|  |  |
| --- | --- |
|  | Methodology Checklist 1: Systematic Reviews and Meta-analysesNotes for completion of checklist |
| SIGN gratefully acknowledges the permission received from the authors of the AMSTAR tool to base this checklist on their work: *Shea BJ, Grimshaw JM, WellsGA, BoersM, Andersson N, HamelC,. et al. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. BMC Medical Research Methodology 2007,* ***7****:10 doi:10.1186/1471-2288-7-10. Available from* [*http://www.biomedcentral.com/1471-2288/7/10*](http://www.biomedcentral.com/1471-2288/7/10) *[cited 10 Sep 2012]***Must refers to a statement that has to be fulfilled for the question to receive a yes answer. Should statements are a mark of quality but not a necessity for a yes answer. These should be used to assess the overall quality of the paper.** |
| **Section 1: Internal validity** |
| ***In a well conducted systematic review:*** | Notes |
| 1.1 | The research question is clearly defined and the inclusion/ exclusion criteria must be listed in the paper. | The PICO must be clear in the paper even if not directly referred to. The research question and inclusion criteria should be established before the review is conducted.  |
| 1.2 | A comprehensive literature search is carried out. | At least two relevant electronic sources must be searched. The report must list the databases used (e.g., Central, EMBASE, and MEDLINE). (Cochrane register/Central counts as two sources; a grey literature search counts as supplementary).(PubMed and MEDLINE count as one database.)Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. Dates for the search should be provided.The paragraph above is the minimum requirement. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or/and experts in the particular field of study, and by reviewing the references in the studies found.The paragraph above is a quality criteria which affects the overall rating of the review.*Notes*This criterion will not apply in the case of prospective meta-analysis - this is where meta-analysis is based on pre-selected studies identified for inclusion before the results of those studies are known. Such reports must state that they are prospective.  |
| 1.3 | At least two people should have selected studies. | At least two people should select papers. There should be a consensus process to resolve any differences |
| 1.4 | At least two people should have extracted data. | At least two people should extract data and should report that a consensus was agreed. One person checking the others data extraction is accurate is acceptable. |
| 1.5 | The status of publication was not used as an inclusion criterion. | The authors should state that they searched for reports regardless of their publication status. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status. If review indicates that there was a search for “grey literature” or “unpublished literature,” indicate “yes.” SIGLE database, dissertations, conference proceedings, and trial registries are all considered grey for this purpose. If searching a source that contains both grey and non-grey, must specify that they were searching for grey/unpublished lit. |
| 1.6 | The excluded studies are listed. | Limiting the excluded studies to references is acceptable. |
| 1.7 | The relevant characteristics of the included studies are provided. | In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions and outcomes. The ranges of characteristics in all the included studies e.g., age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported. (Note that a format other than a table is acceptable, as long as the information noted here is provided).Absence of this will make it impossible to form guideline recommendations. Mark as (-) original papers would need to be examined. |
| 1.8 | The scientific quality of the included studies was assessed and documented | It can include use of a quality scoring tool or checklist, e.g. risk of bias assessment, or a description of quality items, with some kind of result for EACH study (“low” or “high” is fine, as long as it is clear which studies scored “low” and which scored “high”; a summary score/range for all studies is not acceptable.Absence of this will make it impossible to form guideline recommendations. Mark as (-)  |
| 1.9 | Was the scientific quality of the included studies used appropriately? | Examples include sensitivity analysis based on study quality, exclusion of poor quality studies, and statements such as ‘the results should be interpreted with caution due to poor quality of included studies’The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations.Cannot score “yes” for this question if scored “no” for question 1.8.  |
| 1.10 | Appropriate methods are used to combine the individual study findings. | Studies that are very clinically heterogeneous should not be combined in a meta-analysis.Look at the forest plot–do the results look similar across the studies? For the pooled result a test should be done to assess statistical heterogeneity i.e. Chi-squared (*χ2*) test for homogeneity and/or *I2* test for inconsistency.If significant heterogeneity is apparent the authors should have explored possible explanations using methods such as sensitivity analysis or meta-regression. A random effects analysis may be used to take account of between-study variation but is not a ‘fix’ for heterogeneity.Planned subgroup analyses should be pre-specified and limited in number because conducting many subgroup analyses increases the probability of obtaining a statistically significant result by chance. Conclusions based on post-hoc subgroup analyses must be interpreted with caution. Cannot score “yes” for this question if scored “no” for question 1.8.  |
| 1.11 | The likelihood of publication bias was assessed appropriately | The possibility of publication bias should be assessed where possible, commonly done by visual inspection of a funnel plot together with a statistical test for asymmetry (e.g., Egger regression test) although other statistical and modelling approaches may be reported.Absence of a funnel plot doesn’t mean the likelihood of publication bias was not assessed appropriately (there are other methods); 10 studies is just a ball-park minimum number for a funnel plot and a plot is of little use when there are few studies. |
| 1.12 | Conflicts of interest are declared. | Potential sources of support should be clearly acknowledged in both the systematic review and the included studies. |
| **Section 2: OVERALL ASSESSMENT OF THE STUDY** |
| 2.1 | What is your overall assessment of the methodological quality of this review?  | Rate the overall methodological quality of the study, using the following as a guide: **High quality** (++): Majority of criteria met. Little or no risk of bias.. **Acceptable** (+): Most criteria met. Some flaws in the study with an associated risk of bias. **Low quality** (-): Either most criteria not met, or significant flaws relating to key aspects of study design. **Reject** (0): Poor quality study with significant flaws. Wrong study type. Not relevant to guideline. |