

Cochrane Policy Manual



Amendments/additions

The pages within this Manual are updated individually as required.

All suggestions for amendments and improvements, please, to:

The Cochrane Collaboration Secretariat [1]

Summertown Pavilion, 18-24 Middle Way, Oxford, OX2 7LG, UK

Tel: +44 (0)1865 310138; Fax: +44 (0)1865 316023; E-mail: secretariat@cochrane.org [2]

1. CENTRAL ORGANISATION

Subheadings in this section

1.1 Description of The Cochrane Collaboration

Mission Statement [3]

The Cochrane Collaboration is an international organisation that aims to help people make well-informed decisions about health care by preparing, maintaining and promoting the accessibility of systematic reviews of the effects of healthcare interventions. It is a not-for-profit organisation, established as a company, limited by guarantee, and registered as a charity in the UK (number 1045921).

Vision Statement [4]

Healthcare decision-making throughout the world will be informed by high <u>quality</u> [5], timely research evidence. The Cochrane Collaboration will play a pivotal role in the production and dissemination of this evidence across all areas of health care.

Principles

The Cochrane Collaboration's work is based on ten key principles:

1. Collaboration, by internally and externally fostering good communications, open decision-



- making and teamwork.
- 2. Building on the enthusiasm of individuals, by involving and supporting people of different skills and backgrounds.
- 3. Avoiding duplication, by good management and co-ordination to maximise economy of effort.
- 4. Minimising bias [6], through a variety of approaches such as scientific rigour, ensuring broad participation, and avoiding conflicts of interest.
- 5. Keeping up to date, by a commitment to ensure that Cochrane reviews are maintained through identification and incorporation of new evidence.
- 6. Striving for relevance, by promoting the assessment of healthcare interventions using outcomes that matter to people making choices in health care.
- 7. Promoting access, by wide dissemination of the outputs of The Cochrane Collaboration, taking advantage of strategic alliances, and by promoting appropriate prices, content and media to meet the needs of users worldwide.
- 8. Ensuring quality, by being open and responsive to feedback, applying advances in methodology, and developing systems for quality improvement.
- 9. Continuity, by ensuring that responsibility for reviews, editorial processes and key functions is maintained and renewed.
- 10. Enabling wide participation in the work of The Cochrane Collaboration by reducing barriers to contributing and by encouraging diversity.

[The principles are available to the public at http://www.cochrane.org/about-us/our-principles [7].]

Structure of The Cochrane Collaboration

Cochrane Review Groups

The main work of The Cochrane Collaboration is done by more than fifty Cochrane Review Groups, within which Cochrane reviews are prepared and maintained. The members of these groups – researchers, healthcare professionals, people using the health services (consumers), and others – have come together because they share an interest in generating reliable, up-to-date evidence relevant to the prevention, <u>treatment</u> [8] and rehabilitation of particular health problems or groups of problems.

To become part of The Cochrane Collaboration, an intending new Cochrane Review Group is required to prepare a plan outlining how it will contribute to The Cochrane Collaboration's objectives. The plan should describe who will have responsibility for planning, co-ordinating and monitoring the Group's work (a co-ordinating editor, supported by an editorial team). It should also describe how the Group will identify and assemble in a specialized register as high a proportion as possible of all the studies relevant to its declared scope; and who, drawing on the studies in the register, will take responsibility for preparing and maintaining which reviews. Every Group appoints an individual to organise and manage the day-to-day activities of the Group – a Managing Editor. The work of Cochrane Review Groups is supported by people working in Methods Groups, Fields and Centres.

Methods Groups

The science of research synthesis is still relatively young and evolving rapidly. Methods Groups have been established to develop methodology and advise The Cochrane Collaboration on how the validity [9] and precision [10] 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 [11] and Recommendations Methods Group is exploring important questions about drawing conclusions regarding implications for practice, based on the results of reviews. The Methods Groups are represented on the Methods Board (see Section 1.1.2.10.1), alongside people with other key methods-related roles within the Collaboration, such as core staff of the Cochrane Methodology Review Group, and the editors of the Cochrane Handbooks.

