

Planning the review methods at protocol stage (C19-C23) 2

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	Standard	Rationale and elaboration	Resources
C19	<i>Planning the search</i>	Mandatory	
	Plan in advance the methods to be used for identifying studies. Design searches to capture as many studies as possible that meet the eligibility criteria, ensuring that relevant time periods and sources are covered and not restricted by language or publication status.	Searches should be motivated directly by the eligibility criteria for the review, and it is important that all types of eligible studies are considered when planning the search. If searches are restricted by publication status or by language of publication, there is a possibility of publication bias, or language bias (whereby the language of publication is selected in a way that depends on the findings of the study), or both. Removing language restrictions in English language databases is not a good substitute for searching non-English language journals and databases.	See <i>Handbook</i> (version 6), Section 1.5 ; 4.3.1.1 Cochrane Training resource: searching studies CIL: module 3 - searching for studies
C20	<i>Planning the assessment of risk of bias in included studies</i>	Mandatory	
	Plan in advance the methods to be used for assessing risk of bias in included studies, including the tool(s) to be used, how the tool(s) will be implemented, and the criteria used to assign studies, for example, to judgements of low risk, high risk and unclear risk of bias.	Predefining the methods and criteria for assessing risk of bias is important since analysis or interpretation of the review findings may be affected by the judgements made during this process. For randomized trials, use of the Cochrane 'risk of bias' tool is Mandatory, so it is sufficient (and easiest) simply to refer to the definitions of low risk, unclear risk and high risk of bias provided in the <i>Handbook</i> .	See <i>Handbook</i> (version 6), Section 1.5 Cochrane Training resource: risk of bias
C21	<i>Planning the synthesis of results</i>	Mandatory	
	Plan in advance the methods to be used to synthesize the results of the included studies, including whether a quantitative synthesis is planned, how heterogeneity will be assessed, choice of effect measure (e.g. odds ratio, risk ratio, risk difference or other for dichotomous outcomes), and methods for meta-analysis (e.g. inverse variance or Mantel Haenszel, fixed-effect or random-effects model).	Predefining the synthesis methods, particularly the statistical methods, is important, since analysis or interpretation of the review findings may be affected by the judgements made during this process.	See <i>Handbook</i> (version 6), Section 1.5 Cochrane Training resources: meta-analysis ; dichotomous outcomes ; continuous outcomes and heterogeneity CIL: module 6 - analysing the data
C22	<i>Planning sub-group analyses</i>	Mandatory	
	Predefine potential effect modifiers (e.g. for subgroup analyses) at the protocol stage; restrict these in number, and provide rationale for each.	Prespecification reduces the risk that large numbers of undirected subgroup analyses will lead to spurious explanations of heterogeneity.	See <i>Handbook</i> (version 6), Section 1.5 Cochrane Training resource: heterogeneity CIL: module 6 - analysing the data
	<i>Planning the GRADE assessment</i>	Mandatory	

C23	<i>and 'Summary of findings' table</i>		
	Plan in advance the methods to be used for assessing the quality of the body of evidence, and summarizing the findings of the review.	Methods for assessing the quality of evidence for the most important outcomes in the review need to be prespecified. In 'Summary of findings' tables the most important feature is to predefine the choice of outcomes in order to guard against selective presentation of results in the review. The table should include the essential outcomes for decision making (typically up to seven), which generally should not include surrogate or interim outcomes. The choice of outcomes should not be based on any anticipated or observed magnitude of effect, or because they are likely to have been addressed in the studies to be reviewed.	See <i>Handbook</i> (version 6), Section 1.5 Cochrane Training resource: evaluating evidence CIL: module 7 - interpreting the findings Planning GRADE and Summary of Findings tables