Session overview

MECIR: brief history

CEU review screening & use of MECIR

MECIR 2.0
MECIR standards

Developed from existing Handbook guidance
Chapter 6: Searching for studies

Authors: Carol Lekhena, Eric Whitmore and Julia Granville on behalf of the Cochrane Information Retrieval Methods Group.

Key points:
- Search terms should start with the Cochrane Registry of Studies (CRS) and the Cochrane Systematic Review (CSR).
- A systematic search of the literature should be conducted using a combination of search terms.
- The search strategy should be reported in the review.

Search methods for systematic reviews:

- Mandatory: Search key databases
- Highly sensitive: Search for highly sensitive studies
- Additional: Search for additional studies
- Latest searches: Provide the date of the last search and the issue of the systematic review

MECIR conduct standard: Document the search process in enough detail to ensure that it can be reported correctly in the review.

Also MECIR conduct standard 1.4 – 1.7 (PRISMA item 7)
MECIR standards

Developed from existing Handbook guidance

Extensive consultation process
# Development of methodological standards for the conduct of intervention reviews

## Annex 2: Feedback and response to consultation

7 October 2011

<table>
<thead>
<tr>
<th>Item number</th>
<th>Status</th>
<th>Item description</th>
<th>Expectation (new/standard)</th>
<th>Change status to...?</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
<td>101</td>
<td>Mandatory</td>
<td>Focusing review questions</td>
<td>Ensure that the review question, and particularly the outcomes of interest, address issues that are important to stakeholders, such as providers</td>
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<td>CR025: Focusing review questions should be clear and unambiguous, not just a statement of the question. There is no specific requirement for the question to be phrased in terms of relative effectiveness.</td>
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<tr>
<td>102</td>
<td>Highly desirable</td>
<td>Focusing review questions</td>
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</table>
MECIR standards

Developed from existing Handbook guidance

Extensive consultation process

Never apply all at once
MECIR standards

Developed from existing Handbook guidance

Extensive consultation process

Never apply all at once

Supported: Software prompts for users
**Abstract**

Continuous Positive Airways Pressure (CPAP) is considered to be the cornerstone of therapy for obstructive sleep apnoea (OSA). However, compliance with this treatment is frequently poor, which may lead to ongoing symptoms of sleep disruption, daytime sleepiness and poor waking cognitive function. Mechanical interventions which involve changing the way that positive pressure is delivered, and the addition of humidification, might improve compliance.

**Objectives**

To determine the efficacy of pressure level modifications and additional humidification in increasing CPAP machine usage.

**Search methods**

We searched the Cochrane Airways Group Specialised Register (September 2008).

**Selection criteria**

Randomised controlled trials (RCTs) assessing interventions to improve compliance with CPAP usage. Control groups received fixed pressure CPAP.

**Data collection and analysis**

Two authors assessed articles for inclusion in the review and extracted data. We made attempts to obtain additional unpublished data from the trialists.

**Main results**

Forty-five studies met the inclusion criteria (1874 participants). Auto-CPAP (38 studies, 1136 participants) had a statistically significant difference in machine usage of 0.21 hours/night (0.08 to 0.35) was observed in favour of auto-CPAP from cross-over studies. This difference is of questionable clinical significance. Pooled effect estimates from parallel group trials detected a similar sized difference for average nightly machine usage, but this was not statistically significant. Evidence from parallel group studies did not identify a statistically significant difference between pressure modes in Epworth Sleepiness Scores, but there was an overall reduction of 0.64 units with cross-over studies (-0.12 to -1.16) in favour of auto-CPAP. Parallel group studies did not identify a significant difference. More participants preferred auto-CPAP to fixed CPAP where this was measured. Bi-level PAP (six studies, 265 participants): no significant differences were observed in machine usage. One small study found no difference in preference. C-Flex (six studies, 318 participants): no significant difference was observed in machine usage.

Humidification (three studies, 135 participants): there were conflicting findings between the studies. Two parallel group trials found no significant difference in machine usage, whereas a cross-over study found a significant difference.

