Versions and changes to MECIR

Version March 2020

- Version October 2019 - changed to - Version March 2020
- 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

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• Version July 2019 - changed to- Version October 2019
• 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 ‘Translations of the MECIR Standards’ section
• Citation to the MECIR Manual as a whole and each section updated to reflect Version October 2019
• U11, column 2: quality -changed to- certainty (x2)
• U5, column 3: quality -changed to- certainty
• U7, column 3: quality -changed to- certainty
• PR39 column 2 and 3: quality -changed to- certainty (x4)
• PR40 column 3: quality -changed to- certainty
• R12, column 3: quality -changed to- certainty
• R55: column 2 and 3: quality -changed to- certainty (x4)
• R96: column 3: quality -changed to- certainty
• R98: column 3: quality -changed to- certainty (x2)
• R99 column 2 and 3: quality -changed to- certainty (x5)
• R100, column 3: Quality -changed to- Certainty

Version July 2019

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• Version 1.07 - changed to- Version July 2019
• 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
• C6: Handbook 5.2 -changed to- Handbook (version 6), Section 3.2.1
• C7: 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
• C11: Handbook 13.1.2 -changed to- Handbook (version 6), Section 3.3
should be sought. -DELETED changed to-
also be collected during this process. TiDieR (Hoffman 2014) will assist selection of which characteristics of interventions
Piloting the form within the review team is highly desirable.
It is important to identify up to seven outcomes from the primary and secondary outcomes that will form the basis of the GRADE assessment. -DELETED 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.

Define in advance which outcomes are primary outcomes and which are secondary outcomes. -DELETED 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.

It is important to identify up to seven outcomes from the primary and secondary outcomes that will form the basis of the GRADE assessment. -DELETED 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.

'Risk of bias' -DELETED changed to-

'Summary of findings' -DELETED 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.

Any outcomes that would not be described as critical or important can be left out of the review.

A PRISMA type flow diagram and a table of 'Characteristics of excluded studies' will need to be completed in the final review. -DELETED changed to-

Any outcomes that would not be described as critical or important can be left out of the review.

A PRISMA type flow diagram and a table of 'Characteristics of excluded studies' will need to be completed in the final review. -DELETED changed to-
only the interventions that meet

- C50 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
- C52 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
- C53 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
- C53 column 4: See Handbook 8.3.4 - changed to - See Handbook (version 6), Section 7.3.2; Chapter 8
- C54 column 2: risk of bias tables - changed to - risk-of-bias tables
- C54 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: See Handbook version 6 (Chapter 8) - changed to - See Handbook (version 6), Section 7.3.2; Chapter 8
- C55 column 2: risk of bias judgement - changed to - risk-of-bias judgement
- C55 column 3: judgments - changed to - judgements
- C55 column 4: See Handbook 8.5.1, 8.11.2, 8.12.2 - changed to - Handbook (version 6), Section 7.3.2; Chapter 8
- C56 column 4: Handbook 8.7 - changed to - Handbook (version 6), Section 7.6.1; Chapter 8
- C57 title: Summarizing risk of bias assessments - changed to - Summarizing risk-of-bias assessments
- C57 column 4: See Handbook 8.5.1, 8.13.2 - changed to - Handbook (version 6), Section 7.3.2; Chapter 8
- C58 column 3: “notable concern of conflicts of interest” - changed to - “notable concern about conflicts of interest”
- C58 column 4: Handbook 8.8.1 - changed to - Handbook (version 6), Section 7.8.6; Chapter 8
- C59 column 4: Handbook version 6 (Chapter 8) - changed to - Handbook (version 6), Section 7.6.1; Chapter 8
- C59 column 4: Handbook 9.2.3.2 - changed to - BLANK
- C59 column 4: See Handbook 9.4.5.3 - changed to - See Handbook (version 6), Section 10.5.3
- C59 column 4: See Handbook 7.7.3.8, 16.5.4 - changed to - See Handbook (version 6), Section 6.2.9 and Chapter 11.
- C60 column 3: and using multiple treatments meta-analysis. - changed to - and using network meta-analysis.
- C60 column 4: See Handbook 9.4.5.3 - changed to - See Handbook (version 6), Section 10.5.3
- C64 column 4: See Handbook 16.2 - changed to - See Handbook (version 6), Section 10.12.1
- C65 column 4: See Handbook 9.4.5.3 - changed to - See Handbook (version 6), Section 10.5.3
- C66 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.
- C67 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
- C70 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
- C71 column 4: see Handbook 9.7 - changed to - See Handbook (version 6), Section 10.14
- C72 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: 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
- C74 column 2: quality of evidence - changed to - certainty of evidence
- C74 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
- C75 column 2: quality of the body of evidence - changed to - certainty of the body of evidence
- C75 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

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- C56: "assess RoB due to lack of blinding......" replaced with **NEW standard** "Ensuring results of outcomes included in SoF are assessed for RoB......."
Version 1.06

- **C73**: Standard changed to: Consider the potential impact of non-reporting biases on the results of the review or the meta-analysis 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.

- **C24**: Standard changed from “Planning the search” to “Searching general bibliographic databases and CENTRAL”

- **C41**: 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....”

- **R56**: 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.”

- **R38**: Status changed to mandatory – Mandating SoF tables.

- **R102**: 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

- **C48**: Upgraded from 'highly desirable' to 'mandatory'.

Version 1.04

- **R55**: 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.