GENERAL INTEREST

CMSG REVIEW AUTHOR RESOURCE PACK

Cochrane Musculoskeletal Review Group (CMSG)
Institute of Population Health, University of Ottawa, Canada
Cabrini Institute, Melbourne, Australia

Cochrane Musculoskeletal Group
www.cochranemsk.org

Thank you for your interest in writing a systemic review for the Cochrane Musculoskeletal Group (CMSG).

As you may know, the Cochrane Collaboration is an international network of individuals who are committed to developing, maintaining and promoting systemic reviews in specific areas of health. The CMSG is one of the 52 review groups that form the Cochrane Collaboration. The CMSG aims to develop systematic reviews on treatments for all areas of musculoskeletal conditions such as gout, lupus erythematosus, osteoarthritis, osteoporosis, pediatric rheumatology, rheumatoid arthritis, soft tissue conditions, spondylo-arthropathy, systematic sclerosis and vasculitis. The CMSG is one of the largest Cochrane review groups consisting of over 700 active health care professionals, researchers and consumer representatives from 26 countries. For more information about the CMSG and resources to help you develop your review, visit our web-site at www.cochranemsk.org. The CMSG Title Registration Form provides the editorial base with an idea of the scope of the topic for your proposed review. This form can be downloaded from the CMSG website.

Please note that the CMSG requires new author teams to have an experienced systematic review author on their team. This person must have been the first author on a published systematic review (Cochrane or non-Cochrane). Please see the title registration form for more details

This package provides essential resources to help you develop your review:

- **Cochrane Handbook for Systematic Reviews of Interventions**
  - Designed to help you make appropriate decisions about the methods you use in your review
- **CMSG Web Page Links**
  - Web sites that provide interesting and essential information for new review authors
- **Review Manager (RevMan)**
  - A software program, which must be used in the preparation and future maintenance of your review.

By contributing your time and knowledge to developing a Cochrane review, you are assisting the Cochrane Collaboration in its goal of helping consumers take charge of their health, assisting health care practitioners in acquiring up-to-date information, and encouraging policy-makers to generate positive strategies for community healthcare. On behalf of Rachelle Buchbinder and Peter Tugwell, co-coordinating editors, and all our members, we'd like to welcome you to the Cochrane Musculoskeletal Group.

Should you have any further questions about your review development or require assistance, please do not hesitate to contact me.

Elizabeth Ghogomu and Renea Johnston,

Managing Editors (Ottawa and Australian Editorial Bases)

Email: cmsg@uottawa.ca and renea.johnston@med.monash.edu.au

THE COCHRANE HANDBOOK FOR SYSTEMATIC REVIEWS OF INTERVENTIONS

The Cochrane Handbook for Systematic Reviews of Interventions is the official document that describes in detail the process of preparing and maintaining Cochrane systematic reviews on the effects of healthcare interventions. The current version of the Handbook is 5.0.1 (updated September 2008). It is available in various formats:

- Printable version
- Browsable version online
- Browsable version from the help menu in RevMan 5

It has a new structure, with 21 chapters divided into three parts.

- **Part 1**, relevant to all reviews, introduces Cochrane reviews, covering their **planning and preparation**, and their **maintenance and updating**, and ends with a **guide to the contents** of a Cochrane review or protocol.

- **Part 2**, relevant to all reviews, provides guidance on preparing reviews, covering **eligibility criteria**, **searching**, **collecting data**, **within-study bias**, **analyzing data**, **reporting bias**, **presenting** and **interpreting results**.

- **Part 3**, relevant to some reviews only, addresses special topics, including particular considerations in addressing **adverse effects**, meta-analysis with **non-standard study designs** and using **individual participant data**. This part has *new* chapters on incorporating **economic evaluations**, **non-randomized studies**, **qualitative research**, **patient-reported outcomes** in reviews, and reviews in **health promotion and public health**. A final chapter describes the new review type of **Overviews of reviews**.

