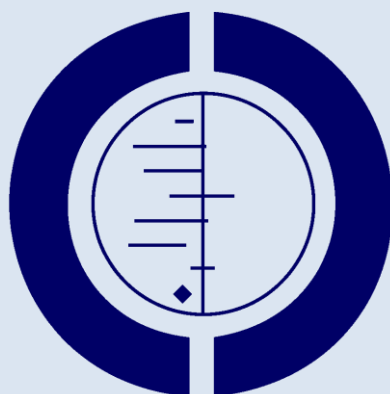


Standards for reporting Plain Language Summaries (PLS) for Cochrane Diagnostic Test Accuracy Reviews

*(interim guidance adapted from Methodological
Expectations of Cochrane Intervention Reviews (MECIR)
guidance for PLS)*

<http://www.editorial-unit.cochrane.org/sites/editorial-unit.cochrane.org/files/uploads/PLSBooklet3.pdf>



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Booklet Version 1 September 2014

Preface

Plain language summaries (PLS) provide rapid access to the content of Cochrane Reviews. Cochrane Reviews should exemplify best practice in the quality of both their conduct and reporting. To maintain this quality there is a need to improve the content of the output of the Cochrane Collaboration as standards and expectations for systematic reviews increase generally; there is also a need to ensure consistency across all Cochrane Review Groups (CRGs) and all reviews. Therefore, the Editorial Unit of the Cochrane Collaboration has defined Plain Language Expectations for Authors of Cochrane Summaries (PLEACS) for intervention reviews. The process for determining the expectations for preparing PLS for intervention reviews, including the methods used to develop the initial list and the management of all feedback received during the consultation process is available at www.editorial-unit.cochrane.org/mecir.

The outputs of the PLEACS project are a valuable starting point for developing guidance for preparing PLS for Cochrane Diagnostic Test Accuracy Reviews (DTARs). This booklet represents draft guidance for the structure of PLS for DTARs for issues that we consider are generic to both intervention and DTA reviews. Work is on-going to address issues more specific to the accessibility of DTARs. We would welcome feedback on both this draft guidance and topics specific to DTARs that require further work and consultation.

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Plain Language Summary (PLS)

Standard	Rationale and elaboration
Plain language summary	Mandatory
<p>Prepare a summary of the review containing all the crucial information in plain language that will be understood by the general public. For DTA reviews clinicians and policy makers may also be unfamiliar with the methods and terminology used.</p>	<p>The plain language summary (PLS) is a stand-alone summary of the systematic review. Above all the PLS should convey succinctly and clearly the key question and findings of the review.</p> <p>The PLS should be written in plain English which can be understood by most readers without a university education. Avoid technical terms and jargon or explain them clearly if they are unavoidable. Examples of jargon are clinical terminology and reviewing jargon (e.g. literature, index tests, meta-analysis, heterogeneity) as well as terms that may have different meanings in medicine than in common usage (e.g. chronic, local, blinding, practice).</p> <p>Dos and don'ts:</p> <ul style="list-style-type: none"> • Limit sentences to one key point • Use short paragraphs. • If your next sentence does not directly follow the previous one, start a new paragraph. • Avoid potentially misunderstood words (more obscure or commonly misunderstood) or phrases or words with dual or nuanced meanings (e.g. drugs; diet); especially those likely to cause difficulty to those who do not have English as a first language. • Avoid hard words such as technical words, jargon or words that are long or with many syllables. • Avoid more than two hard words in a sentence unless you explain them. • Consider introducing an acronym or shorter term for repeated use of long terms. • Write for an international audience. Avoid words or terms that are regional (A&E versus ER). • Use the active voice <p>The SMOG Calculated Index may be useful to check the readability of the PLS. This free online tool (http://www.readabilityformulas.com/free-readability-formula-tests.php) will calculate sentence length and recommend text to be revised for improved readability. For an explanation of SMOG see http://www.readabilityformulas.com/smog-readability-formula.php.</p>
PLS2 Plain language title	Mandatory
<p>Restate the title of the review or the review question.</p>	<p>Give the review title in plain language. Avoid the use of difficult language (including technical words, jargon, and words that are long or have many syllables). If a plain language alternative is not available, include an explanation of the term in the title. Avoid declarative statements and recommendations.</p>

Standard	Rationale and elaboration
Headings	Mandatory
Group the information into sections using standard headers.	<p>Information should be presented in a consistent order under standard headings in PLS. This is because text separated by clear headings is easier to read than a single block. Headings should be bolded.</p> <p>The PLS should be structured according to the following sections : Background (including the index test(s) being evaluated) and rationale for the review, study characteristics, quality of the evidence and key results of the accuracy of the tests being evaluated</p>
Consistency	Mandatory
Ensure that the key messages of the review are reported consistently between the plain language summary, the main text of the review including the abstract, ‘Summary of findings’ tables, and authors’ conclusions.	<p>Tailoring messages across different summary versions of the review may lead to inadvertent inconsistency between the findings or messages conveyed.</p> <p>Pay careful attention to the way that findings are described in different places.</p>

