Health Evidence[™]

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Instructions for completion:

Please refer to the attached dictionary for definition of terms and instructions for completing each section. For each criteria, score by placing a check mark in the appropriate box.

First Author:	
Year:	
Journal:	
Reviewer:	
-	

CRITERIA			NO	
Q1. Did the authors have a clearly focused question [population, intervention (strategy), and outcome(s)]?				
Q2. Were appropriate inclusion criteria used to select primary studies?				
Q3. Did the authors describe a search strategy that was comprehensive?				
Circle all strategies used:	 health databases psychological databases social science databases educational databases other handsearching key informants reference lists unpublished 			
Q4. Did search strategy cover an adequate number of years?				
Q5. Did the authors describe the level of evidence in the primary studies included in the review?				
 Level I → RCTs only Level II → non-randomized, cohort, case-control Level III → uncontrolled studies 				
Q6. Did the review assess the methodological quality of the primary studies, including:				
 (Minimum requirement: 4/7 of the following) Research design Study sample Participation rates Sources of bias (confounders, respondent bias) Data collection (measurement of independent/dependent variables) Follow-up/attrition rates Data analysis 				
Q7. Are the results of the review transparent?				
Q8. Was it appropriate to combine the findings of results across studies?				
Q9. Were appropriate methods used for combining or comparing results across studies?				
Q10. Do the data support the author's interpretation?				
	TOTAL SCORE:		1	
Quality Assessment Rating: (tota	StrongModerateWeakI score 8 - 10)(total score 5 - 7)(total score 4 or less)			



A systematic review is a research approach to accessing, acquiring, qualityassessing, and synthesizing a body of research on a particular topic.

All phases of systematic review development should be well described, such that the process is transparent and replicable by others.

Q1 | Clearly focused research question

The review should have a clearly focused research question that contains the following components: **P**opulation, **I**ntervention, **C**omparisons, and **O**utcomes. **NOTE:** Remember **PICO**.

Population: How would you describe the population of interest?

→ Details on the population of interest should be clearly outlined to the level that it would be appropriate to determine whether the results apply directly to one's patient(s) / community / constituents.

Intervention: Which main intervention or exposure is being considered?

- → The intervention refers to a variety of actions that are undertaken with the expectation of promoting and achieving specific outcomes. This may include an intervention, a strategy, or a policy, including activities such as lobbying, coalitions, and legislation. The focus of the review is to evaluate the impact of these activities on specific outcomes for individuals, communities or the population. The activities being assessed should be similar enough that it is reasonable to assess their combined impact.
- \rightarrow For economic evaluations the research question should include a cost component.

Comparison: What is the main alternative to compare with the intervention?

- → This might be a control group or another intervention. Often the comparison is not stated explicitly in the research question. Either a control group or another intervention can be used as the comparator. In some instances, due to the nature of public health, a comparison and/or control may not be feasible.
- → For economic evaluations a comparator is not always identified. To receive a YES for criterion #1 it would be enough if the population, intervention and outcome are clearly described.

Outcome: What do the researchers hope to accomplish, measure, improve, or affect?

→ Outcomes relate to the measured impact of the activities and can be at the individual, community or population level, e.g. health policies, health programs, or coalition development.

Any part of **PICO** that is not addressed in a review's main research question should be clearly stated in the inclusion criteria to receive a **Yes** for criterion #1. Outcomes can be general in *the research question* (e.g. to allow for a broader search strategy, especially if the topic at-hand has a limited body of literature available), and then be addressed more specifically in the evidence tables and/or highlighted through the process of data extraction. For example, a general question may read: "The aim of this study, therefore, was to systematically review evidence from controlled trials on the efficacy of motor development interventions in young children."

Overall Coding for Q1:

□ If the answer to each of population, intervention and outcome is yes, then place a check mark in the **Yes** column. Otherwise, place a check mark in the **No** column.

Q2 | Provision of inclusion criteria

The review should clearly describe the criteria that were used to select included studies. This includes decisions related to the target population, intervention, outcome(s), as well as the research design (e.g., RCT, cohort, participatory). Using the descriptions "peer-reviewed" and/or "measurement of a quantitative outcome" in the inclusion criteria are NOT sufficient descriptions to count for study design.

If authors mention in their *exclusion* criteria that they rejected reviews, letters, editorials and case reports, but do not specifically address what they chose to *include*, mark a **No** for this criterion.

Overall Coding for Q2:

□ Place a check mark in the **Yes** column if selection criteria were clearly outlined.

