How to report a review?

Come si scrive una review?

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Dear Editor,

In the editorial from Maina and Di Napoli [1], the important issue concerning the number of authors of a review was considered in its essential aspects. The authors stated that, in order «to avoid the uncontrolled proliferation of authors and co-authors», *Reviews in Health Care* decided to fix a maximum of 10 authors for each article.

In this contribution we would like to underline another issue: how to report a review?

The need of specific reporting guidelines for medical journals is beyond dispute. With that regard a number of statements were developed by groups of experts to facilitate reporting of research studies. Most medical journals, including *British Medical Journal* (*BMJ*), the *Journal of the American Medical Association* (*JAMA*), *The Lancet*, and *New England Journal of Medicine,* often require compliance to all or some of the following guidelines: CONSORT Statement (reporting of randomized controlled trials), STARD (reporting of diagnostic accuracy studies), STROBE (reporting of observational studies in epidemiology), PRISMA (reporting of systematic reviews and meta-analyses) and MOOSE (reporting of meta-analyses of observational studies).

The present letter concerns the standards of reporting in research, publication in medical journals and wishes to give an emphasis to the PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) statement.

There is no doubt that, according to the PRISMA statement [2], the number of authors for a systematic review needs to be at least 2 ("Eligibility assessment to be performed independently in an unblended standardized manner by 2 reviewers").

PRISMA is an evidence-based set of 27-item checklist (Table I) and a four-phase flow diagram (Figure 1) and it's basically an expansion of the QUOROM Statement developed in 1996 (QUality Of Reporting Of Meta-analyses).

The Statement was developed by a group of 29 review authors, methodologists, clinicians, medical editors, and consumers [3]. The flow diagram originally proposed by QUOROM was modified to show

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numbers of identified records, excluded articles, and included studies. Items considered essential for transparent reporting of a systematic review were also included in the checklist. After 11 revisions the group approved the checklist and the flow diagram. The items are presented numerically from 1-27, but it is not necessary to address them in that particular order in a report. Fundamentally, what is important is that the information for each item is given somewhere within the report [2].

Section/topic	Item No	Checklist item	Reported on page No
Title			
Title	1	Identify the report as a systematic review, meta-analysis, or both	
Abstract			
Structured summary	2	Provide a structured summary including, 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; systematic review 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 (eg web address), and, if available, provide registration information including registration number	
Eligibility criteria	6	Specify study characteristics (eg PICOS, length of follow-up) and report characteristics (eg years considered, language, publication status) used as criteria for eligibility, giving rationale	
Information sources	7	Describe all information sources (eg databases with dates of coverage, contact with 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, including any limits used, such that it could be repeated	
Study selection	9	State the process for selecting studies (ie, screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis)	
Data collection process	10	Describe method of data extraction from reports (eg piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators	
Data items	11	List and define all variables for which data were sought (eg PICOS, funding sources) and any assumptions and simplifications made	
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis	
Summary measures	13	State the principal summary measures (such as risk ratio, difference in means)	
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (eg I^2 statistic) for each meta-analysis	
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (eg publication bias, selective reporting within studies)	
Additional analyses	16	Describe methods of additional analyses (eg sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified	
Results			
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	

Table continues >

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Section/topic	Item No	Checklist item	Reported on page No
Study characteristics	18	For each study, present characteristics for which data were extracted (eg study size, PICOS, follow-up period) and provide the citations	
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome-level assessment (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 and (b) effect estimates and confidence intervals, ideally with a forest plot	
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency	
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see item 15)	
Additional analysis	23	Give results of additional analyses, if done (such as sensitivity or subgroup analyses, meta-regression) (see item 16)	
Discussion			
Summary of evidence	24	Summarise the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (eg health care providers, users, and policy makers)	
Limitations	25	Discuss limitations at study and outcome level (eg risk of bias), and at review level (eg 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 (eg supply of data); role of funders for the systematic review	

Table I. Checklist of items to include when reporting a systematic review (with or without meta analysis) [2]

