

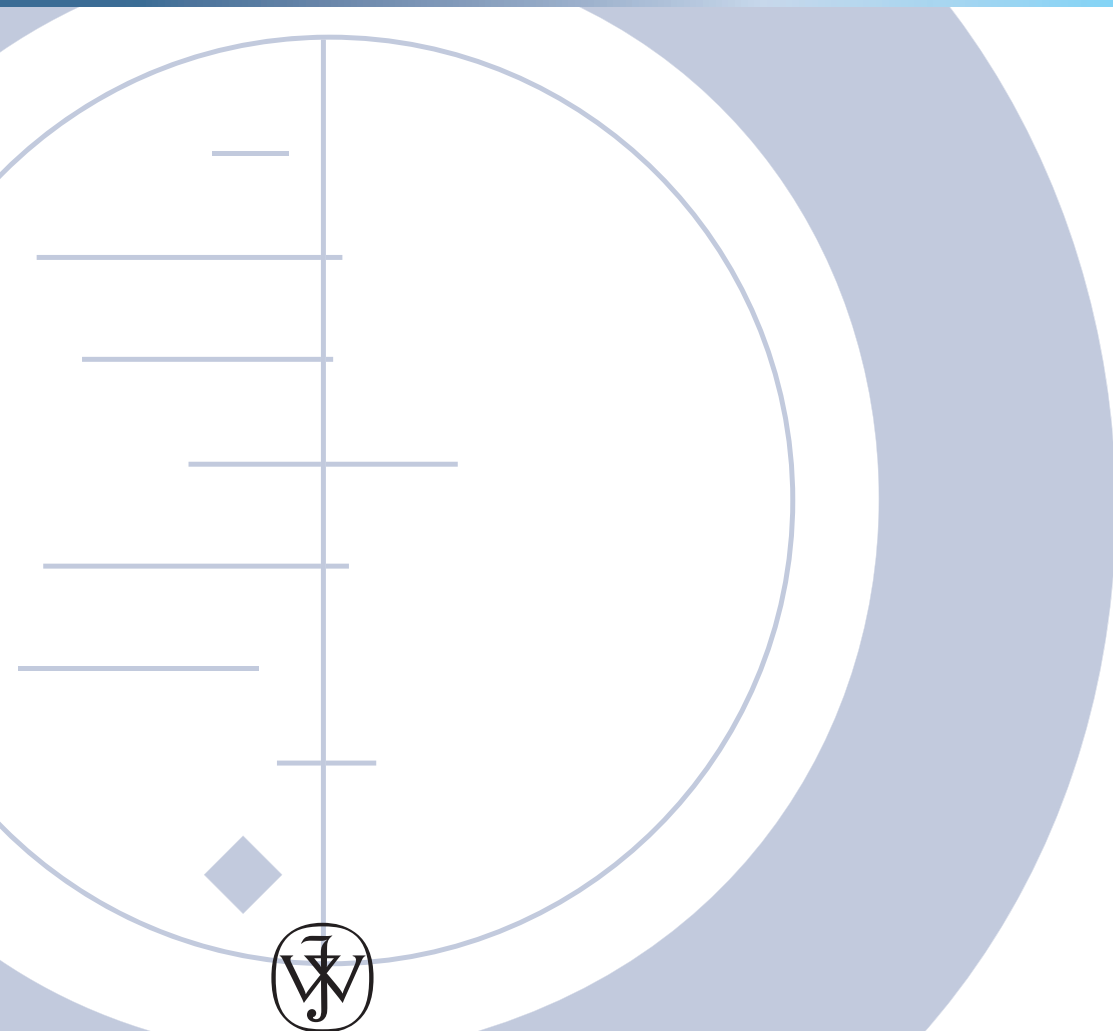


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# COCHRANE METHODS

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Welcome to the first issue of *Cochrane Methods*, the official annual newsletter for methodological issues within The Cochrane Collaboration. Many of you will have seen and contributed to previous issues of the Cochrane Methods Groups Newsletter which has been in circulation since 1997. After more than 13 years, we have redesigned and renamed the newsletter with the aim of giving greater prominence to the work of Cochrane Methods Groups within the Collaboration, and to help raise their profile more widely.

The Cochrane Collaboration is an international, independent, not-for-profit organization of over 27,000 contributors from more than 100 countries, dedicated to making up-to-date, accurate information about the effects of health care readily available worldwide. Its contributors work together to produce systematic reviews of healthcare interventions, diagnostic tests and methodology, published online in *The Cochrane Library*. These reviews help providers, practitioners and patients make informed decisions about their own health care and that of others. The role of the Cochrane Methods Groups is primarily to provide policy advice to The Cochrane Collaboration on how the validity and precision of the Cochrane reviews it produces can be improved. In addition, Methods Groups may also carry out additional tasks such as providing training, peer review and specialist advice, contributing to software developments, or conducting methodological research aimed at improving the quality of Cochrane reviews.

This new-look newsletter highlights the work of Methods Groups and other methodological initiatives within The Cochrane Collaboration. It contains news of relevance to Methods Groups, structured abstracts and commentaries on topical methodological issues, reports of recent methodological research from within the Collaboration, details of Cochrane Methodology reviews and updates on the work of individual Methods Groups.

This issue of *Cochrane Methods* continues to focus on some of the challenging issues facing the methodology of Cochrane and other types of systematic reviews. This year has seen the introduction of a number of changes to the structure and role of Methods Groups within The Cochrane Collaboration, and we begin the issue with a series of short articles outlining some of these important changes, as well as providing news on the recent evaluation of the Cochrane Risk of Bias tool and an update on the training needs of review authors.

As with previous editions, we also include a series of structured abstracts and commentaries on topical methodological issues. This year we include a study examining the relevance of outcome reporting bias, the selective reporting of specific study results and its impact on Cochrane reviews, and another study looking at methods used for indirect comparisons in systematic reviews. We also include commentaries on two influential reporting guidelines, namely the PRISMA Statement for reporting of systematic reviews and a further revision of the CONSORT Statement for reporting of randomized trials. The implications of these two guidelines and their relevance to The Cochrane Collaboration and Cochrane reviews are discussed.

We are, as ever, very grateful to the many people who have contributed to this newsletter. We should also like to thank The Cochrane Collaboration and the UK Cochrane Centre (part of the National Institute for Health Research) for providing resources to produce it.

Finally, we should very much welcome your comments on the new look newsletter and your suggestions for future content.

**Sally Hopewell, Mike Clarke and Julian PT Higgins (Editors of *Cochrane Methods*)**

## A new infrastructure for Cochrane Methods

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Several changes have taken place over the last year relating to the ways in which methodologists contribute to the working of The Cochrane Collaboration. The Steering Group funded a discussion meeting about methods in August 2009, which was generously hosted by Jon Deeks and colleagues in Birmingham, UK. Each Methods Group was represented, and we discussed the recommendations of the recent Strategic Review as well as a series of suggestions on how the methods infrastructure might be revised to enhance collaboration and better allow us to contribute to the production of high quality systematic reviews. The four new initiatives described below arose out of this meeting and subsequent discussions in Singapore and elsewhere. The two articles that follow this one describe two further aspects of the new infrastructure: the Methods Application and Review Standards (MARS) Working Group and important changes to the core functions of Methods Groups.

### *Cochrane Methods Board*

The Cochrane Methods Board brings together people in high level methods roles in The Cochrane Collaboration. This includes the Co-Convenors of all Methods Groups, Co-ordinating Editors of the Methodology Review Group, Co-Editors of Cochrane Handbooks, the Editor in

Chief, representatives of Diagnostic Test Accuracy Reviews and Overviews initiatives, and people who represent methods on various other committees. While the full membership of the Board is inclusive, the main entities that contribute to the Board constitute its *voting membership* (currently comprising 14 Methods Groups, two Handbooks, the Methodology Review Group and the Methods Groups' representative on the Cochrane Collaboration Steering Group).

The purpose of the Methods Board is to provide a broad forum for discussion and formulation of recommendations on methods for Cochrane reviews and other methodological issues faced by The Cochrane Collaboration. It has taken over responsibility from the Handbook Advisory Group for developing methodological guidelines for preparing Cochrane reviews. In addition, it will be asked to approve major methods-related documents, such as shared training materials.

### *Methods Executive*

The Methods Executive comprises eight members of the Methods Board, who will represent the Board on a day-to-day basis. Current members are Mike Clarke (Methodology Review Group), Julian Higgins (Co-Convenor; Methods Groups' representative on the Steering Group), Mariska Leeftang (Screening and Diagnostic Tests Methods Group), Carol Lefebvre (Information Retrieval Methods Group), Jane Noyes (Co-Convenor; Qualitative Research Methods Group), Holger Schünemann (Applicability and Recommendations Methods Group), Ian Shemilt (Campbell and Cochrane Economics Methods Group) and Jonathan Sterne (Bias Methods Group). The Methods Executive acts as a conduit for communication and information flow between the Methods Board and the Steering Group, the Editor

in Chief and other Cochrane Executives or Executive Groups (such as those representing the Co-ordinating Editors, Managing Editors, Trials Search Co-ordinators and Fields).

### *Handbook Editorial Advisory Panel*

As mentioned above, the responsibility of the former Handbook Advisory Group for developing methodological guidance for the conduct of Cochrane reviews has moved to the Methods Board. The Handbook Co-Editors are now supported by a smaller group focussed on implementation, rather than development, of this guidance. This new Handbook Editorial Advisory Panel (HEAP) also brings together the Editors of the Interventions Handbook with those of the Diagnostic Test Accuracy Handbook in order to maximize sharing and consistency of guidance across different types of Cochrane review. HEAP includes representation from systematic review methodologists, authors and editorial bases.

### *Methods Co-ordinator*

At its recent meeting in Auckland, the Steering Group approved the creation of a new post of Methods Co-ordinator. This person will provide support to Methods Groups, to the three committees above and to the MARS Working Group. In addition, he or she will work with MARS and the Editor in Chief (and others) on facilitating a range of projects to assess and improve the methodological quality of Cochrane reviews. Examples include a collation of examples of implementation of methods, development of frequently asked questions about methods (with answers), and assisting with the creation of networks of Cochrane Review Group-based individuals

with interests in similar methodological areas.

The various changes summarised above illustrate that this is an exciting time,

methodologically, for the Collaboration. I very much look forward to working with the new Methods Co-ordinator and with everyone else to ensure that this new

infrastructure is appropriately focussed on the continual improvement of the methodological quality of our systematic reviews.

## Methods Application and Review Standards (MARS) Working Group

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When the substantially revised version 5 of the *Cochrane Handbook for Systematic Reviews of Interventions* was introduced alongside Review Manager 5 in 2008, much new methodological guidance became available to review authors. This included new approaches for assessing and addressing risk of bias in included studies, the introduction of 'Summary of findings' tables, and new guidance on incorporating non-randomized studies, adverse effects, economic outcomes, qualitative evidence and Cochrane overviews, among other special topics. Unfortunately, Review Group editorial teams were required to support review authors trying to implement the new guidance before they were properly familiar with it and could consider the implications for their editorial processes. In response to the challenges experienced by Review Groups in supporting the roll-out of these new methods consistently across The Cochrane Collaboration a working group was set up to facilitate interaction between Methods Groups and Review Groups. Initially known as the 'CoEds-Methods Working

Group', this group is now established as the Methods Application and Review Standards (MARS) Working Group. It also provides support to the Editor in Chief and Cochrane Editorial Unit more widely. With the formation of the Co-ordinating Editors and Methods Boards and their executive groups, as well the Managing Editors executive group, an efficient and productive collaboration is now possible. The purpose of the MARS Working Group is to enhance the quality and relevance of Cochrane reviews. It aims to achieve this by providing a forum in which Methods Groups representatives, Review Groups representatives and the Cochrane Editorial Unit can discuss the introduction of new methods, the specification of methodological quality standards, and processes for monitoring and improving review quality. The current terms of reference for the MARS Working Group are: (i) to enhance communication and understanding between Methods Groups, Review Groups and the Cochrane Editorial Unit; (ii) to ensure, through involvement from an early stage, that methodological guidance (developed by the Methods Board for implementation in the Cochrane Handbook and in Review Manager) is suitable for implementation in Cochrane reviews; (iii) to identify strategies to assist Review Groups to implement the guidance in the Handbook; (iv) to explore and agree on minimum methodological quality standards for Cochrane reviews, and to facilitate their implementation across Review Groups; (v) to develop processes for monitoring and improving methodological quality of Cochrane reviews; (vi)

to consider implications of surveys and empirical studies relating to the methodological quality of Cochrane reviews; and (vii) to discuss emerging research on methods and standards for the reporting of systematic reviews and their relevance to Cochrane reviews.

On a practical level, the MARS Working Group is playing a key role in facilitating the development of minimum methodological standards for Cochrane reviews, and is overseeing a project to develop a suite of exemplar protocols and reviews. Both of these projects will involve all (or most) of the Methods Groups. In particular, we plan to invite all Methods Groups to provide feedback on the exemplar protocols and reviews to ensure that they illustrate the 'gold-standard' application of the guidance in the Cochrane Handbook. The complementary activities of the Training Working Group (TWG) will enhance the organisation and delivery of core training by Cochrane Centres. The involvement of several members of the TWG in MARS ensures that training requirements relating to methodological guidance are also more effectively communicated.

The members of the MARS Working Group include methodologists, Co-ordinating Editors, the Editor in Chief, Co-Editors of the Cochrane Handbook, a Co-Convenor of the Training Working Group, a Managing Editor from the Managing Editors Executive and a representative from the Information Management System team. The Working Group is likely to be co-convened by a methodologist and a Co-ordinating Editor (currently the two of us).

## Revised core functions of Methods Groups

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The Cochrane Collaboration Steering Group has recently approved a revised set of core functions for Methods Groups, in parallel with recent changes to the infrastructure that support method-

ological input to the Collaboration and its reviews. Essentially, revised core functions reflect the idea that the focus of needed methodological input varies across areas of methodology covered by each Methods Group, so that more flexibility is needed in the framework used by Methods Groups to prioritize their activities and outputs.

Under the revised framework, three core functions apply to all Methods Groups:

- Providing policy advice.
- Serving as a forum for discussion.

- Ensuring that the Group functions as part of The Cochrane Collaboration.

Methods Groups may also elect to adopt one or more additional core functions:

- Providing training.
- Hosting a network of Cochrane Review Group-based methods individuals.
- Providing peer review.
- Providing specialist advice.
- Contributing to new products or lines of activity.

- Contributing to software development.
- Conducting Cochrane Methodology reviews.
- Contributing to the Cochrane Methodology Register.
- Helping to monitor and improve the quality of Cochrane reviews.
- Conducting methodological research.

- Communicating Cochrane methodology to external organizations.

Additional core functions are adopted in consultation with the Methods Executive, to reflect the needs of the Collaboration and the aims, scope and resources of the Methods Group, and are reviewed biennially. We anticipate that the current transition to

this new core functions framework will appear seamless to other Cochrane entities, underpinned by effective communication and the new Cochrane Methods infrastructure. Further details can be found in *The Cochrane Policy Manual*, Section 3.5 ([www.cochrane.org/policy-manual/welcome](http://www.cochrane.org/policy-manual/welcome)).

