Methodological Expectations of Cochrane Intervention Reviews (MECIR)

Development of methodological standards for the conduct of intervention reviews

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Toby Lasserson, Rachel Churchill, Julian Higgins, Jackie Chandler, David Tovey

1. Background

High quality Cochrane Reviews adhere to guidance from the Cochrane Handbook for Systematic Reviews of Interventions. There is variation in review methods used both within and across Cochrane Review Groups (CRGs). Some of this is appropriate, whilst some reflects inconsistency with current recommendations or established good practice. The publication of version 5 of the Cochrane Handbook in 2008 coincided with the release of a new version of the review writing software (Review Manager 5). Some CRGs have experienced difficulties in implementing the new guidance and supporting their authors. To ensure the quality of reviews for clinical decision making and foster a greater understanding of the guidance, clearer methodological recommendations were deemed to be required.

The Methods Application and Review Standards (MARS) Working Group was established to facilitate greater collaboration between Methods Groups and CRGs, and provides oversight of methodological aspects of Cochrane Reviews to support the Editor in Chief and the wider Cochrane Editorial Unit (CEU). The group is co-convened by Julian Higgins and Rachel Churchill, with membership including 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 and an Information Management Systems (IMS) representative. Among the terms of reference for MARS WG was an intention to agree on minimum methodological standards for Cochrane Reviews, and to facilitate their implementation across CRGs.

The development of methodological standards was embedded in a wider project, Methodological Expectations of Cochrane Intervention Reviews (MECIR). This paper outlines the process by which the methodological standards were developed; describing early proposals and groundwork by the Editor in Chief and members of the Co-Eds Executive, the establishment of six working groups (WGs), drafting and refinement of the standards, the consultation process, and amendments made in light of the consultation. The document also includes early plans for implementation of the standards.

2. Purpose

The MECIR project aims to specify methodological expectations for Cochrane protocols, reviews, and updates of reviews on the effects of interventions, and to ensure that these methodological expectations are supported and implemented across the Collaboration. The development of appropriate standards required the involvement of individuals from Methods Groups and Cochrane Review Groups (CRG) to ensure that the output was informed by methodological expertise and familiarity with implementation of Handbook guidance. Additionally, it was important to capture
input from those with responsibility for managing editorial processes and training activity in relation to Cochrane Reviews.

The expectations are intended for both internal and external audiences to The Cochrane Collaboration. They will provide authors and users of The Cochrane Library with clear and transparent expectations of review conduct and reporting, will enable CRGs to hold authors accountable during the editorial process, will facilitate monitoring activities and guidance/feedback from CEU and should improve liaison between methodologists and editorial teams.

The implementation of the methodological expectations will involve dissemination of the standards across the Collaboration, appropriate modifications to the Handbook and RevMan; and recommendations on incorporating the methodological expectations into training and editorial processes (e.g. Cochrane Training materials, checklists for editorial staff and referees).

The project was co-ordinated by a team from MARS and the CEU (Rachel Churchill, Julian Higgins, Jackie Chandler, David Tovey and Toby Lasserson).

3. Scope

The Cochrane Handbook for Systematic Reviews of Interventions provides advice and recommendations regarding the methodological approach to conducting a Cochrane Review on the effects of interventions. The process for developing methodological standards was designed to reflect closely the key areas of systematic review methodology as described in the Handbook. The scope of the project was restricted to methodological principles, and did not consider identifying standards for editorial process, conflicts of interests and determining levels of expertise of authoring teams.

4. Methods

To achieve the project’s aims, the following six core methodological aspects of Cochrane intervention reviews were identified:

1. Developing a question and deciding the scope of the review
   - including title; background; objectives and review question; developing criteria for considering studies (including considerations of harms, patient reported outcomes, economic outcomes, equity, qualitative evidence, non-randomised studies, language of publication, availability of usable data).

2. Searching for studies
   - including expectations at protocol stage; details of search strategies; reporting of searches in completed reviews; updating searches.

