Cochrane Methods

Methodological Expectations of Cochrane Intervention Reviews (MECIR)

Standards for the *reporting* of Plain language summaries in new Cochrane Intervention Reviews 2013

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Preface

Plain language summaries (PLS) provide instant access to the content of Cochrane Reviews. Cochrane Reviews are seen as exemplifying best practice in the quality of both their conduct and reporting. To maintain this quality we need to improve the content of our output as standards and expectations for systematic reviews increase generally; we also need to ensure consistency across all Cochrane Review Groups (CRGs) and all reviews. To this end we have undertaken within The Cochrane Collaboration to define Plain Language Expectations for Authors of Cochrane Summaries (PLEACS).

The standards associated with the PLEACS project comprise a portion of the body of work known as the Methodological Expectations for Cochrane Intervention Reviews (MECIR). These standards take a significant step towards ensuring that both authors and editorial teams have a shared understanding of the expectations for reporting the content of reviews in the plain language summary.

The standards in this booklet summarize attributes of the plain language summaries as described in the Cochrane Handbook. These standards are either Mandatory* or highly desirable** for new PLS. Each judgment is accompanied by a rationale that provide guidance on the appropriate style for reporting each standard.. There is a separate project that has clarified expectations for the conduct and reporting of Cochrane Reviews led by the MECIR Co-ordinating team. Please separate booklet.
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).
We have described the process for determining the expectations for reporting of PLS, including the methods used to develop the initial list and the management of all feedback received during the consultation process (see: www.editorial-unit.cochrane.org/mecir). This booklet is a draft format and comments are welcome, please contact cmcilwain@cochrane.org.

Finally, I want to pay tribute to my colleagues who have contributed to this work so far. Catherine McIlwain has led this initiative with great dedication, perseverance and enthusiasm. An important feature of this project, at all levels, has been to reflect the importance of CRG teams, consumers and methodologists working alongside one another. Catherine has been supported by Jackie Chandler and Toby Lasserson, both of whom have made major contributions. In addition, scores of people from within the Collaboration either contributed to the working groups, without which we would have had no ‘long-list’ of proposed expectations to build on, or the consultation that succeeded the working groups. Additionally, I thank invited external stakeholders for comments received on a draft set of reporting standards. I hope that the Collaboration recognises the efforts of all the individuals involved and the true sense of collaboration that the work has engendered.

David Tovey, Editor in Chief of the Cochrane Library

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.

Plain Language Summary (PLS)

Standard	Rationale and elaboration
PLS1 Plain language summary	**Mandatory**
Prepare a summary of the review containing all the crucial information in plain language that will be understood by the general public.	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. 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). Dos and don'ts: • 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. • Write for an international audience. Avoid words or terms that are regional (A&E versus ER). • Use the active voice 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.
PLS2 Plain language title	**Mandatory**
Restate the title of the review or the review question.	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.

Standard	Rationale and elaboration
PLS3 Headings	**Mandatory**
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 bolded. 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 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.	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 Review question	**Mandatory**
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 Background	**Mandatory**
Briefly introduce the topic with the purpose of explaining the relevant background of the review and the uncertainties that the review intended to address	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 - Study characteristics

Standard	Rationale and elaboration
PLS7 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 the search reported in the abstract. Do not include details of search (i.e. databases, search terms).
PLS8 Study characteristics	**Mandatory**
Ensure clear reporting of key characteristics of the included studies.	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. 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.
PLS9 Study funding sources	**Highly desirable**
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 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

Standard	Rationale and elaboration
PLS10 Key results	**Mandatory**
Present the results for all main (primary and key secondary) outcomes Report the findings for harms (adverse events) that are described in the review. State whether the harms have been fully reported by the included RCTs.	Present the effect of the intervention on each of the main outcomes. 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. 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. 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. Explain what an outcome means if it is complicated or not in common usage.
PLS11 Use of statistics	**Highly desirable**
It is not essential to provide numerical data in the plain language summary. 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. Wherever possible relative quantitative effects estimates should be accompanied by measures of absolute effects drawn from the review.	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. When the numerical estimations of effect are imprecise or the effects uncertain (e.g. low or very low quality evidence), presenting numerical data in the PLS may not be helpful. 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’. Explain any statistical terms if data is provided in PLS. If numbers needed to treat (for benefit or harm) are used, explain the concept for the lay reader. 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. In all circumstances any numerical data reported in the PLS must be found elsewhere in the review.

Plain Language Summary - Quality of the evidence

Standard	Rationale and elaboration
PLS12 Quality of the evidence	**Mandatory (for primary outcome)**
Describe the overall quality of the evidence for each of the main outcomes, based on the five GRADE considerations. Describe any factors that could affect the confidence in the results / quality of evidence.	The quality of evidence for each outcome should be based on the five GRADE considerations (risk of bias, indirectness, imprecision, publication bias and inconsistency). Express the quality of evidence in the PLS. 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. 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. If overall quality of evidence is high this should also be reported.