Consumers In Cochrane

An orientation to our role.

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This publication and its contents are prepared by consumers for consumers. Consumers, review authors, review groups, fields and health agencies have worked collaboratively as part of a project funded by the Department of Health and Ageing for Cochrane activities in Australia, managed by the Cochrane Consumer Network.

The experience has been like building a village, each contribution forming the foundation for the next. With lessons learned, we hope this is the start of many villages!

Janet Wale ccnet-contact@cochrane.de
About The Cochrane Consumer Network Web Site

http://www.cochrane.org/consumers

The World Health Organization (1978) states: "The people have the right and duty to participate individually and collectively in the planning and implementation of their health care".

Welcome to Consumers in Cochrane!

The purpose of this web site is to tell you about The Cochrane Collaboration and how we receivers and users of health care can benefit from its mission. We consumers are invited to work collaboratively with healthcare providers and researchers to develop reviews on the benefits and harms of healthcare interventions and treatments.

The Cochrane Collaboration works within some fifty areas of disease-based health care to develop systematic reviews of best evidence. To do this it has a somewhat complex structure; we provide a web site map to guide you on your tour.

This site is developed by consumers for consumers.

OUR CONTACT E-MAIL: ccnet-contact@cochrane.de

ABOUT THE COCHRANE CONSUMER E-MAILING LIST: E-mail us!
Consumer Maryann Napoli writes: There is something I grapple with, how to explain The Cochrane Collaboration in twenty-five words or fewer. I struggle with that whenever I want to reference The Cochrane Collaboration in an article I’ve written. Explain it verbally and you get that stare as if to say: hasn’t medicine always been evidence based?

These days, healthcare providers face a serious challenge to keep up with the latest research and knowledge about methods of health care. Information is being published every day, all over the world. It appears in thousands of medical, scientific and health-related journals. The results of one healthcare study might, however, be different from, or even contradict, the results of another study. Another problem is that reports are written in a number of languages and may appear in less well known journals. And no matter how tempting, it would be wrong for someone to ignore reports. This is why we have systematic reviews.

The Cochrane Collaboration is an international not-for-profit organisation registered in the UK. It sets out to make the current status of healthcare interventions more accessible - as a way of helping people make well-informed decisions about health care. How this is done is by preparing, maintaining and promoting systematic reviews of the effects of healthcare interventions. To achieve its goals, The Cochrane Collaboration is made up of geographically diverse groups that are each based on a particular disease or health problem.

The Cochrane Library
The main activity of the Collaboration is the preparation of Cochrane reviews that are published electronically on The Cochrane Library.
Accessing The Cochrane Library

The Cochrane Collaboration web site (www.cochrane.org/reviews) provides easy access to summaries and abstracts of Cochrane reviews. The web site also has clear links to The Cochrane Library.

You can also go direct to the Library (www.cochranelibrary.com) where abstracts and summaries are freely available. In some countries such as Australia, Finland, Ireland, Latin America, Norway and UK the full library with complete reviews is available. In other countries a subscription is required so that people may have to go to a medical library or large public library to access it.

A Cochrane Library Users Guide developed by the Australasian Cochrane Centre is available to help you find the information you want from The Cochrane Library.

In Australia, you can access The Cochrane Library by going to the National Institute of Clinical Studies web site (http://www.nicsl.com.au/cochrane/).

The Australian Government HealthInSite web site (www.healthinsite.gov.au) is also a good source of health information.

A comments and criticisms feedback facility, available on The Cochrane Library, makes it possible to comment on published protocols and reviews.

The Cochrane Library: www.thecochranelibrary.com
Plain language summaries: www.cochrane.org/reviews
Systematic reviews and levels of evidence

How do I know a healthcare intervention works?
Many factors come in the way of assessing the effects of a healthcare treatment. The best way, therefore, is to use healthcare studies in groups of people. Methods are used that aim to minimise chance effects, preconceived associations of cause and effect, perhaps because of personal expectations, and the influence of how people are chosen to be in the different groups. Randomised controlled trials best serve this purpose.

Randomised controlled trials are studies that are rigorously designed. People are allocated to intervention groups in a way that minimises the chances of predicting which treatment group a study participant is in; the intervention under investigation is compared against a well-known intervention or an inactive treatment (placebo). Studies are controlled so that participants have similar associated care in all ways other than the intervention. Ideally, depending on the type of intervention, the service provider is unaware of which group a participant is in and those assessing outcomes are also unaware: this is termed 'blinding'.