**Authors’ conclusions**

Improvement in average machine use of auto-CPAP was superior in studies with a cross-over design; the point estimate in parallel group trials was similar, but did not reach statistical significance. It is uncertain how use of machines in study settings relates to real world use. Where
Screening

Spot the missing piece
## Implementation of protocol methods

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Item name</th>
<th>Standard</th>
<th>Met?</th>
<th>Comment</th>
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</thead>
<tbody>
<tr>
<td>C27</td>
<td>Searching trials registers</td>
<td>Search trials registers and repositories of results, where relevant to the topic through ClinicalTrials.gov, the WHO International Clinical Trials Registry Platform (ICTRP) portal and other sources as appropriate.</td>
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<tr>
<th>Item No.</th>
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<th>Met?</th>
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<tbody>
<tr>
<td>C37</td>
<td>Re-running procedures</td>
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<tr>
<td>C76</td>
<td>Assessing the quality of the body of evidence</td>
<td>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.</td>
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<tr>
<td>C80</td>
<td>Excluding studies without data</td>
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<tr>
<td>R97</td>
<td>‘Summary of findings’ table</td>
<td>Present 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 clearly defined population group (with few exceptions); indicate the intervention and the comparison intervention; include seven or fewer patient-important outcomes; describe the outcomes (e.g. scales, scores, follow-up).</td>
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<tr>
<td>C68</td>
<td>Comparing subgroups</td>
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<tr>
<td>C73</td>
<td>Interpreting results</td>
<td>Interpret a statistically non-significant P value (e.g. larger than 0.05) as a finding of uncertainty unless confidence intervals are sufficiently narrow to rule out an important magnitude of effect.</td>
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<tr>
<td>C78</td>
<td>Formulating implications for practice</td>
<td>Base conclusions only on findings from the synthesis (quantitative or narrative) of studies included in the review.</td>
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## Completeness of reporting in the abstract & Internal consistency

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Item name</th>
<th>Standard</th>
<th>Met?</th>
<th>Comment</th>
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<tbody>
<tr>
<td>R11</td>
<td>Abstract, Main results: bias assessment</td>
<td>Provide a comment on the findings of the bias assessment.</td>
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<tr>
<td>R12</td>
<td>Abstract, Main results: findings</td>
<td>Report findings for all primary outcomes, irrespective of the strength and direction of the result, and of the availability of data.</td>
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<tr>
<td>R13</td>
<td>Abstract, Main results: adverse effects</td>
<td>Ensure that any findings related to adverse effects are reported. If adverse effects data were sought, but availability of data was limited, this should be reported.</td>
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<tr>
<td>R18</td>
<td>Consistency of summary versions of the review</td>
<td>Ensure that reporting of objectives, important outcomes, results, caveats and conclusions in consistent across the text, the abstract, the plain language summary and the ‘Summary of findings’ table (if included).</td>
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<tr>
<td>R86</td>
<td>Consistency of results</td>
<td>Ensure that all statistical results presented in the main review text are consistent between the text and the ‘Data and analysis’ tables.</td>
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</table>
# Key learning points

<table>
<thead>
<tr>
<th>Implementation of protocol methods</th>
<th>Interpretation</th>
<th>Inconsistency</th>
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<tbody>
<tr>
<td>Excluding studies due to outcome reporting</td>
<td>SoF tables footnotes/downgrading decisions</td>
<td>Results in text/tables</td>
</tr>
<tr>
<td>Unacknowledged departures from protocol</td>
<td>Use of GRADE</td>
<td>Mismatch between full-text &amp; summary versions</td>
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<tr>
<td>Subgroups (misuse &amp; interpretation)</td>
<td>Prescriptive conclusions</td>
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<tr>
<td>Analysis errors</td>
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Feedback loop for MECIR

CEU screening programme: Overview of common errors & good practice in Cochrane intervention reviews

Since September 2013, the CEU has been responsible for pre-publication screening of new intervention reviews. Based on these experiences this resource has been compiled to draw attention to the most prominent challenges faced by authors and editors in the production of Cochrane Reviews. Where possible it also identifies how they might be addressed.