To access the *Handbook* online please visit:
http://www.cochrane-handbook.org/

If you have any questions about the *Handbook*, please feel free to email cmsg@uottawa.ca or renea.johnston@med.monash.edu.au

COCHRANE MUSCULOSKELETAL GUIDELINES FOR QUALITY APPRAISAL OF RANDOMIZED AND NON-RANDOMIZED (OBSERVATIONAL) STUDIES

Note: Review authors are advised to consult and comply with the guidelines in the Cochrane Handbook www.cochrane-handbook.org [Chapter 8: Assessing risk of bias in included studies (for randomized studies) and Chapter 13: Including non-randomized studies (for non-randomized studies)].

1) Randomized studies

All CMSG reviews require a standard measure of quality assessment.

Independent quality assessment using separate, pre-piloted, forms should be undertaken by at least two reviewers. Where differences in assessment cannot be resolved, arbitration by a third person is warranted. The emphasis here is on using a systematic approach and to reach a consensus. At present, masking of trial identifiers such as authors and journals names is not required; the only requirement is a statement in the Methods section of the review of whether masking was done.

In general, empiric research has shown that quality scores (numeric scores based on arbitrary weights given to each item in a scale) are arbitrary, unreliable, and hard to interpret [3,4]. Our suggestion, therefore, is to avoid using quality scores and use the 'Risk of bias' tool that Cochrane review authors are expected to use for assessing risk of bias in randomized trials. This involves consideration of six features:

- sequence generation,
- allocation concealment
- blinding
- incomplete outcome data,
- selective outcome reporting and
- 'other' potential sources of bias.

Items are assessed by:
(i) providing a description of what happened in the study;
(ii) providing a judgment on the adequacy of the study with regard to the item. The judgment is formulated by answering a pre-specified question, such that an answer of 'Yes' indicates low risk of bias, an answer of 'No' indicates high risk of bias, and an answer of 'Unclear' indicates unclear or unknown risk of bias.

2) Non-randomized (observational) studies

Assessment of quality of non-randomized (observational) studies is more difficult than assessment of quality of randomized controlled trials (RCTs). Quality assessment methods for non-randomized studies are still under development. Although several assessment scales and checklists are used, none have been fully validated or shown to include criteria that are associated with the effect size (outcome) in empiric studies. Some general guidelines and suggestions are provided here:

1. Appraising non-randomized studies with checklists/scales designed for RCTs may not be appropriate.

2. There are several checklists/scales targeted towards non-randomized studies available. Please consider using one of the following that is the most appropriate for the studies you are including:

- The "Newcastle-Ottawa Scale (NOS) for assessing the quality of non-randomized studies in meta-analyses" appears quite comprehensive and this instrument has been partly validated (Wells et al). It is easy and quick to use. The NOS instrument is available from http://www.ohri.ca/programs/clinical_epidemiology/oxford.htm. The web site also has two checklists (one for cohort studies and another for case-control studies) and also a manual for coding. (This is the scale recommended by the Cochrane Non-Randomized Studies Methods Working Group).
- If prognosis studies are being evaluated, the criteria proposed by Altman (2001) may be useful. This list of comprehensive criteria, however, is not validated.
- The Agency for Healthcare Research and Quality (AHRQ) in the US has recently published a document titled "Systems to Rate the Strength of Scientific Evidence." (http://www.ahrq.gov/clinic/epcix.htm). This document contains checklists for appraising the quality of RCTs, observational studies and systematic reviews. According to this report, the key domains for quality assessment in observational studies are: comparability of subjects, measurement of exposure or intervention, measurement of outcomes, statistical analysis, and funding or sponsorship.

We suggest the use of one of these (or similar) instruments. A complete description of the instrument should be provided in the review. At least two independent reviewers should perform the quality assessment. Mechanisms for resolving discrepancies in coding should be mentioned in the protocol and the full review.

3. In general, empiric research has shown that quality scores (numeric scores based on arbitrary weights given to each item in a scale) are arbitrary, unreliable, and hard to interpret (Juni 1999, Greenland 1994). Our suggestion, therefore, is to avoid relying solely on the overall quality scores. We suggest using individual components of a checklist (and rating such as 'Met, not met, not clear').

