May the CSG have MECIR on me

COCHRANE SKIN GROUP
MANAGING EDITOR
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MECIR

- **M**ethodological **E**xpectations of **C**ochrane **I**ntervention **R**eviews
  - Set of conduct standards
  - Set of reporting standards
  - Set of standards for plain language summaries (PLEACS)

  - Currently for new not updated reviews

MECIR

- Developed by editors & methodologists, feedback incorporated from Cochrane entities
- Explicitly draws on Handbook advice
- Intended to provide clarity to authors, CRGs, editors & readers
  - What should be done in conducting a review
  - What the review should report

Conduct

Methodological Expectations of Cochrane Intervention Reviews (MECIR)

Methodological standards for the conduct of new Cochrane Intervention Reviews (2.2)

Cochrane Reviews are seen as exemplifying best practice in the quality of both their conduct and reporting. The standards below summarize proposed attributes of the conduct of reviews of interventions described in the *Cochrane Handbook* that have been established as either mandatory (M) or highly desirable (HD) for new Cochrane Reviews. For more information on the MECIR project: www.editorial-unit.cochrane.org/mecir

Julian Higgins, Rachel Churchill, Toby Lasserson, Jackie Chandler and David Tovey

No	Item name	Standard	*H'bk*
C1	Formulating review questions (M)	Ensure that the review question and particularly the outcomes of interest, address issues that are important to stakeholders such as consumers, health professionals and policy makers.	2.3.2 2.3.4 17.2 20.2.2
C2	Pre-defining objectives (M)	Define in advance the objectives of the review, including participants, interventions, comparators and outcomes.	5.1.1
C3	Considering potential adverse effects (M)	Consider any important potential adverse effects of the intervention(s) and ensure that they are addressed.	5.4.3 14.1.1 14.3
C4	Considering equity and specific populations (HD)	Consider in advance whether issues of equity and relevance of evidence to specific populations are important to the review, and plan for appropriate methods to address them if they are. Attention should be paid to the relevance of the review question to populations such as low socioeconomic groups, low or middle income regions, women, children and older people.	
C5	Pre-defining unambiguous criteria for participants (M)	Define in advance the eligibility criteria for participants in the studies.	5.2
C6	Pre-defining a strategy for studies with a subset of eligible participants (HD)	Define in advance how studies that include only a subset of relevant participants will be handled.	5.2
C7	Pre-defining unambiguous criteria for interventions and comparators (M)	Define in advance the eligible interventions and the interventions against which these can be compared in the included studies.	5.3
C8	Clarifying role of outcomes (M)	Clarify in advance whether outcomes listed under 'Criteria for considering studies for this review' are used as criteria for including studies (rather than as a list of the outcomes of interest within whichever studies are included).	5.1.2
C9	Pre-defining study designs (M)	Define in advance the eligibility criteria for study designs in a clear and unambiguous way, with a focus on features of a study's design rather than design labels.	5.5 13.2.2

No	Item name	Standard	*H'bk*
C39	Making inclusion decisions (M)	Use (at least) two people working independently to determine whether each study meets the eligibility criteria, and define in advance the process for resolving disagreements.	7.2.4
C40	Excluding studies without useable data (M)	Include studies in the review irrespective of whether measured outcome data are reported in a 'usable' way.	5.4.1
C41	Documenting decisions about records identified	Document the selection process in sufficient detail to complete a PRISMA flow chart and a table of 'Characteristics of excluded studies'.	6.6.1* 11.2.1*
C42	Collating multiple reports (M)	Collate multiple reports of the same study, so that each study rather than each report is the unit of interest in the review.	7.2.1 7.2.2 7.6.4
C43	Using data collection forms (M)	Use a data collection form, which has been piloted.	7.5
C44	Describing studies (M)	Collect characteristics of the included studies in sufficient detail to populate a table of 'Characteristics of included studies'.	7.3 11.2
C45	Extracting study characteristics in duplicate (HD)	Use (at least) two people working independently to extract study characteristics from reports of each study, and define in advance the process for resolving disagreements.	7.6.2 7.6.5
C46	Extracting outcome data in duplicate (M)	Use (at least) two people working independently to extract outcome data from reports of each study, and define in advance the process for resolving disagreements.	7.6.2
C47	Making maximal use of data (M)	Collect and utilize the most detailed numerical data that might facilitate similar analyses of included studies. Where 2×2 tables or means and standard deviations are not available, this might include effect estimates (e.g. odds ratios, regression coefficients), confidence intervals, test statistics (e.g. t, F, Z, chi-squared) or P values, or even data for individual participants.	7.7
C48	Examining errata (HD)	Examine any relevant retraction statements and errata for information.	6.4.10
C49	Obtaining unpublished data (HD)	Seek key unpublished information that is missing from reports of included studies.	7.4.2
C50	Choosing intervention groups in multi-arm studies (M)	*If a study is included with more than two intervention arms*, include in the review only intervention and control groups that meet the eligibility criteria.	16.5.2

What do we mean by conduct?

