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Standards for planning and conduct of UPDATES of Cochrane Intervention Reviews (U1-U11)

Key points and introduction

Key points:

- Before undertaking an update, authors should consider the currency and relevance of the question, as well as the methodology used to address it.
- A new protocol will be required if important changes are made to the review question or the general methodology.
- An update should be conducted according to the standards required for any review, with the following additional requirements to ensure that any changes are managed appropriately and reported clearly to readers

Since its inception, Cochrane has advocated for the routine updating of systematic reviews, in order to take account of new evidence. However, before undertaking an update, it is important to consider carefully whether an update is warranted. See Handbook Chapter IV, section 2 for a framework and checklist on deciding whether or when to update a Cochrane Review. All CRGs are encouraged to classify their reviews by their update status, to denote whether the review is up to date, an update is pending or no update is planned (see the Updating Classification System).

Several important decisions are required at the beginning of the planning of an update. The first is whether the original review question is still relevant. The second is whether the general methodological approach is still appropriate to answer the review question: this will need a review of the original protocol. Third, authors need to address whether the scope of the review is appropriate, whether it should be split into two or more reviews, or whether it should be merged with other reviews. Important changes of this nature indicate a need for a new protocol.

The following updating standards reflect two key stages: planning and conducting the update. Expectations are that review authors will consider each of these sections before updating a review. Authors should examine and address any feedback on the original review before embarking on an update or a new derivative review. Planning an update should involve discussion with the Cochrane Review Group (CRG) over the adoption of new methods or changes to the review question proposed. The following standards for updates should be used in conjunction with the conduct and reporting standards for new Cochrane Reviews and these are cited where necessary.

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Deciding on and performing an update (U1-U11)

Planning the update (U1-U5)

Planning the update

	Standard	Rationale and elaboration	Resources
U1	<i>Reconsidering review questions</i>	Mandatory	
	Confirm or amend review question (PICO) and objectives.	Consider whether it is important to modify or add new objectives to make the review relevant to its users. Consider whether the review will be split, merged with another review or otherwise	See Handbook Section IV.3.1 , Section 2.1 and Section 2.3

		<p>changed substantially. If so, a new protocol might be warranted and the <i>MECIR conduct standards</i> should be followed rather than these <i>update standards</i>. It will be necessary to agree the approach to updating the review with the CRG.</p> <p>MECIR conduct standards C1, C2</p>	
U2	<i>Reconsidering outcomes</i>	Mandatory	
	Confirm or amend outcomes of interest	<p>Consider whether it is necessary to modify or add outcomes to ensure all user-important outcomes, including adverse effects, are addressed. Define which outcomes are primary outcomes and which are secondary outcomes. Keep the total number of outcomes as small as possible. Consider core outcome sets where available. Prioritize outcomes that will be assessed with the GRADE considerations.</p> <p>MECIR conduct standards C3, C14-C18, C23</p>	<p>See Handbook Section 1.5, Section 2.1, Section 3.2.4.1, Section 5.4.1</p>
U3	<i>Reconsidering eligibility criteria</i>	Mandatory	
	Confirm or amend eligibility criteria.	<p>Changes to the review objectives (e.g. additional consideration of rare adverse effects, economic issues or qualitative issues) may require modification of the eligibility criteria, possibly extending the scope to additional types of studies.</p>	
U4	<i>Planning the search</i>	Mandatory	
	Decide appropriate search methods	<p>There are four considerations in planning search methods for updates:</p> <ol style="list-style-type: none"> 1. Changes to eligibility criteria may require the search methods to be modified, or additional search strategies to be developed. 2. Additional sources might need to be searched (e.g. trials registers) if not searched for the last published version of the review. Consideration should also be given to the importance of 	<p>See Handbook Section IV.3.4</p> <p>Study flow diagrams in Cochrane systematic review updates: an adapted PRISMA flow diagram</p>