Toby Lasserson, Senior Editor

<table>
<thead>
<tr>
<th>Section of the review</th>
<th>Common error</th>
<th>Good practice</th>
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</thead>
<tbody>
<tr>
<td><strong>Global</strong></td>
<td><strong>Unclear or misleading title.</strong></td>
<td>Clear link between the review title and review question.</td>
</tr>
<tr>
<td></td>
<td>In empty reviews, too much prominence can be given to findings from ineligible studies, or extrapolation of positive results from other reviews.</td>
<td>Emphasis on the lack of evidence to address the review question and acknowledgement of any ongoing studies.</td>
</tr>
<tr>
<td></td>
<td>Inconsistent messages across conclusions, PLS, Discussion &amp; Implications for practice &amp; research.</td>
<td>Using GRADE ratings to inform the review abstract, Summary of Findings (SoF) tables, PLS, Effects of interventions, Discussion (especially quality of evidence) and conclusions.</td>
</tr>
<tr>
<td><strong>Abstract main results</strong></td>
<td><strong>Primary outcomes and harms under-reported, often with emphasis on positive secondary endpoints.</strong></td>
<td>Reporting main outcomes of interest irrespective of the strength of evidence. As a general approach, outcomes important enough to feature in the Summary of Findings table should be considered for the abstract and vice versa.</td>
</tr>
</tbody>
</table>
Feedback loop for MECIR

Incorporating GRADE in Cochrane Reviews: Feedback from the CEU screening programme

1. Describing methods for assessing the quality of the evidence under the ‘Data collection & analysis’ section of protocols and full reviews.
2. Explaining decisions about the quality of the evidence in reporting of results.
3. Incorporating information about the quality of evidence in the Discussion.
4. Drawing on quality of evidence ratings when summarising and interpreting the results e.g. abstracts, plain language summaries and implications for practice sections.
MECIR 2.0
Of sets & standards…
New developments

4 sets (conduct; reporting protocol; reporting review & updating)

Booklet format

Standards revised to reflect what screening has taught us
Contents

1. Introduction 3

2. Standards for the conduct of new Cochrane Intervention Reviews 5

3. Standards for the reporting of protocols for new Cochrane Intervention Reviews 34

4. Standards for the reporting of new Cochrane Intervention Reviews 22

5. Standards for the planning, conduct and reporting of updates of Cochrane Intervention Reviews 55
Changes to conduct standards

5 fewer conduct standards (75 versus 80)

Surviving standards draw on learning points from screening & related audit work
<table>
<thead>
<tr>
<th>C756</th>
<th>Assessing the quality of the body of evidence</th>
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<tr>
<td>Use the five GRADE considerations (risk of bias, 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 approach system for summarizing confidence in effects of the interventions by outcome across studies. It is preferable to use the GRADE tool (as implemented in GRADE profiler or GDT 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 and reach a consensus view on any downgrading decisions. The five GRADE considerations should be addressed irrespective of whether the review includes a ‘Summary of findings’ table. It is helpful to draw on this information in the Discussion, in the conclusions and to convey the certainty in the evidence in the abstract and Plain Language Summary. See Handbook 12.2</td>
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<tr>
<th>C789</th>
<th>Avoiding recommendations</th>
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<tr>
<td>Avoid providing recommendations for practice.</td>
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</table>

<table>
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<tr>
<th>C7980</th>
<th>Formulating implications for research</th>
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<tbody>
<tr>
<td>Structure the implications for research to address the nature of evidence required, including population, intervention comparison, outcome, and type of study.</td>
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Anyone wishing to conduct a study in the topic area of the review should be provided with a clear sense of what the remaining uncertainties are. A useful framework for considering implications for research is EPICOT (evidence, population, intervention, comparison, outcome and time stamp). See Handbook 12.7.3
New set for reporting protocol

44 standards to mirror Conduct Standards

Investing effort in formulating question
### Standard

<table>
<thead>
<tr>
<th>Standard</th>
<th>Rationale and elaboration</th>
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<tbody>
<tr>
<td>PR3</td>
<td>Background</td>
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</table>

Provide a concise description of the condition or problem addressed by the review question, definition of the intervention and how it might work, and why it is important to do the review. Include the four standard headings.

### PR14  Outcome domains of interest

State which outcomes are primary outcomes and which are secondary outcomes, up to seven outcomes should be pre-specified for inclusion in a ‘Summary of findings’ table (see PR40); it may be convenient to highlight them here.

