

Author pre-submission checklist for protocols

This checklist is to be used by the review author to check their protocol before submission to the editorial team. Please submit this to the editorial base when checking-in your draft protocol to Archie. Incomplete forms will be returned.

# For additional information, please see EPOC-specific resources for review authors <http://epoc.cochrane.org/resources/epoc-resources-review-authors>

Title of protocol:

Contact Author:

| Item(items are hyper-linked to relevant MECIR guidance for ease of reference)  | Standard | Done(**including page number where found**) | Comments |
| --- | --- | --- | --- |
| [Title](https://community.cochrane.org/mecir-manual/standards-reporting-protocols-new-cochrane-intervention-reviews-pr1-pr44/reporting-review-plan-pr1-pr44/title-and-authors-pr1-pr2) | Guidance to structure the title is offered in the handbook. See section [ii-1-3](https://training.cochrane.org/handbook/current/chapter-ii#section-ii-1-3) and table [ii.1.a](https://training.cochrane.org/handbook/current/chapter-ii#section-ii-1-3). Titles should succinctly state the intervention(s) to be reviewed and the problem at which the intervention is directed. In some cases, it may be sensible to include the specific population of setting. The [Cochrane Style Manual](https://community.cochrane.org/style-manual/cochrane-review-specific/titles-cochrane-reviews) is another useful resource of guidance.  |  |  |
| [Background headings](https://community.cochrane.org/mecir-manual/standards-reporting-protocols-new-cochrane-intervention-reviews-pr1-pr44/reporting-review-plan-pr1-pr44/background-pr3-pr4) | Provide a clear description of the condition, intervention(s) (including a framework for categorising them), how they might work, and why the review is needed. (See [Protocol template](http://epoc.cochrane.org/sites/epoc.cochrane.org/files/public/uploads/Resources-for-authors2017/epoc_protocol_template.pdf)). Key supporting statements should ALL be supported by suitable reference citation.  |  |  |
| [Study population or setting](https://community.cochrane.org/mecir-manual/standards-reporting-protocols-new-cochrane-intervention-reviews-pr1-pr44/reporting-review-plan-pr1-pr44/criteria-considering-studies-review-pr9-pr16) | State eligibility criteria for participants, including any criteria around location, setting, diagnoses or definition of condition and demographic factors, and how studies including subsets of relevant participants will be addressed (See [MECIR PR11](https://community.cochrane.org/mecir-manual/standards-reporting-protocols-new-cochrane-intervention-reviews-pr1-pr44/reporting-review-plan-pr1-pr44/criteria-considering-studies-review-pr9-pr16) See [Handbook (version 6) Section III.3.3.1](https://training.cochrane.org/handbook/current/chapter-iii#section-iii-3-3-1) and [Section 3.2.1](https://training.cochrane.org/handbook/current/chapter-03#section-3-2-1)) |  |  |
| [Interventions](https://community.cochrane.org/mecir-manual/standards-reporting-protocols-new-cochrane-intervention-reviews-pr1-pr44/reporting-review-plan-pr1-pr44/criteria-considering-studies-review-pr9-pr16)  | State eligibility criteria for interventions, including any criteria around delivery, dose, duration, intensity and cointerventions. Criteria for complex interventions should be made explicit, e.g. by stating mandatory components. (See [MECIR PR11](https://community.cochrane.org/mecir-manual/standards-reporting-protocols-new-cochrane-intervention-reviews-pr1-pr44/reporting-review-plan-pr1-pr44/criteria-considering-studies-review-pr9-pr16) See [Handbook (version 6) Section III.3.3.1](https://training.cochrane.org/handbook/current/chapter-iii#section-iii-3-3-1) and [Section 3.2.1](https://training.cochrane.org/handbook/current/chapter-03#section-3-2-1)) |  |  |
| [Comparators](https://community.cochrane.org/mecir-manual/standards-reporting-protocols-new-cochrane-intervention-reviews-pr1-pr44/reporting-review-plan-pr1-pr44/criteria-considering-studies-review-pr9-pr16) | State comparators clearly, including any criteria around delivery, dose, duration, intensity and cointerventions. Criteria for complex interventions should be made explicit, e.g. by stating mandatory components. (See [MECIR PR11](https://community.cochrane.org/mecir-manual/standards-reporting-protocols-new-cochrane-intervention-reviews-pr1-pr44/reporting-review-plan-pr1-pr44/criteria-considering-studies-review-pr9-pr16) See [Handbook (version 6) Section III.3.3.1](https://training.cochrane.org/handbook/current/chapter-iii#section-iii-3-3-1) and [Section 3.2.1](https://training.cochrane.org/handbook/current/chapter-03#section-3-2-1)) |  |  |