4. Once quality is assessed (using individual components of one of the available checklists), the influence of quality on effect estimates (summary relative risk, etc.) could be evaluated by sensitivity analysis (stratifying by criteria met or not met). Separate summary effect estimates can be generated for studies that meet and do not meet the individual quality criterion. Only when a large number of studies are identified for inclusion, approaches such as meta-regression might be

useful. The meta-regression analysis models the outcome (odds ratio, for example) of each study as the dependent variable and will include quality variables as co-variates (independent variables). Incorporating quality scores in the analysis as weights is not recommended.

5. Lastly, in reviews that include both randomized and non-randomized studies, it is more appropriate to present the summary results separately for each of these two broad categories.

References:

1. Jadad 1996. Jadad AR, Moore RA, Carroll D, et al. Assessing the quality of reports of randomized clinical trials: Is blinding necessary? Controlled Clin Trials 1996; 17:1-12.
2. Schulz KF, Chalmers I, Hayes RJ, Altman D. Empirical evidence of bias: dimensions of methodological quality associated with estimates of treatment effects in controlled trials. JAMA;273:408-12.
3. Altman DG. Systematic reviews of prognostic variables. BMJ 2001;323:224-228.
4. Wells GA , Shea B, O'Connell D, Peterson J, Welch V, Losos M, Tugwell P. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses. Department of Epidemiology and Commuunity Medicine, University of Ottawa, Canada. URL: http://www.lri.ca/programs/ceu/oxford.htm
5. Agency for Healthcare Research and Quality. Systems to Rate the Strength of Scientific Evidence. AHRQ Evidence-based Practice Report/Technology Assessment No.47; AHRQ Publication No. 02-E016. US Department of Health and Human Services, USA, 2002. URL: http://www.ahrq.gov/clinic/epcix.htm
6. Juni P, Witschi A, Bloch R, Egger M. The hazards of scoring the quality of clinical trials for meta-analysis. JAMA 1999;282(11):1054-60.
7. Greenland S. Invited commentary: a critical look at some popular meta-analytic methods. Am J Epidemiol 1994;140(3):290-6.

COCHRANE MUSCULOSKELETAL REVIEW GROUP INFORMATION AND RESOURCE WEB PAGES

- **The Cochrane Musculoskeletal Group:**
  (www.cochranemsk.org)
  - Learn more about CMSG and the process of writing a systemic review

- **The Cochrane Collaboration Authors and Researchers Portal**
  (http://cochrane.org/index_authors_researchers.htm)
  Links to key items for authors of Cochrane systematic reviews

- **The Cochrane Handbook for Systematic Reviews of Interventions:**
  (www.cochrane-handbook.org)
  - The official Cochrane document which describes the process of creating Cochrane systematic reviews

- **The Cochrane Style Resource:**
  (http://www.cochrane.org/style/home.htm)
  - The official Cochrane document which describes the formatting requirements for Cochrane systematic reviews

- **CMSG Reviews of Arthritis:** (http://www.arthritis.ca/look at research/cochrane reviews/)
  - Read the consumer summaries of Cochrane reviews on the Canadian Arthritis Society's web page

- **The Canadian Cochrane Network and Centre:**
  (http://www.ccnc.cochrane.org/en/index.html)
  - Recent Cochrane workshops and conference materials are available
  - Find information about upcoming workshops

- **The Cochrane Manual:**
  (http://www.cochrane.org/admin/manual.htm)
  - The official Cochrane document which describes the Collaboration's organization, policies and operations

- **The Equity checklist:**
  (http://www.equity.cochrane.org/Files/equitychecklist2008.pdf)
  - For authors who would like to consider equity in their reviews.

REVIEW MANAGER (REVMAN)

The Review Manager (RevMan) is the Cochrane Collaboration's software program for preparing and maintaining Cochrane reviews. A review author must use this program to enter protocols, as well as complete reviews, including text, characteristics of studies, comparison table, and study data. It can perform meta-analysis of the data entered, and present the results graphically.

Together with Archie, RevMan forms the Cochrane Information Management System (IMS), which is designed to enable contributors to the Cochrane Collaboration to meet the demands of producing high quality systematic reviews of the evidence of the effects of healthcare and deliver these for publication in The Cochrane Library and elsewhere.

More information and the most recent version to download can be found at http://www.cc-ims.net/RevMan.