The evidence about the effectiveness of an intervention is increased further by systematically looking at, or reviewing, all available reports using relevant randomized controlled trials.

What is a systematic review?
The aim of a systematic review is to thoroughly assess, by means of a set procedure, the best possible evidence about the effects of a healthcare intervention or treatment.

The process of a review is decided beforehand and is clearly defined in a protocol as a way of reducing bias in the studies that are included and how findings are interpreted.

Bias is a systematic ‘error’ or mistake in judgements and decisions that influence the results of a study, and review, because of prior opinions. It differs from a placebo effect where participants of a study perceive a beneficial effect, or harm, even when receiving an inactive treatment.
Levels of evidence for healthcare interventions defined here in two important ways

The National Health and Medical Research Council, of Australia defines the ‘dimensions of evidence’ using three main areas:

1. The strength of the evidence

- Level of evidence: the study design used - a systematic review of all relevant randomised controlled trials is the highest level, followed by at least one randomised controlled trial, then a pseudo-randomised trial
- Quality of evidence: the methods used to minimise bias within a study design
- Statistical precision: the degree of certainty about the existence of a true effect;

2. Size of effect

How much the determined intervention effect is above a ‘no apparent effect’ value, with only clinically relevant effects considered;

3. The relevance of the evidence

How appropriate for the healthcare problem the outcome measure is, and its usefulness.

- Using a measure of variability of results (Confidence Intervals):

**Level I.** For a randomised controlled trial, the lower limit of the confidence interval, expressed as a range, for a measure of effect is still above a meaningful benefit in healthcare terms;

**Level II.** For a randomised controlled trial, the lower limit of the confidence interval, expressed as a range, for a measure of effect is less than a meaningful beneficial effect in healthcare terms; but the point estimate of effect still shows effectiveness of the intervention;

Lower levels of evidence:

**Level III.** Measures of effectiveness are taken from non-randomised studies of groups of people where a control group has run concurrently with the group receiving the intervention being assessed;

**Level IV.** Measures of effectiveness are taken from non-randomised studies of groups of people where intervention effects are compared with previous or historical information;

**Level V.** Evidence is from single case studies.

(Adapted from AD Oxman (1994))
Checklists for review articles. BMJ 309: 648-51)
Where are systematic reviews found?
Systematic reviews are recognised as the gold standard of healthcare evidence.

Like other medical reports, published reviews may vary in the stringency of methodologies used. The Cochrane Collaboration aims to overcome such variations in quality by dictating set methodologies and a peer review process. Cochrane reviews are grouped together to form The Cochrane Library, which is available electronically (www.thecochranelibrary.com).

The Library covers a wide range of healthcare interventions and areas of health care. There are, however, many healthcare problems with innumerable interventions and The Cochrane Library may not contain the information you are looking for in the form of a Cochrane review. A Database of Abstracts of Reviews of Effectiveness (DARE) is included so that you can check what else is available.

What makes a Cochrane review?
A Cochrane review sets a clearly formulated healthcare question. It then uses systematic and explicit methods to identify, select and critically appraise relevant research.

Information on how the interventions used alter the measured outcomes of health care are collected and analysed to obtain overall conclusions. Statistical methods (meta-analyses) are used, where possible, to analyse and summarise the results of the included studies. This strengthens the evidence but is dependent on the availability and reporting of the outcomes, and their reliability.

Important considerations are the overall size of the effect of the intervention on an outcome and how likely it is that people will show this effect (the observed variability of response).

Why consumer input?
Researchers and healthcare providers generally prepare Cochrane reviews. A consumer perspective is important to ensure that review questions are relevant to people requiring health care, and that areas of high importance are given priority. The inclusion of outcomes of health care that are valid for consumers is also important.

Sometimes, the benefits of an intervention have to be weighed up against the potential harms; only consumers can identify the issues that are most important for them, their carers and their families.