## Training Working Group

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Training and support for people engaged in all aspects of the preparation and maintenance of Cochrane reviews underpins The Cochrane Collaboration's primary purpose of preparing high quality evidence for decision makers and is essential for the Collaboration's long-term sustainability. Preparing a Cochrane review involves many people (authors, editorial staff, methods experts, consumers, etc.) and requires multiple competencies and skills. Until recently, most training within the Collaboration has focused on authors and been delivered through face-to-face workshops. But as the number and geographic distribution of authors increase and reviews become more complex to prepare and support, there's an urgent need to provide a greater range of training and support opportunities to the various groups of people involved. These trends, coupled with better access to new technologies for delivering training and support, have highlighted the need for a Collaboration-wide approach to determining training

priorities and developing appropriate strategies.

The Training Working Group (TWG) has expanded its remit to support everyone involved in preparing and maintaining Cochrane reviews (not just authors) and was given the responsibility by the Cochrane Collaboration Steering Group for developing and implementing a Collaboration-wide training strategy. In April 2010, the TWG met in Oxford to discuss the contents of the training strategy and to identify priority projects. Leading up to the meeting, we identified the competencies and skills required to carry out the various tasks involved in preparing reviews (from title registration to publication), and mapped these to existing training and support.

A full report and funding proposal is being prepared for the Steering Group for consideration later in 2010. Some of the key projects to emerge from the meeting that are likely to feature in the training strategy include:

- Better explanatory information about what is involved in doing Cochrane reviews (linking with the work on minimum competencies for review author teams).
- Expansion of the Online Learning Resources to include additional core topics and new specialized topics.
- Continued development of the Standard Author Training Materials to include specialized topics, multimedia resources and translations.

- Use of webinars to supplement online and face-to-face training.
- Collaboration with the Methods Application and Review Standards Working Group to develop training materials based around minimum review standards and common errors (for authors and editorial teams).
- Expansion of the successful Managing Editors' induction and mentoring scheme to other entity staff (Trials Search Co-ordinators, Field administrators, etc.).
- Development of training packages for technical editing, publication ethics, peer reviewing and consumer refereeing.

As part of its co-ordination function, the TWG will be responsible for setting up a dedicated training website and a trainers' network, and for advising on tools and technologies to facilitate training and support initiatives.

The involvement of Methods Groups in these proposed training projects will be critical, particularly as more advanced and specialized training is made available through webinars, slidecasts and practical examples. Several Methods Groups are currently contributing to the Standard Author Training Materials and it is proposed that the Methods Board will have an oversight role in approving training resources that will be made available through the training website.

## Risk of Bias tool evaluation: process, survey results and recommendations

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Version 5 of the *Cochrane Handbook for Systematic Reviews of Interventions* introduced the Risk of Bias (RoB) assessment tool, which represents a more comprehensive undertaking than previously recommended procedures for assessing study quality. The Bias Methods Group, funded by the Cochrane Opportunities Fund, has conducted an evaluation of the RoB tool. This aimed to obtain feedback from a range of stake-

holders within The Cochrane Collaboration regarding their experiences with, and perceptions of, the RoB tool and associated guidance materials, and to recommend improvements where necessary. We used qualitative and quantitative methods to conduct our evaluation. In the first stage, four semi-structured focus groups were held with 25 participants, both by telephone and at the Cochrane Colloquium in Singapore in October 2009.

Results from the focus groups informed development of two questionnaires that were used in online surveys (distributed through established Cochrane mailing lists) of review authors and Managing Editors and other Cochrane Review Group staff.

We received 190 responses from review authors who had used the RoB tool, 132 from authors who had not, and 58 from Cochrane Review Group staff. RoB assessments were reported to take an average of 10 to 60 minutes per study to complete: 83% of respondents deemed this acceptable. Most respondents thought that RoB assessments were better than past approaches to trial quality assessment. Most authors liked the standardized approach (81%) and the ability to provide quotes to support judgments (74%). About a third of participants did not like the increased workload, and found the wording describing judgments of RoB to be unclear. Most authors (75%) thought availability of training materials was sufficient, but many expressed an interest in online training. Following the surveys, we held a meeting in Cardiff on 1 March 2010 of Cochrane methodologists, review authors,

Managing and Co-ordinating editors, and the Cochrane Editorial Unit, just before the UK- and Ireland-based Cochrane Contributors' Meeting. They discussed the findings from the focus groups and online surveys, and developed draft recommendations for improvements to the RoB tool. The main recommendations include:

#### *Immediate to short term:*

- Change wording of bias judgments from 'yes/no' to 'low/high risk of bias'.
- Introduce category headings for selection, performance and detection, attrition, reporting, and other bias.
- Manually split the assessment of blinding into (i) participants and personnel, and (ii) outcome assessment.
- Clarify guidance, particularly for incomplete outcomes and selective outcome reporting, and 'other sources of bias'.
- Produce clearer and more explicit guidance on decision-making for

incorporation of risk of bias assessments into meta-analyses.

#### *Medium term (implementation with Review Manager 6 or later):*

- Structurally split assessment blinding into participants, personnel (performance bias heading) and blinding of outcome assessment (detection bias heading).
- Weight RoB graphs by study size.
- Provide an algorithm for reaching a summary assessment of risk of bias per study/outcome.
- Develop online guidance and training materials including an online frequently asked questions bank and examples of assessments.

The evaluation team hopes that these changes will make it easier for authors to use the RoB tool, improve the reliability of assessments and improve the quality of Cochrane reviews.

## **Core reporting of outcomes in effectiveness trials**

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Everyone who embarks on a systematic review has probably experienced the frustration of carefully planning the outcomes to be sought and analysed, only to find that the original researchers either did not measure these outcomes or measured them in such different ways that it will be difficult or impossible to compare, contrast or combine them. People trying to use the findings of individual randomized trials are also hampered by inconsistencies in the patient outcomes assessed across the different studies. Indeed, trialists themselves often struggle with identifying the outcomes to collect which would be of most value to eventual users of their research.

One way to address all these difficulties would be through the adoption of an

agreed minimum set of core outcomes for each medical condition.<sup>1</sup> Consistent measurement and reporting of these core outcomes in all clinical trials would reduce the potential for selective outcome reporting, since trial reports should focus on presenting their findings for the core outcomes. Core outcomes would make it easier to compare results across different studies and would enhance systematic reviews and the combination of results in meta-analyses. Statistical power would be increased and the potential for bias in the overall estimates reduced, because fewer studies would have to be omitted.

Over the last couple of decades, several groups have been working on core outcome sets in specific areas of health care, including rheumatology, pain and maternity care. In January 2010, the COMET (Core Outcome Measures in Effectiveness Trials) initiative was launched at a meeting in Liverpool to try to encourage, highlight and facilitate such activities more widely. More than 100 people, including those working on core outcome sets, journal editors, regulators, consumers, clinicians, policy makers, trial funders, trialists and systematic reviewers, discussed what had already been achieved and the opportunities for the

future. The presentations are available from the COMET website (see below). The meeting was made possible by funding from the MRC North West Hub for Trials Methodology Research, and we are now planning a second meeting, in Bristol in early 2011.

The COMET initiative is an international network bringing together individuals and organizations interested in the development, application and promotion of core outcome sets. We aim to collate relevant resources, both applied and methodological, facilitate exchange of ideas and information, and foster methodological research. Further information about COMET can be found at the website [www.liv.ac.uk/nwhtmr/](http://www.liv.ac.uk/nwhtmr/) and we should be delighted to hear from anyone interested in this topic. The website will include examples of a matrix of outcomes that could be used within systematic reviews.<sup>2</sup> We encourage authors of Cochrane reviews to consider including these in their reviews and, if they wish, to send them to us for the collection of examples. Where a core outcomes set has been established in their topic area, Cochrane authors might also wish to draw attention to the use of these outcome measures within their 'Implications for research'.

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## Priority setting in The Cochrane Collaboration

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Identifying and prioritizing key topics is crucial to the relevance and applicability of Cochrane reviews for end-users. There have been several attempts within The Cochrane Collaboration to improve the methods to identify topics for future Cochrane reviews. In a 2008 survey, 29 Cochrane entities reported having made attempts to inform the selection or prioritization of topics for Cochrane reviews.<sup>1</sup>

In a meeting in 2006, the need for a more strategic approach to improve the prioritization process was recognized by the Cochrane Collaboration Steering Group. This led to the creation of the Cochrane Prioritization Fund, which funded five initiatives to explore prioritization in the production and updating of Cochrane reviews.

The five projects were:

- Delivering on priorities: developing and implementing effective collaboration between a Cochrane Review Group and a Cochrane Field.
- Using practice guidelines to determine review priorities: a pilot project.
- Prioritization of Cochrane reviews for consumers and the public in low- and high-income countries as a way of promoting evidence-based health care.
- Prioritizing Cochrane review topics to reduce the know-do gap in low- and middle-income countries.
- Piloting and evaluation of a patient professional partnership approach to prioritizing Cochrane reviews and other research.

The findings from these five projects were presented and discussed during a special session at the Cochrane Colloquium in Singapore in October 2009.<sup>2</sup> The projects have shown that there are different approaches to identifying and

prioritizing topics. Although it is difficult to define one single approach to prioritizing topics for the whole Cochrane Collaboration, central guidance might support and harmonize these activities and avoid duplication of effort. Some of the prioritization research teams have got together and intend to publish a series of articles in the near future. These projects have also shown that there is still a lot of uncertainty regarding the best methods to set a research agenda for Cochrane reviews. Therefore, we also proposed a new Cochrane Methods Group on prioritization and agenda setting for Cochrane reviews that will work with the James Lind Alliance ([www.lindalliance.org](http://www.lindalliance.org)) to fill this gap.

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## The impact of outcome reporting bias in randomised controlled trials on a cohort of systematic reviews

Kirkham JJ, Dwan KM, Altman DG, Gamble C, Dodd S, Smyth R, Williamson PR. *BMJ* 2010; 340: c365.

### Structured Abstract

**Background:** Selective reporting bias in a study is defined as the selection, based on the study results, of a subset of analyses to be reported.

**Objective:** To examine the prevalence of outcome reporting bias (the selection for publication of a subset of the original recorded outcome variables on the basis of the results) and its impact on Cochrane reviews.

**Design:** A nine point classification system for missing outcome data in randomized trials was developed as part of the Outcome Reporting Bias in Trials (ORBIT) study and applied to a cohort of new Cochrane reviews published in *The Cochrane Library* (Issue 4, 2006 to Issue 2, 2007). Researchers who conducted the trials included in the Cochrane reviews were contacted and the reason sought for the non-reporting of data. A sensitivity analysis was undertaken to assess the impact of outcome reporting bias on reviews that included a single meta-analysis of the review's primary outcome.

**Main results:** One hundred and fifty-seven of the 283 (55%) Cochrane reviews assessed did not include data from all eligible trials addressing the primary outcome in the review. The median amount of missing data (missing for any reason) was 10%, whereas 50% or more of the potential data were missing in 70 (25%) reviews. Of the 2562 reports of randomized trials included in the 283 Cochrane reviews, the researchers of 155 (6%) trials measured and analysed the primary outcome for the review but did not report, or only partially reported, the results. For reports that did not mention the primary outcome for the review, the ORBIT classification scheme regarded the presence of outcome reporting bias to have a sensitivity of 88% (95% CI 65% to 100%) and specificity of 80% (95% CI 69% to 90%) on the basis of responses from 62 trialists. A third of Cochrane reviews (96/283 (34%)) contained at least one trial with a high suspicion of outcome reporting bias for the primary outcome of the review. In a sensitivity analysis undertaken for 81 reviews with a single meta-analysis of the primary outcome of interest, the treatment effect estimate was reduced by 20% or more in 19 (23%) Cochrane reviews. Of the 42 meta-analyses with a

statistically significant result, eight (19%) became non-significant after adjustment for outcome reporting bias and 11 (26%) would have overestimated the treatment effect by 20% or more.

**Conclusions:** Outcome reporting bias is an under-recognised problem that affects the conclusions in a substantial proportion of Cochrane reviews. People conducting systematic reviews need to address explicitly the issue of missing outcome data for their review in order for it to be considered a reliable source of evidence. Extra care is required during data extraction, and review authors should identify when a trial reports that an outcome was measured but no results were reported or events observed.

### Commentary

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Chan and colleagues published the first empirical investigation of outcome reporting bias defined as a selective reporting of favorable outcomes in published studies.<sup>1</sup> Several methodological studies have since been published.<sup>2-4</sup> These studies showed that statistically significant outcomes had higher odds of being fully reported than non-significant outcomes (odds ratio 2.2 to 4.7).<sup>3</sup> Discrepancies between the primary outcome published and that reported in the protocol was identified in 40% to 62% of studies.<sup>3</sup> When comparing publication data to data recorded in trial registries, discrepancies in primary outcomes were identified in 31% of the studies, mainly favouring statistically significant results.<sup>4</sup> Considering the importance of selective reporting bias, a specific item is now dedicated to 'selective outcome reporting' in the Risk of Bias tool of The Cochrane Collaboration.

Kirkham and colleagues evaluated an unselected cohort of Cochrane reviews published in 2006 and 2007 to estimate the prevalence and impact of selective reporting of outcomes. For about one-third of the reports of randomized trials evaluated, the review's primary outcome was partially or not reported. Among these reports, half were highly suspected to contain outcome reporting bias. More than one-third of the reviews contained at least one randomized trial report with high suspicion of outcome reporting bias for the review's primary outcome. Furthermore, sensitivity analyses showed that outcome reporting had an important impact on meta-analyses, with about 20% of the statistically significant meta-analyses results becoming non-significant after adjusting for outcome reporting bias.

The Outcome Reporting Bias in Trials (ORBIT) project published by Kirkham and colleagues also offers a new classification scheme that could help systematic reviewers identify selective reporting bias. This tool, developed and evaluated by the authors, considers nine different categories classified under four headings related to whether it was (1) clear that the outcome was measured and analyzed, (2) clear that the outcome was measured, (3) unclear that the outcome was measured, and (4) clear that the outcome was not measured. For each category, review authors should determine whether the risk of bias is null, low or high.

This tool is a very important step for review authors and has advantages in evaluating selective reporting bias without the need to examine the trial protocol. However, use of this scheme relies on the review authors' subjectivity, and further research is needed to evaluate the reproducibility of this classification scheme and develop training materials.

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## Risk of bias versus quality assessment of randomised controlled trials: cross sectional study

Hartling L, Ospina M, Liang Y, Dryden DM, Hooton N, Krebs Seida J, Klassen TP. *BMJ* 2009; 339: b4012.

**Background:** The methodological quality of studies included in a systematic review can have a substantial impact on the results of a review and validity of its conclusions.

**Objective:** To evaluate inter-rater agreement and validity of The Cochrane Collaboration Risk of Bias tool, for assessing the internal validity of randomized trials, compared to the Jadad Scale and Schulz approach for assessing allocation concealment; to assess the relationship between risk of bias and effect estimates.

**Design:** This was a cross sectional study on a sample of 163 reports of randomized trials in child health. Two reviewers independently assessed trials using the Risk of Bias tool, one reviewer assessed trials using the Jadad and Schulz approaches. The inter-rater agreement between reviewers assessing trials using the Risk of Bias tool (weighted kappa), and the time taken to apply the tool was compared with the other approaches to quality assessment. The degree of correlation for overall risk was compared with the overall quality scores, and the magnitude of effect estimates for

studies classified as being at high, unclear, or low risk of bias was compared.

**Main results:** The inter-rater agreement between reviewers on individual domains of the Risk of Bias tool ranged from slight ( $\kappa = 0.13$ ) to substantial ( $\kappa = 0.74$ ) depending on the domain assessed. The mean time taken to complete the tool was significantly longer than for the Jadad Scale and Schulz approach. The average time taken for one reviewer to complete the tool was 8.8 minutes (SD 2.2) per study compared with 0.5 minutes (SD 0.3) for the Schulz approach and 1.5 minutes (SD 0.7) for the Jadad approach. There was low correlation between the risk of bias overall compared with the Jadad scores ( $P = 0.395$ ) and Schulz approach ( $P = 0.064$ ). Effect sizes differed between studies assessed as being at high or unclear risk of bias compared with those at low risk.