Plain Language Summary - Review question

Review question	Mandatory
Describe the question(s) addressed by the review including the POPULATION(s) (Presentation, Prior tests (test received by participants before the index test) INDEX TEST(s) TARGET CONDITION The condition the index test is trying to detect	<p>The PLS needs to convey the question addressed by the review so that results and conclusions can be contextualised.</p> <p>For Diagnostic Test Accuracy Reviews:</p> <ul style="list-style-type: none"> -Presentation of participants: (for example whether participants have symptoms or are asymptomatic) and prior tests they might have had before the index test (this might be conveyed by stating the healthcare setting in which participants present) -The index test(s) being evaluated. It is usual for a review to estimate the accuracy of more than one index test and to compare these. An index test may be a new test or a test already used in practice. -The target condition is the condition the index tests is trying to detect. This might be an indication for treatment (eg high blood pressure) or a pathological condition (eg a fracture). <p>To help clarify these issues, you may want to use an introductory statement. For example: ‘We reviewed the evidence about the accuracy of test X for the detection of target condition Y in people presenting with Z’.</p>

Plain Language Summary - Background

Background	Mandatory
Briefly introduce the topic with the purpose of explaining the relevant background of the review and the questions that the review intended to address	<p>The PLS needs to convey the question addressed by the review so that results and conclusions can be contextualised.</p> <p>Reviewers should comment on the potential for the introduction of the index test in the proposed role to benefit participant outcomes. For example one or more of: improved accuracy; more rapid results; a less invasive test; a less expensive test.</p> <p>-Details of the index test(s) should be included to help contextualise the review. For example there may be different versions of the same test (different manufacturers, older and newer versions of the same test).</p>

Plain Language Summary - Study characteristics

Standard	Rationale and elaboration
Search date	Mandatory
Provide the date up to which some or all studies have been incorporated.	It is important that readers understand the date up to which the evidence provided by the review is current (e.g. 'The evidence is current to MM YYYY.'). This should be based on the date of the search reported in the abstract. Do not include other search details (i.e. databases, search terms).
Study characteristics	Mandatory
Ensure clear reporting of key characteristics of the included studies.	<p>Study characteristics are important for readers to assess the applicability of the information provided by the review. Include information on the target condition (s), the specifics of index test(s), the population and the conditions under which that test has been used in included studies (details about patient presentation / healthcare setting).</p> <p>Include population details such as severity of target condition, age and sex Not all details of the included studies need to be reported fully; however, the total number of included studies and number of participants contributing to the estimates of the accuracy of each index test must be stated.</p>

Study funding sources	Desirable
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Describe the funding sources of any included studies.

Provide information about funding sources. Please consider the following when reporting this information:

- Give facts about funding sources (i.e. 10 out of 20 studies were funded by the test manufacturer or by an agency with a commercial interest in the results of the studies, seven received charitable funding and three were funded by government agencies).
- If the review explicitly considers how funding sources may affect the quality of the evidence including contributing to heterogeneity then include a statement indicating the impact in the PLS.

Plain Language Summary - Quality of the evidence

Standard	Rationale and elaboration
Quality of the evidence	Mandatory
Describe the overall quality of the evidence in terms of risk of bias and applicability as assessed using QUADAS-2	For DTA reviews the recommended quality assessment tool is QUADAS-2 which is topic specific in recognition of the importance of context on the quality assessment of test accuracy evaluations. A PLS should identify the most important threats to validity (internal and external) as a result of application of QUADAS-2. At present the use of GRADE for DTA reviews remains in development and GRADE terminology should be avoided in the PLS.
Describe any factors that could affect confidence in the results / quality of evidence.	

Plain Language Summary - Key results

Standard	Rationale and elaboration
Key results	Mandatory
Present the results for primary and secondary) outcomes. For DTA reviews primary outcomes are estimates of the accuracy of index test(s) and a comparison of these. Secondary outcome are usually concerned with investigation of sources of heterogeneity in estimates of test accuracy including the test positivity threshold.	<p>Present the accuracy of the index tests(s) in terms of sensitivity and specificity and include an explanation of what these outcome measures mean in terms of the size of false positive and false negative test errors: as sensitivity increases the proportion of false negative test errors decrease and as specificity increases the number of false positive test errors decrease.</p> <p>With reference to the clinical pathway, present the potential implications of the introduction of the index test(s) on patient outcomes as a result of changing test positive errors and / or changing test negative errors. This summary will rely on reference to clinical implications whilst recognising that a systematic review of the effects of test errors on patient outcomes will not have been undertaken as part of a DTA review.</p> <p>Acknowledge other outcomes that you looked for even when there is little or no available data from the studies included in the review (for example indeterminate test results).</p>
	Use consistent wording across outcomes (use of words such as "will, may, probably, little, uncertain"). For example, Test X will probably reduce false positive test errors which will result in a reduction in further testing OR test X probably has a similar accuracy to test Y but will reduce time to diagnosis.

Use of statistics	Mandatory
<p>It is essential to provide numerical data in the plain language summary for DTARs.</p> <p>Such data should be understandable to a non-trained audience and provide a valid and digestible summary of the size and precision of the effect estimates described.</p> <p>Wherever possible normalised frequency representations of results should be presented.</p>	<p>The impact of test performance on patient outcomes is not directly addressed by DTA reviews. The most valuable output of DTA reviews is to provide reliable and applicable estimates of test performance. Whilst it is essential that the clinical pathway is described in a DTA review, the findings a DTA review alone will not be used to provide a recommendation about patient management.</p> <p>For this reason the numerical results of a DTA review are considered essential in a PLS.</p> <p>Research has shown that use of normalised frequencies improves the accessibility of probabilities. Probabilities presented in DTA PLS should also be explained using a frequency format. For example, in addition to stating that an index test has a sensitivity of 70% a PLS should state that: ‘Based on these results we would expect 70 of 100 affected women (those with the target condition) to be detected with the index test whilst 30 affected women would be missed (would be false positives) and not receive appropriate treatment’.</p> <p>Any numerical data reported in the PLS must also be reported elsewhere in the review.</p>