Selecting outcomes to be addressed for studies included in the review (C14-C18)

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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 outcomes that are critical to the review, and any additional important 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 <i>critical outcomes</i> 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. Additional important outcomes may also be specified. Up to seven critical and important outcomes will form the basis of the GRADE assessment and summarized in the review's abstract and other summary formats, although the review may measure more than seven	See Handbook <u>Section 3.2.4.1</u> <u>Planning GRADE and</u> <u>Summary of Findings tables</u>
		outcomes.	
C15	Choosing outcomes	Mandatory	
	Choose only outcomes that are critical or 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 critical or 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	See Handbook Section 3.2.4.1

		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. Any outcomes that would not be described as critical or important can be left out of the review.	
C16	Predefining outcome measures	÷ ;	
	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 <u>Section 3.2.4.1</u>
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 <u>Section 3.2.4.1</u>
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-term' outcomes and to take no more than one from each interval from each study for any particular outcome.	