**Conclusions:** The inter-rater agreement varied across domains of the Risk of Bias tool. Generally, agreement was poorer for those items that required more judgment. There was low correlation between assessments of overall risk of bias and the Jadad Scale and Schulz approach to allocation concealment. Overall risk of bias, as assessed by the Risk of Bias tool differentiated effect estimates, with more conservative estimates for studies at low risk.

## Commentary

Prepared by Lise Lotte Gluud

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The interesting study by Hartling and colleagues published in the *BMJ* is most definitely worth reading. The study highlights a potential problem for systematic reviewers and those who read and rely on systematic reviews. Part of the strength of Cochrane reviews is that they provide a thorough assessment of the quality of the available evidence. There is increasing evidence to support the importance of this assessment, but we still have not reached a complete agreement on how exactly to perform the assessment of quality or how to deal with low quality trials.

In line with previous research,<sup>1</sup> Hartling and colleagues found a low correlation between quality scores. The findings support recommendations to base quality assessments on components rather than composite scores. Likewise, the inter-rater agreement varied even for this group of experienced researchers, even though a guideline for how the quality assessment was developed and applied systematically was used. Accordingly, additional research is necessary to improve the quality assessment of randomized trials. Continued improvement of the *Cochrane Handbook for Systematic Reviews of Interventions* is also essential. Furthermore, it may be argued that since the quality assessment of trials is not (yet) perfect, exclusion of randomized trials defined as having a low quality of bias control is debatable. Since the extent and direction of the influence of bias varies in different research areas, tools to help weigh trials according to the quality of bias control may be a feasible way forward.

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# Retrieving randomized controlled trials from MEDLINE: a comparison of 38 published search filters

McKibbin KA, Wilczynski NL, Haynes RB, The Hedges Team. *Health Information and Libraries Journal* 2009; 26: 187–202.

**Background:** People search MEDLINE for trials of healthcare interventions for clinical decisions, or to produce systematic reviews, practice guidelines, or technology assessments. Finding all relevant randomized trials to address a specific question can be challenging due to the large volume of available articles and the imperfections of indexing in bibliographic databases.

**Objective:** To provide comparative data on the sensitivity, specificity and precision of search filters designed to retrieve randomized trials from MEDLINE.

**Design:** Search filters designed to identify reports of randomized trials in MEDLINE were found by searching PubMed (1991 to May 2008), bibliographies of published papers and the internet. A test database of reports of randomized trials compiled from handsearching 161 clinical journals indexed in MEDLINE was used to calculate the sensitivity, specificity and precision of each search filter.

**Main results:** Thirty-eight search filters were identified for use in MEDLINE. The number of terms and the sensitivity, specificity and precision of each search filter varied considerably. Twenty-four of the 38 search filters had a statistically significant higher sensitivity when compared to the retrieval using the single term randomized controlled trials.pt. (sensitivity 93.7%); six of the 24 filters had a sensitivity of at least 99%. Four other filters had specificities (non-retrieval of non-randomized trials) that were either no different or better than the single term randomized controlled trials.pt. (specificity 97.6%). Precision (proportion of retrieved articles that were randomized trials) was poor, only two filters had precision statistically similar to that of the single term (56.4%); all others were lower. Search filters with more search terms and high sensitivity often had lower specificity.

**Conclusions:** A number of search filters to identify reports of randomized trials in MEDLINE exist. The data in this study will allow users to identify the most appropriate search filter to suit their information needs, depending on simplicity of the searching desired and the performance required.

## Commentary

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This paper reports on the performance of 38 search filters to identify randomized controlled trials (RCTs) in MEDLINE. The filters were tested using a gold standard set of 1587 reports of RCTs identified from 161 MEDLINE-indexed journals handsearched for the year 2000. The most sensitive single term filter was randomized controlled trial.pt. with 93.7% sensitivity and 56.4% precision (Number Needed to Read [NNR] = 1.77). Six other filters offered sensitivity of 99% or over but with considerable reductions in precision (range: 5.6% to 10%, NNR range: 10 to 18). The authors offer a look-up table, ranked by sensitivity, so

that searchers can select filters which meet their specific sensitivity and precision level requirements.

This type of study offers valuable performance data: many filters are validated within their own gold standards only and the performance of some filters has never been tested. The more additional validation that occurs, in particular of a range of similar filters across one or more gold standards, the clearer the picture of search filter performance and the easier it may become to select the filter that meets specific needs. The findings of this performance assessment broadly support a previous performance assessment.<sup>1</sup>

The finding that randomized controlled trial.pt. is a relatively sensitive search term to identify reports of RCTs in MEDLINE is valuable corroboration that it is now easier to identify such records in MEDLINE. This reflects the successful efforts of the US National Library of Medicine (NLM) and The Cochrane Collaboration over the last 15 years to achieve better access to such reports. Which filter to use to identify the trials missed by the term randomized controlled trial.pt. will depend on review authors' requirements with respect to levels of sensitivity and tolerance for the resulting trade-off in precision/specificity. For example, the 'Clinical Queries—sensitive' filter developed by the study authors has 99.2% sensitivity, 70.1% specificity and 10% precision, whereas the 'Cochrane Highly Sensitive Search Strategy—sensitivity-maximizing version', from the *Cochrane Handbook for Systematic Reviews of Interventions*, (referred to in the paper as HSS-Sensitive) has a slightly lower sensitivity of 98.4% but higher specificity (77.9%) and precision (13%).

The factors which inform the selection of search filters is a largely unexplored process, which may be assisted by the use of critical appraisal tools such as the UK InterTASC Information Specialists Sub-Group Search Filter Appraisal Checklist ([www.york.ac.uk/inst/crd/intertasc/critical\\_appraisal\\_search\\_filters.htm](http://www.york.ac.uk/inst/crd/intertasc/critical_appraisal_search_filters.htm)).<sup>2</sup> Such checklists provide structured assessments of the focus and methods used to develop and validate search filters and can also usefully be applied to studies such as this. For example, the ISSG Search Filter Appraisal Checklist suggests that the development of the gold standard used for performance testing should be evaluated. The gold standard used in this study was developed by extensive handsearching. The journals which were selected for handsearching, however, were those with a high impact factor. The titles and abstracts of those journals may, therefore, be of higher quality in terms of reporting research methods clearly than journals which have lower impact factors. This, in turn, would make those records easier for an indexer to identify and index correctly and easier to identify with free-text search terms. If that is the case, then the search filters may over-perform for high impact factor journals and the true sensitivity of the filters may be lower than reported in this study.

The authors also noted that their own search filters (the Clinical Queries RCT strategies) might over-perform in this gold standard because they were developed using this gold standard and so might be expected to perform well. In addition, the records in the gold standard are all indexed in MEDLINE, so the performance of the filters in un-indexed e.g. in-process records, is unknown.

The reports selected for the gold standard had to meet the authors' definition of a randomized controlled trial. This definition includes random allocation of patients, that outcomes had to be reported for at least 80% of participants with the analysis consistent with the study design. The single term filter 'randomized

controlled trial.pt.’ had a precision of only 56.4% in searching this gold standard. This indicates that nearly 44% of the records retrieved by this term, all of which had been indexed by NLM indexers as RCTs, were considered not to be RCTs according to the definition used by the study authors. The authors’ definition may differ from that used when selecting trials for Cochrane reviews. In that case, the filters’ performance when used for Cochrane reviews may be different to that presented in this study.

All the records in the gold standard were published in 2000. It is unclear to what extent the findings of this study might be generalisable to searches to retrieve more recent or older records, as styles of reporting change over time, in particular with respect to initiatives such as CONSORT and guidance on use of the word ‘randomized’ in the title/abstract of a journal article.

The authors also note that ‘although indexing vocabulary changes over time, our careful review of changes that could affect classification of RCTs showed that few pertinent adjustments occurred since 2000.’ They do not comment on the change in NLM indexing policy, introduced in 2006, to cease ‘redundant indexing’ of RCTs and Controlled Clinical Trials with the additional ‘parent’ term Clinical Trial and the effect this may have had on the performance of the filters they tested.<sup>3</sup> Similarly, they do not comment on the fact that some, but not all, of the filters included various techniques to exclude animal studies and how this might affect comparative performance.

There are additional issues which need to be considered before adopting a specific filter. The authors of the study note that they have translated or adapted some of the filters from different interfaces. This translation process is not described in detail, so before adopting a strategy the translation should be checked with the original version. Incorrect translation or adaptation may impact on performance. Search filters are designed very specifically and translations need to take this into account carefully.

This study is broadly useful but the choice of search filters for use for Cochrane reviews needs to be informed by an assessment of the relevance of the gold standard to these reviews and any adaptations made to filters by the authors. The development of further gold standards, which more closely reflect the eligibility criteria for studies for inclusion in Cochrane reviews, could be helpful.

Declarations of interest: the authors of this commentary are authors of some of the search filters tested in this study—and authors of filters which were used as a basis for some of the other filters.

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## Systematic reviews of low back pain prognosis had variable methods and results: guidance for future prognosis reviews

Hayden JA, Chou R, Hogg-Johnson S, Bombardier C. *Journal of Clinical Epidemiology* 2009; 62: 781–96.

**Background:** Systematic reviews of prognostic research can help clinicians educate patients and can be used to target specific interventions to modify prognostic factors. However, there is limited guidance available on how to conduct systematic reviews of prognosis and their design and conduct can vary substantially.

**Objective:** To identify, describe, and synthesise systematic reviews of low back pain prognosis, and to explore the potential impact of review methods on the conclusions of the review.

**Design:** MEDLINE, EMBASE and CINAHL were searched (up to June 2007) to identify systematic reviews of prognosis of low back pain. One reviewer extracted information from each included review on characteristics of the review question, review methods and analysis; a second reviewer checked the extracted data. Two reviewers independently assessed review quality.

**Main results:** Seventeen systematic reviews of prognosis of low back pain were identified. The review questions and selection criteria varied and included both focused and broad reviews of prognostic factors. A quarter of reviews did not clearly define search strategies. The number of included prognosis studies per review ranged from three to 32 (median 17; interquartile range 10 to 22). Seventy percent of reviews assessed the quality of the included studies, but only assessed a median of four out of six potential biases. All reviews reported associations based on statistical significance using a variety of strategies for syntheses. Only a small number of important prognostic factors were consistently reported: older age, poor general health, increased psychological or psychosocial stress, poor relations with colleagues, physically heavy work, worse baseline functional disability, sciatica, and the presence of compensation. There were discrepancies across reviews in selection criteria which influenced the studies included, and various approaches to data interpretation influenced the review conclusions about evidence for specific prognostic factors.

**Conclusions:** There is an immediate need for methodological research in the area of prognosis systematic reviews. Due to methodological shortcomings in the primary and review literature, there remains uncertainty about the reliability of conclusions regarding prognostic factors for low back pain.

## Commentary

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Hayden and colleagues conducted a review of systematic reviews about the prognosis of low back pain to examine the potential impact of review methods on findings. To do this, they used sound methods for conducting a review of systematic reviews

and applied current best practice for assessing the quality of the included prognosis systematic reviews. The collective expertise of the authors in this content area also allowed them to assess the clinical nuances of the population included, outcomes used and associations or prognostic factors reported.

This study is important in relation to primary prognosis studies and prognosis systematic reviews across all health topics. Currently there is renewed interest in prognosis research and evidence on prognosis.<sup>1</sup> As treatments and diagnostic tests have developed it has become increasingly clear to clinical and policy decision-makers that prognosis and prognostic factors (factors that are associated with or influence outcome) underpin all decisions about investigation pathways and intervention choices. To guide decision-making high quality, transparently synthesised evidence about prognosis and prognostic factors will need to become an integral part of diagnostic test and intervention research as we move towards assessing 'clinical utility' of health evidence.<sup>2</sup> Hayden and colleagues identified considerable heterogeneity in the systematic review methods across the 17 reviews of low back pain prognosis, leading to variation in studies included in each review. Although no individual factors were identified that clearly influenced systematic review findings, the degree of variability speaks clearly to the need for reporting standards for primary prognosis studies, guidance on methods for systematic reviews of prognosis, and further methodological work in the field. As such the research by Hayden and colleagues is relevant to work currently underway internationally in areas described under 'research framework' on the Prognosis Methods Group's website (<http://prognosismethods.cochrane.org/whats-new>).

The review of reviews by Hayden and colleagues also presents findings that resonate with findings of reviews of systematic reviews of interventions, where variations in systematic review methodology and risk of bias of included studies, as well as the presentation of information about different populations, with different outcomes and treatments, present problems for interpretation and application of 'evidence'. Experience from prognosis, diagnostic test and intervention reviews of systematic reviews may come together 'as more than the sum of the parts' in working towards solutions to this problem.

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## Methodological problems in the use of indirect comparisons for evaluating healthcare interventions: survey of published systematic reviews

Song F, Loke YK, Walsh T, Glenny AM, Eastwood AJ, Altman DG. *BMJ* 2009; 338: b1147.

**Background:** It is generally accepted that evidence from well designed head-to-head randomized trials provides the most rigorous and valid research evidence on the relative effects of

different interventions. However, evidence from these trials is often limited or not available and evidence from indirect comparisons may be necessary.

**Objective:** To determine which methods have been used for indirect comparisons in systematic reviews of competing healthcare interventions and to identify any methodological problems in these applications.

**Design:** Systematic reviews published between 2000 and 2007 in which an indirect approach had been explicitly used were identified by searching PubMed (up to October 2008). Identified reviews were assessed for comprehensiveness of the literature search, method for indirect comparison, and whether assumptions about similarity and consistency were explicitly mentioned. One reviewer extracted data and a second reviewer checked each study.

**Main results:** Eighty-eight systematic reviews involving indirect comparisons were identified. In 13 of the 88 reviews the indirect comparison was informal, with no calculation of relative effects or testing for statistical significance. In six reviews, results from different trials were compared without using a common treatment control. Forty-nine reviews used an adjusted indirect comparison using classic frequentist methods and 18 reviews used more complex methods. The key assumption of trial similarity was explicitly mentioned in only 40 of the 88 reviews. The consistency assumption was not explicit in most cases where direct and indirect evidence were compared or combined (18 out of 30 reviews). Evidence from head-to-head comparison trials was not systematically searched for or was not included in nine reviews.

**Conclusions:** Identified methodological problems included an unclear understanding of the underlying assumptions, inappropriate search and selection of relevant trials, use of inappropriate or flawed methods, lack of objective and validated methods to assess or improve trial similarity, and inadequate comparison or inappropriate combination of direct and indirect evidence. Adequate understanding of basic assumptions underlying indirect and mixed treatment comparisons is crucial to resolve these methodological problems.

## Commentary

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Song and colleagues have done an impressive job assessing indirect and multiple treatment comparisons published up to 2007. Their recommendations are both intelligent and intelligible, and will be highly valuable to systematic review authors embarking on conducting indirect and multiple treatment comparisons. However, as this field is evolving rapidly, some additions may be needed to their recommendations. Most recent multiple treatment comparisons have employed Bayesian methods that facilitate ranking of treatments according to their relative efficacy and safety profile. Presumably, this trend will continue. Since treatment rankings will undoubtedly influence health policy, it is important that recommendations are made to ensure validity and adequate reporting of treatment rankings.

