Guidance for Consumer reviewers.

You have been invited to provide consumer comments on a Cochrane Review or Cochrane Protocol. This guidance document aims to help you complete our forms for providing your comments.

What are Cochrane Protocols?
A Cochrane Protocol is a plan for a full Cochrane Review. A Cochrane Protocol outlines the healthcare question that will be addressed, and describes the methods that will be used in the Cochrane Review. The information contained within a Cochrane Protocol will be included in the full Cochrane Review when it is completed.

What are Cochrane Reviews?
Cochrane Reviews summarise the evidence about interventions for a healthcare need.

Interventions can be drugs, behavioural programmes (such as counselling), devices, or some other form of care. An intervention is a process of ‘intervening’ on people, groups, entities or objects, with the aim of enhancing health. Some interventions are ‘complex’, and combine a number of individual components. All interventions should be studied to find out if they do more good than harm.

Cochrane Reviews define a healthcare question (such as ‘What are the effects of antibiotics for people with an infection?’), and they aim to answer the question by finding and synthesising all relevant research evidence. Cochrane Reviews are intended to be used by people making a decision about health care, such as policy makers, clinicians, and consumers of health care. Some of the language in Cochrane Reviews is technical, but the plain language summary should be straightforward to read, and is intended to be used by consumers to help them make decisions about health care.

A consumer perspective is valuable
The Cochrane Collaboration encourages the involvement of healthcare consumers in the development of Cochrane Reviews and Protocols, to help ensure that they:

- address questions that are important to people;
- take account of outcomes that are important to those affected;
- are accessible to people making decisions; and
- adequately reflect variability in the values and conditions of people, and the circumstances of health care in different countries.

Other peer-reviewers also provide comments on Cochrane Reviews and Protocols. These people include clinicians, researchers, statisticians and methodologists, and they are chosen for their specific expertise. Your input is particularly valuable for your expertise on what it is like to have a particular condition, or care for someone with a particular condition – although not all consumer peer reviewers will have first-hand experience of the condition. You may not feel you have enough
knowledge to comment on all sections of the checklist, but your views on specific sections would be particularly valuable, and these have been highlighted in the checklists.

**Commenting constructively**
When providing comments on a Cochrane Review or Protocol, we encourage you to explain the changes you would make to correct any problems. This could mean suggesting specific word changes. We also ask that your comments are respectful and objective.

**The checklists**
The checklists include boxes for you to provide your comments. Most of the boxes relate directly to sections within the Cochrane Review or Protocol that we would like you to comment on. A description of what these sections in Cochrane Review or Protocol should include is provided below.

**Sections within a Cochrane Review**
**Title**: The title should explain to the reader what the Cochrane Review or Protocol is about, and it should be relatively easy to understand. Authors of Cochrane Reviews and Protocols are asked to keep to a basic format for the title of ‘[Intervention] for [healthcare need]’.

**Abstract (Review only)**: Abstracts are a summary of the whole Cochrane Review. They should be brief without sacrificing important content. Abstracts to Cochrane Reviews are freely available on the Internet; therefore, it is important that they can be read as stand-alone documents.

**Plain language summary (Review only)**: The plain language summary is a summary of the whole Cochrane Review. It should be written in a straightforward style that can be understood by consumers of health care, and should help them make healthcare decisions. The language should be as accessible as possible to those not familiar with the particular area or specialist language. Plain language summaries are made freely available on the Internet, so will often be read as stand-alone documents. Plain language summaries have two parts: a plain language title (a restatement of the Cochrane Review’s title using plain language terms) and the summary text.

**Background (Protocol and Review)**: The background should explain the reason for doing the Cochrane Review, and why the Cochrane Review is important. The background should be concise (generally around one page when printed) and be understandable to people who might use the intervention. It should address relevant issues for consumers in different countries, and should include appropriate references.