For checking the language in a review: that it is sensitive to consumers, uses medical terminology sparingly and explains jargon wherever possible; the intention is that reviews can be read more easily and by a wider audience.
What consumers can, and cannot, get from systematic reviews

Systematic reviews:

* ask a very specific research question about a particular intervention in a clearly defined group of people with a clear health condition or problem;

How does this group of people, and how the intervention was used, differ from your situation? In this way you can assess whether the findings of the review are relevant to you. Reviews cannot offer a broad guideline for treatment, especially if people differ from those defined in the review, such as, having accompanying problems and receiving more than one intervention.

* follow stringent guidelines as to what types of studies are included and how healthcare measures of effectiveness can be expressed;

There may be no information on the outcome you are particularly interested in, or on long term effects of a treatment.

* the studies considered in a review may be limited in the healthcare setting in which they take place;

Conclusions from reviews may not be relevant to all situations, for example, elderly people living at home and those in nursing homes.

* are dependent on the studies and information that are available;

Randomised controlled trials are expensive to run and are time consuming; they may have limitations in how many participants are involved, the outcomes measured, the length of the trial and how many people complete the study.

* healthcare studies differ dramatically in how well they are carried out and, therefore, how much weight one can put on their conclusions;

Part of the reason for performing systematic reviews is to reduce the importance of these problems, including issues of conflict of interest with regard to funding of trials.

* well designed healthcare studies generally set out to determine the efficacy of a healthcare intervention.

Information on potential harms may be less well investigated. Harms may be less common than benefits and occur over a different time period, for example, only with long term treatment. Further more, participants of studies are selected to reduce the risk of other unrelated medical problems interfering with the findings of the study.
Creating the way for consumer participation.

A consumer in Cochrane:

* is an individual with personal experiences that enable an effective healthcare user/receiver perspective to questions addressed in a systematic review;

* may be an individual or representative of a community health support organisation or group and who is without specialized medical knowledge;

* brings an impartial, strong and realistic attitude to the current state of healthcare knowledge and is dedicated to the development of evidence based health care and information;

* is able to identify gaps in our knowledge from a consumer perspective and accepts an intellectual, longer term approach to improving health care;

* seeks information from other health consumers and may also support other consumers in providing consumer input into review questions, while maintaining the confidentiality of the review teams.

The Cochrane Consumer Network:

* supports consumers by enabling communication and guidance in providing a consumer perspective to Cochrane reviews;

* encourages consumers throughout the world to give their perspectives and have their say on priorities;

* encourages the concept of evidence based practice and a forward thinking approach to improvement of health care.

Making contact
E-mail to: ccnet-contact@cochrane.de with your name and enquiry.
Cochrane disease-based groups ask for your assistance

Points to keep in mind if you are asked to comment on a review:

☆ a review uses the best available evidence, internationally;
☆ the review is confidential until it has been published on The Cochrane Library, however, you can consult other consumers about its content;
☆ you form part of a team, others on the team include a service provider or researcher in the same area of health care as the review (content editor), a statistician and members of the editorial board of the Cochrane review group, you are given about three weeks in which to feed back your comments to a review group;
☆ positive comments are helpful as well as expressions of concern.

How to approach a systematic review

A framework to help consumers

1. Parts of a Cochrane systematic review

A Review has set headings that divide it into the different processes that are involved during its development. The items in blue first appear in a PROTOCOL that sets out how the review is to undertaken; it is published on The Cochrane Library, for comment, before the reviewers continue the defined review process.

Title (part of the ‘Cover sheet’) a statement of an intervention for a health problem in a certain group of people - what the review sets out to ‘determine’

Plain language summary (synopsis) a brief summary of the review findings in very simple terms

Abstract a summary of the review divided into the major sections and including the reviewers’ conclusions

Background information about the health problem under study and interventions used

Objectives what the review is trying to determine and the comparisons being made
Criteria
for considering clinical studies for inclusion in the review

Types of studies
- participants
- interventions
- outcome measures: how the effects of an intervention are being determined for the review

Search Strategy
for identifying the studies that have been carried out

Methods
how the review is carried out and how the information is combined with statistical methods

Description of Studies
Methodological quality of included studies
how well the clinical studies were or could be carried out to limit factors other than the intervention being considered having an effect on the results, which can vary with different health interventions and conditions

Results
a statement of the results, often given in numerical form

Discussion
what needs to be considered when trying to make sense of or interpret the results

Reviewers Conclusions

Implications for practice
what the results mean in practice – for service providers and receivers of health care