There are a number of limitations associated with treatment rankings that review authors should be aware of. A recent

commentary on a multiple treatments meta-analysis of 12 new-generation anti-depressants pointed out that the exclusion of all placebo-controlled trials in the original publication had a dramatic impact on the treatment ranking.<sup>1</sup> Although more research is needed, this example illustrates how sensitive treatment rankings can be to the systematic review inclusion/exclusion criteria. Other well-known limitations are the risks of overestimation (or underestimation) due to bias and imprecision.<sup>2-5</sup> Including an overestimated comparative treatment effect in a multiple treatment comparison will cause other treatments to receive artificially relatively lower ranking (and vice versa for underestimated comparative effects). Estimates of heterogeneity may also be over or underestimated due to bias or imprecision.<sup>6-7</sup> In this case, credible intervals may become artificially wide or narrow, and thus distort treatment rankings. Lastly, Bayesian analysis necessitates that priors are elicited for the heterogeneity parameter. Although the conventionally used truncated flat prior (the uniform distribution) is believed to be a 'vague' prior, this may not always be true when only a few trials are available per comparison.<sup>8</sup>

To ensure that adequate inferences are drawn from treatment rankings, authors should disclose sensitivity to inclusion/exclusion criteria, high risk of bias trials and comparisons, and the choice of prior distribution. Treatment rankings should always be interpreted according to the overall risk of bias and imprecision. To assess the overall risk of bias, one can follow the criteria outlined in the GRADEProfiler<sup>9</sup> for each direct comparison and assume that 'the chain of evidence is no stronger than its weakest link.' To interpret treatment rankings in relation to precision, one should present treatment rankings with treatment effect point estimates and credible intervals. This can be achieved by presenting treatment rankings, direct, indirect and pooled (combined) estimates in one table.

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## CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials

Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, Elbourne D, Egger M, Altman DG. *BMJ* 2010; 340: c869.

Overwhelming evidence shows the quality of reporting of randomized trials is not optimal. Without transparent reporting, readers cannot judge the reliability and validity of trial findings nor extract information for systematic reviews. Recent methodological analyses indicate that inadequate reporting and design are associated with biased estimates of treatment effects. Such systematic error is seriously damaging to randomized trials, which are considered the gold standard for evaluating interventions because of their ability to minimise or avoid bias.

A group of scientists and editors developed the CONSORT (Consolidated Standards Of Reporting Trials) Statement to improve the quality of reporting of randomized trials. It was first published in 1996 and updated in 2001. The Statement consists of a checklist and flow diagram that authors can use for reporting a randomized trial. Many leading medical journals and major international editorial groups have endorsed the CONSORT Statement. The Statement facilitates critical appraisal and interpretation of randomized trials.

During the 2001 CONSORT revision, it became clear that explanation and elaboration of the principles underlying the CONSORT Statement would help investigators and others to write or appraise trial reports. A CONSORT explanation and elaboration article was published in 2001, alongside the 2001 version of the CONSORT Statement.

After an experts meeting in January 2007, the CONSORT Statement has been further revised and was published as the CONSORT 2010 Statement. This update improves the wording and clarity of the previous checklist and incorporates recommendations related to topics that have only recently received recognition, such as selective outcome reporting bias.

The explanatory and elaboration document intended to enhance the use, understanding, and dissemination of the CONSORT Statement has also been extensively revised. It presents the meaning and rationale for each new and updated checklist item providing examples of good reporting and, where possible, references to relevant empirical studies. Several examples of flow diagrams are included.

The CONSORT 2010 Statement, this revised explanatory and elaboration document, and the associated website ([www.consort-statement.org](http://www.consort-statement.org)) should be helpful resources to improve reporting of randomized trials.

## Commentary

Prepared by Gerd Antes

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Full and transparent reporting of results of clinical trials is essential for assessing the quality of healthcare interventions. Inadequate reporting of trials is common, and it impedes the use of trial results in healthcare research and practice.<sup>1</sup> Underreporting of trial results is highly detrimental for the evidence base for medical decision-making because it is likely that bias is introduced into systematic reviews if they are built on a patchy or distorted body of evidence.

Consequently, a series of reporting guidelines have been developed during the past 15 years ([www.equator-network.org](http://www.equator-network.org)). The pioneering first step of this framework was the CONSORT Statement (CONsolidated Standards Of Reporting Trials) in 1996 for the publication of randomized controlled clinical trials. It has now been published as the 2010 (substantial) update of the Statement,<sup>2</sup> after the last revision in 2001. A few particularly relevant new items have been introduced: registration is now required before inception, researchers must state where the protocol can be accessed (if this is possible), and where the funding comes from.

The CONSORT Statement has received broad acceptance and support within the scientific community and from medical journal editors. However, progress in the quality of reporting is far from what could be expected.<sup>3</sup> Several investigations have assessed whether the quality of reporting has improved since publication and revision of the CONSORT Statement. Although these have shown that improvements have occurred, the quality of reporting is far from satisfactory, even for items that are crucial for the assessment of trial quality. Essential items like sample size estimation (45%), the randomization procedure (34%) or the concealment of treatment allocation (25%) are described in an unacceptably low number of reports.<sup>3</sup>

Even among high impact journals, fewer than 50% of the investigated journals recommend that authors comply with the CONSORT Statement. Of those, only a minority have procedures that support adherence to the guidance in the CONSORT Statement. Among non-English language journals, the situation is even more irritating although CONSORT has been translated into 10 other languages ([www.consort-statement.org/database/consort-statement](http://www.consort-statement.org/database/consort-statement)). Of 30 German journals which produced a considerable yield of reports of randomized trials from handsearching, not one of them even mentioned the CONSORT Statement in their author guidelines.

Even after almost 15 years the CONSORT Statement has not achieved the endorsement and adherence it deserves, in spite of impressive evidence of benefit. The quality of literature-based systematic reviews is so heavily dependent on the report quality of trial results that The Cochrane Collaboration should increase its efforts to motivate editors and journals to implement procedures which directly adhere to the CONSORT Statement and the corresponding checklist.

## References

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Ioannidis JP, Simes J, Williamson PR. Systematic review of the empirical evidence of study publication bias and outcome reporting bias. *PLoS One* 2008; 3(8): e3081.

2. Schulz KF, Altman DG, Moher D, the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMJ* 2010; 340: c332.

3. Antes G. The new CONSORT statement. *BMJ* 2010; 340: c1432.

## The PRISMA Statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration

Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JP, Clarke M, Devereaux PJ, Kleijnen J, Moher D. *PLoS Medicine* 2009; 6(7): e1000100.

Systematic reviews and meta-analyses are essential to summarise evidence relating to efficacy and safety of healthcare interventions accurately and reliably. The clarity and transparency of these reports, however, is not optimal. Poor reporting of systematic reviews diminishes their value to clinicians, policy makers, and other users.

Since the development of the QUOROM (Quality Of Reporting Of Meta-analyses) Statement, a reporting guideline published in 1999, there have been several conceptual, methodological, and practical advances regarding the conduct and reporting of systematic reviews and meta-analyses. Also, reviews of published systematic reviews have found that key information about these studies is often poorly reported. Realizing these issues, an international group that included experienced authors and methodologists developed PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) as an evolution of the original QUOROM guideline for systematic reviews and meta-analyses of evaluations of healthcare interventions.

The PRISMA Statement consists of a 27-item checklist and a four-phase flow diagram. The checklist includes items deemed essential for transparent reporting of a systematic review. In the Explanation and Elaboration document, the meaning and rationale for each checklist item is explained. For each item, an example of good reporting and, where possible, references to relevant empirical studies and methodological literature is provided. The PRISMA Statement, this explanation and elaboration document, and the associated website ([www.prisma-statement.org](http://www.prisma-statement.org)) should be helpful resources to improve reporting of systematic reviews and meta-analyses.

## Commentary

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The recent proliferation of reporting guidelines reflect deficiencies in all types of published articles that can lead to invalid conclusions and misinterpretation. As systematic reviews are increasingly used to inform decision-making in clinical practice and

health policy, it is crucial that they are conducted and reported in a manner that minimises bias and promotes understanding.

After 10 years, the QUOROM (Quality Of Reporting Of Meta-analyses) Statement has evolved into the PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) Statement. PRISMA, like QUOROM, aims to improve the quality of reporting of systematic reviews, but the guidelines have been updated to reflect developments in systematic review methodology, including clearer guidance on evaluating risk of bias of included studies. This is particularly important given the finding by Moher and colleagues in 2007 that 'For therapeutic reviews ... only half of the non-Cochrane Reviews assessed the quality of included studies (43/87; 49.4%).'<sup>1</sup> The acronym alone reflects the evolution in terminology, from 'meta-analysis' to 'systematic review', with the former term now being reserved for quantitative pooling of results.

The PRISMA Statement was developed through an inclusive, consensus process, informed by evidence whenever possible, involving review authors, methodologists, clinicians, medical editors, and consumers. The PRISMA Statement companion paper provides an explanation for the inclusion of the checklist items along with examples. Most items can be implemented in practice, although at least one item – systematic review registration – is not yet always practical.

The PRISMA Statement may bring challenges for review authors and editors: the new checklist is longer than the QUOROM checklist (increased from an 18-item to a 27-item checklist) and has lengthy associated documentation; the new checklist may result in longer articles (an adverse effect noted by the PRISMA authors); and, unlike other reporting guidelines, it has had a name change, which may contribute to the challenges in uptake as many people are familiar with QUOROM. Fortunately for authors and editors, the latest versions of PRISMA and other reporting guidelines are now hosted in one place by the Enhancing the Quality and Transparency Of health Research (EQUATOR) Network ([www.equator-network.org](http://www.equator-network.org)). Importantly, the PRISMA Statement is not intended as a quality measure for systematic reviews, concentrating as it does on reporting rather than conduct. However, since these are inextricably linked, there is no doubt that it will be widely used as a component of any evaluation of review quality.

The Co-ordinating Editors of Cochrane Review Groups have endorsed the PRISMA Statement to improve the reporting of Cochrane reviews. Compliance with most requirements will not be a cause for concern – authors are required to report on most of the items by the nature of the structured format of Cochrane reviews. However, Cochrane review titles do not identify the review as a systematic review and not all Cochrane reviews include a flow diagram for search results. Work is ongoing to ensure that these will become features of future Cochrane reviews, incorporated into the Review Manager software where possible, as The Cochrane Collaboration continues to ensure that it retains its reputation for creating reviews that meet the highest possible standards for quality, transparency and completeness of reporting.

## Reference

1. Moher D, Tetzlaff J, Tricco AC, Sampson M, Altman DG. Epidemiology and reporting characteristics of systematic reviews. *PLoS Medicine* 2007; 4(3): e78.

## AMSTAR is a reliable and valid measurement tool to assess the methodological quality of systematic reviews

Shea BJ, Hamel C, Wells GA, Bouter LM, Kristjansson E, Grimshaw J, Henry DA, Boers M. *Journal of Clinical Epidemiology* 2009; 62: 1013-20.

**Background:** Systematic reviews have become a standardised way to assess and summarise healthcare research, however, the underlying quality of these reviews has received relatively little attention. AMSTAR has been developed as a tool for evaluating the quality of systematic reviews.

**Objective:** To measure the agreement, reliability, construct validity, and feasibility of a measurement tool to assess systematic reviews (AMSTAR).

**Design:** A random sample of 30 systematic reviews, including 11 Cochrane and 19 non-Cochrane reviews was selected. Each review was assessed by two reviewers using: the enhanced quality assessment questionnaire (Overview Quality Assessment Questionnaire [OQAQ] originally developed by Oxman and Guyatt, 1991); the Sacks' instrument, 1987; and the newly developed measurement tool AMSTAR. The reliability (inter-observer kappas of the 11 AMSTAR items), intraclass correlation coefficients (ICCs) of the sum scores, construct validity (ICCs of the sum scores of AMSTAR compared with those of the other instruments), and completion times were assessed.

**Main results:** The inter-observer agreement of the individual items in the AMSTAR was high with a mean kappa of 0.70 (95% confidence interval [CI] 0.57 to 0.83). However, items four (publication status), seven (report of assessment of scientific quality), and nine (appropriate method to combine studies) scored fair to moderate at 0.38, 0.42, and 0.45, respectively. The mean kappa statistics recorded for the other instruments were 0.63 (95% CI 0.38 to 0.78) for the enhanced OQAQ tool and 0.40 (95% CI 0.29 to 0.50) for the Sacks' instrument. The ICC of the total score for AMSTAR was 0.84 (95% CI 0.65, 0.92) compared with 0.91 (95% CI: 0.82 to 0.96) for OQAQ and 0.86 (95% CI 0.71 to 0.94) for the Sacks' instrument. AMSTAR took a mean of 14.9 (95% CI 17.0 to 12.8) minutes to complete, OQAQ took 20.3 (95% CI 22.5 to 18.0) minutes, and the Sacks' instrument took 34.4 (95% CI 37.3 to 31.6) minutes.

**Conclusions:** AMSTAR has good agreement, reliability, construct validity, and feasibility. These findings need confirmation by a broader range of assessors and a more diverse range of reviews.

## Commentary

Prepared by Steff Lewis

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AMSTAR is a measurement tool to assess the methodological quality of systematic reviews. It is an 11 point scale, which the authors of this paper claim has good inter-rater agreement, and is reasonably quick to use.

Cochrane review authors spend a lot of time assessing the quality (or risk of bias) of individual studies, but as yet, the Collaboration

does not routinely assess the methodological quality of the reviews it produces. If the Collaboration were to assess the quality of its reviews, is AMSTAR something it could use?

When assessing individual trials, The Cochrane Collaboration has recommended assessing individual domains of quality, or risk of bias, such as allocation concealment and blinding of outcome assessors. However, AMSTAR provides a total quality score (out of 11), which goes against this advice. AMSTAR assumes that each of its domains are equally important. In providing a single numeric summary, the details of the areas where a particular systematic review falls short are lost.

AMSTAR asks several questions relating to searching for and documenting the studies in the review, but only asks one question relating to the statistical methods used to summarise the studies 'Were the methods used to combine the findings appropriate?' As a statistician, I have spent weeks of my life assessing this particular point in Cochrane reviews, and it is hard for me to accept that all the multitude of errors that I have seen can be summarised into one sentence. If I were using AMSTAR, I would want a separate checklist of mistakes to look, for so that I could assess this one point.

In summary, I think this paper describes a good study assessing the inter-rater agreement and usability of the AMSTAR scale. However, I'm not sure that the AMSTAR scale is something that The Cochrane Collaboration should use in its current form.

## An evidence-based practice guideline for the peer review of electronic search strategies

Sampson M, McGowan J, Cogo E, Grimshaw J, Moher D, Lefebvre C. *Journal of Clinical Epidemiology* 2009; 62: 944-52.

**Background:** Systematic reviews require complex and highly sensitive electronic literature search strategies however there are no current guidelines for their peer review. Poor search strategies may fail to identify existing evidence because of poor sensitivity or may increase the resources required to conduct reviews as a result of inadequate precision.

**Objective:** To create an annotated checklist for the peer review of electronic search strategies.

**Design:** A systematic review of the literature was conducted to identify existing instruments that evaluate or validate the quality of literature searches in any discipline, and to identify which elements of electronic search strategies have demonstrable impact on search performance. A survey of people experienced in systematic review searching was also conducted to gather expert opinion regarding both the impact of various search elements on the search results and the importance of each element in the peer review of electronic search strategies.