The background may have the following sub-headings:

- Description of the condition
- Description of the intervention
- How the intervention might work
- Why it is important to do this review

When considering the background, it may be helpful to think through the following questions:

- Is the nature and importance of the health problem clearly described, including personal and global impact?
- Does it reflect the potential influence of personal characteristics (such as age, gender, ethnicity or risk status)? Would such information be helpful?
• Is the intervention, and the context of its use, clearly described?
• Are the most important issues for consumers addressed?
• Is there any information missing?

Objectives (Protocol and Review): The objectives are a precise statement of the aim of the Cochrane Review, ideally in a single sentence. The sentence should be in the form “To assess the effects of [intervention] for [health problem] for/in [types of people, disease or problem, setting]”. This sentence might be followed by a series of more specific objectives.

Criteria for considering studies for this review (Protocol and Review)

Types of studies: This section describes the type of studies to be included in the Cochrane Review. Studies provide the evidence for Cochrane Reviews, and they are tests for generating data about the safety and efficacy of an intervention. There are many types of studies, but the most common type of study to be included in Cochrane Reviews is the ‘randomised controlled trial’ or ‘RCT’. RCTs compare the effects of interventions (or the effects of an intervention compared with no intervention), in people who are randomly assigned to receive one intervention or the other. RCTs are generally the preferred type of study for assessing healthcare interventions. Each Cochrane Review Group has their own policy on the types of trials that they accept in their Cochrane Reviews.

Types of participants: This section describes the type of participants to be included in the Cochrane Review, including the diseases or conditions of interest, and any restrictions such as diagnoses, age groups and settings.

Types of interventions: This section states the intervention(s) to be studied, and what these interventions will be compared with. Restrictions on dose, frequency, intensity or duration should be stated.

Outcome measures: This section describes the type of outcomes that will be assessed in the Cochrane Review. Outcomes are measures of health status, and examples of outcomes include: symptoms, pain, death, emotional well-being, quality of life, impact on daily living, and adverse effects of an intervention. This section should include the ‘primary outcomes’ and ‘secondary outcomes’. Primary outcomes should be the most important, and the results from assessing the primary outcomes usually form the basis for the conclusions of a Cochrane Review. There should be as few primary outcomes as possible, and they should cover at least one potential benefit or harm of the intervention. All other less important outcomes should be secondary outcomes.

When commenting on the ‘Outcome measures’ it may help to consider the following:

• Are the outcomes the most important to consumers? These might include quality of life, emotional wellbeing, social relationships and the ability to cope with day to day activities.
• Are the outcomes that the review intends to measure clearly described?
• Will the review address both benefits and risks, and what would happen if the intervention is not used?
• Will adverse effects and long term outcomes be considered?
• Are there any missing outcomes you think the authors should include?

Search methods for identification of studies (Protocol and Review): This section should describe the methods used to find the studies. This section can often be very technical and will
have been developed in collaboration with the Trials Search Co-ordinator (or information specialist) of the Cochrane Review Group.

**Data collection and analysis (Protocol and Review):** This section describes the methods for collecting data and how it will be analysed. Again the section can be very technical.

**Results (Review only):** This section is split into ‘Description of studies’, ‘Risk of bias in included studies’ and ‘Effects of interventions’, and can be long and technical. Consumers may find the ‘Summary of main results’ in the ‘Discussion’ provides a more understandable description of the results. The results section should summarise the results of the search, and the key characteristics of the included studies (the participants (condition, sex, age range), location of the study, setting (if important), interventions, comparisons and outcome measures). Important differences between studies should also be mentioned. Any risk of bias of the included studies should be included (this can often be very technical). The effects of interventions section should directly address the objectives of the Cochrane Review rather than list the findings of the included studies in turn; this section will contain statistical information. Outcomes should normally be addressed in the order in which they are listed under ‘Types of outcome measures’. Subheadings are encouraged if they make understanding easier.

**Discussion (Review only):** This section should summarise the main findings (without repeating the ‘Effects of interventions’ section) and any outstanding uncertainties. It should balance important benefits against important harms of the intervention(s). It should be written in clear language.

