Versions and changes to MECIR	

# Versions and changes to MECIR

# Process for updating MECIR

• For details on when and how updates to MECIR are made, please see here.

# Updates pending for the next version

#### No updated pending.

# Version August 2023 (PDF Version)

- Updates made to MECIR authors' affiliations.
- Jacqueline Chandler and David Tovey have stepped down as authors of MECIR.
- Cochrane has retired its Protocol, Reporting and Update Reporting standards (MECIR items PR1 to PR44, R1 to R109 and UR1 to UR7) and now endorses PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analysis) reporting guidelines for use in Cochrane Reviews of interventions. This change does not affect the MECIR Conduct standards or the Planning or Conduct standards for Updates.
- Links to version 6.4 of the Cochrane Handbook for Systematic Reviews of Interventions added to all relevant standards.
- C34 updated to: "(...) but do not use filters in pre-filtered databases e.g. do not use a randomized trial filter in CENTRAL."
- C48 rationale updated to: "Some studies may have been found to be fraudulent or articles about them may have been retracted since publication for other reasons (...)"

# Version February 2022 (PDF version):

- <u>C52 and C56</u> merged into one assessing risk of bias Conduct Standard (C52: Assess the risk of bias for each study result contributing to an outcome in the 'Summary of findings' table. For randomized trials, the RoB 2 tool should be used, involving judgements and support for those judgements across a series of domains of bias, as described in the *Handbook*); C57 to become C56, C58 to become C57, C59 to become C58, C60 to become C59 and there will no longer be a C60 MECIR Conduct Standard. The standard now makes it more explicit that the original risk of bias tool can still be used.
- <u>C26</u> rationale updated to: Sometimes a review will address questions about adverse effects, economic issues or qualitative research using a different set of eligibility criteria from the main (effectiveness) component. In such situations, the searches for evidence must be suitable to identify relevant study designs for these questions. Different searches may need to be conducted for different types of evidence.
- <u>C28</u> updated to: Search relevant grey literature sources such as reports, dissertations, theses and conference abstracts.
- C37 updated to: Rerun or update searches for all relevant sources...

## Version February 2021 (PDF version):

- <u>C56: Highly desirable -changed to- C56: Mandatory</u>
- R106: 'Declarations of interest', updated to reflect Cochrane's new Conflict of interest policy.

## Version March 2020 (PDF version):

- During February and March 2020 edits were made to the PR, R, U and UR Standards in MECIR to update referencing to the new *Handbook* (version 6). All changes are reflected at the bottom of each page.
- PR14: Define in advance which outcomes are primary outcomes and which are secondary outcomes. -changed to- Define in advance outcomes that are critical to the review, and any additional important outcomes.
- PR27: Assess the risk of bias for each included study. For randomized trials, the Cochrane 'Risk of bias' tool should be used, involving judgements and supports for those judgements across a series of domains of bias, as described in Chapter 8 of the *Handbook* (version 5 or later). -changed to-Assess the risk of bias in at least one specific result for each included study. For randomized trials, the RoB 2 tool should be used, involving judgements and support for those judgements across a series of domains of bias, as described in *Handbook* (version 6).
- PR28: If the Risk of Bias 2 tool (see *Handbook* (version 6) Chapter 8) is to be used, state whether interest will be in the effect of assignment to intervention or the effect of adhering to intervention, and explain how results will be selected to be assessed for risk of bias (i.e. for which outcome domains, outcome measures, time points and analyses). ADDED
- PR35: according to summary risk of bias, or restricted to studies at low risk of bias. -changed to- according to summary risk of bias, restricted to studies at low risk of bias or restricted to low-and-some-concerns of risk of bias.
- R32: Define in advance which outcomes are primary outcomes and which are secondary outcomes. -changed to- Define in advance outcomes that are critical to the review, and any additional important outcomes.

