

**Protocol checklist**

**Cochrane Review of Prognosis Studies**

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| --- | --- |
| Title: |  |
| Authors: |  |
| Type of prognosis review: | Overall prognosis  Prognostic factors  Prognostic models |
| Name of referee: |  |
| Date sent to referee: |  |
| Date to be returned to editorial base: |  |

Thank you for agreeing to comment on this **protocol** for a Cochrane Review of Prognosis Studies. A protocol for a systematic review is published in advance of the review and indicates the intention to carry out a review. It should describe the rationale for the review, the objectives, and the methods that will be used to locate, select, and critically appraise studies, and to collect and analyse data from the included studies.

Prognosis is a description of the probable course or prediction of the occurrence of a certain health outcome (e.g. a disease recurrence or complication) over time in targeted individuals with a certain health condition (e.g. disease or diagnosis). Prognosis studies are aimed at understanding the course of individuals with a certain condition, the probability of health outcomes in these individuals (overall prognosis), and factors associated with these health outcomes (prognostic factor and prognostic model studies) To synthesize evidence on prognosis, we here distinguish three types of prognosis studies that investigate: 1. Overall prognosis, 2. Prognostic factors, 3. Prognostic models.

This checklist is intended to serve as a tool to help you assess protocols for these three types of prognosis study reviews. This checklist will provide guidance on the areas we at least would like you to comment on, but feel free to comment on any aspect of the protocol, if needed. Note that the protocol will be copy-edited before publication. Please observe the normal conventions regarding confidentiality in dealing with this protocol.

Cochrane Reviews have a highly structured format and authors are expected to follow this format. Each protocol needs to be explicit and comprehensive. Please consider whether the planned action is appropriate and fits in with the objectives of the review.

Further information on the Cochrane Peer Review policy is available from the Editorial and Publishing Policy Resource (<http://community.cochrane.org/editorial-and-publishing-policy-resource/cochrane-review-management/cochrane-peer-review-policy>).

**By submitting this form, you consent to Cochrane storing your contact details on our system to facilitate the peer review process. We never share personal data with third parties, all data are treated respectfully and securely. If you do not wish to be involved in Cochrane peer review, and would like your contact information to be deleted from our system, please email** [**support@cochane.org**](mailto:support@cochane.org)**.**

**Note that this form is still in pilot phase and will be adapted based on user feedback. If you are planning to use this form, make sure you have the most current version. Please contact Anneke Damen at** [**CochranePMG@umcutrecht.nl**](mailto:CochranePMG@umcutrecht.nl) **if you are planning to use the form and in case you have any questions or queries.**

**Potential conflicts of interest: peer referee statement**

Do you have any potential conflict of interest?  Yes (details below)  No conflict of interest

You should declare and describe any present or past affiliations or other involvement in any organisation or entity with an interest in the outcome of the review that might lead to a real or perceived conflict of interest. You should report relationships that were present during the last 36 months, including, but not restricted to, financial remuneration for lectures, consultancy, travel, and whether you are an author of, or contributor to, a study that might be included in this review. You should declare potential conflicts even if you are confident that your judgement is not influenced.

**If a conflict of interest is declared, you should discuss this with the Cochrane Review Group before proceeding with peer review.**

**Conflict of interest statement:**

**Overall impression**

Was this protocol easy to read? Yes  No  Comments

Was this protocol easy to understand? Yes  No  Comments

Is the question important and clinically relevant? Yes  No  Comments

What are your thoughts on the timeliness of this proposed review?

Other comments?

**Clinical question, title, scope**

We recommend using these underlying principles to guide the scope for prognosis reviews.

* Does the title reflect the objectives, and vice versa?
* Are the review objective and type of prognosis review clearly specified (e.g. overall prognosis, prognostic factor or prognostic model review)?
* Are the health condition and clinical context for which the (overall) prognosis or prognostic factor or model under review is intended clearly described? Are the setting in which the prognosis is being made and the intended moment of prognostication described?
* Is the prognostic factor or model of interest clearly described? This item is not applicable to overall prognosis reviews.
* Are the health outcomes that are being studied and the time horizon over which the prognosis towards these health outcomes is being made clearly described?
* Are sources of heterogeneity that are expected a priori described?
* Are the scope of the review and rationale defined? Broad systematic reviews may investigate all prognostic factors or models for a certain health outcome or for a certain health condition. Rationale should be provided as broad reviews may be difficult to synthesize. Focused systematic reviews investigate one prognostic factor or model or domain; this type of review may allow more quantitative assessment, meta-analysis and interpretation of the synthesized evidence
* Is the review question important to consumers, policy makers and healthcare providers?

**Based on these principles, is the title appropriate and does it match the objectives?** Yes  No

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| **Comment:** |

**Based on these principles, is the clinical question of the review appropriate, clearly described, and suitably supported?** Yes  No

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| **Comment:** |

**Based on these principles, is the scope of the review appropriate, clearly described, and suitably supported?** Yes  No

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| **Comment:** |

**Criteria for including studies for this review**

The proposed study design, population, prognostic factor(s) or model(s), outcomes, timing and setting, should be clearly stated and described.