**Main results:** The checklist for the peer review of electronic search strategies includes six elements on which there was strong consensus: the accurate translation of the research question into search concepts; the correct choice of Boolean operators and of line numbers; the adequate translation of the search strategy for

each database; the inclusion of relevant subject headings, and the absence of spelling errors. Seven additional elements had partial support and are included in this guideline.

**Conclusions:** This evidence-based guideline facilitates the improvement of search quality through peer review, and thereby the improvement in quality of systematic reviews. It is relevant for librarians and information specialists, journal editors, developers of knowledge translation tools, research organizations, and funding bodies.

## Commentary

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This paper provides much needed guidance on the parameters which could be most useful when assessing the quality of searches. This is a helpful paper because of its focus on the types of searching used to inform systematic reviews, which tend to have an emphasis on recall (sensitivity). The guidance was developed specifically for database searches.

The guidance was developed by systematically reviewing information retrieval literature to identify the evidence on important elements in database search strategy performance. Once key elements which might impact on search strategy performance had been identified, searchers experienced in conducting literature searches to inform systematic reviews were surveyed to obtain their ratings of the importance of the elements.

The elements which emerged as most key to successful sensitive searches included ensuring that the research question was captured by the search, using the correct combination of Boolean operators and proximity operators, checking for spelling and syntax errors, checking that line numbers were correct, checking that translation between search interfaces had been achieved correctly and ensuring that the subject headings used were sensitive enough to capture the research question. Some issues were assessed as unimportant to the quality of the search including search term redundancy, combining subject headings and free text in a single search statement and using additional database-specific fields.

The guidance recommends that peer review of search strategies should be conducted near the beginning of the review process to ensure the search strategy is fit for purpose and the review is informed by the best possible searches. The guidance offers a structure for standardised assessment, but when used in practice it is likely to need expansion. Practical guidance needs to be more detailed as each recommendation contains several aspects which might need to be assessed. The guidance is pitched at experienced information professionals, but even they might benefit from an annotated version of the guidance with explanations and examples, for example, further explanation of why using the MeSH term REHABILITATION/ in searches is not recommended, and more examples of how to limit safely in specific databases.

The guidance can assist Trials Search Co-ordinators and other searchers to improve the quality of their own searches and provides a clear structure for peer reviewers who have been asked to review a strategy.

This section aims to highlight some of the current methodological research being carried out within The Cochrane Collaboration. To register ongoing methodological research within The Cochrane Collaboration please contact [shopewell@cochrane.ac.uk](mailto:shopewell@cochrane.ac.uk).

## Use of qualitative methods alongside randomised controlled trials of complex healthcare interventions: methodological study

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**Background:** Complex interventions are made up of characteristics such as elements that may act both independently and interdependently, complex systems for intervention delivery, interventions that are difficult to describe and replicate, have complex explanatory pathways, or uncertainty about the mechanism of action of the intervention. Randomized trials are sometimes used to evaluate complex interventions, whilst qualitative approaches can contribute to both their development and evaluation. The use of multiple, integrated approaches may be particularly useful in evaluating the effects of complex health and social care interventions as these involve social or behavioural processes that are difficult to explore using quantitative methods only.

**Objective:** To examine the use of qualitative approaches alongside randomized trials of complex healthcare interventions.

**Methods:** A systematic sample of 100 trials from 492 trials published in English during 2001 to 2003 by the Cochrane Effective Practice and Organisation of Care Review Group were analysed. Two reviewers extracted data describing the randomized controlled trials and qualitative studies, the quality of the studies and how, if at all, qualitative and quantitative findings were combined.

**Summary of main results:** Thirty trials had associated qualitative work and 19 of these were published studies. Fourteen qualitative studies were done before the trial, nine during the trial and four after the trial. Thirteen studies reported an explicit theoretical basis and 11 specified their methodological approach. Approaches to sampling and data analysis were poorly described. For 20 trials there was no indication of integration of qualitative

and quantitative findings at the level of analysis or interpretation. The quality of the qualitative studies was highly variable.

**Conclusions:** Qualitative studies alongside randomized controlled trials remain uncommon. The findings of qualitative studies seemed to be poorly integrated with those of trials and often had major methodological shortcomings.

## Reference

Lewin S, Glenton C, Oxman AD. Use of qualitative methods alongside randomised controlled trials of complex healthcare interventions: methodological study. *BMJ* 2009; 339: b3496.

## An encouraging assessment of methods to inform priorities for updating systematic reviews

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**Background:** Systematic reviews can become rapidly out of date as new research evidence emerges. Arbitrary update strategies such as updating all reviews according to a perpetual rota may result in inefficient use of resources in slowly developing fields or delayed incorporation of knowledge in rapidly evolving fields. Update prioritization strategies devised for a collection of existing reviews, such as those of Cochrane Review Groups, may offer a more effective way of keeping clinical recommendations up to date and accurate for a limited resource.

**Objective:** To consider the use of statistical methods that aim to prioritize the updating of a collection of systematic reviews based on preliminary literature searches.

**Methods:** A new simulation-based method estimating statistical power and the ratio of weights assigned to the predicted new and old evidence, and the existing Barrowman *n* approach were used to assess whether the conclusions of a meta-analysis are likely to change when the new evidence is included. Using only information on the number of subjects randomized in the 'new' trials, these were applied retrospectively, by removing recent studies, to the 12 systematic reviews of 67 reviews in the Cochrane Infectious Diseases Group Database which met the inclusion criteria for the study.

**Summary of main results:** When the removed studies were reinstated, inferences changed in five of them. These reviews were ranked, in order of update priority, 1, 2, 3, 4 and 11 (Barrowman *n* approach) and 1, 2, 3, 4 and 12 (simulation-based power approach). The low ranking of one significant meta-analysis by both methods was due to unexpectedly favourable results in the reinstated study.

**Conclusions:** This study demonstrates the feasibility of the use of analytical methods to inform update prioritization strategies. Under conditions of homogeneity, Barrowman's *n* and simulated power were in close agreement. Further prospective evaluation of these methods should be undertaken.

## Reference

Sutton AJ, Donegan S, Takwoingi Y, Garner P, Gamble C, Donald A. An encouraging assessment of methods to inform priorities for updating systematic reviews. *Journal of Clinical Epidemiology* 2009; 62: 241–51.

## Reporting and methodologic quality of Cochrane Neonatal Review Group systematic reviews

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**Background:** The Cochrane Neonatal Review Group is one of the 51 Review Groups registered with The Cochrane Collaboration. Members of the Group prepare reviews of the results of randomized trials of interventions for the prevention and treatment of disease in newborn infants. In preparing their reviews, review authors follow systematic methods summarised in the *Cochrane Handbook for Systematic Reviews of Interventions* and in a checklist developed by the Group's editors for neonatal reviews. Assessment of the methodological quality of systematic reviews and how well they are reported is essential in judging whether the findings warrant a change in clinical practice. The most commonly used tools for the assessment of review quality are the QUality Of Reporting Of Meta-analyses (QUOROM) Statement, published in 1999 and recently updated as the PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) Statement (see page 13), and the Overview Quality Assessment Questionnaire (OQAQ).

**Objective:** To assess the methodological and reporting quality of systematic reviews published in the Cochrane Neonatal Review Group and to evaluate whether the publication of the QUOROM Statement is associated with an improvement in review quality.

**Methods:** A random sample of all neonatal reviews published in the *Cochrane Database of Systematic Reviews* Issue 4 2005 was selected for analysis. Two reviewers independently extracted data and assessed review quality, using the items of the QUOROM Statement to assess the quality of reporting, and total scores of the OQAQ to assess methodological quality.

**Summary of main results:** A sample of 61 of the 210 neonatal reviews was analysed. Eighty-two per cent were published after the publication of the QUOROM Statement. Most of the reviews published before the QUOROM Statement had been updated

and the most recent version was used for the analysis. Overall, the reviews were of good quality with minor flaws based on OQAQ total scores. Areas needing improvement include abstract reporting, *a priori* plan for heterogeneity assessment and how to handle heterogeneity, assessment of publication bias, reporting of agreement among review authors, documentation of trials flow, and discussion of possible biases in the review process. Reviews published after the QUOROM Statement had significantly higher quality scores.

**Conclusions:** The systematic reviews produced by the Cochrane Neonatal Review Group are generally of good quality with minor flaws, but efforts should be made to improve the quality of reports. Readers should assess the quality of published reports before implementing the recommendations.

## Reference

Al Faleh K, Al-Omran M. Reporting and methodologic quality of Cochrane Neonatal review group systematic reviews. *BMC Pediatrics* 2009; 9: 38.

## Analysis of the reporting of search strategies in Cochrane systematic reviews

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**Background:** The *Cochrane Handbook for Systematic Reviews of Interventions* provides instructions for documenting a systematic review's electronic search strategy, listing seven elements that should be included. Comprehensive reporting of the search strategy is important in enabling readers to evaluate the search when critically appraising the review's quality.

**Objective:** To determine to what extent these instructions for reporting electronic search strategies have been followed in recently published Cochrane reviews.

**Methods:** Sixty-five reviews added to the *Cochrane Database of Systematic Reviews* in the first quarter of 2006 were examined for their adherence to the instructions in the *Cochrane Handbook* for reporting electronic search strategies. A further 18 reviews were excluded as their searches were conducted only in the specialized registers of Cochrane Review Groups.

**Summary of main results:** No review reported all seven recommended elements. Four reviews (6%) included six elements. Twenty-one (32%) included five or more elements and 44 (68%) four or fewer. Three reviews reported only two elements. The 65 reviews came from 41 Cochrane Review Groups.

**Conclusions:** The instructions from the *Cochrane Handbook* for reporting search strategies are not being consistently followed by groups producing Cochrane reviews.

## Reference

Yoshii A, Plaut DA, McGraw KA, Anderson MJ, Wellik KE. Analysis of the reporting of search strategies in Cochrane systematic reviews. *Journal of the Medical Library Association* 2009; 97: 21–9.

## Searching for unpublished trials in Cochrane reviews may not be worth the effort

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Australia.

**Background:** Minimizing bias related to the studies included in a systematic review is an important issue in Cochrane reviews. This includes attempts to locate unpublished studies, as studies with significant results are more likely to be published. However, unpublished studies may lack information, be of poor methodological quality or both, and their inclusion could introduce bias rather than prevent it.

**Objective:** To assess the value of searching for unpublished data by exploring the extent to which Cochrane reviews include unpublished data and by evaluating the methodological quality of included unpublished trials.

**Methods:** The reference lists of all completed Cochrane reviews published since 2000 in the *Cochrane Database of Systematic Reviews* Issue 3, 2006 were checked for the inclusion of unpublished studies. All 116 references from a random sample of 61 of the 292 reviews which included unpublished trials were studied. MEDLINE, CENTRAL and websites of pharmaceutical companies were searched for formal publications of these trials. The methodological quality of trials marked as 'unpublished data only' was assessed on three items relating to the control of bias, allocation concealment, blinding and withdrawals.

**Summary of main results:** Of the 2689 completed Cochrane reviews, 292 (12%) included references to unpublished data. Unpublished trials made up 9% of all trials included in the sample analysed. Thirty-eight per cent of the unpublished trials were found to have been published. Allocation concealment was rated as unclear or not adequate in 54%, blinding was not reported in 39% and in 43% the randomization procedure was unclear. In 43% of reviews, the reported withdrawal rates were above 20%. Trials that were eventually published had larger mean population sizes than those that remain unpublished ( $P = 0.02$ ). Methodological quality and publication bias were mentioned in half of the reviews and explored in a third.

**Conclusions:** A minority of Cochrane reviews include unpublished trials and many of these are eventually published. Truly unpublished studies are of poor or unclear methodological quality. It may be better to invest in regular updating of reviews than in extensive searching for unpublished studies.

### Reference

van Driel ML, De Sutter A, De Maeseneer J, Christiaens T. Searching for unpublished trials in Cochrane reviews may not be worth the effort. *Journal of Clinical Epidemiology* 2009; 62: 838–44.

## Thomas C Chalmers M.D. Award—2009

The Thomas C Chalmers M.D. prize is awarded annually for the best oral or poster presentation at the Cochrane Colloquium. In

2009, in Singapore, the best oral presentation was awarded to Yemisi Takwoingi, Jac Dinnes, Mariska Leeflang and Jon Deeks for their study entitled 'An empirical assessment of the validity of uncontrolled comparisons of the accuracy of diagnostic tests'. The best poster presentation was awarded to Lukas Staub, Sarah Lord and Nehmat Houssami for their study entitled 'Including evidence about the impact of tests on patient management in systematic reviews of diagnostic test accuracy'.

## An empirical assessment of the validity of uncontrolled comparisons of the accuracy of diagnostic tests

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**Background:** Cochrane reviews of diagnostic test accuracy aim to provide evidence to support the selection of diagnostic tests by comparing the performance of tests or test combinations. Studies that directly compare tests within patients or between randomized groups are preferable but are uncommon. Consequently, between-study uncontrolled (indirect) comparisons of tests may provide the only evidence of note. Such comparisons are likely to be more prone to bias like indirect comparisons between healthcare interventions, and maybe more severely due to considerable heterogeneity between studies and the lack of a common comparator test.

**Objective:** To estimate bias and reliability of meta-analyses of uncontrolled comparisons of diagnostic accuracy studies compared to meta-analyses of comparative studies.

**Methods:** Meta-analyses that included test comparisons with both comparative studies and uncontrolled studies were identified from a cohort of higher quality diagnostic reviews (Dinnes et al 2005) indexed in the Database of Abstracts of Reviews of Effects up to December 2002 supplemented by more recent searches. The hierarchical summary ROC model was used to synthesize pairs of sensitivity and specificity in each meta-analysis and estimate and compare accuracy measures for both the uncontrolled test comparison and the comparative studies.

**Summary of main findings:** Ninety-four comparative reviews were identified of which 30 provided data to conduct both direct and uncontrolled test comparisons. The degree of bias and variability of relative sensitivities, specificities and diagnostic odds ratios between comparative and uncontrolled comparisons was analysed. Further results will be available at the Colloquium.

**Conclusions:** Test selection is critical to health technology assessment. In the absence of comparative studies, selection has often relied on comparisons of meta-analyses of uncontrolled studies. Limitations of such comparisons should be considered when making inferences on the relative accuracy of competing tests, and in encouraging funders to ensure future test accuracy studies address important comparative questions.

## Reference

Takwoingi Y, Dinnes J, Leeflang M, Deeks J. An empirical assessment of the validity of uncontrolled comparisons of the accuracy of diagnostic tests [abstract]. *17th Cochrane Colloquium*; 2009 Oct 11-14; Singapore: 11.

## Including evidence about the impact of tests on patient management in systematic reviews of diagnostic test accuracy

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NHMRC Clinical Trials Centre, University of Sydney, Australia.

**Background:** Systematic reviews (SRs) provide more precise estimates of test sensitivity and specificity than single studies. Their interpretation requires consideration of the impact of test results on patient management and consequences for patient outcomes.

**Objective:** To describe concepts for the inclusion of data about patient management as an extension to SRs of test accuracy.

**Methods:** We apply standard epidemiological principles and present examples to define key concepts for reporting test impact on patient management in SRs of test accuracy.

**Summary of main findings:** Review authors should state assumptions about changes in management and consequences for patient outcomes due to detection of 'extra' true-positives (TP)/false-negatives (FN)/true-negatives (TN)/false-positives (FP) when comparing the sensitivity and specificity of two tests: a) If assumptions that all extra cases will receive the specified management change are straightforward, no further evidence about management is needed; b) If uncertainty exists, additional data may be required to estimate what proportion of extra cases will receive a change in management. These data may be found in accuracy studies and can be summarised to aid interpretation of SRs to clinical practice. Unfortunately, they are often not clearly or adequately reported. The GRADE approach can then be used to judge evidence about the effects of these management changes on patient outcomes.