		<p>searching data repositories and information available from regulatory agencies.</p> <p>3. The update search (for unchanged eligibility criteria) will normally be limited to material added or indexed after the date of the previous search. The yield of the previous searches may be useful to decide whether the full search is repeated or whether only a subset of sources should be searched for the update.</p> <p>4. The original database search strategies may need to be modified, for example by adding search terms, adding new database subject headings, or by removing unhelpful search terms that identified many irrelevant studies in the original search.</p> <p>MECIR update standards U6 and UR3</p>	
U5	<i>Reconsidering data collection and analysis methods</i>	Mandatory	
	<p>Consider whether methods for data collection and analysis (including a GRADE assessment) need to be amended in the light of recent methodological developments.</p>	<p>Decide if changes are required to make better use of existing data or to incorporate new data by referring to the current version of the Handbook. Recent developments in 'Risk of bias' assessment, statistical methods or narrative synthesis approaches may lead to more inclusive or more robust synthesis of the evidence.</p> <p>The GRADE assessment will require evaluation of risk of bias, inconsistency, imprecision, indirectness and publication bias. See MECIR update standard U11.</p> <p>If a 'Summary of findings' table is not included in the current version, decide on the main outcomes and comparisons to be included and ensure that the relevant data have been (or will</p>	<p>Planning GRADE and SoF tables.</p>

		be) collected. See MECIR update standard UR5 MECIR update standards U9-U10	
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Conduct standards specific to updates (U6-U11)

Conduct standards specific to updates

	Standard	Rationale and elaboration	Resources
U6	<i>Searching</i>	Mandatory	
	Undertake a new search	An updated review must include an update search for new (or additional) studies. For issues to consider in planning the search, see MECIR update standard U4 . The most recent search must be no more than 12 months (preferably six months) from the intended publication date, and the results screened for potentially eligible studies. See MECIR conduct standard C37 : Rerun or update searches for all relevant databases within 12 months before publication of the review or review update, and screen the results for potentially eligible studies.	See <i>Handbook</i> Section IV.4 and Section 4.4.10
U7	<i>Including new studies</i>	Mandatory	
	Implement conduct standards for study selection and data collection for any newly identified studies (with updated criteria or methods as determined above).	MECIR conduct standards C39 - C51	See <i>Handbook</i> Section 4.4.6 , Section 5.3.6 , Section 4.6.3 , Section 4.6.4 , Section 4.6.2 , Section 5.2 , Section 5.2.1 , Section 5.2.3 , Section 5.3.1 , Section 5.3.6 , Section 5.4.1 and Section 5.5.2
U8	<i>Reconsider previously identified studies</i>	Mandatory	
	Consider studies previously identified as included, awaiting classification, ongoing and excluded, and collect additional information from them if necessary.	Ensure appropriate methodology is followed to select included studies and collect information from them. It will be necessary to establish whether any studies previously identified as ongoing have now been completed. Ensure that reasons for excluding studies are consistent with current eligibility	

		<p>criteria and methodological standards.</p> <p>A redesign of the data collection form may be required if review questions or objectives have been modified.</p>	
U9	<i>Assessing risk of bias</i>	Mandatory	
	Ensure all studies are consistently assessed for risk of bias.	<p>The updated review must include a 'Risk of bias' assessment of all new and previously included studies. If the previous version used the original risk of bias tool to assess randomised trials, consider whether or not to switch to the Risk of Bias 2 tool (see <i>Handbook</i> (version 6) Chapter 8), including how many randomised trials were assessed in the previous version, how many new studies are expected for inclusion in the update, how well it was implemented in the previous version and whether it is feasible to switch.</p> <p>MECIR conduct standards C52 - C60</p>	<p>See <i>Handbook</i> Section 7.1.2, Section 7.3.2, Section 7.5, Section 7.6.1, Section 7.8.6 and Chapter 8.</p>
U10	<i>Synthesizing results</i>	Mandatory	
	Implement review synthesis methods (possibly revised for the update) according to conduct standards for synthesis, across all included studies.	<p>MECIR conduct standards C61 - C73</p>	<p>See <i>Handbook</i> Section 6.2.1, Section 6.2.9, Section 10.5.3, Section 10.10.2, Section 10.10.3, Section 10.11.3.1, Section 10.11.5.2, Section 10.12.1, Section 10.14, Chapter 11, Section 13.4, Section 15.3.1.</p>
U11	<i>Assessing the certainty of evidence</i>	Mandatory	
	Assess certainty of evidence using GRADE considerations of risk of bias, inconsistency, imprecision, indirectness and publication bias.	<p>This must be applied to the full body of evidence for the key outcomes included in the updated review. The most convenient way to present GRADE assessments is in a 'Summary of findings' table.</p> <p>MECIR conduct standards C74-C75 and MECIR reporting standard R97</p>	<p>See <i>Handbook</i> Section 14.2.1</p>