Q3 | Comprehensive search strategy

A well-described comprehensive search strategy will include multiple database searches and a variety of other search strategies. Relevant databases, chosen based on the key concepts in the research question, will include those from <u>health databases</u> (e.g. MEDLINE, CINAHL, BIOSIS, EMBASE), <u>psychological databases</u> (e.g. PsycINFO), <u>social science databases</u> (e.g. sociological abstracts), and/or <u>educational databases</u> (e.g. ERIC). 'Other' databases may be used and should be described in the space provided (e.g. TRIP, Centre for Reviews and Dissemination (CRD), DARE, National Health Service Economic Evaluation Database/Health Economic Evaluations Database (NHS EED/HEED), National Health Service Health Technology Assessment (NHS HTA)). Google Scholar is categorized as an 'Other' database, while Google web search is an "unpublished (grey) literature" source.

For reviews measuring *specifically health-related outcomes* (e.g. vaccine effectiveness), **at least 2 health databases** need to be employed to allow for only *ONE* type of database to be searched. (**NOTE:** The two do not have to include MEDLINE)

'Column 2' search strategies include:

- → Handsearching journals of relevance to the review topic
- → Reference lists reference lists of relevant reviews and single studies should be reviewed for potential titles
- → Key informants should demonstrate consultation with experts in the field for relevant titles; this can include pharmaceutical representatives. 'Author's own collection' would also be coded as this.
- → Unpublished (grey) literature efforts to locate unpublished literature should be described. This can include the use of the electronic database SIGLE (which is specific to grey literature), and the searching of conference proceedings or scientific meetings. A Google search can be considered 'unpublished'.
- → Citation tracking a citation tracking tool (e.g. Web of Science) should be used to search for other related articles where included studies have been cited

NOTE: If the author(s) describe the manual searching of reference lists, score as 'Reference Lists', NOT as both 'Handsearching' *and* 'Reference Lists'.

Overall Coding for Q3:

□ To answer **Yes**, the author(s) should have used at least two strategies from each column (one database type may be appropriate, as described above). In addition to using at least two types of electronic databases, the author(s) must have utilized a minimum of two of the other strategies (i.e., handsearching; key informants; reference lists; and/or unpublished literature).

Q4 | Search strategy covers an adequate number of years

In order to ensure that the entire body of relevant research is included in the review, the search strategy should cover a sufficient time period. The number of years that are adequate to search for included studies will vary depending on the topic and the amount of literature being developed in that field. Generally, at least 10 years should be used as a minimum length of time, however, this may be increased if there has been little published in that time frame, or may be shortened if the review is an update of previous work, if there has been a large volume of literature published in a short time frame, or if the review is focused on a newer topic and/or a topic of relevance to a shorter timeframe, e.g. SARS.

Overall Coding for Q4:

□ Answer **Yes** if the search strategy covered enough years that it is unlikely that important studies were missed. The authors must state the years searched (e.g. "from database inception to... search end date").

Q5 | Level of evidence of included studies described

It is important to understand and to clearly describe the different levels of evidence contained within a review; the level of evidence of included studies can help to explain variations in results from study to study. Level 1 includes randomized controlled trials (RCTs), including quasi-randomized controlled trials. Level 2 includes non-randomized designs that contain a control group (e.g. case control; cohort). Level 3 includes all other uncontrolled designs (e.g. observational, case studies/series, modeling studies).

For reviews of reviews, select the level of evidence based on the types of included studies that appeared in the systematic reviews/meta-analyses included in the review of reviews.

Overall Coding for Q5:

□ Place a check mark in the **Yes** column if the study design(s) (e.g. review of reviews, RCTs, uncontrolled studies) of the included studies is clearly identified in the review; and, indicate the appropriate level of evidence.

Q6 Quality assessment of included studies

Each included study should be assessed for methodological quality using a standardized assessment tool/scale

For reviews of reviews:

If a review of reviews reports an <u>overall quality rating</u> for each included study (i.e., each included review), we rate this criterion Yes.

For reviews that use GRADE:

If a review shows a table of the GRADE assessment, that <u>includes assessment of Risk of Bias</u>, then we rate this criterion Yes. If the authors indicate they used GRADE, but they do not mention Risk of Bias or quality appraisal of included studies (in the methods or results sections), we rate this criterion No.

For reviews that do not mention use of GRADE:

Review authors need to do more than state their intent to extract quality-related data. They must also report their assessment of each quality criterion, for each included study.