### PR39  Quality of the evidence

State the methods to be used to assess the quality of the body of evidence (using the five GRADE considerations).

If the current GRADE guidance for these assessments will be followed in its entirety (see Handbook Chapter 12), then a reference to this is sufficient to provide the criteria used to make judgements.

**MECIR conduct standard 74** (Use the five GRADE considerations (risk of bias, 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.)

### PR40  ‘Summary of findings’ table

State which outcomes and which comparisons are intended to be included in a ‘Summary of findings’ table. Up to a maximum of seven important outcomes should be pre-specified for inclusion in a ‘Summary of findings’ table. If possible, sources of any assumed risks to be presented in a ‘Summary of findings’ table should be explained.

**MECIR conduct standard 23** (Plan in advance the methods to be used for assessing the quality of the body of evidence, and summarizing the findings of the review.)
Changes to reporting standards

Reporting standards revised to incorporate learning points from review screening

Clarification based on user feedback
Report findings for all important primary outcomes, irrespective of the strength and direction of the result, and of the availability of data.

Findings should typically include concise information about the size of effect and quality of the body of evidence for the outcome (such as study limitations, risk of bias, consistency of effect, imprecision, indirectness and publication bias), for example using GRADE. Outcomes reported in the abstract should not be selected solely on the basis of the findings. In general, the same outcomes in the abstract should be presented in the Plain Language Summary and Summary of Findings tables. If no studies measured the primary outcomes, then a comment should be made to that effect.

Discuss limitations of the review at study and outcome level (e.g. regarding risk of bias), and at review-level (e.g. incomplete identification of studies, reporting bias).

Review authors must explicitly state the limitations of their review. One aspect that is easily overlooked is that of adverse effects. In particular, if the review methods do not allow for detection of serious and/or rare adverse events, the review authors must explicitly state this as a limitation. Additional considerations here include currency and completeness of the search, completeness of data collection processes, assumptions regarding classification of interventions, outcomes or subgroups, and methods to account for missing data.

**MECIR conduct standard 74** (Consider the potential impact of reporting biases on the results of the review or the meta-analyses it contains.) [PRISMA item 25]
Updating

Challenge notion that updating = adding studies

Start with a re-evaluation of the original research question (new protocol if necessary)

Separation of standards between planning & considerations for reporting
DECIDING ON AND PERFORMING AN UPDATE

Planning the update

<table>
<thead>
<tr>
<th>Standard</th>
<th>Rationale and elaboration</th>
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<tbody>
<tr>
<td><strong>U1</strong> Reconsidering review questions</td>
<td>Consider whether it is important to modify or add new objectives to make the review relevant to its users.</td>
</tr>
</tbody>
</table>

Confirm or amend review question (PICO) and objectives.

Consider whether the review will be split, merged with another review or otherwise changed substantially. If so, a new protocol might be warranted and the MECIR conduct standards should be followed rather than these update standards. It will be necessary to agree the approach to updating the review with the Cochrane Review Group.

**U2** Reconsidering outcomes

Confirm or amend outcomes of interest.

**U3** Reconsidering eligibility criteria

Confirm or amend eligibility criteria.

**U4** Planning the search

Decide appropriate search methods.

**U5** Reconsidering data collection and analysis methods

Consider whether methods for data collection and analysis (including a GRADE assessment) need to be amended in the light of recent methodological developments.

**U11** Assessing quality of the evidence

Assess quality of evidence using GRADE considerations of risk of bias, inconsistency, imprecision, indirectness and publication bias.
Changes to scope

Explain any changes to questions, objectives or eligibility criteria.

Flow of studies

Provide information on the flow of studies into the updated review, ideally using a 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:

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.

What’s new?

It is important that changes are explained to inform returning readers about what’s new. This should be achieved in several ways.

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.

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.
Where next?
Supporting implementation

Finalise & circulate the final sets as booklet

Handbook & software integration

Update learning resources

Produce targeted guidance on aspects of conduct & reporting that pose greatest challenge
Summary

MECIR should not be seen in isolation from Handbook guidance

Shared ownership

Some standards easier to attain than others

Recent changes encourage earlier adherence to standards & reinforce good practice