**Conclusions:** Patient management cannot always be inferred from test accuracy results but are relevant for interpretation of these results, for example, if the index test is more sensitive and less specific than the comparator, information about the proportion of extra true-positives who will receive a change in treatment may be important when weighing up treatment benefits against the harms of extra false-positives. Review authors can identify situations where empirical evidence about the changes in management will assist interpretation of accuracy results and present available data in a table with a summary estimate.

## Reference

Staub LP, Lord SJ, Houssami N. Including evidence about the impact of tests on patient management in systematic reviews of diagnostic test accuracy [abstract]. *17th Cochrane Colloquium*; 2009 Oct 11-14; Singapore: 74-5.

## Cochrane Methodology Review Group

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In 2009, the editorial base for the Cochrane Methodology Review Group moved from its original home in Oslo in Norway, to Dublin, Ireland and Oxford, England. We are very grateful for the considerable input to the Group by Elizabeth Paulsen and Marit Johansen who stepped down as Managing Editor and Trials Search Co-ordinator respectively at that time. The editorial team continues to be co-ordinated by Mike Clarke and Andy Oxman, supported now by Nicola McDowell (Managing Editor) and Sarah Chapman (Trials Search Co-ordinator), based in Oxford. The other editors are Paul Glasziou, Peter Gøtzsche, Gordon Guyatt (Criticism Editor), Peter Jüni, Philippa Middleton and Karen Robinson. During the last year, one Cochrane Methodology Review was updated (see below) and the protocol for a new review looking at the impact of the CONSORT guidelines on reporting of trials was published in *The Cochrane Library*. This brings the total number of Cochrane Methodology reviews to 14 protocols and 14 full reviews.

The *Cochrane Methodology Register* (CMR) continues to grow year on year, with infrastructure support from the UK Cochrane Centre, which is part of the National Institute for Health Research, and a grant from The Cochrane Collaboration during 2009. Sally Hopewell and Anne Eisinga at the UK Cochrane Centre work with Mike on CMR and by mid 2010 it contains more than 13,000 references to studies and other reports relevant to the methods of systematic reviews and other evaluations of health and social care. Over a thousand records were added in the last twelve months.

If you are interested in contributing to the work of the Cochrane Methodology Review Group, as an author, referee or in some other way, please contact the Managing Editor (nmcdowell@cochrane.ac.uk).

## Cochrane Methodology review on recruitment strategies for randomized trials

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In the last year, one of the Cochrane Methodology reviews<sup>1</sup> underwent a major face lift and updating, with a new author team taking over responsibility for this review of ways to improve the recruitment of participants into research studies, assisted by an award from the National Institute for Health Research's incentive scheme for Cochrane reviews. Shaun Treweek and colleagues ran new searches and focused the scope of the research on recruitment to randomized trials, producing an updated review with 27 included studies and identifying strategies which might help boost the number of people agreeing to take part in trials.

Finding studies that are about recruitment to trials, rather than the trials themselves is not easy. As well as looking in the *Cochrane Methodology Register*, the team of authors searched MEDLINE,

EMBASE, the educational database ERIC, and The Campbell Collaboration's SPECTR collection of controlled trials in education and other non-healthcare areas. They checked 10,000 potentially relevant references, and worked their way through more than 180 full articles, before settling on the 27 reports that were suitable for inclusion in the review. There were 24 studies with interventions targeted at the potential participants for randomized trials and three studies where the interventions were aimed at people recruiting others to trials. As well as recruitment to real trials, the review also includes research in which strategies were tested for hypothetical trials, to see if people would say that they would be willing to be randomized, even if a trial was not immediately available for them. The authors did find some such studies. The whole collection of research allowed nine categories of intervention to be assessed.

Studies among potential participants filled seven of these categories: open versus blinded randomized trial, placebo versus another comparator, conventional randomized trial design versus another design, modifications to the consent process, modifications to the approach made to potential participants, financial incentives to participants, and reminders about the trial. The two categories for the studies that targeted recruiters were modifications to their training, and greater contact between the trial co-ordinator and the trial sites.

For most of the interventions investigated, the updated Cochrane Methodology review was able to draw on a single trial only. But, some of these did suggest that the intervention tested would increase recruitment. The promising interventions were telephone reminders to non-responders for a trial of ways to help people return to work after illness; opt-out procedures requiring potential participants to get in touch with the researchers, if they did not want to be contacted about a trial of decision aids for colorectal cancer screening; and mailing a home safety questionnaire to

potential participants for an injury prevention trial. A trial of vitamin and mineral supplementation, and another of hormone replacement therapy both found that making the trial open rather than blinded boosted the number of people willing to take part.

The effects of the other strategies tested by studies in the review were less clear. One strategy based on payments to participants worked in the context of a hypothetical trial, but the review authors are not sure if this would translate into a real trial. The study, which was published in 2004, presented pharmacy students in the USA with a range of hypothetical trials involving different levels of potential harm. It found that increasing the incentive payment by several hundred dollars increased the number of people who said they would be willing to be randomized.

A further updating of the review is taking place now. Bringing in information from more recent research and completing the thorough investigation of some studies that were identified for the current version but for which more information needed to be collected. This update should be ready and published in *The Cochrane Library* in the coming year. In the meantime, you can listen to the lead author, Shaun TrewEEK discuss the review in The Cochrane Collaboration's special collection of material for International Clinical Trials Day 2010 ([www.cochrane.org/podcasts/international-clinical-trials-day-2010/recruitment-strategies-clinical-trials](http://www.cochrane.org/podcasts/international-clinical-trials-day-2010/recruitment-strategies-clinical-trials)).

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# Cochrane Methods Groups

The science of research synthesis is still young and evolving rapidly. Methods Groups have been established to develop methodology and advise The Cochrane Collaboration on how the validity and precision of systematic reviews can be improved. For example, the Statistical Methods Group is assessing ways of handling different kinds of data for statistical synthesis, and the Applicability and Recommendations Methods Group is exploring important questions about drawing conclusions regarding implications for practice, based on the results of reviews.

There are 14 registered Methods Groups and, although their main role is to provide policy advice to The Cochrane Collaboration, they may also carry out additional core functions such as providing training, peer review and specialist advice, contributing to software developments, or conducting methodological research aimed at improving the quality of Cochrane reviews (see pages 16–20). Reports on the activities from most of the 14 registered Methods Groups are given below. Contact details for

each of the Methods Groups can be found on the inside front cover of this edition of *Cochrane Methods*.

## **Registered groups**

Adverse Effects  
Applicability and Recommendations  
Bias  
Economics  
Equity  
Individual Patient Data Meta-analysis  
Information Retrieval  
Non-Randomised Studies  
Patient Reported Outcomes  
Prognosis  
Prospective Meta-Analysis  
Qualitative Research  
Screening and Diagnostic Tests  
Statistical Methods

## **Cochrane Adverse Effects Methods Group**

*Yoon Loke, Andrew Herxheimer, Su Golder and Sunita Vohra*

This has been, as usual, a busy year for the Cochrane Adverse Events Methods Group. We had workshops at the Cochrane Colloquium in Singapore in 2009 and the UK- and Ireland-based Cochrane Contributors' Meeting in Cardiff in March 2010, which were excellent opportunities to help review authors in tackling adverse effects. Later on in the year, for those who are unable to attend our workshops in person, we plan to run 'webinars' with the help of our friends at the Canadian Cochrane Centre. This will certainly be a new challenge in transferring our usual hands-on workshop to a virtual

setting. The first webinar on data extraction for adverse effects was scheduled for 17 June 2010 (after *Cochrane Methods* went to press) (<http://ccnc.cochrane.org/cochrane-canada-live-webinars>). If you have any suggestions on what you would like us to cover in future webinars, please contact us via our website. We are glad to welcome Sunita Vohra from the University of Alberta, Canada, who has kindly agreed to join us as one of the Co-Convenors. We are also very pleased to have Su Golder (MRC Fellow in Health Services Research) back from maternity leave, and look forward to further methodological expertise from Sunita and Su in improving the ways in which we review adverse effects.

We welcome questions, suggestions, and new ideas from review authors and editors; please e-mail any of us. Contact details and specific areas of interest are given on our webpage: <http://aemg.cochrane.org/contact-us>.

## **Cochrane Bias Methods Group**

*David Moher, Doug Altman, Jonathan Sterne, Isabelle Boutron and Lucy Turner*

Over the past five years, the Bias Methods Group (BMG) has continued to raise awareness of methodological discussion and codes of practice for dealing with bias in systematic reviews. The BMG

is active within the Cochrane community hosting workshops, training sessions, giving presentations, conducting priority topic research and methods reviews. The BMG has experienced a 30% increase in membership over the past year, with 115 members in 18 countries who share an interest in bias.

In 2009, the BMG welcomed a fourth Co-Convenor, Dr. Isabelle Boutron whose expertise is proving to be a considerable asset to the Group. Dr. Boutron's work on the risk of bias is contributing

to the current evaluation of the Risk of Bias (RoB) tool (see page 4) led by the BMG alongside Jelena Savovic, Julian Higgins and David Tovey. The objective of the tool is to provide an easily accessible, comprehensive means of assessing and reporting bias in reviews. The update of the RoB tool has involved focus groups sessions, discussion meetings and an extensive survey completed by Cochrane authors, editors and Review Group staff. The updated and improved version of the tool is due to be published in the next edition of the *Cochrane Handbook for Systematic Reviews of Interventions*. We aim to present results of the evaluation at the Joint Colloquium of the Cochrane and Campbell Collaborations in Keystone in October 2010, where we also hope to run a workshop at which further discussion of proposed improvements to the RoB tool can take place.

We are delighted to announce that Co-Convenor Professor Jonathan Sterne has been elected as a member of the Collaboration's recently established Methods Executive. The Methods Executive will provide advice on methodological issues to the Cochrane Collaboration Steering Group, and provides a focal point for Collaboration-wide methods discussions and initiatives (see page 2).

The Collaboration has also established a new Methods Board (see page 2), which will be the body responsible for developing methods guidance and strengthening the communications among Methods Groups, the Methodology Review Group and various other individuals with methods roles in the Collaboration. We look forward to working with the Methods Board to establish a network of Review Group-based methodologists who will take responsibility for the way that Cochrane reviews address bias.

Current, in progress, Cochrane Methodology reviews by BMG members include:

- Adjusted indirect comparison for estimating relative effects of competing healthcare interventions (Fujian Song).

- Comparison of protocols to published articles for randomised controlled trials (Rebecca Smyth).
- CONSolidated Standards Of Reporting Trials (CONSORT) and the quality of reporting of randomized controlled trials (David Moher).

Recently completed BMG Cochrane Methodology reviews:

- Checking reference lists to find additional studies for systematic reviews [Pending Publication] (Tanya Horsley).
- Publication bias in clinical trials due to statistical significance or direction of trial results (Sally Hopewell).
- When and how to update systematic reviews (David Moher).

The BMG is also involved in initiatives related to the reporting of health research. Without adequate reporting, it is impossible to identify and assess risk of bias in primary studies. Our convenors are among the founders of the EQUATOR Network ([www.equator-network.org](http://www.equator-network.org)) which seeks to improve the quality of scientific publications by promoting transparent and accurate reporting of health research. Our members have also been integral to the recent 2010 update of the CONSORT Statement ([www.consort-statement.org](http://www.consort-statement.org)) (see page 12) and the new PRISMA Statement (see page 13).

The BMG will be holding our next meeting at the Joint Colloquium of the Cochrane and Campbell Collaborations in Keystone in October 2010 and we should like to invite all those interested to attend. We thank our current and potential funders, the Canadian Institutes of Health Research, without whose support our continued progress would not be possible. For further information about the Group, please visit the BMG website at [www.ohri.ca/bmg](http://www.ohri.ca/bmg) or contact our Research Co-ordinator, Lucy Turner: [ltturner@ohri.ca](mailto:ltturner@ohri.ca).

## Campbell and Cochrane Economics Methods Group

Ian Shemilt

Economics is the study of the optimal allocation of limited resources for the production of benefit to society. The Campbell and Cochrane Economics Methods Group (CCEMG) focuses on the development and application of approaches to evidence synthesis that combine economics and systematic review methods—both the role of economics methods in the evidence review and synthesis process, and conversely the role of evidence review and synthesis methods in economic evaluation.

For Cochrane and Campbell reviews, we advocate that authors should at least comment on economic aspects of interventions and if possible evaluate included evidence from an economic perspective. Additionally, we support systematic approaches to incorporating searches for, and critical summaries of, evidence on resource use, costs and cost-effectiveness into reviews, alongside evidence on beneficial and adverse effects. The primary objective here is not to synthesise precise estimates of incremental resource use, costs or cost-effectiveness, but to explore economic trade-offs between interventions and to present findings in formats that facilitate new economic analyses.

Economic methods guidelines are published in Part 3, Chapter 15 of the *Cochrane Handbook for Systematic Reviews of Interventions*. We encourage Cochrane authors and Review Groups to become familiar with these guidelines and to seek specialist advice and peer review from the CCEMG for any protocols and reviews which have economics components, including those incorporating measures of resource use, costs and/or cost-effectiveness as primary or secondary outcomes. We also invite Cochrane contributors to access economics methods training at colloquia and other network events, or via our website ([www.c-cemg.org](http://www.c-cemg.org)). In 2009 and 2010, CCEMG Co-Convenors have edited a new Wiley-Blackwell book, *Evidence-Based Decisions and Economics* (April 2010), which describes how the activities and outputs of evidence synthesis, systematic review, economic analysis and decision-making interact within and across different spheres of health and social policy and practice, and profiles the latest methods proposals and controversies in the field (<http://eu.wiley.com/WileyCDA/WileyTitle/productCd-1405191538.html>). Other activities and outputs have included: a new web-based tool and supplementary guidance for use in reviews to adjust estimates of costs collected from included studies to a common target currency and price year ([epi.ioe.ac.uk/costconversion/default.aspx](http://epi.ioe.ac.uk/costconversion/default.aspx)); work on incorporating evidence on resource use and costs into Summary of findings tables (see forthcoming 'GRADE Guidelines' series in the *Journal of Clinical Epidemiology*); and provision of free-trial access

to the Health Economic Evaluations Database for Cochrane authors and Trials Search Co-ordinators ([www.c-cemg.org](http://www.c-cemg.org)). Miranda Mugford stepped down as Chair of Co-Convenors of the CCEMG in May 2010, and was replaced by Luke Vale. We

thank Miranda for her leadership and many contributions to the CCEMG over almost 20 years since its inception and wish her well in her retirement from academia. To contact the CCEMG, please e-mail Ian Shemilt ([i.shemilt@uea.ac.uk](mailto:i.shemilt@uea.ac.uk)).

## Campbell and Cochrane Equity Methods Group

*Peter Tugwell, Mark Petticrew, Vivian Welch, Jordi Pardo Pardo, Elizabeth Kristjansson and Erin Ueffing*

At the end of 2009, the Cochrane Health Equity Field became a Cochrane Methods Group. This change recognises our work in systematic review methods around equity, and facilitates discussion of these methodological challenges within the Collaboration. Our thanks go out to those who supported us! Our aim is to improve the quality of Campbell and Cochrane reviews on interventions to reduce socioeconomic inequalities in health and to promote their use to the wider community. Ultimately, this will help build the evidence base on such interventions and increase our capacity to act on the health gap between rich and poor.