Implications for research
what needs to be done to improve the evidence base for use of an intervention in a healthcare condition or problem

Acknowledgements

Potential conflicts of interest
a declaration of any interests the reviewers have that may influence how the review has been carried out and the conclusions

Tables
a listing of included and excluded studies/results and sometimes of results

References
where to find the reports and articles in the review.
Confidence interval (CI): even studies perfectly designed and carried out may show variable results because of the play of chance. CI covers the likely range of the true effect. For example, the result of a study may be that 40 per cent (95% CI: 30% to 50%) of people are helped by a treatment. That means that we can be 95 per cent certain the true effect is between 30 and 50 per cent (Smart Health Choices web site).

Randomised controlled trials are studies that are rigorously designed. People are allocated to intervention groups in a way that minimises the chances of predicting which treatment group a study participant is in; the intervention under investigation is compared against a well-known intervention or an inactive treatment (placebo). Studies are controlled so that participants have similar associated care in all ways other than the intervention. Ideally, depending on the type of intervention, the service provider is unaware of which group a participant is in and those assessing outcomes are also unaware: this is termed ‘blinding’.

In quasi-randomised studies participants are allocated to a treatment in a way that is not strictly random, such as, date of birth, hospital record number or alternation.

For non-randomised studies the investigators set out to have participants in the different groups who are similar in all ways they identify, such as, health problem, age, and cultural background.
prompt sheet

A prompt sheet for consumers to consider reviews

Title

* Does the title mean anything to you – is it clearly focused and in a way that is potentially relevant for consumers?

* After you have read the review, is it what the review is about!

General overview

Re Style of writing as you read through the review:

* are the medical terms and jargon used necessary? Are they used sparingly and given a brief explanation? Maybe you could suggest words and terms to appear in a ‘glossary’ for consumers.

* is there any language which disturbs you, or you find insensitive to people like yourself?

* does the review follow on, one section to the next, in a way that you can follow? Do you find the review (its purpose and the findings) interesting?

Overall

* Are there any aspects of the review you particularly like; or are unclear to you?

* Is the review interesting and/or useful (even if it is lack of evidence of effect)? Does it give you useful information that would inform a healthcare decision?

* You may be able to think of ways of making it more useful (reviews are updated so these ideas may be kept in mind for such a time)

Plain language summary (synopsis) and Abstract

Scan the Summary and Abstract as you prepare to read the review and then carefully think about what they say after you have read the review.
Background
This is where the review authors can write about why they have chosen to develop the review, explaining its importance and the relevance of the review topic.

* Does the Background describe the healthcare problem and give information on the setting of the problem, the available knowledge and current practices?

* Are options for care described in a balanced tone that does not prejudge any conclusions that the review may come to? Does it describe what is, and is not, known about the intervention(s), its expected benefits and possible harms?

* Are these controversial in any way and of public interest? If so, do you agree with how it has been presented?

* Are the relevance and implications for the review question explained in more than one country so that you can relate to them?

* Generally, do you think the review question is reasonable and is well presented?

Objectives
Ask yourself, are you clear what exactly is being investigated, in whom and how outcomes of intervention are measured; do you agree?

* Do you consider the objective is practical for you?

* Can you relate to the people who are in the healthcare studies, their health problems, the intervention/s and the outcomes measured; or is something missing?

* Will the review give useful information to consumers or is it too narrow and does not measure what you really need to know?
Types of studies
These will generally be randomised trials (so that it cannot be predicted which treatment group a study participant will be in) and quasi-randomised studies (allocating participants to a treatment in a way that is not strictly random such as date of birth, hospital record number or alternation). Studies are also controlled in that the intervention under investigation is compared against a well-known intervention or an inactive treatment (placebo) and participants have similar associated care in all ways other than the intervention. Ideally, depending on the type of intervention, the service provider is unaware of which group a participant is in and those assessing outcomes are also unaware; this is termed ‘blinding’. These procedures aim to eliminate chance effects and associations of cause and effect because of personal expectations.

Are all reasonable steps been taken in this review to select appropriate studies?

Interventions
The intervention under review is generally compared against either a dummy treatment or a commonly used, accepted treatment.