A **minimum of four** of the following areas should be assessed and the results described (in narrative or table form for **each** included study) for **<u>quantitative studies</u>**:

- → *Research design* (most rigorous design given the research question)
- → Study sample (generalizability, baseline characteristics)
- → Participation rate
- → Sources of bias (confounders, respondent bias, blinding)
- → *Data collection* (measurement of independent and dependent variables, assessment tools).
- → Follow-up/attrition rates
- → Data analysis (e.g., intention-to-treat)

For **Cochrane Reviews** authors are required to conduct a standardized 'Risk of Bias' assessment (see <u>http://www.cochrane-handbook.org/</u> Figure 8.6a). Their results are typically included in the *Characteristics of Included Studies* table. These characteristics translate to the Health Evidence QA tool as follows:

If Cochrane Authors assess		On the Health Evidence QA tool select
Sequence generation	\rightarrow	Research design
Allocation concealment	\rightarrow	Research design
Blinding	\rightarrow	Source of bias
Free of selective reporting	\rightarrow	Data collection
Incomplete long-term/short-term outcome data (authors describe assessing intention-to-treat analysis & whether incomplete data was dealt with correctly)	\rightarrow	Data analysis

The **JADAD** and **EPOC** tools are well-reputed and typically code **Yes**, however they must still report the results of each criteria for each study. Systematic reviews from the Cochrane Library often employ criteria from the *Cochrane Reviewers' Handbook*, however it is important to clarify the areas of assessment as 4 out of the 7 are not always considered.

The British Medical Journal (*BMJ*), *Quality of Health Economic Studies* (*QHES*), *Consolidated Health Economic Evaluation Reporting Standards* (*CHEERS*) AND Consensus Health Economic Criteria (*CHEC*) tools are acceptable tools and typically code **YES** for reviews of economic evaluations, however they must still report the results of each criteria for each study. If the review is an effectiveness review and economic evaluation review the quality of both types of studies MUST be assessed to receive a **YES** for this question.

When review authors assess whether or not a primary study used a "validated measure(s)", this counts toward a point for *Data Collection*.

Use of a **Funnel plot** *can* be used towards a point for *Sources of Bias*, as long as it appears in the body of the paper and is part of a larger QA.

In some instances, different quality assessment criteria may be used for different study designs included in the same review. For example the EPOC tool has different criteria for interrupted time series studies, compared to randomized controlled trials. In this case, as long as the *majority* of reviews are assessed with 4+ criteria then **Yes** is appropriate.

NOTE: Reviews synthesizing <u>qualitative primary studies address questions on aspects other than</u> <u>effectiveness, and as such do not meet our relevance</u> criteria. Reviews synthesizing both quantitative and qualitative studies may be relevant to Health EvidenceTM if they include outcome data and evaluate the effectiveness of an intervention / program / service / policy.

Overall Coding for Q6:

□ For a review of quantitative studies, place a check mark in the **Yes** column if at least four of the seven criteria are assessed and reported on.

Q7 | Are quality assessments transparent?

For <u>guality assessments</u> to be transparent a minimum of two review authors should assess each included study, *independently*, for methodological quality and the method of conflict resolution described. A numerical level of agreement may be identified (i.e., Kappa), but is not required. If only inter-rater agreement scores are reported, however, review authors must report a Kappa score of at least 0.80 in order to score a **Yes** for this criterion.

Overall Coding for Q7:

- □ Place a check mark in the **Yes** column if two (or more) independent reviewers assessed each included study for methodological quality, with a method of conflict resolution identified.
- Q8 Did review authors assess appropriateness of combining study results (i.e., test of homogeneity, or assess similarity of results in some other way)?

It is important that primary study results be assessed for similarity prior to combining them (both statistically and/or non-statistically).

If a **meta-analysis** is conducted, a test for homogeneity or heterogeneity is the minimum requirement that should be assessed across studies prior to determining the overall effect size. If significant heterogeneity is detected, the author(s) should indicate use of a Random Effects Model, as opposed to a Fixed Effects Model.

On occasion, an author may indicate the presence of significant heterogeneity and still combine data using a Fixed Effects Model. This IS appropriate if analyses have been conducted with both the inclusion and exclusion of data sets that may notably skew results. The results of these separate analyses, however, MUST be reviewed for the reader's consideration. This process, often called 'sensitivity analysis', assesses the moderators that may have contributed to the heterogeneity.

If a **systematic review** or a **narrative review** is conducted for which statistical analysis is not appropriate, the results of each study should be depicted in graph/table format in order to assess similarity across the primary studies. Often the results will be in the form of a table, but in the case of a narrative review the results of each study will be described at length within the body of the review.

In some cases confidence intervals/effect sizes are *NOT* required. For a **review of reviews**, a narrative presentation is appropriate (e.g. "the intervention had a positive effect on 20% of participants); ideally, with a table listing main features of each of the systematic reviews under review, or thorough, CONSISTENT discussion of the main features in the body of the review. If the review of reviews doesn't consistently present the actual numerical results (e.g. effect sizes from the original reviews) in the text, then it should score a **No**.

In general, trust the review author(s)' judgment of what is significant heterogeneity. A declaration of the specific number that was calculated (e.g. Chi-square score) is not mandatory.