- R45: Assess the risk of bias for each included study. For randomized trials, the Cochrane 'Risk of bias' tool should be used, involving judgements and supports for those judgements across a series of domains of bias, as described in Chapter 8 of the Handbook (version 5 or later). -changed to- Assess the risk of bias in at least one specific result for each included study. For randomized trials, the RoB 2 tool should be used, involving judgements and support for those judgements across a series of domains of bias, as described in Handbook version 6.
- R53: according to summary risk of bias, or restricted to studies at low risk of bias. -changed to- according to summary risk of bias, restricted to studies at low risk of bias or restricted to low-and-some-concerns of risk of bias.
- R55: (Include a 'Summary of Findings' table according to recommendations described in Chapter 10 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 certainty of the body of evidence)

-changed to-

Justify and document all assessments of the certainty of the body of evidence (for example downgrading or upgrading if using GRADE).

R55: MECIR conduct standard 76 (Use the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the certainty of the body of evidence for each outcome, and to draw conclusions about the certainty of evidence within the text of the review.) [PRISMA item 12]
 changed to-

MECIR conduct standard 74: Use the five GRADE considerations (risk of bias, consistency of effect, imprecision, indirectness and publication bias) to assess the certainty of the body of evidence for each outcome, and to draw conclusions about the certainty of evidence within the text of the review.

- R56: to complete a PRISMA type flow chart -changed to- to be able to complete a flow diagram
- R73: Present a 'Risk of bias' table for each included study -changed to- Present at least one 'Risk of bias' table for each study that is included in a synthesis
- R73: The 'Risk of bias' table in RevMan should be used, this is an extension of the table of 'Characteristics of included studies'. -changed to- 'Risk of bias' presentation tools in RevMan should be used wherever possible.
- R73: Assess the risk of bias for each included study. For randomized trials, the Cochrane 'Risk of bias' tool should be used, involving judgements and supports for those judgements across a series of domains of bias, as described in Chapter 8 of the *Handbook* (version 5 or later) -changed to- Assess the risk of bias in at least one specific result for each included study. For randomized trials, the RoB 2 tool should be used, involving judgements and support for those judgements across a series of domains of bias, as described in *Handbook* (version 6).
- R74: Summarize the risk of bias -changed to- Present an overall risk of bias assessment
- R76: the heading hierarchy -changed to- any heading hierarchy
- R76: in RevMan5 ADDED
- R76: This standard will not be required when using the study-centric data structure of RevMan Web. ADDED
- R101: Consider the potential impact of reporting biases -changed to- Consider the potential impact of non-reporting biases
- U9: For randomized trials, they must be assessed using a currently accepted version of the Cochrane 'Risk of bias' tool. The separation of performance bias and detection bias in the evaluation of blinding is highly desirable. -changed to- 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 *Handbook* (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.

#### Version October 2019 (PDF version):

- Updates made to MECIR authors' affiliations
- Links to version 6 of the Cochrane Handbook for Systematic Reviews of Interventions added to all relevant standards (Conduct Standards C1-C75)
- Links to the Cochrane Editorial and Publishing Policy Resource updated
- James Thomas and Ella Flemyng added as co-authors
- Edits made to the MECIR Standards 'Key points and introduction' page (see 'Section info' on the page for details).
- Edits made to the 'Development and consultation' page (see 'Section info' on the page for details)
- New 'Implementation of the standards' section written by Karla Soares-Weiser (see 'Section info' on the page for details)
- Edits made to the 'Key points and introduction' pages for each of the four sections (see 'Section info' on the conduct,

reporting of protocols, reporting and updates pages for details)

- Added a new '<u>Translations of the MECIR Standards</u>' section
- Citation to the MECIR Manual as a whole and each section updated to reflect Version October 2019
- <u>U11</u>, column 2: quality -changed to- certainty (x2)
- UR5, column 3: quality -changed to- certainty
- UR7, column 3: quality -changed to- certainty
- PR39 column 2 and 3: quality -changed to- certainty (x4)
- PR40 column 3: quality -changed to- certainty
- <u>R12</u>, column 3: quality -changed to- certainty
- <u>R55</u>: column 2 and 3: quality -changed to- certainty (x4)
- <u>R96</u>: column 3: quality -changed to- certainty
- <u>R98</u>: column 3: quality -changed to- certainty (x2)
- R99 column 2 and 3: quality -changed to- certainty (x5)
- <u>R100</u>, column 3: Quality -changed to- Certainty

#### Version July 2019

<u>Version July 2019</u> is an archived version of MECIR, provided for historical reference. Please see the current version of MECIR <u>here</u>.