* Is there a description of types of studies to be included (e.g. cohort, randomised trials)?
* Is the targeted population, considering e.g. age, gender, disease or diagnosis, localization or stage and setting (outpatient, inpatient, clinic, etc.) described?
* Is the prognostic factor (type, measure, etc.) or prognostic model (if applicable) described?
* Are the outcomes to be predicted described?
* Is the timing of prognostic model/factor assessment (e.g. right after being diagnosed with a certain disease) described?
* Is the timing of outcome measures described (e.g. short-term, intermediate, long-term with specification of follow-up duration)?
* Is a pilot test of the inclusion criteria planned to ensure similar approach across review team?

**Based on these factors, are the inclusion/exclusion criteria and their implementation clearly and completely described?** Yes  No

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| **Comment:** |

**Are the reasons for in- and excluding studies appropriate?**  Yes  No

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| **Comment:** |

**Literature search**

PMG recommends these sources and approaches to searching the literature (also see the [PRISMA](http://www.prisma-statement.org/PRISMAStatement/Default.aspx) statement):

* Is an electronic search of MEDLINE, Embase, plus any topic-specific databases planned?
* Electronic search strategy might include broad search filter added with comprehensive content specific terms (e.g. terms related to the targeted health condition, to the targeted health outcomes, or to the index prognostic factors or models under review).
* Is at least one search strategy (usually MEDLINE) included as an appendix?
* Supplemental search strategy is important in prognosis reviews. Is there a plan to screen reference lists, use citation tracking and communicate with content experts?
* Is there the plan to apply no language restrictions?

**Based on these strategies and approaches, were the search methods clearly and adequately reported?** Yes  No

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| **Comment:** |

**Do you see any flaws in the search strategy or are there any additional resources that should be searched?**Yes  No

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| **Comment:** |

**Data collection**

The PMG recommends data extraction include at least the following characteristics and approaches:

* Will the CHARMS checklist be used to extract information on characteristics of targeted population, index prognostic factor(s) or model(s), predicted outcomes, follow-up duration, moment of prognostication, study design, results?
* Will data be independently extracted and agreed upon by two review authors, and disagreements resolved by author consensus?
* Will standardized forms used and pilot tested to make sure all important data are included and similar approach is used across review team?
* Will authors of included studies be contacted if information lacking?

**Based on these factors, is the process of extracting data appropriate and are no important items missed?** Yes  No

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| **Comment:** |

**Risk of bias assessment**

The PMG recommends using the QUIPS tool for assessment of risk of bias in prognostic factor studies. The PROBAST tool is recommended for prognostic model studies. For overall prognosis studies an adaptation of the QUIPS tool is recommended. The protocol should describe how the review will address the following:

* Are all risk of bias items explicitly defined and operationalized for the review question?
* Will there be independent assessment by 2 reviewers, plus a neutral third party if consensus is not reached?
* Is a pilot test of assessment tool planned to ensure similar approach and assessment across the review team?
* Will authors of included studies be contacted if information is lacking to make a decision?
* Will bias be judged separately for each risk of bias domain within each study included in the review (no ‘quality score’)?
* Is there a plan to incorporate results of quality appraisal into the review’s synthesis?
* Is there a description of how risk of bias assessment will be used, for example:
  + Inclusion of studies (parameters included)
  + Stratified analysis (parameters included)
  + Sensitivity analysis (parameters included)
  + Meta-regression (relationship between risk of bias and magnitude of effect)?

**Based on these factors, was the risk of bias assessment clearly and completely described?**   
Yes  No

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| **Comment:** |

**Will the appropriate tool be used for risk of bias assessment and were the criteria for assessing risk of bias appropriate?** Yes  No

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| **Comment:** |

**Data analysis**

The PMG recommends data analysis include at least the following decision points and approaches:

* Is the choice of narrative or meta-analysis approach described and explained?
* Is a comparisons of various factors or models (i.e. one versus another) related to the review question planned?
* Is there a clear description of methods for making decisions on clinical/statistical heterogeneity?
* Is there a clear description of the use of the meta-analysis models (e.g. random effects)?
* Are subgroup analyses related to the review question?
* Is a GRADE or modified GRADE approach described to assess the certainty of the synthesized evidence for each outcome?

**Based on these factors, are the planned methods for analyzing the data clearly and completely described?** Yes  No

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| **Comment:** |

**Are the appropriate analyses planned?** Yes  No

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| **Comment:** |

**Are the appropriate subgroup and sensitivity analyses planned?** Yes  No

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| **Comment:** |

**Are the appropriate GRADE assessments planned?** Yes  No

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| **Comment:** |

**Additional comments**

**Do you have any additional comments not included above?** Yes  No

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| **Comment:** |

**Overall assessment**

Please select one of the following options and add any final comments in the space provided below.

The protocol is acceptable for publication in its present form.

The protocol is acceptable for publication with minor revisions.

The protocol is acceptable for publication with substantial revisions.

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| **Comment:** |

**Peer referee acknowledgement / anonymity**

Please complete the following:

I agree to be acknowledged in the published protocol. Yes  No

I agree to be acknowledged on the CRG website. Yes  No

Please include your name and any affiliation as you wish it to appear:

**Name:**

**Date:**