| [Outcomes](https://community.cochrane.org/mecir-manual/standards-reporting-protocols-new-cochrane-intervention-reviews-pr1-pr44/reporting-review-plan-pr1-pr44/criteria-considering-studies-review-pr9-pr16) | Separate out primary and secondary outcomes and include outcome measures and time points for measurement**.** It is helpful to indicate how outcomes were selected (and if stakeholders were invited to comment) and how outcomes have been prioritised.  |  |  |
| Adverse effects  | Consider any important potential adverse effects of the intervention(s) and ensure that they are identified in the protocol. We would expect that adverse events relating to an intervention should be one of the outcomes of interest (see: [what outcomes should be included in EPOC reviews](https://epoc.cochrane.org/sites/epoc.cochrane.org/files/public/uploads/Resources-for-authors2017/what_outcomes_should_be_reported_in_epoc_reviews.pdf). |  |  |
| Equity  | Relevant disadvantaged groups should be identified in the protocol, including plans for potential subgroup analyses. (See [Equity considerations in EPOC reviews](http://epoc.cochrane.org/sites/epoc.cochrane.org/files/public/uploads/Resources-for-authors2017/equity_considerations_in_epoc_reviews.pdf)) |  |  |
| [Study designs](https://community.cochrane.org/mecir-manual/standards-reporting-protocols-new-cochrane-intervention-reviews-pr1-pr44/reporting-review-plan-pr1-pr44/criteria-considering-studies-review-pr9-pr16) | Justify the choice of eligible study designs. Consistent terminology should be used. Inclusion of other study designs or exclusion of study designs suggested by EOPC should be justified. (See [What study designs should be included in an EPOC review](http://epoc.cochrane.org/sites/epoc.cochrane.org/files/public/uploads/Resources-for-authors2017/what_study_designs_should_be_included_in_an_epoc_review.pdf)) |  |  |
| [Include studies without useable data](https://community.cochrane.org/mecir-manual/standards-reporting-protocols-new-cochrane-intervention-reviews-pr1-pr44/reporting-review-plan-pr1-pr44/data-collection-analysis-pr22-pr40) | Include studies in the review irrespective of whether measured outcome data are reported in a ‘usable’ way. Studies that meet the inclusion criteria should be included and described in the characteristics of included studies table, even if they do not report usable results. |  |  |
| PRISMA flow chart and excluded studies table  | Document the selection process in sufficient detail to complete a PRISMA flow chart and a table of ‘Characteristics of excluded studies’. The protocol should indicate which studies will be reported in the excluded studies table and how the selection process will be documented. |  |  |
| [Incorrect analyses](https://community.cochrane.org/mecir-manual/standards-reporting-protocols-new-cochrane-intervention-reviews-pr1-pr44/reporting-review-plan-pr1-pr44/data-collection-analysis-pr22-pr40) | Describe how incorrect analyses (unit of analysis errors and inappropriately analysed time series data will be managed. (See [Analysis in EPOC reviews](http://epoc.cochrane.org/sites/epoc.cochrane.org/files/public/uploads/Resources-for-authors2017/analysis_in_epoc_reviews.pdf)) |  |  |
| [Risk of bias](https://community.cochrane.org/mecir-manual/standards-reporting-protocols-new-cochrane-intervention-reviews-pr1-pr44/reporting-review-plan-pr1-pr44/data-collection-analysis-pr22-pr40)  | Plan in advance the methods to be used for assessing risk of bias in included studies, including the tool(s) to be used, how the tool(s) will be implemented, and the criteria used to assign studies, for example, to judgements of low risk, high risk and unclear risk of bias. See 2 pagers. Review authors should routinely be sent these after a title is registered. Any deviation from the suggested criteria should be justified. RoB tables should be completed for all new and updated reviews. (See [Suggested risk of bias criteria for EPOC reviews](http://epoc.cochrane.org/sites/epoc.cochrane.org/files/public/uploads/Resources-for-authors2017/suggested_risk_of_bias_criteria_for_epoc_reviews.pdf) and [Summary assessments of the risk of bias](http://epoc.cochrane.org/sites/epoc.cochrane.org/files/public/uploads/Resources-for-authors2017/summary_assessments_of_the_risk_of_bias.pdf)) |  |  |