3. Selecting studies and collecting data
   - including use of data collection forms; minimum datasets; extraction of non-standard data; personnel involved in data extraction; dealing with multiple reports of a study; submission of forms to CRGs; dispute resolution.

4. Assessing risk of bias in studies
   - including ‘Risk of Bias’ (RoB) tool; tables and graphs for RoB assessments; expectations of updates of reviews.
5. Analysing data and undertaking meta-analyses
   • including statistical manipulations and transformations of data; meta-analysis; presentation
   of analysis results; interpretation; special topics from Part 3 of the Handbook.

6. Interpretation and presenting results
   • including ‘Summary of Findings’ (SoF) tables; GRADE; links between SoF tables and
   abstract/plain language summary; addressing reporting biases.

Six Working Groups (WGs) were set up to cover these areas. Each WG was co-led by a methodologist
and a co-ordinating editor from a CRG, with involvement from the CEU (David Tovey, Rachel
Marshall or Toby Lasserson). Additional membership of the groups was drawn from individuals
working in CRGs and Methods Groups, as invited by the WG leads. The contributors to the Working
Group are listed in Annex 1.

Contributions from the WGs were obtained in two phases. In the first phase, the WGs were asked to
identify items for the following categories within their respective scopes:

A. Essential minimum standards for all Cochrane intervention reviews.
   • These standards were to be considered mandatory. Reviews not meeting these standards
     would not be published.
   • Examples of specific implementations of these standards would be useful.
   • These would be interpreted as ‘must do’s.
B. Desirable standards for all Cochrane intervention reviews
   • These standards represent good practice. They were not to be considered mandatory, and
     might not be applicable to every review.
   • Examples of specific implementations of these standards should be sought.
   • These would be interpreted as ‘should do’s.
C. Common errors that review authors make in Cochrane intervention reviews
   • These are aids to help authors and editors avoid known pitfalls.
   • Examples of specific instances of these errors should be sought.
   • These would be interpreted as ‘should not do’s.
D. Fatal flaws in Cochrane intervention reviews
   • These were to be errors that are sufficiently serious to cause serious concern as to the
     validity of the review’s findings. Reviews with these errors would not be published.
   • Examples of specific instances of these errors would be useful.
   • These would be interpreted as ‘must not do’s.

The key source of methodological expectations was the Cochrane Handbook for Systematic Reviews
of Interventions. In preparing their proposals, the WGs built on work already undertaken by
members of the Co-ordinating Editors’ Executive, who had collated items from the Summary points
of Handbook chapters, the AMSTAR tool for assessing the quality of a systematic review and the
PRISMA checklist for reporting a systematic review. Other sources of information included guidelines
for preparing systematic reviews produced by other organizations (in particular the US Institute
of Medicine) and empirical studies of Cochrane reviews that have identified errors.

Although the Cochrane Handbook for Systematic Reviews of Interventions was the source of many of
the methodological expectations, it was expected that modifications would be necessary to reflect
final decisions. Each Working Group was therefore requested to provide specific recommendations
on how Handbook guidance should be modified. The WGs were further given additional
responsibilities to list important methodological uncertainties, to identify instructive examples and
to contribute to establishing a network of CRG-based methods individuals in their topic area (where appropriate).

Where definitive recommendations for methodological expectations could not be provided, this was to be stated explicitly. These would provide important context for those involved in training authors and editors, as well as providing motivation for further research.

The co-ordinating group compared the outputs of the first phase of work by the WGs and, in consultation with the MARS WG, initiated a second phase of WG contributions. At this point an emphasis was placed on the production of mandatory and highly desirable methodological standards, thus concentrating on categories A and D and, to a lesser extent, B from the first phase. The WGs were also asked to produce a rationale for each of their standards.

The coordinating group met in person to assess the six sets of standards, to identify and manage overlap, and to ensure that related items were classified consistently. At this point it was decided to develop separately the standards for conduct and the standards for reporting of Cochrane Reviews. This allowed for a clearer distinction between methodological conduct and mechanisms for assessing whether the standards have been met.