- <u>Version 1.07</u> changed to- <u>Version July 2019</u>
- Previous pages titled 'Latest substantive changes' and 'Versions' have been merged into one page titled 'Versions and changes to MECIR'
- Citation to the MECIR Manual as a whole and each section updated to reflect version July 2019
- C1: See Handbook 2.3.2, 2.3.4, 17.2, 20.2.2 -changed to- See Handbook (version 6), Section 2.1
- C2: See Handbook 5.1.1 -changed to- See Handbook (version 6), Section 2.3
- C3: See Handbook 5.4.3, 14.1.1, 14.3 -changed to- See Handbook (version 6) Section 2.1
- C4: added: See Handbook (version 6), Section 2.4
- C5: Handbook 5.2 -changed to- Handbook (version 6), Section 3.2.1
- <u>C6</u>: Handbook 5.2 -changed to- Handbook (version 6), Section 3.2.1
- <u>C7</u>: Handbook 5.3 -changed to- Handbook (version 6), Section 3.2.2
- C8: Handbook 5.1.2 -changed to- Handbook (version 6), Section 3.2.4.1
- C9: Handbook 5.5, 13.2.2 -changed to- Handbook (version 6), Section 3.3
- C10: Handbook 5.5, 13.1.3 -changed to- Handbook (version 6), Section 3.3.1
- <u>C11</u>: Handbook 13.1.2 -changed to- Handbook (version 6), Section 3.3
- <u>C12</u>: Handbook 10.3.2 -changed to- Handbook (version 6), Section 3.4
- C13: Handbook 5.2, 5.7 -changed to- Handbook (version 6), Section 3.2.1
- <u>C14</u>, column 2: Define in advance which outcomes are primary outcomes and which are secondary outcomes. -changed to-Define in advance outcomes that are critical to the review, and any additional important outcomes.
- <u>C14</u>, column 3: The primary outcomes -changed to- The critical outcomes
- <u>C14</u>, column 3: It is important to identify up to seven outcomes from the primary and secondary outcomes that will form the basis of the GRADE assessment. -changed to- 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 outcomes.
- C14, column 4: Handbook 5.4.2 -changed to- Handbook (version 6), Section 3.2.4.1
- <u>C15</u>, column 2: that are important -changed to- that are critical or important
- C15, column 3: that are important -changed to- that are critical or important
- <u>C15</u>, column 3 new text: Any outcomes that would not be described as critical or important can be left out of the review.
- C15, column 4: Handbook 5.4.2 -changed to- Handbook (version 6), Section 3.2.4.1
- C16, column 4: Handbook 5.4.1 -changed to- Handbook (version 6), Section 3.2.4.1
- C19, column 4: Handbook 6.3, 6.4 -changed to- Handbook (version 6), Section 1.5; 4.3.1.1
- C20, column 3: 'Risk of bias' -changed to- 'risk of bias'
- C20, column 4: Handbook 8.3 -changed to- Handbook (version 6), Section 1.5
- C21, column 4:Handbook 9.1.2 -changed to- Handbook (version 6), Section 1.5
- C22, column 4:Handbook 9.6.5 -changed to- Handbook (version 6), Section 1.5
- C23, column 4:Handbook 11.5 -changed to- Handbook (version 6), Section 1.5
- <u>C24</u> column 3: Supplementary searches should be performed as described in sections 6.3.2 and 6.3.3 of the Handbook. -changed to- DELETED
- <u>C24</u>: BLANK -changed to- See Handbook (version 6) Section 4.3.1.1
- C25: Handbook 6.2.1.4, 6.2.1.5 -changed to- Handbook (version 6), Section 4.3.1.4
- C26: Handbook 13.3; 14.5; 15.3; 20.3.2.1 -changed to- Handbook (version 6), Section 4.4.1

