Cochrane
Pregnancy and Childbirth

METHODOLOGICAL CHECKLIST: PROTOCOL

REVIEW TITLE:
REVIEW NUMBER:
CONTACT PERSON FOR THE REVIEW TEAM:
CONTACT EDITOR FOR THE REVIEW:
FEEDBACK TO BE RETURNED BY:

Most of the issues that are likely to arise in protocols can be addressed by standard sections of text that can be included in the template methods section.

	Addressed adequately	Not adequately addressed	Not applicable	Comments
Background				
Rationale for proposed outcome measures				
Rationale for proposed subgroup analyses				
Methods				
Type of studies				
List of types of study design that will be included				
Specify whether quasi-randomised designs included				
Inclusion of studies presented only as abstracts addressed				
Type of participants				
Populations defined and appropriate				
Type of interventions				
Interventions to be included listed and described				
Comparisons to be included				
Type of outcome measures				
Primary outcomes defined and appropriate				
Number of primary outcomes appropriate				
Secondary outcomes defined				
Number of secondary outcomes appropriate				
Comparisons to be included				

Composite outcomes defined				
Data extraction and management				
Methods described for data extraction process				
Methods for calculation of outcomes from data extracted from study report				
Assessment of risk of bias				
Assessment of random sequence generation				
Assessment of allocation concealment				
Assessment of blinding - participants				
Assessment of blinding – clinicians or caregivers				
Assessment of blinding – outcome assessment				
Assessment of incomplete outcome data				
Assessment of selective reporting				
Assessment of other aspects of quality important to the specific review (e.g. outcome measurement)				
Measures of treatment effect				
Summary statistics for dichotomous outcomes				
Summary statistics for continuous outcomes				
Summary statistics for other types of outcome (e.g. ordinal)				
Unit of analysis issues				
Methods for cluster randomised trials				
Methods for crossover trials				
Methods for multiple pregnancies				
Methods for multi-armed trials				
Dealing with missing data				
ITT analysis (as far as possible) specified				
Assumptions to be made if data incomplete				
Imputation methods described				
Sensitivity analyses for effects of missing data				
Actions to obtain missing data				
Assessment of heterogeneity				
Methods of measuring				

heterogeneity				
Criteria for considering heterogeneity important				
Actions to be taken if heterogeneity identified				
Assessment of reporting biases				
Criteria for investigating reporting biases				
Tests to be used for funnel plot asymmetry				
Exploratory analyses of funnel plot asymmetry				
Data synthesis				
Specify fixed or random effects analysis				
Choice of analysis method justified and reasonable				
Criteria for excluding any outcome data from the analysis				
Denominators specified for outcomes that apply to subsets of participants (e.g. neonatal outcomes where there are fetal deaths)				
Comparisons to be made by the review specified				
Subgroup analyses and investigation of heterogeneity				
List of subgroup analyses to be performed				
Subgroup analysis by trial quality if quasi-randomised studies included				
Subgroup analysis by study design if cluster randomised trials included				
Number of subgroup analyses appropriate				
Subgroup analyses defined by appropriate variables				
Subgroup analyses specified as comparisons (i.e. subgroup A versus subgroup B)				
Outcomes to be included in subgroup analyses				
Methods for comparing treatment effects between subgroups				
Other investigations of heterogeneity (meta-regression, sensitivity analyses)				
Sensitivity analyses				
List of sensitivity analyses to be conducted				
Outcomes to be included in sensitivity analyses				