| [Synthesis](https://community.cochrane.org/mecir-manual/standards-reporting-protocols-new-cochrane-intervention-reviews-pr1-pr44/reporting-review-plan-pr1-pr44/data-collection-analysis-pr22-pr40) | Plan in advance the methods to be used to synthesize the results of the included studies, including how unit of analysis errors will be managed, how inappropriately analysed time series data will be managed (if relevant), whether meta-analysis is planned, how heterogeneity will be assessed, choice of effect measure (e.g. odds ratio, risk ratio, risk difference or other for dichotomous outcomes), methods for a structured synthesis, and methods for meta-analysis (e.g. inverse variance or Mantel Haenszel, fixed-effect or random-effects model), if relevant. (See [Analysis in EPOC reviews,](http://epoc.cochrane.org/sites/epoc.cochrane.org/files/public/uploads/Resources-for-authors2017/analysis_in_epoc_reviews.pdf)  [Synthesising results when meta-analysis does not make sense](http://epoc.cochrane.org/sites/epoc.cochrane.org/files/public/uploads/Resources-for-authors2017/synthesising_results_when_meta-analysis_does_not_make_sense.pdf) and the [Cochrane Handbook for Systematic Reviews of Interventions](http://training.cochrane.org/handbook)) |  |  |
| [Subgroup analyses](https://community.cochrane.org/mecir-manual/standards-reporting-protocols-new-cochrane-intervention-reviews-pr1-pr44/reporting-review-plan-pr1-pr44/data-collection-analysis-pr22-pr40)  | Pre-define potential effect modifiers in the protocol; restrict these in number; provide rationale for each; and plan on addressing factors that affect interpretation and judgement about the reliability of subgroup estimates. (See [What are explanatory factors and why should they be included in protocols?)](http://epoc.cochrane.org/sites/epoc.cochrane.org/files/public/uploads/Resources-for-authors2017/what_are_explanatory_factors.pdf) |  |  |
| [Sensitivity analysis](https://community.cochrane.org/mecir-manual/standards-reporting-protocols-new-cochrane-intervention-reviews-pr1-pr44/reporting-review-plan-pr1-pr44/data-collection-analysis-pr22-pr40) | Plan sensitivity analyses to assess the robustness of results, such as the impact of notable assumptions, imputed data, borderline decisions and studies at high risk of bias. (See [Analysis in EPOC reviews](http://epoc.cochrane.org/sites/epoc.cochrane.org/files/public/uploads/Resources-for-authors2017/analysis_in_epoc_reviews.pdf)) |  |  |
| [Summary of Findings tables](https://community.cochrane.org/mecir-manual/standards-reporting-protocols-new-cochrane-intervention-reviews-pr1-pr44/reporting-review-plan-pr1-pr44/data-collection-analysis-pr22-pr40)  | Plan in advance the methods to be used for summarising the findings of the review, including the assessment of the quality of the body of evidence. Up to seven outcomes can be included in summary of findings tables. These are usually the primary outcomes and adverse events or cost outcomes. The outcomes selected for inclusion should be set out in the protocol with explanation as to how these outcomes have been selected. (See [Worksheets for preparing Summary of Findings tables using GRADE](http://epoc.cochrane.org/sites/epoc.cochrane.org/files/public/uploads/Resources-for-authors2017/worksheets_for_preparing_a_summary_of_findings_using_grade.docx))Please include draft summary of findings tables using the skeleton table provided by EPOC at title registration.  |  |  |
| [Declarations of interest](https://community.cochrane.org/mecir-manual/standards-reporting-protocols-new-cochrane-intervention-reviews-pr1-44/reporting-review-plan-pr1-44/declarations-interest-pr43)[Sources of support](https://community.cochrane.org/mecir-manual/standards-reporting-protocols-new-cochrane-intervention-reviews-pr1-44/reporting-review-plan-pr1-44/sources-support-pr44)  | Please ensure that ALL authors have completed and have updated their COI forms prior to submission of this checklist. Ensure that all sources of financial and on-financial support for the review are listed. BY SUBMITTING YOUR PROTOCOL YOU ARE CONFIRMING THAT ALL DECLRATIONS ARE UP-TO-DATE AND THAT THERE HAS BEEN NO CHNAGES SINCE TITLE RGEISTRATION. |  |  |

In addition, please make sure that you have completed the following items before submitting your protocol to the editorial base:

[x]  Complete a validation check in RevMan (File menu > Reports > Validation report), and make corrections where possible.

[x]  Complete a spell check in RevMan (Tools menu > Check spelling).

[x]  Check that all references are in the correct format and are consistent with the [Cochrane Style Guide](http://www.cochrane.org/training/cochrane-style-resource/cochrane-style-guide)

[x]  Ensure that all author details have been completed, that they are reported accurately in the same language, and are up-to-date. See [MECIR guidance](https://community.cochrane.org/mecir-manual/standards-reporting-protocols-new-cochrane-intervention-reviews-pr1-pr44/reporting-review-plan-pr1-pr44/title-and-authors-pr1-pr2).

[x]  Proofread the Cochrane Protocol carefully in accordance with the [Cochrane Style Guide](http://www.cochrane.org/training/cochrane-style-resource/cochrane-style-guide)