- **Process** for doing a systematic review
  - **Pre-defining** objectives & criteria (C2, C5)
  - **Assessing** studies for inclusion (C5 to C13)
  - **Collecting** data (C43 to C61)
  - **Analysing** data (C62 to C74)

Reporting

Methodological Expectations of Cochrane Intervention Reviews (MECIR)

Methodological standards for the reporting of new Cochrane Intervention Reviews (1.1)

Cochrane Reviews are seen as exemplifying best practice in the quality of both their conduct and reporting. The standards below summarize proposed attributes of the reporting of reviews of interventions described in the *Cochrane Handbook* that have been established as either mandatory (M) or highly desirable (HD) for new Cochrane Reviews. For more information on the MECIR project: www.editorial-unit.cochrane.org/mecir

Jackie Chandler, Rachel Churchill, Julian Higgins, Toby Lasserson and David Tovey

No	Item name	Standard	H C or P**
R1	Format of title (HD)	Follow the standard template for a Cochrane review title.	H 4.2.a
R2	Authors (M)	List names and affiliations of all authors	H 4.2.2
R3	Writing the abstract (M)	Prepare a structured abstract to provide a succinct summary of the review. In the interests of brevity it is highly desirable for authors to provide an abstract of less than 700 words, and it should be no more than 1000 words in length.	H P 2
R4	Abstract, Background (M)	Summarize the rationale and context of the review.	H 11.1
R5	Abstract, Objectives (M)	State the main objective(s), preferably in a single concise sentence	H 11.1
R6	Abstract, Search methods (M)	Provide the date of the last search from which records were evaluated and any studies identified were incorporated into the review, and an indication of the databases and other sources searched.	
R7	Abstract, Selection criteria (M)	Summarize eligibility criteria of the review, including information on study design, population and comparison.	
R8	Abstract, Data collection and analysis (M)	Summarize any noteworthy methods for selecting studies, collecting data, evaluating risk of bias and synthesizing findings. For many reviews it may be sufficient to state "We used standard methodological procedures expected by The Cochrane Collaboration."	
R9	Abstract, Main results: number of studies and participants (M)	Report the number of included studies and participants.	
R10	Abstract, Main results: study characteristics (HD)	Provide a brief description of key characteristics that will determine the applicability of the body of evidence (e.g. age, severity of condition, setting, study duration).	
R11	Abstract, Main results: bias assessment (M)	Provide a comment on the findings of the bias assessment.	

No	Item name	Standard	H C or P**
R57	Excluded studies (M)	List key excluded studies and provide justification for each exclusion.	H 7.2.5.
R58	Studies awaiting classification (HD)	List the characteristics of any studies that have been identified as potentially eligible but have not been incorporated into the review.	
R59	Ongoing studies (M)	Provide details of any identified studies that have not been completed.	
R60	Table of 'Characteristics of included studies' (M)	Present a table of 'Characteristics of included studies' using a uniform format across all studies.	C 44 P 18
R61	Included studies (M)	Provide a brief narrative summary of any included studies. This should include the number of participants and a summary of the characteristics of the study populations and settings, interventions, comparators and funding sources.	H 4.5
R62	Table of 'Characteristics of included studies': sample sizes (M)	Include the sample size for each included study in the table of 'Characteristics of included studies'.	
R63	Table of 'Characteristics of included studies': methods (M)	Provide the basic study design or design features (e.g. parallel group randomized trial, cluster-randomized trial, controlled before and after study).	H 13.2 P 18
R64	Table of 'Characteristics of included studies': participants (M)	Provide sufficient information about the study populations to enable a user of the review to assess the applicability of the review's findings to their own setting.	P 18
R65	Table of 'Characteristics of included studies': interventions (M)	Provide sufficient information to enable users of the review to assess the applicability of the intervention to their own setting, and if possible in a way that allows the intervention to be replicated.	P 18
R66	Table of 'Characteristics of included studies': outcomes (M)	Provide clear and consistent information about outcomes measured (or reported), how they were measured and the times at which they were measured.	

What do we mean by reporting?

- How processes or outputs are conveyed to a reader
  - **Describing** search (R34-38) or data collection (R40,41) process
  - **Presenting** graphical overview of bias assessments (R72,74)
  - **Reporting** findings of analyses (R81)
  - **Commenting** on strength of evidence or applicability of review findings (R88)

MECIR

- Developed from PRISMA
- In MECIR each item considered either
  - Mandatory (compliance required for publication)
  - Highly desirable (generally should be done)
- Some are expectations of process
  - Duplicate data collection (mandatory)
  - Searching reference lists of other reviews (highly desirable)

MECIR

- Some standards are fairly obvious
  - List names and affiliations of all the review authors (R2)
  - Back up all key supporting statements with references (R21)
  - List all sources searched (R34 follows from C36)

- Some necessitate degree of judgment
  - Tools used to assess risk of bias (R46 follows from C52)

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- Some conditional on review question
  - *If health economics evidence is being reviewed*, state this explicitly in the Objectives (as secondary objective) (R24-25)

- Some conditional on review results
  - *If a review identifies no eligible studies*, restrict the Results section to a description of the flow of studies and any brief comments about reasons for exclusion of studies (R56)

Summary of Findings

We are now adding a sentence under Data Collection & Analysis:

> **'We plan to include at least one Summary of Findings table in our review. In this we will summarise the primary outcomes for the most important comparison. If we feel there are several major comparisons or that our findings need to be summarised for different populations we will include further Summary of Findings tables'.**

This is because we are encouraging all author teams to include Summary of Findings tables (see MECIR C75 and 76).