**Authors’ conclusions (Review only):** Conclusions of the authors are divided into two sections:

**Implications for practice:** The implications for practice should be as practical and unambiguous as possible. They should not go beyond the evidence that was reviewed and be justifiable by the data presented in the Cochrane Review. Authors should not make recommendations but report on the implications for practice based on the data reviewed.

**Implications for research:** This section of Cochrane Reviews is used increasingly often by people making decisions about future research, and authors should try to write something that will be useful for this purpose. As with the ‘Implications for practice’, the content should be based on the available evidence and should avoid the use of information that was not included or discussed within the Cochrane Review.

**Summary of findings table (Review only):** Some Cochrane Reviews have a ‘Summary of findings’ table or tables. These tables present the main findings of a Cochrane Review in a transparent and simple tabular format. In particular, they provide key information concerning the quality of evidence, the size of effect of the interventions for the main outcomes.

**Declarations of interest (Protocol and Review):** Authors should report any present or past affiliations or other involvement in any organisation or entity with an interest in the Cochrane Protocol or Review that might lead to a real or perceived conflict of interest. Situations that might be perceived by others as being capable of influencing an author’s judgement include personal, political, academic and other possible conflicts, as well as financial conflicts. Authors must state if they have been involved in a study included in the Cochrane Review.

Financial conflicts of interest cause the most concern, and should be avoided, but must be reported if there are any. Disclosing a conflict of interest does not necessarily reduce the worth of
a Cochrane Review or Protocol, and it does not imply dishonesty; however, conflicts of interest can influence judgements in subtle ways. If there are no known conflicts of interest, the authors should state ‘None known’.

**Other boxes in the checklists**

**Language and style of writing:** One of the main reasons for consumers to comment on Cochrane Reviews and Protocols is to ensure that people who are not experts can understand them, especially the Plain Language Summary. Abbreviations, research terms and medical words should be explained when first used. The writing should also be sensitive to the perception and experience of possible readers.

**Additional comments:** This section of the form allows you to provide any additional comment on the Cochrane Review or Protocol.

**Conflicts of interest:** We have included a section on conflicts of interest for the consumer reviewer to ensure transparency of any real or perceived conflicts of interest that could influence the comments made by you. Just as authors of systematic reviews declare present or past involvement in any organization with an interest in the review that might lead to a real or perceived conflict of interest, so do people who comment on and edit the review. Situations that might be perceived by others as being capable of influencing a review author’s judgements include personal, political, academic and other possible conflicts, as well as financial conflicts.

It is up to the individual Cochrane Review Group to decide their policy on whether people with conflicts of interest are allowed to comment on Cochrane Reviews and what constitutes a conflict of interest. Therefore this section may be modified by the Cochrane Review Group. Having a medical condition related to the review topic is not a conflict of interest and indeed it is experience of living with it that the Cochrane review Group and author team are after to help ensure that the Cochrane Review group is relevant to people making decisions about healthcare.

**Your acknowledgement:** This section asks whether you would like your name and status as a consumer peer reviewer to be given to the authors of the Cochrane Review or Protocol, whether you would like to be acknowledged in the published Cochrane Review or Protocol as a contributor, and if you would like to be acknowledged in a list of peer-reviewers/contributors associated with the Cochrane Review Group.

Please note that explicit details about medical conditions you have will never be provided, either to authors or in the printed acknowledgement. However, you should contact the Managing Editor of the Review Group for more details or if you have concerns.

**Further information**

If you would like more information on being a consumer contributor in general, please visit the Cochrane Consumer website (http://consumers.cochrane.org/); this website provides additional information and resources. You can also contact Cochrane Consumers with queries at rmorley@cochrane.org or via telephone +44-207 183 7503.

There is more detail about the content of Cochrane Reviews and Protocols in the Cochrane Handbook for Systematic Reviews of Interventions (www.cochrane-handbook.org), although please note that the information can be technical.