Are the interventions relevant to you, and are they ethically acceptable?
Is there a need to specify timing of dosing of a drug or procedure: how often, how much and for how long; where; and with what? Do people usually have the same interventions in your experience; do they sometimes have other treatments as well, or other problems?

Outcomes
These provide a measure of the effectiveness, or harm, of an intervention. The primary or most important outcome is one that can be easily measured to give a measure for the management of the health problem. Other outcomes (secondary) may be less easily measured effects, of benefits or harms, and how the person receiving the intervention feels: quality of life, ability to cope functionally, emotionally and socially, longer term effects, a sense of satisfaction i.e. the ups and downs of treatment.

Do you consider that the outcomes are the right ones?

Search strategy
This is how review authors look for the healthcare studies for their review. They usually look in Cochrane databases and others such as Medline. It is good if they can look for reports of studies in English and other languages as well, include handsearching of conference proceedings and ask experts in the area of interest to see if they know of any studies that are not published – and to capture negative as well as positive results.

Is this the case?
Do the search terms make sense to you when you consider what the review is about?
Methods
More than one author is generally involved at each stage of the review eg selecting studies, determining which can be included, assessing their quality, extracting the information, to check on the process.

Description of studies
The Selection criteria are pre-set to minimise bias or personal views about which of the studies found can be included in the review and which have to be excluded.

• Could you follow which studies were included in the review, those excluded, and why?
• Is this clear from the text or do you need to look at the tables of included/excluded studies to follow the process and do you agree with the decisions made?
• Are there any interesting features of the included studies that have not been mentioned and that you think may be relevant for you?
• Do the inclusion/exclusion criteria make the review more, or less, useful for you?

How many studies are included, are there many?
• in what settings, countries, how many people are involved, did these people have any special characteristics,
• how many years ago were the studies carried out – are any recent studies included?
• Do you think the studies found will help answer what the review sets out to do, or your questions?

Quality of studies
A measure of quality is used to identify how rigorously studies were carried out as this will make a difference in the accuracy of the outcomes. Insufficient reporting of studies may influence the measure of quality and is why reviewers may request further information from the authors of the reports.

• Can you follow and do you agree with the decisions made about the quality of the studies?
• Are the findings likely to affect how valuable the results of the review will be?
Possible treatment of results and statistical analysis was decided before the search for studies took place - it is always best if information from the various studies can be synthesised statistically (meta-analysis) to give an overall effect. Was this possible in this review or were the individual studies too different from each other (heterogeneous) to group?

Do you consider the treatment of results appropriate?

- Is the treatment of the individual study findings reasonable and helpful from your consumer perspective?
- Did leaving out poorer quality studies (sensitivity analysis) alters the results of the review?

Whether findings can be separated into sub-groups has also been decided before the review. Reviewers may have good reason, from a healthcare perspective, to believe that effects of an intervention may differ in studies that are less strictly controlled, or that interventions may be more or less beneficial in some people, for example those who have more severe problems, people of differing age or cultural backgrounds and in different healthcare systems.

Results

Do the results mean anything to you in the way they are expressed in the review?

- Is the effect likely to be meaningful in real healthcare terms?
- Is the effect precise or does it have large variation?
- Will the intervention make a difference to how well people feel?
- Do there need to be considerations of what is important to the consumer, their values?
- Are long term effects likely to play a role – is there a balance of short- and long-term effects?
Discussion

- Do the authors discuss the limitations of the included studies sufficiently; are any inconsistencies talked about?
- Are limitations of the review itself may clear?
- Do the authors fit the review findings into other reported evidence and current practice?
- Can you see a practical application of the review findings? Do they make any difference to you about how you feel about the intervention?

Conclusions

Implications for practice

As far as you are concerned

- Are the stated conclusions supported by what was in the review and using the strongest evidence?
- As a consumer do you agree with these conclusions?
- Are all the implications of this review included?

Implications for research

- Are these reasonable?
- Do the research priorities, as identified, reflect needs, interests and concerns of consumers?
Conflict of Interests
Are there any issues about

- Funding of the studies or the financial and public standing issues of the authors themselves that may influence the review?
- If so, are these clearly stated, and are they acceptable?

Ask yourself, do you as a consumer have any conflict of interests that you need to state (shares, funding of support eg for your group, bad experiences)?

