for at least one database (e.g. Medline), including any limits used, such that it could be replicated.
Study selection	9	State the process for selecting studies (i.e. screening, eligibility, included in systematic review and, if applicable, included in the quantitative synthesis).
Data collection process	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.
Data items	11	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
Assessment of risk of bias in included studies	12	Describe methods used for assessing risk of bias of included studies, and how this information is to be used in the data synthesis.
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).
Synthesis	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each quantitative synthesis.
Assessment of bias across studies	15	Specify any assessment of bias that may affect the cumulative evidence (e.g. publication bias, selective reporting within studies).
Additional analyses	16	Describe methods of additional analyses (e.g. sensitivity analyses, subgroup analysis, meta-regression), if done, indicating which were pre-specified.
RESULTS		
Results of the study selection	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.
Study characteristics	18	For each study present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citation.
Risk of bias	19	Present data on risk of bias of each included study (see item 12).
Results of individual studies	20	For all outcomes considered (benefits or harms) present, for each study: (a) simple summary data for each intervention group (e.g., 2x2 table of counts, means and variance), (b) effect estimates (e.g., risk ratio, difference in means) and confidence intervals, ideally with a forest plot.
Synthesis	21	Describe studies and their consistency. Present results of each quantitative synthesis done, including confidence intervals and measures of consistency.
Assessment of bias across studies	22	Present results of any assessment of bias (see item 15).
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity analyses, subgroup analyses, meta-regression).
DISCUSSION		
Summary of evidence	24	Summarise the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers and users, policy makers).
Limitations	25	Discuss study-level limitations (e.g., study design) and review-level limitations (e.g., incomplete retrieval of identified research, reporting bias).
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.
FUNDING		
Funding	27	Describe sources of funding for the systematic review and other support (e.g. data analysis); role of funders.

Methods

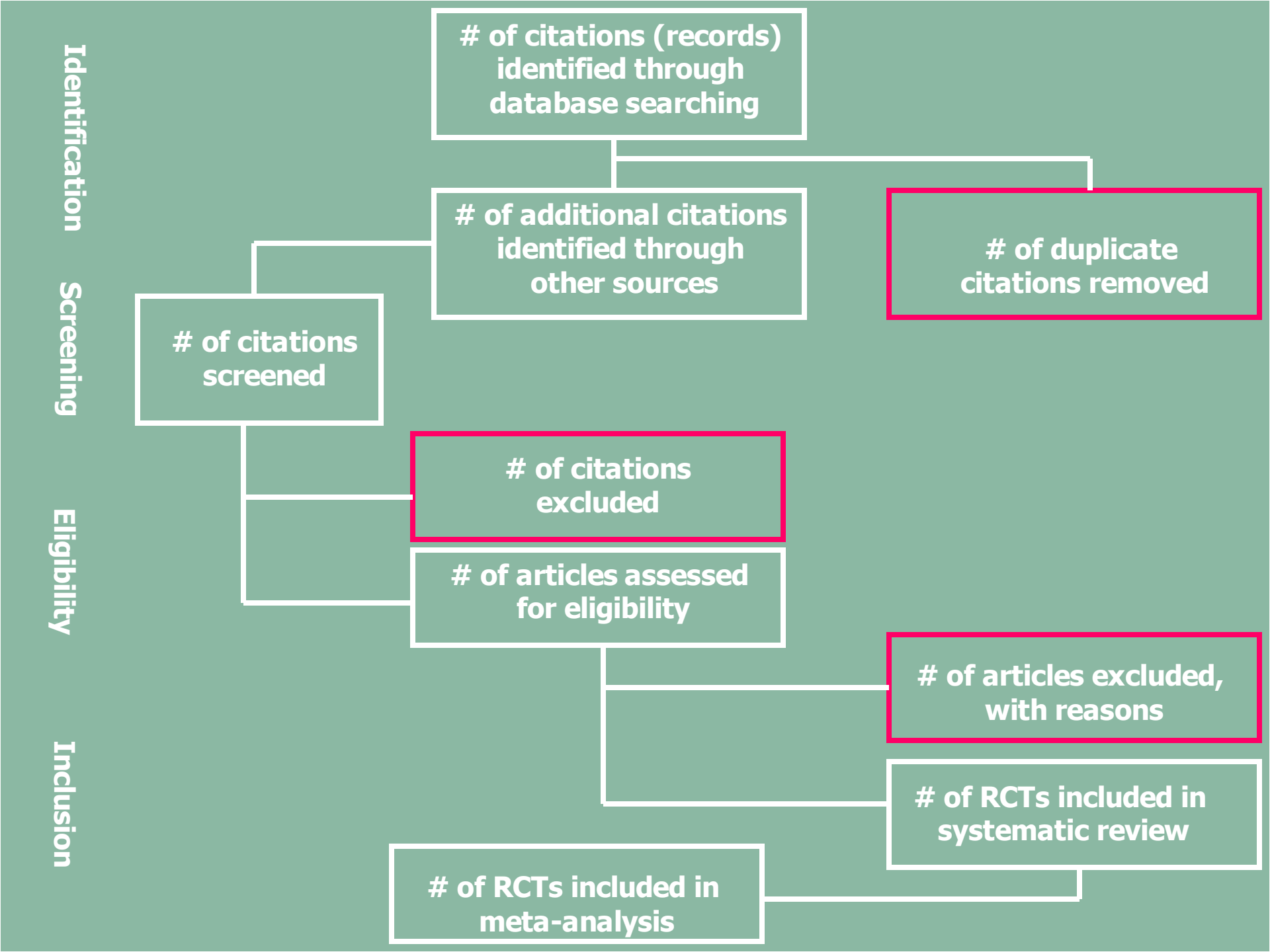
- **Protocol,** item 5
  - indicate if a review protocol exists, if and where it can be accessed (e.g. web address)

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


# of citations (records) identified through database searching
# of additional citations identified through other sources
# of duplicate citations removed
# of citations screened
# of citations excluded
# of articles assessed for eligibility
# of articles excluded, with reasons
# of RCTs included in systematic review
# of RCTs included in meta-analysis
Identification
Screening
Eligibility
Inclusion

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