- C27: Handbook 6.2.3.1, 6.2.3.2, 6.2.3.3 -changed to- Handbook (version 6), Section 4.4.3
- C28: Handbook 6.2.1.7, 6.2.1.8, 6.2. 2-changed to- Handbook (version 6), Section 4.3.5
- C29: Handbook 6.2.2.5 -changed to- Handbook (version 6), Section 4.3.5
- C30: Handbook 6.2.2.5 -changed to- Handbook (version 6), Section 4.3.5
- C31: Handbook 6.2.3-changed to- Handbook (version 6), Section 4.3.2
- C32: Handbook 6.4.2, 6.4.4, 6.4.7-changed to- Handbook (version 6), Section 4.4.2
- C33: Handbook 6.4.5, 6.4.6, 6.4.8 -changed to- Handbook (version 6), Section 4.4.4
- C34: Handbook 6.4.11, 6.4.2; 13.3.1.2; 14.5.2; 15.3.1; 17.5; 20.3.2.1 changed to- Handbook (version 6), Section 4.4.7
- C35: Handbook 6.4.9 -changed to- Handbook (version 6), Section 4.4.5
- C36: Handbook 6.6.1 -changed to- Handbook (version 6), Section 4.5
- C37: BLANK -changed to- Handbook (version 6), Section 4.4.10
- <u>C38</u>: BLANK -changed to- Handbook (version 6), Section 4.4.10
- C39 column 4: Handbook 7.2.4 -changed to- Handbook (version 6), Section 4.6.4
- <u>C40</u> column 4: Handbook 5.4.1 -changed to- Handbook (version 6), Section 4.6.3
- <u>C41</u> column 3: A PRISMA type flow diagram and a table of 'Characteristics of excluded studies' will need to be completed in the final review. -changed to- DELETED
- C41 column 4: Handbook 6.6.1; 11.2.1 -changed to- Handbook (version 6), Section 4.6.4
- C42 column 4: Handbook 7.2.1, 7.2.2, 7.6.4 -changed to- Handbook (version 6), Section 4.6.2; 5.2.1
- C43 column 2: that has been -changed to- which has been
- <u>C43</u> column 3: Piloting the form within the review team using a sample of included studies is highly desirable -changed to-Piloting the form within the review team is highly desirable.
- C43 column 4: Handbook 7.5 -changed to- Handbook (version 6), Section 5.4.1
- <u>C44</u> column 3: Details of funding source for each study and the declarations of interest for the primary investigators should also be collected during this process. TiDieR (Hoffman 2014) will assist selection of which characteristics of interventions should be sought. -changed to- DELETED
- C44 column 4: Handbook 7.3; 11.2 -changed to- Handbook (version 6), Section 5.3.1
- <u>C45</u> column 3: not a mandatory standard for study characteristics. -changed to- not a mandatory standard for the former.
- C45 column 4: Handbook 7.6.2, 7.6.5 -changed to- Handbook (version 6), Section 5.5.2
- <u>C46</u> column 4: Handbook 7.6.2 -changed to- Handbook (version 6), Section 5.5.2
- C47 column 4: Handbook 7.7 -changed to- Handbook (version 6), Section 5.3.6
- C48 column 4: Handbook 6.4.10 -changed to- Handbook (version 6), Section 4.4.6; 5.2
- C49 column 3: Risk of bias -changed to- risk of bias
- C49 column 4: Handbook 7.4.2 -changed to- Handbook (version 6), Section 5.2.3
- C50 title: Choosing intervention groups in multi-arm studies -changed to- Choosing interventions in multi-arm studies
- <u>C50</u> column 2: include in the review only the intervention and control groups that meet -changed to- include in the review only the interventions that meet
- <u>C50</u> column 3: intervention groups (x2) -changed to- interventions (x2)
- C50 column 4: Handbook 16.5.2 -changed to- Handbook (version 6), Section 5.3.6
- <u>C52</u> column 3: Recommendations for assessing bias in randomized studies included in Cochrane Reviews are now well established. -changed to- DELETED
- C52 column 3: as described in this Handbook -changed to- as described in Handbook version 6
- C52 column 4: See Handbook version 6 (Chapter 8) -changed to- See Handbook (version 6), Section 7.1.2; Chapter 8
- <u>C53</u> column 2: risk of bias tool -changed to- risk-of-bias-tool
- C53 column 3: the risk of bias assessment -changed to- the risk-of-bias assessment
- <u>C53</u> column 4: See Handbook 8.3.4 -changed to- See Handbook (version 6), Section 7.3.2; Chapter 8
- <u>C54</u> column 2: risk of bias tables -changed to- risk-of bias tables
- <u>C54</u> column 3: Items that are judged to be at an unclear risk of bias but are without accompanying information supporting the judgment appear as empty cells in the graphical plots based on the 'Risk of bias' tool in the published review. -changed to- DELETED
- C54 column 4: Handbook 8.5.2 -changed to- Handbook (version 6), Section 7.3.2; Chapter 8
- <u>C55</u> column 2: risk of bias judgement -changed to- risk-of-bias judgement
- <u>C54</u> column 3: judgments -changed to- judgements
- <u>C55</u> column 4: Handbook 8.5.2 -changed to- Handbook (version 6), Section 7.3.2; Chapter 8
- <u>C56</u> column 4: Handbook 8.5.1, 8.11.2, 8.12.2 changed to- Handbook (version 6), Section 7.3.2; Chapter 8
- C57 title: Summarizing risk of bias assessments changed to- Summarizing risk-of-bias assessments
- <u>C57</u> column 4: Handbook 8.5.1, 8.13.2 -changed to- Handbook (version 6), Section 7.5; Chapter 8
- C58 column 4: Handbook 8.7 -changed to- Handbook (version 6), Section 7.6.1; Chapter 8
- <u>C59</u> column 4: Handbook version 6 (Chapter 8) -changed to- Handbook (version 6), Section 7.6.1; Chapter 8
- C60 column 3: "notable concern of conflicts of interest" -changed to- "notable concern about conflicts of interest"
- C60 column 4: Handbook 8.8.1 -changed to- Handbook (version 6), Section 7.8.6; Chapter 8
- C61 column 4: Handbook 9.2.3.2 -changed to- BLANK