**Staff:** This year, we were pleased to welcome Jordi Pardo Pardo to our team as a Knowledge Translation Specialist.

**Extrapolation:** There is a need for improved guidance on how policy-makers, clinicians, practitioners, and the public can apply (extrapolate) the results from systematic reviews to disadvantaged groups. The question that these stakeholders really have is 'In my setting/ population, will this intervention have the same effects that it had in the studies in the systematic review?' We have been awarded a grant from the Cochrane Opportunities Fund for our work in this area, and plan to hold a meeting/workshop at the Joint Colloquium of the Cochrane and Campbell Collaborations in Keystone in October 2010.

**Non-randomized methods:** We are collaborating with the Cochrane Non-Randomised Methods Group to host a two-day workshop session in Ottawa, Canada. Participants will discuss methodological issues that arise when doing systematic reviews that include non-randomized studies, such as 'Is some evidence (irrespective of the risk of bias) always better than none?'

**Equity 101:** We are developing training modules/workshops on basic equity principles and how the differential effects of interventions on disadvantaged populations can be considered in systematic reviews. Please contact us to participate in a session.

**Open Equity Meeting:** Friday, October 22 2010 at 07:30 (during the Joint Colloquium of the Cochrane and Campbell Collaborations in Keystone). We welcome your contributions and involvement.

**Logic models:** The role and value of theory in systematic reviews are sometimes contested. Logic models describing mechanisms of action, with consideration of context and policy, social and cultural environments are one method of including theory. Analytic frameworks, with their map of relationships and outcomes, are also useful for critiquing linkages in evidence in systematic reviews. We will be giving a workshop on logic models in collaboration with the Cochrane Public Health Review Group: please join us at the Joint Colloquium.

**Membership/Contact:** The Equity Methods Group has nearly 400 members from 35 countries. For more information or to join our listserv, please contact Erin Ueffing ([erin.ueffing@uottawa.ca](mailto:erin.ueffing@uottawa.ca)) or visit [www.equity.cochrane.org](http://www.equity.cochrane.org).

## Cochrane Individual Patient Data Meta-analysis Methods Group

*Larysa Rydzewska, Jayne Tierney, Lesley Stewart, Mike Clarke and Maroeska Rovers*

The Individual Patient Data (IPD) Meta-analysis Methods Group has 73 members (35 active, 38 passive) from 17 countries, with interests spanning a wide range of health care, including cancer, epilepsy, stroke, perinatal care, and malaria, and research questions in prevention, treatment, rehabilitation and prognosis. With this diversity in mind, we are considering changing the name of the Group to 'Individual Participant Data', retaining the 'IPD' abbreviation.

During our meeting at the Cochrane Colloquium in Freiburg in October 2008, attended by many new members of the Group, one of the main issues discussed was the difficulty in obtaining funding for IPD projects. Although there are well established advantages of collecting IPD for systematic reviews, this is not always apparent to funders. Also, it is not clear to them that for some types of systematic review, such as those of prognostic studies, the collection of IPD may be the only way to perform reliable meta-analyses. Therefore, we have been compiling a

list of both criticisms and positive feedback from funders for use by our members. We are also planning a collection of articles about current topics in relation to IPD with examples from the Methods Group. This should bring the literature on this topic up to date and provide examples and information that can be cited in future funding applications. Furthermore, an article on the rationale, conduct and reporting of IPD in meta-analyses has recently been published by a member of the Group.<sup>1</sup>

At the Cochrane Colloquium in Singapore in October 2009 and again at the UK- and Ireland-based Cochrane Contributors' Meeting in March 2010, we ran training workshops on when and how to use IPD in systematic reviews. This training helps review authors to decide whether an IPD approach is appropriate to their own review question and circumstances, and provides practical guidance on all aspects of the IPD approach. We intend to run this workshop during the forthcoming Joint Colloquium of the Cochrane and Campbell Collaborations in Keystone in October 2010. We also ran a further training workshop at the UK- and Ireland-based Contributors' Meeting in March 2010, led by Catrin Tudur-Smith, on statistical methods for the meta-analysis of IPD. This workshop covered methods for modelling IPD, combining IPD and aggregate data, and estimating treatment-covariate interactions.

As part of the organizational changes in the way that Methods Groups participate in The Cochrane Collaboration (see page 3), we have adopted the following as our core functions:

- Providing training.
- Providing peer review on the IPD element of Cochrane reviews.
- Providing specialist advice on IPD.
- Contributing to the development of software relevant to using IPD meta-analyses in Review Manager (RevMan).
- Conducting Cochrane Methodology Reviews relevant to IPD topics.
- Contributing to the Cochrane Methodology Register.
- Helping to monitor and improve the quality of Cochrane reviews.

## Cochrane Information Retrieval Methods Group

*Julie Glanville, Carol Lefebvre, Jessie McGowan, Alison Weightman and Bernadette Coles*

There are approximately 190 members of the Information Retrieval Methods Group (IRMG), many of whom have been active in a number of the projects outlined below. Our Co-ordinator (BC) continues to maintain members' contact details in Archie. In November 2009 we transferred our discussion list to the Collaboration mailing lists system supported by the German Cochrane Centre and in March 2010 we transferred our website to the new web system, also supported by the German Cochrane Centre. We welcome feedback on the website ([irmg.cochrane.org](http://irmg.cochrane.org)) from IRMG members and others.

In March 2010, Julie Glanville became an additional Co-Convenor of the IRMG. She brings a wealth of experience in information retrieval research and teaching in the context of systematic reviews and is co-author of the Searching for Studies chapter of the *Cochrane Handbook for Systematic Reviews of Interventions*.

The Co-Convenors and members of the IRMG continued to serve on various Cochrane Collaboration policy advisory groups relevant to information retrieval including the Handbook Advisory Group, the Publishing Policy Group, the Quality Advisory Group and the Trials Search Co-ordinators Executive. There have been a number of changes in policy advisory group structures over the last year with existing groups being wound down and new groups and committees being formed. For example, the IRMG is represented on the newly formed Methods Executive (see page 2).

Two of the Co-Convenors (CL and JG) together with another member of the IRMG updated the Searching for Studies chapter in the *Cochrane Handbook for Systematic Reviews of Interventions*.<sup>1</sup> The revised chapter contains Collaboration policy on study identification for Cochrane reviews and information on search methods and sources to search, together with revised versions of the Cochrane Highly Sensitive Search Strategies for identifying reports of randomized trials in MEDLINE.

Following on from the three-day Cochrane Collaboration Steering Group-funded meeting in Cambridge in July 2008 to explore approaches and identify solutions to meet the training and support requirements across the Collaboration, the Co-

We are also holding regular teleconferences in which the convenors can discuss issues relevant to the organization of the Group, including, for example, the preparation of the papers on IPD methods. If you would like to join the IPD Methods Group or are interested in finding out more, please contact Larysa Rydzewska ([lhr@ctu.mrc.ac.uk](mailto:lhr@ctu.mrc.ac.uk)) or visit [www.ctu.mrc.ac.uk/cochrane/ipdmg](http://www.ctu.mrc.ac.uk/cochrane/ipdmg), where you will find searchable databases of completed and ongoing IPD meta-analyses and methodology research projects, as well as general information about IPD meta-analyses.

## Reference

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Convenors have been involved in revising their training materials, based on the Searching for Studies chapter of the *Cochrane Handbook for Systematic Reviews of Interventions*. These slides will contribute to Collaboration-wide training materials for Cochrane Centres and others to use when training review authors. Progress continues to be made on the PRESS project (Peer Review of Electronic Search Strategies), led by Co-Convenors (CL and JMcG) together with other IRMG members, to develop guidance for evaluating search strategies for systematic reviews. In addition to the full project report published by the project funder, the Canadian Agency for Drugs and Technologies in Health (CADTH),<sup>2</sup> an evidence-based practice guideline for peer-reviewing search strategies has been published<sup>3</sup> and also a checklist<sup>4</sup>. The peer review forum, which forms the final element of this project, is still under development at the pilot stage and how this might be implemented across Review Groups in the Collaboration will be discussed with IRMG members, Trials Search Co-ordinators and others when the pilot is complete. All Cochrane Trials Search Co-ordinators and all members of the IRMG were invited to contribute to the survey that underpinned this project.

The funding application to undertake an audit of search strategies in new and / or updated Cochrane reviews, reported in the previous issue of this newsletter, was not successful but it is hoped that an audit will take place in the near future.

Several members of the IRMG including two of the Co-Convenors (JG and CL) are involved in updating the Cochrane Methodology Review on handsearching versus electronic searching to identify reports of randomized trials, which was first published in 2003, to provide advice to the Cochrane Collaboration Steering Group through the Monitoring and Registration Group on the value of handsearching.

Filters for importing records from *The Cochrane Library* into ProCite, Reference Manager and EndNote continue to be updated on the IRMG's website (<http://irmg.cochrane.org/filters-reference-management-software-procite-reference-manager-and-endnote>). If you are aware of any filters for importing records from *The Cochrane Library* into any other reference management software, please contact Bernadette Coles ([colesbm@cardiff.ac.uk](mailto:colesbm@cardiff.ac.uk)).

Work on expanding and updating the web resource of search filters compiled by the InterTASC Information Specialists' Sub-Group (ISSG) continues ([www.york.ac.uk/inst/crd/intertasc](http://www.york.ac.uk/inst/crd/intertasc)). Two of the Co-Convenors (JG and CL) are editors of the site and many

members of the IRMG are contributors. It currently records known search filters, filter design projects in progress, and research on the development and use of search filters. There are also critical appraisals for some of the filters, which have been carried out using an appraisal checklist developed by the ISSG<sup>5</sup>. We should like to encourage searchers to test the filters in practice where possible, so that the results can be recorded on the website.

Several members of the IRMG have been involved in a project, led by one of the Co-Convenors (AW), to build up the Specialized Register for the recently registered Cochrane Public Health Review Group (PHRG). In line with the underlying principles of public health, PHRG reviews have a significant focus on equity and the Specialized Register is being developed so that equity-related studies can easily be identified. A particular effort is being made to identify studies for reviews that reflect the needs of low- and middle-income countries. The work is supported by the Welsh Assembly Government, Cardiff University and the EPPI Centre, and the Public Health Review Group's editorial base at the University of Melbourne.

Funding was awarded from the Cochrane Opportunities Fund to the IRMG and other Cochrane Groups for a project led by one of the Co-Convenors (AW) to develop global resources for literature searches. This included a list of databases of value for locating evaluation studies previously identified as hard to access, particularly from low- and middle-income countries (the LMIC Database). The list is currently available via the EPOC Group, IRMG and the Public Health Group websites.

The UK Medical Research Council (MRC) has awarded funding for a two-year project on search filter performance. The project is being led by two of the Co-Convenors (CL and JG) and is due for completion in May 2012.

Members of the IRMG have continued to be active in developing areas within The Cochrane Collaboration including adverse events, diagnostic test accuracy, economic evaluation and the project to develop a new Cochrane Register of Studies (CRS). Two of the Co-Convenors (CL and JMcG) assisted in updating the Cochrane Glossary. Members of the Campbell IRMG continue to be members of the Cochrane IRMG. The Searching for Studies chapter of the *Cochrane Handbook for Systematic Reviews of Interventions* was used extensively as the basis for the revised version of the Campbell Information Retrieval Policy Brief. The IRMG discussion list is used to notify members of activities such as the annual IRMG Meeting at Cochrane Colloquia and to circulate the minutes. It has been used to find possible

collaborators in projects associated with information retrieval, including those listed above. To join the list, please contact Bernadette Coles (colesbm@cardiff.ac.uk).

Co-Convenors and members of the IRMG conducted a number of workshops at recent Colloquia and further workshops are planned for the Joint Colloquium of the Cochrane and Campbell Collaborations in Keystone in 2010, including two specific IRMG workshops: one workshop for review authors on study identification and one on clinical trials registers. An open meeting of the IRMG was held during the Cochrane Colloquium in Singapore in 2009 and a further meeting is planned for the Joint Colloquium in Keystone in October 2010. Infrastructure support for time and funding for Colloquium attendance of the Co-Convenors is provided by Cardiff University, the UK Cochrane Centre and the University of Ottawa. Support for the time of the Co-ordinator and administrative assistance, with funding for Colloquium attendance, is provided by Cardiff University and Cancer Research Wales.

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## Cochrane Non-Randomised Studies Methods Group

Barney Reeves

In last year's Cochrane Methods Groups Newsletter, I described the inclusion of non-randomized studies (NRS) in reviews about the benefits of healthcare interventions as an 'underlying tension in the Collaboration'. Chapter 13 in the *Cochrane Handbook for Systematic Reviews of Interventions* appears to have heightened this tension and the risk that Cochrane Review Groups are choosing to go their own way. In order to address this directly, the Non-Randomised Studies Methods Group (NRSMG) hosted an invited workshop in Ottawa in June 2010. The meeting brought together methodologists, review authors and senior

representatives of organizations such as the National Institute for Health and Clinical Excellence (NICE) and the Agency for Healthcare Research and Quality (AHRQ) that commission reviews to discuss the most important issues facing authors who want to include NRS. The meeting is expected to provide the basis for revisions to Chapter 13 of the *Cochrane Handbook* and to prioritize methodological research questions that need to be answered in order to provide better guidance in areas that are currently evidence free.

The NRSMG has also been investigating how to bring the assessment of the risk of bias in non-randomized studies into line with the existing Risk of Bias (RoB) tool which has been implemented across Cochrane reviews of effectiveness. We reasoned that this is important in order to provide a 'level playing field' for assessing the risk of bias. It should be possible

since the main bias domains are the same, although other domains may have to be added. The NRSMG workshop at the Cochrane Colloquium in Singapore in October 2009 piloted an initial attempt to adapt the RoB tool to non-randomized studies. Further discussions were held with the NRSMG, and between the NRSMG and the Bias Methods Group, resulting in the NRSMG being represented at the workshop in Cardiff to evaluate the RoB tool (see page 5). The workshop endorsed the principle that assessing risk of bias in non-randomized studies should follow the same principles. However, the Bias Methods Group's immediate priority has to be revising the RoB tool to take into account authors' feedback (primarily in reviews that include randomized trials only). One issue that has emerged is the need to distinguish varying degrees of risk of bias between different types of non-randomized studies—users of reviews will not be greatly helped by uniformly red RoB graphs in Cochrane

reviews. Unfortunately, this is something which cannot be accommodated by the current RevMan structure (designed to accept only high, low or unclear response options). These deliberations led to further revisions to the NRSMG training workshop at the UK- and Ireland-based Cochrane Contributors' Meeting in Cardiff in March 2010, which will be repeated at the Joint Colloquium of the Cochrane and Campbell Collaborations in Keystone in October 2010.

Selection bias is one of the key bias domains, currently covered by sequence generation and allocation concealment items. Assessment of risk of bias in non-randomized studies clearly has a confounding item and this has been another area of activity. A proposal for a discussion workshop has been submitted for the Joint Colloquium at Keystone. We expect that the workshop will inform the design of a training workshop on this subject in 2011.

