Selecting outcomes to be addressed for studies included in the review (C14-18)

Selecting outcomes to be addressed for studies included in the review

Cochrane Training resource: defining the review question

Cochrane Interactive Learning: module 2 - writing the review protocol

	Standard	Rationale and elaboration	Resources
C14	*Predefining outcome domains*	***Mandatory***	
	Define in advance which outcomes are primary outcomes and which are secondary outcomes.	Full specification of the outcomes includes consideration of outcome domains (e.g. quality of life) and outcome measures (e.g. SF-36). Predefinition of outcome reduces the risk of selective outcome reporting. The *primary outcomes* should be as few as possible and should normally reflect at least one potential benefit and at least one potential area of harm. It is expected that the review should be able to synthesize these outcomes if eligible studies are identified, and that the conclusions of the review will be based largely on the effects of the interventions on these outcomes. It is important to identify up to seven outcomes from the primary and secondary outcomes that will form the basis of the GRADE assessment.	See *Handbook* 5.4.2 Planning GRADE and Summary of Findings tables
C15	*Choosing outcomes*	***Mandatory***	
	Choose only outcomes that are important to users of the review such as healthcare consumers, health professionals and policy makers.	Cochrane Reviews are intended to support clinical practice and policy, and should address outcomes that are important to consumers. These should be specified at protocol stage. Where available, established sets of core outcomes should be used. Patient-reported outcomes should be included where possible. It is also important to judge whether evidence of resource use and costs might be an important component of decisions to adopt the intervention or alternative management strategies around the world. Large numbers of outcomes, while sometimes necessary, can make reviews unfocussed, unmanageable for the user, and prone to selective outcome reporting bias. Biochemical, interim and process outcomes should be considered where they are important to decision makers.	See *Handbook* 5.4.2
C16	*Predefining outcome measures*	***Highly desirable***	
	Define in advance details of what will constitute acceptable outcome measures (e.g. diagnostic criteria, scales, composite outcomes).	Having decided what outcomes are of interest to the review, authors should clarify acceptable ways in which these outcomes can be measured. It may be difficult, however, to predefine adverse effects.	See *Handbook* 5.4.1
C17	*Predefining choices from multiple outcome measures*	***Highly desirable***	
	Define in advance how outcome measures will be selected when there are several possible measures (e.g. multiple definitions, assessors or scales).	Prespecification guards against selective outcome reporting, and allows users to confirm that choices were not overly influenced by the results. A predefined hierarchy of outcomes measures may be helpful. It may be difficult, however, to predefine adverse effects. A rationale should be provided for the choice of outcome measure.	See *Handbook* 5.4.1
C18	*Predefining time points of interest*	***Highly desirable***	
	Define in advance the timing of outcome measurement.	Prespecification guards against selective outcome reporting, and allows users to confirm that choices were not overly influenced by the results. Authors may consider whether all time frames or only selected time points will be included in the review. These decisions should be based on outcomes important for making healthcare decisions. One strategy to make use of the available data could be to group time points into prespecified intervals to represent ‘short-term’, ‘medium-term’ and ‘long-	See *Handbook* 5.4.1

		term’ outcomes and to take no more than one from each interval from each study for any particular outcome.	