Reporting empty reviews and results from excluded studies

Sometimes no studies are found that meet the inclusion criteria for an EPOC review. This is sometimes referred to as an “empty review”. Suggestions regarding how to report an empty review and when and how to report results from studies that do not meet the inclusion criteria for a review are provided below.

Descriptions of the intervention and how the intervention might work

These two Background sections can provide readers with a basis for understanding the types of interventions that might have been included in the review, differences and similarities amongst potentially included interventions, how the interventions might work, and similarities and differences in how different types of interventions that meet the inclusion criteria might work. They can also provide a logic model that includes intermediary outcomes.

Sometimes review authors might want to revise this section based on information collected while conducting the review.

Objectives

The *primary objective* of EPOC reviews is to systematically summarise evidence of the effects of interventions. Occasionally, when it is anticipated that little if any reliable evidence of the effects of relevant interventions will be found, a *secondary objective* might be to describe the range of strategies that have been tried (but not evaluated rigorously) and to guide future evaluations of promising strategies for which there is insufficient evidence.

Types of studies

When a review has a secondary objective such as the one noted above, consideration should be given to systematically identifying other types of evidence, such as descriptive and evaluative case studies or modelling studies, to address that objective. Such studies might be used, for example, to identify:

- The range of strategies that have been tried and described
- Potentially promising strategies that have been used and warrant further evaluation
- Strategies that have been used and appear unlikely to warrant further evaluation (e.g. because they were found not to be feasible or acceptable)
- Potential adverse consequences of strategies

Consideration should be given to further specifying criteria that must be met for such studies to be included in an analysis that addresses a secondary objective, such as the above. These criteria may include the type of design, comparisons (where appropriate) and types of data (quantitative, qualitative, mixed) and analysis. For example, it might be specified that for a case study to be included, the intervention must be described clearly; the questions that the case study address must

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be stated explicitly and be relevant to at least one of the objectives of the secondary analysis; and the methods used to collect and analyse data must be stated. You should consult with the EPOC Information specialist regarding the best approaches to searching for these studies.
The criteria used should be stated in the *Methods* section under *Types of studies*.
It may not be worthwhile to update reviews of studies that do not address the primary objective of the review (i.e. evaluating the effects of interventions). Review authors should consider whether this is the case and, if so, state that updates of the review will focus only on studies meeting the primary inclusion criteria.

Data extraction and management
Consideration should also be given to systematically collecting data from studies that meet the secondary objectives of a review. The methods that are used to do this should be reported in the *Methods* section under *Data extraction and management*. For example: "For included case studies we will collect the following information: the design and data collection methods that were used, the main findings, the interpretation of the investigators and any factors that may have affected the reliability of the findings."

Assessment of the risk of bias
Consideration should also be given to how the risk of bias will be assessed for studies that address the secondary objective. For example:
For case studies that meet the inclusion criteria described above under Types of studies we will use the following criteria to assess the risk of bias. For each criterion we will judge whether it is met, unclear or not met and include the basis for those judgements in a risk of bias table.

- *The basis for case selection was appropriate.*
- *The time span of the study was long enough to address the core issues fairly.*
- *The methods for data collection were appropriate for the purpose of the study.*
- *The sources of information were appropriate for the purpose of the study.*
- *The methods used to analyze the data were appropriate for the purpose of the study.*
- *The methods used to identify explanatory factors were appropriate for the purpose of the study.*
- *The linkages are transparent between the data that were reported and inferences.*

In addition we will assess whether adequate information was provided to judge the applicability of the findings to other settings.

Differences between protocol and review
If the methods used to address a secondary objective were not reported in the protocol, they should be reported in the section 'Differences between protocol and review'. The same applies to methods used to address the primary objective using studies that did not meet the inclusion criteria for the review.

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Lengthy aspects of the protocol that were not implemented because no studies were found that met the inclusion criteria for the primary objectives should also be documented in the section 'Differences between protocol and review' (or in an appendix) rather than in the Methods section.

Results

The findings of studies that address a secondary objective or that address the primary objective, but did not meet the inclusion criteria for the review, should be reported in the results section under an appropriate heading. To add a user-defined heading:

1. Enter the heading text on a separate line.
2. Apply the relevant heading style using the pull-down list in the tool bar under Format and then Style.

Discussion

Occasionally studies that address a secondary objective or that address the primary objective, but did not meet the inclusion criteria for the review, will not have been systematically reviewed (i.e. the review did not search for these additional studies systematically). It may, nonetheless, be helpful to readers of the review to summarise key messages from studies that were identified while undertaking the review. In these circumstances, it may be best to consider these findings in the discussion section, acknowledging that such studies were not systematically reviewed. This should be done cautiously, since such non-systematic reviews are prone to the same sources of bias and errors as other non-systematic reviews.

Preparation of a table using systematic methods to extract and assess data from studies that did not meet the inclusion criteria for a review can help to reduce the risk of bias and errors in extracting and summarising data from these studies. It will not, however, reduce the risk of bias and errors in selecting studies to be included in the table or the discussion. When preparing such a table, consideration should be given to the same issues that are outlined above.

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