

Standards for the reporting of Plain Language Summaries in new Cochrane Intervention Reviews (PLEACS)

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Status: Mandatory means that a new review should not be published if this is not reported. Highly desirable means that this should generally be done, but that there are justifiable exceptions.

Preface

Plain Language Expectations for Authors of Cochrane Summaries (PLEACS) have been established by a special working group comprised of consumers, methodologists and editors from The Cochrane Collaboration. During 2012, this group developed a set of standard requirements for plain language summaries (PLS) of Cochrane Intervention Reviews. This work complements the MECIR project which has so far delivered standards relating to the conduct and reporting of Cochrane Intervention Reviews (see: <http://www.editorial-unit.cochrane.org/mecir>).

The standards below summarize proposed attributes of reporting that we consider either mandatory or highly desirable for PLS of Cochrane Intervention Reviews. For each standard we have given a reason for our judgment alongside some examples.

During July and August 2012, members of the collaboration and the public were invited to comment on the draft standards through an open consultation process. Key comments revolved around the issues of 1) reading age for PLS, 2) the presentation of information about systematic reviews and Cochrane in PLS, 3) the use of headings to break-up the text, and 4) explanations about the quality of the evidence. The working group reviewed all the comments and amended the standards in response.

The ordering of the standards reflects the position in which each issue might be expected to be addressed in the PLS. Work on establishing the most suitable format for structuring the PLS is ongoing and as an interim measure we have associated each standard with provisional considerations to help orientate authors, editors and readers (*see PLS3 below*).

During the early part of 2013, the PLEACS working group will begin development of good-practice examples to aid authors and Cochrane Review Groups implement the standards

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Item #	Status	Item name	Standard	Rationale and elaboration
PLS1	Mandatory	Plain language summary (PLS)	Prepare a summary of the review containing all the crucial information in plain language that will be understood by the general public.	<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. It is highly desirable for the PLS to be 400 words and it should be no more than 700 words.</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 Cochrane/reviewing jargon (e.g. outcome, literature, case series, efficacy and effect size) as well as terms that may have slightly different meanings in medicine than in common usage (e.g. local, blinding, control, 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 (i.e. that are obscure or commonly misunderstood) or phrases or words with dual or nuanced meanings (e.g. drugs; diet) and 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. • 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 might be useful in implementing the standards for all 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	Mandatory	Plain Language Title	Restate the title of the review or the review question.	<p>The title of should be given in plain language. Difficult language includes technical words, jargon or words that are long or with 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>

PLS3	Mandatory	Headings	Group the information into sections using standard headers.	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 in bold . Work to finalize headings for the different sections of the PLS is ongoing. However, as an interim measure the PLS may be structured according to the sections about the review question, background, study characteristics, key results and quality of the evidence.
PLS4	Mandatory	Consistency	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.	Tailoring messages across different summary versions of the review may lead to inadvertent inconsistency between the findings or messages conveyed. Careful attention should be paid to the way that findings are described in different places.
Plain Language Summary - Review Question				
PLS5	Mandatory	Review question	Describe the question(s) addressed by the review including the population(s), intervention(s), comparison(s) and the main outcomes if applicable.	The PLS needs to convey the question addressed by the review so that results and conclusions can be contextualised. To help clarify these issues, you may want to use an introductory statement. For example: 'We reviewed the evidence about the effect of X on Y in people with Z. We found xx number of studies.'
Plain Language Summary – Background				
PLS6	Mandatory	Background	Briefly introduce the topic with the purpose of explaining the relevant background of the review and the uncertainties that the review intended to address	Provide a short description of the population, intervention, and outcomes. For example, 'We wanted to discover whether using the single inhaler therapy was better or worse than other alternatives, such as receiving the same drugs in two separate inhalers. Single inhaler therapy is the use of one inhaler containing both a reliever drug and a preventer drug.'
Plain Language Summary - Study Characteristics				
PLS7	Mandatory	Search Date	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 details of the search strategy (i.e. databases, search terms).