- <u>C62</u> column 4: See Handbook 9.1.4 -changed to- BLANK
- C63 column 4: See Handbook 9.5.2 -changed to- See Handbook (version 6), Section 10.10.2
- <u>C64</u> column 3: Risk of bias tool -changed to- 'risk-of-bias' tool
- C64 column 4: See Handbook 16.2 -changed to- See Handbook (version 6), Section 10.12.1
- <u>C65</u> column 4 See Handbook 9.4.5.3 -changed to- See Handbook (version 6), Section 10.5.3
- <u>C66</u> column 3: and using multiple treatments meta-analysis. -changed to- and using network meta-analysis.
- C66 column 4: See Handbook 7.7.3.8, 16.5.4 -changed to- See Handbook (version 6), Section 6.2.9 and Chapter 11.
- <u>C67</u> column 4:See Handbook 9.6.3.1 -changed to- See Handbook (version 6), Section 10.11.3.1
- C68 column 4: See Handbook 9.6.5.2 -changed to- See Handbook (version 6), Section 10.11.5.2
- C69 column 4: See Handbook 9.5.4 -changed to- See Handbook (version 6), Section 10.10.3
- <u>C70</u> column 3: of the study, i.e., to give it (x2) -changed to- of the study, that is, to give it (x2)
- C70 column 4: see Handbook 9.3, 16.3, 16.4 -changed to- See Handbook (version 6), Section 6.2.1
- <u>C71</u> column 4: see Handbook 9.7 -changed to- See Handbook (version 6), Section 10.14
- <u>C72</u> column 2: 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. -changed to- (Do not describe results as statistically significant or non-significant. Interpret the confidence intervals and their width.) Focus interpretation of results on estimates of effect and their confidence intervals, avoiding use of a distinction between "statistically significant" and "statistically non-significant".
- C72 column 4: See Handbook 12.4.2, 12.7.4 -changed to- See Handbook (version 6), Section 15.3.1
- C73 column 4: See Handbook 10.1, 10.2 -changed to- See Handbook (version 6), Section 13.4
- C74 column 2 title: Assessing the quality -changed to- Assessing the certainty
- C74 column 2: quality of the body of evidence -changed to -certainty of the body of evidence
- <u>C74</u> column 2: quality of evidence -changed to- certainty of evidence
- <u>C74</u> column 3: quality of the body of evidence -changed to -certainty of the body of evidence
- C74 column 4: See Handbook 12.2 -changed to- See Handbook (version 6) Section 14.2.1
- <u>C75</u> column 2 title: quality of the body of evidence -changed to -certainty of the body of evidence
- <u>C75</u> column 2: quality of the body of evidence -changed to -certainty of the body of evidence
- C75 column 4: See Handbook 12.2.1 -changed to- See Handbook (version 6) Section 14.2.1