For economic evaluations, authors should describe how data across studies was aggregated/compared (e.g. method for converting results to one currency and accounting for inflation). If authors do not describe how aggregation was done then it should score a **No**.

NOTE: Despite extensive search strategies, some Cochrane reviews are unable to retrieve any applicable studies. In this case, a priori methodologies are often described. Subheadings alone, however, are sufficient to score a **Yes**, as Cochrane requires that they are filled in adequately before publication. Without a **Yes** for these criteria, these types of reviews will be of only *Moderate* quality, which may result in them being missed by users who are looking only for *Strong* reviews.

Overall Coding for Q8:

□ Place a check mark in the **Yes** column if a test of homo/heterogeneity has been conducted and the corresponding model applied, or if the individual study results have been disclosed graphically or narratively. Please note that if study results are listed narratively, the information must have been provided consistently for all studies within the review text.

Q9 | Weighting

Whether a meta-analysis or a systematic/narrative review the overall measure of effect should be determined by assigning those studies of highest methodological quality greater weight.

In a **meta-analysis**, weighting is typically based on a variety of factors including sample size, and variation in the outcome data. This is usually demonstrated by the size of the boxes in the forest plot.

If review authors have named a specific statistical software package (e.g. RevMan) they have used to combine data, this is sufficient for weighting, as the vast majority of this software incorporates the weighting of studies by a number of participants. Review authors may describe using the DerSimonian and Laird approach to random-effects meta-analysis which *also* incorporates weighting. Higgins and Green (2009) explain that:

"The random-effects method (DerSimonian 1986) incorporates an assumption that the different studies are estimating different, yet related, intervention effects [...] The method is based on the inverse-variance approach, making an adjustment to the study weights according to the extent of variation, or heterogeneity, among the varying intervention effects."

In a **narrative synthesis**, quality of EACH of the included studies must be discussed *consistently* throughout the conclusions/discussion section to receive a **Yes** for this criterion. If the authors show a GRADE assessment table, this qualifies as weighting for narrative syntheses.

If the authors set a threshold for the quality of reviews to be included in their synthesis (e.g., only synthesizing strong & moderate quality studies), this is considered weighting and we rate **Yes** for this criterion.

In a mixed-methods review which contains both a meta-analysis and a narrative synthesis, both should incorporate a discussion of quality into the analysis.

In some cases review authors disclose the QA scores of primary studies - in table format, for example - and discuss those scores, but do not actually 'weigh' them; essentially, allowing the readers to determine which ones have the most weight. This is *NOT* sufficient to score a **Yes** for this criterion, as the review authors should be doing all summative work.

Reviews that weight conclusions/discussion by included study quality still receive a **Yes** even if < 3 quality parameters were assessed (as per QA criterion #6).

For economic evaluations authors should state IF they have used any form of weighting of the evidence (either by methodological quality and/or size of the study for example) and if yes, then describe how studies were weighted. If they have done these activities, then answer **Yes** for this criterion.

Overall Coding for Q9:

□ Place a check mark in the **Yes** column if a weighting system has been used in determining the overall impact.

Q10 | Interpretation of results

Consider the reported data and assess whether the review author's interpretation of the results of the included studies are supported by the data. If no numerical values or p values/confidence intervals are given, then the reviewer cannot determine whether any conclusions are supported by the data and should respond **No** to criteria #10.

Overall Coding for Q10:

□ Place a check mark in the **Yes** column if the data for the included studies supports the interpretations outlined in the review.

Overall Coding for the Review

An overall assessment of the methodological quality of the review will be determined based on the results from each question. The total score is <u>out of 10</u>. Add all the check marks in the **Yes** column

and add to the Total column under **Yes**. Do the same for the **No** column. Use the following decision rule to determine the overall assessment for the review based on the numbers in the Total columns.

- → Reviews with a score of 8 or higher in the Yes column will be rated as Strong
- → Reviews with a score between 5-7 in the Yes column will be rated as Moderate
- → Reviews with a score of 4 or less in the Yes column will be rated as Weak

In the case that a score does not necessarily reflect your impression of the actual quality of a review (i.e., Strong/Moderate/Weak), consider revisiting some of the criteria and **Yes** and/or **No** scores, or discuss with a second reviewer, so that the corresponding quality category is a reflection of the review's overall methods and the score will be an accurate reflection for use by public health decision-makers.

This tool was adapted from:

Guyatt, G., Rennie, D., Meade, M.O., Cook, D.J. (Eds.). (2002). Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice. Chicago, Ill: AMA Press.

Guyatt, G., & Rennie, D. (Eds.). (2002). Users Guides to the Medical Literature: Essentials of Evidence-Based Clinical Practice. Chicago, III: AMA Press.