PLS8	Mandatory	Study characteristics	Ensure clear reporting of key characteristics of the included studies.	<p>Study characteristics are important so that the reader can assess the applicability of the information. Include information on the condition, the specifics of the intervention(s), the population and the setting.</p> <p>Include population details such as severity of condition, age, gender and comparators. Not all details of the included studies need to be reported fully; however, the total number of included studies, the duration of the trials and number of participants must be stated.</p>
PLS9	Highly Desirable	Study Funding Sources	Describe the funding sources of any included studies.	<p>Provide information about funding sources. Please consider the following when reporting this information:</p> <ul style="list-style-type: none"> • Give facts about funding sources (i.e. 10 out of 20 studies were funded by the drug 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). • Convey factual information as a characteristic of the studies included in the review. Comment on this as a source of bias if an assessment of its impact has been carried out and reported in the full review. • If the review explicitly considers how funding sources may affect the quality of the evidence then include a statement indicating the impact in the PLS.
Plain Language Summary - Key Results				
PLS10	Mandatory	Key Results	<p>Present the results for all main (primary and key secondary) outcomes</p> <p>Report the findings for harms (adverse events) that are described in the review.</p> <p>State whether the harms have been fully reported by the included RCTs.</p>	<p>Present the effect of the intervention on each of the main outcomes.</p> <p>Present results for all primary and key secondary outcomes that are important to patients irrespective of what the actual results were. Acknowledge patient-centred outcomes that you looked for even when there is little or no available data from the studies included in the review.</p> <p>Summary versions of the review should enable readers to evaluate the balance between benefit and harms of an intervention. If none of the included studies reported harms or only limited information was included in the reports from the studies, this should be described in the PLS.</p> <p>Use consistent wording across outcomes (see the suggestions for use of words such as "will, may, probably, little, uncertain"). For example, Drug X may reduce pain, probably improves quality of life, and there is little or no difference in side effects.</p> <p>Explain what an outcome means if it is complicated or not in common usage.</p>

PLS11	Highly Desirable	Use of Statistics	<p>It is not essential to provide numerical data in the plain language summary.</p> <p>If such data are provided it is important that the information is understandable to a non-trained audience and provides a valid and digestible summary of the direction, size and precision of the effect estimates described.</p> <p>Wherever possible relative quantitative effects estimates should be accompanied by measures of absolute effects drawn from the review.</p>	<p>Summary of findings tables include an absolute measure of the treatment effect, so when available, it should be used as a source for numerical data given in the PLS.</p> <p>When the numerical estimates of effect are imprecise or the effect is otherwise uncertain (e.g. low or very low quality evidence), presenting numerical data in the PLS may not be helpful.</p> <p>Numerical data may be provided using natural frequencies for dichotomous outcomes. For example, 'Based on these results we would expect that out of 1000 elderly women who are not taking the drug over three years, 20 would experience a hip fracture compared with between six and 13 elderly women who would experience a hip fracture if they took the drug every day.'</p> <p>Explain any statistical terms if data are provided in PLS. If numbers needed to treat (for benefit or harm) are used, explain the concept for the lay reader.</p> <p>Relative effects estimates should always be accompanied by an estimate of the absolute effect taken from the review using natural frequencies (absolute risks) for dichotomous outcomes and mean differences (or scales) for continuous outcomes.</p> <p>In all circumstances any numerical data reported in the PLS must be found elsewhere in the review.</p>
Plain Language Summary - Quality of the Evidence				
PLS12	Mandatory	Quality of the evidence	<p>Describe the overall quality of the evidence for each of the main outcomes based on the five GRADE considerations.</p> <p>Describe any factors that could affect the confidence in the results/quality of evidence.</p>	<p>The quality of evidence for each outcome reported in the PLS should be based on the five GRADE considerations (risk of bias, indirectness, imprecision, publication bias and inconsistency).</p> <p>If the GRADE levels are used to express the quality of evidence, provide the level (very low, low, moderate, high quality). If the GRADE levels are not used, be consistent with the use of other terms.</p> <p>Provide key reasons for the quality of the evidence or limitations in lay terms (e.g. poorly conducted studies; results not similar across studies; relevance of outcomes; issues with study design; not enough data). This information needs only to be stated briefly and in plain language.</p> <p>If overall quality of evidence is high this should also be reported.</p>