#### Version 1.07, 2018

Version 1.07 is an archived version of MECIR, provided for historical reference. Please see the current version of MECIR here.

- <u>C56</u>: "assess RoB due to lack of blinding......" replaced with NEW standard "Ensuring results of outcomes included in SoF are assessed for RoB......"
- C57: "RoB due to incomplete outcome data...." replaced with "Summarizing RoB assessments...."
- <u>C58</u>: "Summarizing RoB assessments...." replaced with "Addressing RoB in the synthesis...."
- <u>C59</u>: "Addressing RoB in the synthesis...." replaced with "Incorporating assessments of RoB...."
- C60: "Incorporating assessments of RoB...." replaced with NEW standard "Addressing Col in included trials....."

#### Version 1.06

- <u>C73</u>: Standard changed to: Consider the potential impact of non-reporting biases on the results of the review or the metaanalysis it contains. Rationale and elaboration changed to: There is overwhelming evidence of non-reporting biases of various types. These can be addressed at various points of the review. A thorough search, and attempts to obtain unpublished results, might minimize the risk. Analyses of the results of included studies, for example using funnel plots, can sometimes help determine the possible extent of the problem, as can attempts to identify study protocols, which should be a routine feature of Cochrane Reviews.
- <u>C24:</u> Standard changed from "Planning the search" to "Searching general bibliographic databases and CENTRAL"
- <u>C41</u>: Standard changed to: "Document the selection process in sufficient detail to be able to complete a flow diagram and a table of 'Characteristics of excluded studies'. Change elaboration to read: "A PRISMA type flow diagram and a table of 'Characteristics of excluded studies' will need to be completed in the final review......"
- <u>R56:</u> Standard changed to: Provide information on the flow of studies....., ideally using a PRISMA type flow diagram.....individual studies".
- UR4: Elaboration changed to: "Provide information on the flow of studies into the updated review, ideally using a PRISMA type flow diagram."
- <u>R98:</u> Status changed to mandatory Mandating SoF tables.
- <u>R102</u>: Changed elaboration to: "When formulating implications for practice base conclusions only on findings from the synthesis (quantitative or narrative) of studies included in the review. 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 result, and without drawing on data that were not systematically compiled and evaluated as part of the review."

#### Version 1.05

• <u>C48:</u> Upgraded from 'highly desirable' to 'mandatory'.

#### Version 1.04

- <u>R55:</u> New Standard inserted. There is subsequent renumbering of all Standards in section up to R108.(23/01/2018)
- C28: Changed from 'mandatory' to 'highly desirable'.(23/01/18)
  Links to Cochrane Interactive Learning modules have been added where needed.

MECIR Booklet 2016

MECIR Booklet Version 2, December 2013

MECIR Booklet Version 2, September 2013

MECIR Booklet 2012