Fields

Fields focus on dimensions of health care other than health problems, such as the setting of care (e.g. primary care), the type of consumer (e.g. older people), or the type of intervention (e.g. vaccines). People associated with Fields search specialist sources for relevant studies, help to ensure that priorities and perspectives in their sphere of interest are reflected in the work of



Cochrane Review Groups, compile specialized databases, co-ordinate activities with relevant agencies outside The Cochrane Collaboration, and comment on systematic reviews relating to their particular area of interest. The Cochrane Consumer Network (<u>CCNet</u> [12]) provides information and a forum for networking among consumers involved in The Cochrane Collaboration, and a liaison point for consumer groups around the world.

Centres

The work of Cochrane Review Groups, Methods Groups and Fields is facilitated in a variety of ways by the work of Cochrane Centres around the world, some of which have branches in other countries. Centres share responsibility for helping to co-ordinate and support members of The Cochrane Collaboration in areas such as training, and they promote the objectives of The Cochrane Collaboration at national level.

Steering Group [13]

Members of registered Cochrane Review Groups, Methods Groups, Fields, the Consumer Network and Centres are eligible to vote in the election of members to The Cochrane Collaboration's board of trustees - the Steering Group. The Steering Group meets face-to-face twice a year, once during the annual Cochrane Colloquium and on one other occasion. In between these meetings, the Steering Group's working groups hold regular discussions by teleconference. Steering Group decisions are guided by goals and objectives which are set out in The Cochrane Collaboration's Strategic Plan [14].

Secretariat [1]

The Steering Group and its several sub-committees are supported by a small secretariat, based in the UK. Contact details for this office are:

The Cochrane Collaboration Secretariat Summertown Pavilion 18-24 Middle Way Oxford OX2 7LG UK

Telephone +44 (0)1865 310138 Fax +44 (0)1865 316023

E-mail <u>secretariat@cochrane.org</u> [2]

Following is a list of some of the Steering Group's working groups, some of which are no longer current:

- 1. Editorial Resources Committee (former CRG [15] Procedures Collection Working Party)
- 2. Diagnostic Test Accuracy Reviews Working Party
- 3. Elections Working Group
- 4. Funding Working Group
- 5. New Interface Working Party
- 6. Style Guide Working Group
- 7. Evidence Aid Working Group (former Tsunami Working Group)
- 8. Umbrella Reviews Working Group
- 9. Updating Working Group

For information about the remit, membership and timetables of these and other working groups, contact Lucie Jones at the Cochrane Collaboration Secretariat (<u>liones@cochrane.org</u> [16]).

Sources of support

The rapid evolution of The Cochrane Collaboration owes much to the voluntary effort of thousands of individuals worldwide. In addition, the work of The Cochrane Collaboration is being supported by



a large variety of institutions and funding organisations in many countries, and a list of these can be found on the Collaboration website (www.cochrane.org [17]).

The Cochrane Library [18]

The Cochrane Library is the main output of The Cochrane Collaboration, updated quarterly and distributed on an annual subscription basis via the Internet and on CD-ROM. It contains the following databases:

- The Cochrane Database of Systematic Reviews contains protocols and reviews prepared and maintained by Cochrane Review Groups. It includes a 'Feedback' system to enable users to help improve the quality of Cochrane reviews.
- The *Database of Abstracts of Reviews of Effects*, assembled and maintained by the Centre for Reviews and Dissemination in York, UK, contains critical assessments and structured abstracts of other systematic reviews, conforming to explicit quality criteria.
- The <u>Cochrane Central Register of Controlled Trials</u> [19] (CENTRAL) contains bibliographic information on tens of thousands of controlled trials, including reports published in conference proceedings and many other sources not currently listed in other bibliographic databases.
- The *Cochrane Methodology Register* contains references to articles and books on the science of reviewing research.