Plain language summary

- Is this accurate – does it provide the gist of the review - the important message for consumers?
- Is it useful? (remember the summary and abstract is all many people see)

Abstract

- Is the information consistent with the full review?
- Is anything important left out?
- Does the style of writing convey the key messages clearly?

Again, this may be all of a review that some people see or read. And what happens now

After you have returned your comments to the review group, they pass your comments on to the reviewers for them to consider, often collated with other referees comments. Your input may also be acknowledged at the end of a review.

Thank you for taking the time to give your comments on this review – both your time and the comments are important!
Checklist for Consumers Commenting on a Review

Review title and number:

Your name:

Please highlight and colour your selected response, or insert a number according to your views in the box below, and include any comments in the expandable box

1. Title
   a) The title is easy to understand.
      Agree  1  2  3  4  5  Disagree

   b) The title clearly states what the review is about.
      Agree  1  2  3  4  5  Disagree

2. Plain language summary (synopsis)
   The summary briefly summarises the main results of the review in language that is easy to understand and agrees with the review.
   Agree  1  2  3  4  5  Disagree

3. Abstract
   The abstract is consistent with the full review and easy to understand?
   Agree  1  2  3  4  5  Disagree
4. Background

a) This section explains the healthcare problem and intervention clearly and in an unbiased way.
Agree 1 2 3 4 5 Disagree

b) The review addresses the most important and relevant issues for consumers all over the world.
Agree 1 2 3 4 5 Disagree

5. Objectives

a) The objectives are clear.
Agree 1 2 3 4 5 Disagree

b) The objectives are relevant to consumers.
Agree 1 2 3 4 5 Disagree

6. Participants

The participants are adequately described and are representative of consumers requiring the intervention being considered.
Agree 1 2 3 4 5 Disagree
7. Interventions
The interventions are practical and relevant.
Agree 1 2 3 4 5 Disagree

8. Outcomes
a) The outcomes are clear and include those of interest to consumers.
Agree 1 2 3 4 5 Disagree

b) The missing outcomes are:

9. Search Strategy
a) This covers a wide number of areas.
Agree 1 2 3 4 5 Disagree

b) The search terms make sense to you.
Agree 1 2 3 4 5 Disagree

10. Methods
The methods are complete and reasonable.
Agree 1 2 3 4 5 Disagree
11. Description of Studies
You could easily follow which studies were included and excluded and why.

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<tr>
<th>Agree</th>
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<th>3</th>
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<th>Disagree</th>
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12. Quality of Studies
You can follow, and agree with, the decisions made about the quality of the studies.

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<tr>
<th>Agree</th>
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<th>Disagree</th>
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13. Results
The results are practical to someone receiving the intervention.

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<thead>
<tr>
<th>Agree</th>
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14. Discussion

a) The limitations of the trials and the review findings are made clear.

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<th>Agree</th>
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b) The review findings are clearly stated and useful.

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<th>Disagree</th>
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15 Conclusions: Implications for Practice

a) The stated conclusions are supported by the review.

Agree 1 2 3 4 5 Disagree

b) The conclusions are useful to consumers.

Agree 1 2 3 4 5 Disagree

16. Conclusions: Implications for Research

a) The conclusions are relevant.

Agree 1 2 3 4 5 Disagree

17. Conflict of Interests

Any conflicts of interest are made clear.

Agree 1 2 3 4 5 Disagree

18. Style of Writing

The language used was clear enough to follow the review and sensitive to consumers.

Agree 1 2 3 4 5 Disagree

Are there any words that would be useful in a glossary?

Overall, what is your response to the review? Please make any additional comments you may have.

Thank you very much!
Your Contact Details

We would appreciate you completing the following so that we can contact you with information relating to Consumers in Cochrane. Please e-mail to: ccnet-contact@cochrane.de

Name:
Contact Address:
Postcode:
Phone Number:
Email Address:
Area of work (Parent, Carer, Nurse, Teacher, Librarian, Advocate etc.):

Healthcare area(s) that most concern you:

Any consumer or patient support groups that you are associated with:

I wish to be put into contact with the appropriate disease based Cochrane group: Yes/No

Privacy Agreement

Any personal information collected is kept strictly under Privacy Regulations and is used solely for consumers participation activities of The Cochrane Collaboration. We can also use your information to put you into contact with a Cochrane group, if that is what you want.