C75	Highly desirable	Including a 'Summary of Findings' table	Include a 'Summary of Findings' table according to recommendations described in Chapter 11 of the Cochrane Handbook (version 5 or later). Specifically: • include results for one population group (with few exceptions); • indicate the intervention and the comparison intervention; • include seven or fewer patient-important outcomes; • describe the outcomes (e.g. scale, scores, follow-up); • indicate the number of participants and studies for each outcome; • present at least one baseline risk for each dichotomous outcome (e.g. study population or median/medium risk) and baseline scores for continuous outcomes (if appropriate); • summarize the intervention effect (if appropriate); and • include a measure of the quality of the body of evidence.	These are standards which should be consistently applied across reviews. Authors should justify why a 'Summary of Findings' table is not included if this is the case.	11.5
C76	Mandatory	Assessing the quality of the body of evidence	Use the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for each outcome, and to draw conclusions about the quality of evidence within the text of the review.	GRADE is the most widely used system for summarising confidence in effects of the interventions by outcome across studies. It is preferable to use the GRADE tool (as implemented in GRADEprofiler and described in the help system of the software). This should help to ensure that author teams are accessing the same information to inform their judgments. Ideally, two people working independently should assess the quality of the body of evidence. The five GRADE considerations should be addressed irrespective of whether the review includes a 'Summary of Findings' table.	12.2
C77	Mandatory	Justifying assessments of the quality of the body of evidence	Justify and document all assessments of the quality of the body of evidence (for example downgrading or upgrading if using the GRADE tool).	By adopting a structured approach, transparency is ensured in showing how interpretations have been formulated and the result is more informative to the reader.	12.2.
	Reaching conclusions				
C78	Mandatory	Formulating implications for	Base conclusions only on findings from the synthesis (quantitative or narrative) of	The conclusions of the review should convey the essence of the synthesis of included studies, without selective reporting of particular findings on the basis of the	12.7.

PLS

Methodological Expectations of Cochrane Intervention Reviews (MECIR)

Standards for the reporting of Plain Language Summaries in new Cochrane Intervention Reviews (PLEACS)

Version 3.0 28 February 2013

Status: Mandatory means that a new review should not be published if this is not reported. Highly desirable means that this should generally be done, but that there are justifiable exceptions.

Preface

Plain Language Expectations for Authors of Cochrane Summaries (PLEACS) have been established by a special working group comprised of consumers, methodologists and editors from The Cochrane Collaboration. During 2012, this group developed a set of standard requirements for plain language summaries (PLS) of Cochrane Intervention Reviews. This work complements the MECIR project which has so far delivered standards relating to the conduct and reporting of Cochrane Intervention Reviews (see: http://www.editorial-unit.cochrane.org/mecir).

The standards below summarize proposed attributes of reporting that we consider either mandatory or highly desirable for PLS of Cochrane Intervention Reviews. For each standard we have given a reason for our judgment alongside some examples.

During July and August 2012, members of the collaboration and the public were invited to comment on the draft standards through an open consultation process. Key comments revolved around the issues of 1) reading age for PLS, 2) the presentation of information about systematic reviews and Cochrane in PLS, 3) the use of headings to break-up the text, and 4) explanations about the quality of the evidence. The working group reviewed all the comments and amended the standards in response.

The ordering of the standards reflects the position in which each issue might be expected to be addressed in the PLS. Work on establishing the most suitable format for structuring the PLS is ongoing and as an interim measure we have associated each standard with provisional considerations to help orientate authors, editors and readers (*see PLS3 below*).

During the early part of 2013, the PLEACS working group will begin development of good-practice examples to aid authors and Cochrane Review Groups implement the standards

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MECIR

- Plain language summary 12 standards
  - Clear title
  - Population of interest
  - The primary outcome
  - Lay description of the quality of the evidence
  - Consistency with the abstract and review
  - Jargon-free
  - International audience

International audiences

Cochrane summary translations now in

French: 3936
Spanish: 5124
Croatian: 111
Portuguese: 44
Traditional Chinese: 64
Simplified Chinese: 100

http://summaries.cochrane.org/

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International audiences

- MECIR
  - The Iberoamerican Cochrane Centre has translated the conduct and reporting standards into Spanish.

MECIR in languages other than English

Expectativas metodológicas de las revisiones Cochrane de intervenciones

Methodological expectations of Cochrane intervention reviews

(MECIR)

Estándares metodológicos para la realización y para el informe de nuevas revisiones Cochrane de intervenciones

Traducción a cargo del Centro Cochrane Iberoamericano

Estándares de realización correspondientes a la versión 2.2. y Estándares de informe correspondientes a la versión 1.1.