

Table 1. Protocol Items for Meta-Analysis compared to Record Review -- Part 1		
	Record Review	Meta-analysis
<u>Study Objectives</u>	Identify treatments/exposures and outcomes to be studied Define major and secondary hypotheses to be tested	Identify treatments/exposures and outcomes to be studied Define effects to be estimated and whether focus is on estimating effect, explaining variability of results or both
<u>Study Population</u> Observational Unit Inclusion/exclusion Criteria Randomization	Subject Prespecified characteristics of subjects Not Applicable	Study Prespecified characteristics of studies such as design, population, treatment Determine whether limited to randomized studies or not
<u>Identification/Locating Subjects</u>	All or a random sample of all subjects with the condition of interest	Attempt to find <u>all</u> studies of the condition and treatment of interest
<u>Screening and Evaluation</u> Evaluation Blinding	Informed consent needed, physical examination and tests Raters should be blinded to exposure or outcome	Quality of information about the study Reviewers should be blinded to identity of study investigators and either methods or results
<u>Data Collection</u> Method Outcome Data Collected	Systematically measured on individual subjects, as specified in the study protocol Same outcome data collected on all subjects	Systematically abstract results from individual studies as specified in the protocol Various outcome measures available in different studies
<u>Data Analysis</u>	Standard methods for analysis of individual variables	Special methods for meta-analysis

Table 1. Protocol Items for Meta-Analysis compared to Record Review -- Part 2

<p><u>Reporting and Interpretation</u></p>	<p>Demographic description of study population</p> <p>Graphic displays of comparison values, scatter plots</p> <p>Summary statistics and test results</p> <p>Evaluation including quality of data</p> <p>Statistical significance versus clinical importance</p>	<p>Description of all studies reviewed</p> <p>Details of studies analyzed, including results, quality scores</p> <p>Graphical displays of individual study outcomes</p> <p>Effect size and test results from Meta-analysis</p> <p>Evaluation including quality of studies</p> <p>Statistical significance versus clinical importance</p>
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