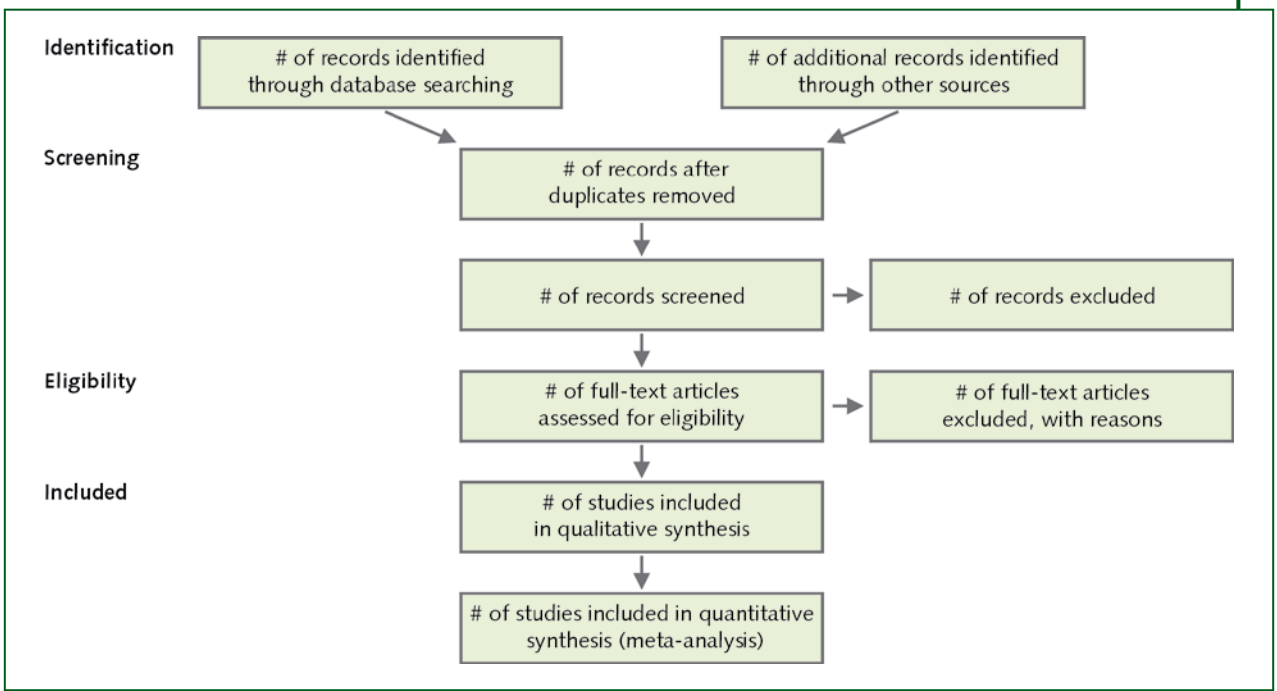

Figure 1. Flow of information through the different phases of a systematic review

Systematic reviews (SRs) and meta-analyses are essential tools for summarising evidence accurately and reliably. They help clinicians keep up-to-date; provide evidence for policy makers to judge risks, benefits, and harms of health care behaviours and interventions; gather together and summarise related research for patients and their carers; provide a starting point for clinical practice guideline developers; provide summaries of previous research for funders wishing to support new research [4]; and help editors judge the merits of publishing reports of new studies [5].

Poor reporting of key information is often in SRs and that diminishes their potential usefulness [6]; therefore, PRISMA focuses on ways in which authors can ensure the transparent and complete reporting of their researches. It does not address directly or in a detailed manner the conduct of SRs, for which other guides are available [7,8].

Several research and publication ethics standards have been set up. These include the Nuremberg Code, the Declaration of Helsinki, the International Committee of Medical Journal Editors (ICMJE) Uniform Requirements for Manuscripts to Biomedical Journals, recommendations of the World Association of Medical Editors and the Committee on Publication Ethics [9].

The study carried out in 2010 by Pitak-Arnnop revealed the lack of disclosures of human subject protection (obtaining ethical approval and subject's consent), financial conflicts, and academic-industry relationship in oral-maxillofacial surgery (OMS) journals and innovations. Funding sources were disclosed in only 26.4% of controlled trials published in OMS journals. Their recent studies demonstrated that 9 of 29 clinical studies (31%) on piezoelectric OMS procedures were dual or fragmented publications in journals of different disciplines or different languages and that OMS authors had a considerably different understanding of research ethics. Multiple factors may contribute to such scientific misconduct. These include inadequate research experience, bias from career self-interest or financial gains, lack of knowledge about research and publication ethics, or a combination of these [9]. Moreover, guidelines for authors are usually limited and inconsistent among different journals [10,11].

Other factors could lead to a bias in evidence, for instance unpublished grey literature or publications in non-electronic journals are difficult to identify and are often not detected in systematic searches. Even though a study is published in electronic journals not every journal is listed on the major databases like PubMed.gov or Embase which hinders its identification. Most of the published studies are not accessible openly and in addition many large clinical centres do not have all the necessary licenses for all the relevant publications which limit the number of studies they can identify [12]. Therefore, knowing that publication bias is always present it's advisable to take it into account when reading meta-analyses and systematic reviews.

Publication bias occurs when «investigators, reviewers, and editors submit or accept manuscripts for publication based on the direction or strength of the study findings» [13]. The ICMJE underlines that negative studies should be published: «Editors should seriously consider for publication any carefully done study of an important question, relevant to their readers, whether the results for the primary or any additional outcome are statistically significant. Failure to submit or publish findings because of lack of statistical significance is an important cause of publication bias».

The impact of publication bias has been widely examined for clinical trials [14-16], for which it has been suggested that studies with statistically positive results and large effect sizes can exaggerate a treatment's effectiveness by 20% [17].

The PRISMA Statement calls for an international registry for SR protocols [18], which is under development [19]. An international registry may decrease the number of unpublished SRs and will hopefully decrease redundancy, increase transparency and collaboration within the SR community.

The interpretation of SR results may be improved by using the PRISMA Statement and GRADE (Grading of Recommendations Assessment, Development, and Evaluation) which considers four factors in grading the strength of recommendations: quality, benefit versus harm, values, preferences and re-

sources [20,21]. A categorisation guide for meta-analysis results would be also useful. Such efforts will increase the applicability and relevance of the SR findings and may help to ensure adequate interpretation of the results.

The purpose of this letter is to encourage health care journals and editorial groups, such as the World Association of Medical Editors and the International Committee of Medical Journal Editors, to endorse PRISMA in much the same way as they have endorsed other reporting guidelines, such as CONSORT. We also encourage editors of health care journals to support PRISMA by updating their ''Instructions to Authors'' and including the PRISMA Web address, and by raising awareness through specific editorial actions.

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