5. Consultation

The standards were circulated to all registered entities for consultation between 16 June and 8 August 2011. One response was sought from every entity, with the expectation that comments from their membership would be collected and collated into a single submission. In total, 51% all registered entities submitted a response. The numbers of entities of different types are given in Table 1. The full set of responses to the consultation has been collated into an accompanying Annex 2 to this document. We received an additional response from the author representative on the Cochrane Collaboration Steering Group.

Table 1: Number of entities submitting responses by type.

<table>
<thead>
<tr>
<th>Entity</th>
<th>CRGs</th>
<th>Methods Groups</th>
<th>Centres</th>
<th>Centre branches</th>
<th>Fields</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>n respondents (n registered)</td>
<td>35 (53)</td>
<td>8 (15)</td>
<td>5 (14)</td>
<td>2 (15)</td>
<td>5 (11)</td>
<td>CEU; TWG; Author representative</td>
</tr>
</tbody>
</table>

The responses from the entities and the author representative were collated for each standard and discussed at a three-day face-to-face meeting of the coordinating group held in London, UK in August 2011. In general, the feedback indicated high levels of support for the standards among the entities who responded. Each proposed standard was considered, with responses from CRGs, Methods Group, Centres, Fields and the author representative examined in turn. The coordinating group’s responses to the comments, and an outline of any amendments made, are described in the accompanying Annex 2. The meeting also took account of comments that had been invited on omitted items and other considerations. At the end of the August meeting there were 85 methodological standards. A further two-day meeting of the coordinating group in September 2011 reduced the list to 80 standards.
6. Next steps

The conduct standards will be presented and discussed during the Madrid Colloquium at meetings of CRG and Methods boards and executives, with additional discussion at plenary and workshop sessions. Beyond Madrid, there will be additional work to develop guidance on application of the standards to updates of reviews.

Standards for reporting of full intervention reviews, protocols and updates are in development, which are designed to facilitate the evaluation of conduct. A consultation process will take place after the Madrid Colloquium, involving the MECIR Working Groups and the wider Collaboration, the latter following a similar format to that for the conduct standards.

Good practice guidance and a list of common errors are also in development and we hope to collect more examples and include them as these evolve over time.

We anticipate that the set of MECIR documents will be reflected in future versions of the documents developed by the Editorial Resources Committee, feed into training materials for Cochrane Review authors, and contribute to future iterations of the Cochrane Handbook.
Annex 1: Contributors to MECIR Working Groups

Doug Altman
Mohammed Ansari (Methods lead, WG1)
Sally Bell-Syer
Patrick Bossuyt
Deborah Caldwell
Christopher Cates
Rachel Churchill (Co-Eds lead, WG4)
Mike Clarke (Co-Eds co-lead, WG2)
Jan Clarkson (Co-Eds co-lead, WG6)
Philippa Davies
Marina Davoli (Co-Eds lead, WG1)
Ruth Foxlee
Chantelle Garrity
Davina Ghersi (Co-Eds co-lead, WG2)
Julie Glanville (Methods co-lead, WG2)
Peter Herbison
Julian Higgins
Sophie Hill (Co-Eds lead, WG3)
Toby Lasserson
Edith Leclercq
Carol Lefebvre (Methods co-lead, WG2)
Jessie McGowan
Rachel Marshall
Ruth Mitchell
Donal O’Mathuna
Anna Noel-Storr
Georgia Salanti (Methods lead, WG5)
Doug Salzwedel
Margaret Sampson
Jelena Savovic
Holger Schünemann (Methods lead, WG 6)
Ian Shemilt
Nandi Siegfried
Jonathan Sterne (Methods lead, WG4)
Britta Tendal (Methods lead, WG3)
David Tovey
Peter Tugwell
Lucy Turner
Claire Vale
Julia Walters
Helen Worthington (Co-Eds lead, WG 5 and Co-Eds co-lead, WG6)
Janelle Yorke