## Cochrane Prognosis Methods Group

*Doug Altman, Riekie de Vet, Jill Hayden, Richard Riley, Katrina Williams and Susan Wolfenden*

Over the past year, the Convenors of the Cochrane Prognosis Methods Group have been working together to establish the processes required to produce high quality methods for undertaking systematic reviews and meta-analyses of prognosis studies and to provide advice to review authors wishing to write prognosis systematic reviews or incorporate prognosis information into their intervention or diagnostic reviews. This information will be provided through Cochrane Newsletters, the Cochrane Prognosis website ([www.prognosismethods.cochrane.org/en/index.html](http://www.prognosismethods.cochrane.org/en/index.html)) and via e-mail to the Prognosis Review Network. If you are interested in joining this network and/or the Cochrane Prognosis Methods Group, please contact Katy Sterling-Levis ([katy.sterling-levis@sesiahs.health.nsw.gov.au](mailto:katy.sterling-levis@sesiahs.health.nsw.gov.au)).

Progress to date includes establishment of a research framework for the Prognosis Methods Group. A research framework is currently being updated following feedback from members of the Prognosis Methods Group and the latest version will soon be available on the Prognosis Methods Group website. The aim of the research framework is to identify research priorities for the Group and we encourage members of the Group to provide feedback on the framework, identify where their research activities may lie in the matrix that is provided and provide this feedback to the Prognosis Methods Group Co-ordinator, Greta Ridley, at [ridleyresearch@aapt.net.au](mailto:ridleyresearch@aapt.net.au).

A Prognosis Methods Group Meeting held at the Cochrane Colloquium in Singapore in 2009 identified specific key priorities for the research agenda including:

- Consideration of baseline risk stratification for intervention reviews and trials.
- To what extent can diagnostic test accuracy systematic review methods be applied to prognostic studies including risk of bias, literature searching, etc.
- What study designs should be searched for and included in prognosis systematic reviews. Is there a hierarchy of study design methods?
- Reporting guidelines for prognosis studies and reviews.
- Consensus regarding nomenclature in prognosis research.

A Convenors' task list is currently being developed to clarify and progress the research and administrative activities of the Group. Public meetings involving Convenors of the Prognosis Methods Group have been organized to raise the profile of prognosis research and the need for funding.

A database of prognosis studies and a methodological resource for the Prognosis Methods Group is currently underway as a result of funding received by Dr Jill Hayden (Prognosis Methods Group Convenor) from the Nova Scotia Health Research Foundation in Canada ([www.nshrf.ca](http://www.nshrf.ca)), to form the Methodology Resource Group, a subgroup of the Prognosis Methods Group. This subgroup will help to co-ordinate and facilitate methodological research relevant to prognosis reviews. The subgroup aims to develop and maintain databases of relevant methodological studies, protocols, and systematic reviews of prognosis.

Discussions between the Screening and Diagnostic Tests Methods Group, the Diagnostic Test Accuracy Working Group and the Prognosis Methods Group are ongoing in regard to a combined Methods Group Journal.

## Cochrane Qualitative Research Methods Group

*Janet Harris*

The Cochrane Qualitative Research Methods Group (CQRMG) has completed draft guidance for integrating qualitative research into intervention reviews [www.joannabriggs.edu.au/cqrmg/tools.html](http://www.joannabriggs.edu.au/cqrmg/tools.html). The guidance

is being reviewed by the Cochrane Collaboration Steering Group. It will be piloted through collaboration with the Cochrane Consumers and Communication Review Group, using the protocol 'Peer support strategies for improving the health and well-being of individuals with chronic disease' as an exemplar.

Our latest workshop at the UK- and Ireland-based Cochrane Contributors' Meeting in Cardiff in March 2010 showed that we have two distinct groups within The Cochrane

Collaboration that have different training needs. There is a need for introductory sessions introducing Cochrane editors, statisticians, and those with primarily quantitative research backgrounds to the potential utility of qualitative research to some Cochrane intervention protocols. Qualitative and mixed methods researchers want opportunities to develop skills in synthesis. We have pointed the latter group to the qualitative synthesis workshops that are organized by various Convenors of CQRMG. The University of Sheffield co-ordinates Evidence Synthesis of Qualitative Research in Europe (ESQUIRE). The next ESQUIRE workshop is 7 to 9 September 2010 (esquiresheffield.pbworks.com). The Catholic University of Leuven

organizes a three-day systematic review course. The third day of the programme consists of an introduction to different methodologies of qualitative evidence synthesis, a critical appraisal workshop and a workshop on meta-aggregation of qualitative data. Please e-mail Bartel.wilms@ped.kuleuven.be if you or one of your colleagues are interested in participating.

CQRMG has started offering technical assistance to several Cochrane Review Groups, focusing on protocol development for reviews incorporating qualitative evidence. If you have queries regarding technical support please e-mail one of us or visit [www.joannabriggs.edu.au/cqrmg/convenors.html](http://www.joannabriggs.edu.au/cqrmg/convenors.html).

## Cochrane Screening and Diagnostic Tests Methods Group

*Petra Macaskill, Constantine Gatsonis, Roger Harbord and Mariska Leeflang*

The work of the Cochrane Screening and Diagnostic Tests Methods Group continued to diversify during 2009 as the number of diagnostic reviews that are planned, or underway, has increased. Members of our Methods Group have contributed their time and expertise to deal with the growing need for peer reviewers to comment on protocols. It is very pleasing to see the increasing level of activity.

We have also contributed to a range of training activities run by the support units (the UK Support Unit (UKSU) based in Birmingham, and the Continental Europe Support Unit (CESU) based in Amsterdam) in the UK, Continental Europe, Australasia and Canada. The strong links between our Methods Group and the support units, with some members common to both, has helped to ensure the quality and success of these initiatives. The input of our Methods Group members was particularly important for the

training workshop for methodologists held in July in Birmingham in 2009. This workshop was attended by methodologists from around the world, many of whom are responsible for statistical aspects of Cochrane reviews. The mix of presentations and practical work was very successful. The workshop was useful in building links between participants (including presenters). It also highlighted the successful completion of key aspects of the diagnostic initiative such as the integration of diagnostic reviews into Review Manager software.

Methods Group members were again involved in presenting diagnostic training workshops at the Cochrane Colloquium held in Singapore in 2009. We plan to offer a comprehensive range of training workshops under the umbrella of our Methods Group at the Joint Colloquium of the Cochrane and Campbell Collaborations in Keystone in October 2010. These workshops will be conducted in collaboration with the support units.

We would like to thank everyone who has contributed to the activities of our Methods Group over the past year. Much has been achieved over past years, but there is still much to do. We look forward to seeing many of you at the Joint Colloquium in 2010.

## Cochrane Statistical Methods Group

*Joseph Beyene, Doug Altman, Steff Lewis, Joanne McKenzie and Georgia Salanti*

The Statistical Methods Group (SMG) has contributed to several activities of The Cochrane Collaboration over the past year including training and research. One of the highlights of last year's activities was the successful award of funding from The Cochrane Collaboration's Opportunities Fund for the SMG to run a short course for statisticians. The two-day course, aimed at statisticians who provide support to Cochrane Review Groups (CRGs) or Centres, was held from 4 to 5 March 2010 in Cardiff, UK. Thirty-four participants attended the course. The course was taught by several experienced statisticians and methodologists with a mix of didactic and interactive sessions. A wide range of advanced issues in meta-analysis and assessment of bias

were addressed (see [www.smg.cochrane.org](http://www.smg.cochrane.org) for more details). The course ended with an open and informal discussion about general issues related to the statistical contribution to CRGs. Georgia Salanti presented the results of a survey of CRG statisticians which stimulated discussion. Participants exchanged helpful ideas drawing from their own CRG experiences. The course evaluation form showed that the participants responded favourably to the course and felt that similar courses should be organized by SMG more frequently in the future. The material of the course will be made available on the SMG website. Many SMG members facilitated workshops on a range of topics at the Cochrane Colloquium in Singapore in 2009 and at other regional meetings and symposia.

We thank all those who have contributed to the SMG activities over the previous year and look forward to seeing many of you at the Joint Colloquium of the Cochrane and Campbell Collaborations in Keystone in October 2010.



# Campbell Collaboration Methods Groups (C2)

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*Terri Pigott, Peter Tugwell, Erin Ueffing and Ryan Williams*

The Campbell Methods Group supports the production of Campbell Collaboration reviews by improving the methodology of research synthesis, and disseminating guidelines for state of the art review methods.

The Campbell Methods Group has subgroups that play a key role in helping the editors to ensure the quality of Campbell's systematic reviews. The subgroups serve as forums for discussion on research models, and provide advice on specific topics of methodology and methods policy. They also provide training and support to review authors, editors, and those who wish to undertake a systematic review. The subgroups are Economics, Equity, Information Retrieval, Process and Implementation, Statistics Methods, and Training.

For the first time, the Campbell and Cochrane Collaborations are coming together for a joint Colloquium in Keystone, Colorado on 18 to 22 October 2010. Working with leading methodologists from both the Campbell and Cochrane Collaborations, Ian Shemilt has organized a joint symposium on Cochrane Camp-

bell Methods for the Colloquium on Monday 18 October at 09:30. Please mark your calendars and save the date. We will be discussing key methods issues relevant for both Collaborations, such as fixed versus random effects models, inclusion of non-randomized studies, and publication bias.

We will also be holding an open meeting of the Campbell Methods Group at the Joint Colloquium on Tuesday 19 October at 07:30. You are most welcome to join us, your contributions would be greatly appreciated as we discuss Campbell methods, activities, and updates. Further methods meetings and training workshops on systematic review methods are also planned. This year's workshops range from introductory topics such as 'Introduction to systematic reviews in the Campbell Collaboration' to the more advanced 'Meta-regression with dependent effect size estimates'. Please visit the Colloquium website for an updated schedule. We look forward to seeing you in Keystone.

For more information about the Campbell Methods Group, please contact Erin Ueffing ([erin.ueffing@uottawa.ca](mailto:erin.ueffing@uottawa.ca)) or visit our website at [www.campbellcollaboration.org](http://www.campbellcollaboration.org).

## Joint Colloquium of the Cochrane and Campbell Collaborations

*Keystone, Colorado  
18 to 22 October 2010*

This year will see the first ever Joint Colloquium between the Cochrane and Campbell Collaborations. It aims to focus on raising evidence-based decision-making to new heights. Colorado is known for its towering mountain peaks and natural beauty, and this meeting aims to be a coming together of multi-disciplinary learning and sharing at its best.

As part of the Colloquium, an open Joint Symposium on Cochrane–Campbell Methods will be held on Monday 18th October between 9.30am and 1.45pm. This is being organised jointly by the Cochrane Methods Board and the Campbell Methods Coordinating Group. Leading Cochrane and Campbell methodologists will present key current methods issues and challenges faced in the preparation and maintenance of Cochrane and Campbell reviews for discussion. The symposium will also discuss how we can improve collaboration between Cochrane and Campbell methodologists, including the potential for more joint activities and outputs.

The Cochrane Methods Board will meet (by invitation only) on Monday 18 Oct between 7.30am and 9.30am, continuing from 4.30pm to 6.30pm.

More information is available at [www.colloquium.info](http://www.colloquium.info).

## COMET Symposium

*Bristol, UK  
2011*

The COMET initiative (Core Outcome Measures in Effectiveness Trials) was launched in January 2010 (see page 5) to facilitate the development and use of sets of core outcome measures in health care. A symposium is now being planned for early next year. This will be an opportunity to hear from people who have developed core outcome sets, as well as those who are using them in research and practice. There will be ample opportunity to discuss the processes for developing core outcomes, and the challenges of doing so. Further information, including registration details, will be available from the COMET website: [www.liv.ac.uk/nwhtmr](http://www.liv.ac.uk/nwhtmr).

## Acknowledgements

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## Availability of *Cochrane Methods*

Additional copies of *Cochrane Methods* may be obtained free of charge from the UK Cochrane Centre, which is based at:

UK Cochrane Centre  
National Institute for Health Research  
Summertown Pavilion  
Middle Way  
Oxford OX2 7LG  
UK

*Cochrane Methods* is also available electronically via The Cochrane Collaboration website at [www.cochrane.org/newslett/index.htm](http://www.cochrane.org/newslett/index.htm) and via The Cochrane Library website at [www.thecochranelibrary.com](http://www.thecochranelibrary.com)

## Comments and Feedback

If you want to make sure that you receive the next issue of *Cochrane Methods* please contact us at the address below. Comments are welcome. Let us know what you liked and what you did not like and any suggestions you have for the next issue.

Thank you!

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## The Cochrane Library

*The Cochrane Library* is available at [www.thecochranelibrary.com](http://www.thecochranelibrary.com). It contains six databases: the *Cochrane Database of Systematic Reviews* (CDSR), the *Database of Abstracts of Reviews of Effects* (DARE), the *Cochrane Central Register of Controlled Trials* (CENTRAL), and the *Cochrane Methodology Register* (CMR) as well as the *Health Technology Assessment Database* and the *NHS Economic Evaluation Database*. In addition, *The Cochrane Library* contains information about the Collaboration and Cochrane entities. Information about how to subscribe is available from:

Jennifer Coates  
Cochrane Library Customer Services Advisor  
John Wiley & Sons Ltd  
1 Oldlands Way  
Bognor Regis  
West Sussex, PO22 9SA  
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Tel: +44 1243 843367  
[cs-cochrane@wiley.com](mailto:cs-cochrane@wiley.com)  
[www.thecochranelibrary.com/view/0/HowtoOrder.html](http://www.thecochranelibrary.com/view/0/HowtoOrder.html)

## The Cochrane Collaboration

A wide range of Cochrane Collaboration information is available from [www.cochrane.org](http://www.cochrane.org) including the abstracts from all the Cochrane reviews in the current issue of *The Cochrane Library*, details of Cochrane e-mail lists, opportunities to download Cochrane software (including Review Manager 5), contact details for all Cochrane entities, copies of previous editions of the Cochrane Methods Groups Newsletter and much more.

## International Cochrane e-mail list: CCINFO

This moderated list offers an excellent means of keeping informed about the activities and policies of The Cochrane Collaboration. The list is used for announcements and discussion of matters relevant to the Collaboration as a whole. To subscribe go to the following webpage: [lists.cochrane.org/mailman/listinfo/ccinfo](http://lists.cochrane.org/mailman/listinfo/ccinfo)

## Cochrane Centre Internet Sites

There are 14 Cochrane Centres around the world; to speak to someone about The Cochrane Collaboration, please contact your local Centre.

### Australasian Cochrane Centre

[www.cochrane.org.au](http://www.cochrane.org.au)

### Brazilian Cochrane Centre

[www.centrocochranedobrasil.org](http://www.centrocochranedobrasil.org)

### Canadian Cochrane Centre

[www.ccmc.cochrane.org](http://www.ccmc.cochrane.org)

### Chinese Cochrane Center

[www.ebm.org.cn](http://www.ebm.org.cn)

### Dutch Cochrane Centre

[www.cochrane.nl](http://www.cochrane.nl)

### French Cochrane Centre

e-mail: [juliane.ried@hfd.aphp.fr](mailto:juliane.ried@hfd.aphp.fr)

### German Cochrane Centre

[www.cochrane.de](http://www.cochrane.de)

### Iberoamerican Cochrane Centre

[www.cochrane.es](http://www.cochrane.es)

### Italian Cochrane Centre

[www.cochrane.it](http://www.cochrane.it)

### Nordic Cochrane Centre

[www.cochrane.dk](http://www.cochrane.dk)

### South African Cochrane Centre

[www.mrc.ac.za/cochrane](http://www.mrc.ac.za/cochrane)

### South Asian Cochrane Centre

[www.cochrane-sacn.org](http://www.cochrane-sacn.org)

### UK Cochrane Centre

[www.cochrane.ac.uk](http://www.cochrane.ac.uk)

### United States Cochrane Center

[www.cochrane.us](http://www.cochrane.us)