Reporting standards specific to updates (UR1-UR7)

Reporting standards specific to updates

	Standard	Rationale and elaboration	Resources
UR1	<i>Background</i>	<i>Mandatory</i>	
	Review and update background as necessary to reflect changes over time.	Examples of changes that should be addressed include updated estimates of disease burden, new understanding of how people are affected by the disease or condition, new insights into mechanisms of action, or changes in policy or practice. Up-to-date references should be supplied to support this information.	See Handbook Section IV.5
UR2	<i>Changes to scope</i>	<i>Mandatory</i>	
	Explain any changes to questions, objectives or eligibility criteria.	Motivations to amend review questions and objectives for the update (such as addition of new interventions, or concerns over adverse effects) should be explained in the Background, and changes to eligibility criteria should be explained, dated and justified as 'Differences between the protocol and the review'.	
UR3	<i>Search for studies</i>	<i>Mandatory</i>	
	Describe the update search.	Describe which sources of information were searched for the update, and how. If any of the sources originally searched were not searched for the update, this should be explained and justified. There are at least four possibilities for providing information about search methods in an updated review: <ol style="list-style-type: none"> 1. An <i>integrated</i> approach is to describe all searches together, which may be most feasible if the same search was repeated. 2. An <i>incremental</i> approach is to add information at each update to describe explicitly which searches were done for the update, retaining all information about previous searches. 3. A <i>replacement</i> approach is to describe only the searches done for the update, using the previous review as one source of studies. 	See Handbook Section IV.5

		4. A <i>hybrid</i> approach is to describe only the searches done for the update in the main text, using Appendices to provide information about previous searches.	
UR4	<i>Flow of studies</i>	Mandatory	
	Record the flow of studies.	<p>Provide information on the flow of studies into the updated review, using a PRISMA type flow diagram. There are two broad options for providing information about how studies were identified that are included in the updated version of the review:</p> <ol style="list-style-type: none"> 1. The results of previous searches can be retained in the review and supplemented with information about studies identified in the update. 2. Alternatively, only information about searches in the current update can be presented, with the previous version of the review serving as one particular source of studies. <p>Either approach is acceptable. If taking the latter approach, the flow diagram should show one box for the number of studies included in the original review or previous update and an additional box for the new studies retrieved for the current update. If multiple searches have been conducted for the current update, the results of all the searches should be added together.</p>	See Handbook Section IV.5
UR5	<i>"Summary of findings" tables</i>	Highly desirable	
	Present a 'Summary of findings' table according to recommendations described in the Handbook (version 5 or later). Specifically, include results for one clearly defined population group (with few exceptions).	Efforts should be made to incorporate information presented in 'Summary of findings' tables (such as absolute effects, GRADE certainty ratings and downgrading decisions) in other parts of the review including the Abstract, Plain language summary, Effects of	See Handbook Chapter 14 Common issues in Summary of Findings tables

		interventions, Discussion and Authors' conclusions.	
UR6	<i>Integrating findings</i>	Mandatory	
	Present findings integrated across new and previously included studies and not just for the new studies (in the main text, Abstract, 'Summary of findings' tables and Plain language summary).	The main findings should be presented for the totality of evidence: it is not helpful to a new reader to be told about incremental updates to the evidence base. However, the impact of new evidence on review findings may be useful to draw on when interpreting the results.	
UR7	<i>What's new?</i>	Mandatory	
	Explain what's new.	<p>It is important that changes are explained to inform returning readers about what's new. This should be achieved in several ways.</p> <p>A comment should be inserted to explain that the review is an update of a previously published review. This might be placed at the beginning or end of the Background or the start of the section 'Search methods for identification of studies'. It can be helpful to explain also whether the article describes the first, second, third and so on update of the review.</p> <p>Changes in review questions, eligibility criteria and methods should be reported in the section 'Differences between protocol and review', making it clear that they are changes since the previous version.</p> <p>Changes in findings must be reported and dated in the 'What's new' section. This should include the numbers of new studies and participants in those studies; and the nature of any changes in assessments of the certainty of the evidence (e.g. using GRADE) and in the clinical implications of the findings. For particularly notable changes it is useful to comment on these within the text of the review.</p>	See <i>Handbook</i> Section IV.5 Common issues in Summary of Findings tables

Citation

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