The Cochrane Library also contains two additional databases: the Health Technology Assessment Database, and the NHS Economic Evaluation Database.

The section 'About The Cochrane Collaboration' in *The Cochrane Library* contains contact details and other information about Cochrane Review Groups and other contributing <u>entities</u> [20] within The Cochrane Collaboration.

For information on how to subscribe to *The Cochrane Library*, see www.thecochranelibrary.com [21]

Subheadings in this section

1.1.1 The Cochrane Collaboration Secretariat

The work of The Cochrane Collaboration Steering Group [13] and its three sub-groups (the Executive, the Monitoring and Registration Group, and the Publishing Policy Group) is supported by a small Secretariat [1] based in Oxford, UK. This office is staffed by a full-time Chief Executive Officer, Administrator and Company Secretary, Deputy Administrator, Project Support and Business Communications Officer, and Team P. A., working closely with The Cochrane Collaboration's Co-Chairs and Treasurer.

Subheadings in this section

1.1.1.1 Editor in Chief/ Cochrane Editorial Unit

The role of Editor in Chief (EiC) was established in January 2009. It is a full-time leadership position within the Collaboration. The Editorial Unit is based in London, England.

Working closely with the editorial teams of <u>Cochrane Review</u> [22] Groups, the EiC is responsible for:

• developing, implementing, and directing the editorial policies and vision of The Cochrane



<u>Library</u> [18] in relation to the vision and objectives of the Collaboration;

- improving the <u>quality</u> [5] in the editing process and product with respect to scientific content;
- providing a strong and visionary lead for conceptualising and developing new products derived from Cochrane Reviews; and
- acting as the main focus for this work, and for applying ethical and scientific standards consistent with the goals of the Collaboration.

The EiC is accountable to the Cochrane Collaboration Steering Group [13] (CCSG [23]) for the delivery of a high quality product (The Cochrane Library) in line with the Collaboration's mission, ethos and agreed standards. He has executive authority over what is published in The Cochrane Library, and attends the CCSG's biennial face-to-face meetings and monthly telephone conferences to report on progress.

The Co-ordinating Editors (forming the Co-ordinating Editors' Board, represented by the Co-ordinating Editors' executive) are accountable to the EiC for the quality and delivery of the Cochrane Systematic Reviews produced through their editorial bases, and for the editorial processes used to develop and deliver these.

Methodologists and other scientific and technical experts are responsible to the CCSG for ensuring that the EiC receives good advice on the scientific and technical components of Cochrane Systematic Reviews; the EiC is accountable to the CCSG for ensuring that this advice is given proper weight within the overall aim of publishing high quality output.

Business and finance (including profit and loss) responsibility for the Collaboration's core functions rests with the Chief Executive Officer (CEO), who remains accountable for these areas of responsibility. The EiC works closely with the CEO to ensure an effective interface between operational, business, finance, scientific and technical responsibilities, while respecting the collaborative nature of the organisation's ethos and working practices.

1.1.2 Special roles within The Cochrane Collaboration

Subheadings in this section

1.1.2.1 Co-Chairs of the Steering Group

General description

In the early years, the Cochrane Collaboration Steering Group [13] (CCSG [23]) had a single Chair. More recently, a system of co-chairing has evolved, to share the workload, to utilize complementary skills and experience, and to permit continuity by the Co-Chairs stepping down in alternate years.

Responsibilities

The Co-Chairs are chosen by the Steering Group. Co-Chairs agree upon an appropriate division of responsibilities, which include:

• To serve as the official spokesperson(s) for the Cochrane Collaboration Steering Group, with



the authority to delegate this responsibility to others.

- To ensure and facilitate strategic planning by the Cochrane Collaboration Steering Group.
- To chair meetings of the Cochrane Collaboration Steering Group.
- To convene the Executive of the Cochrane Collaboration Steering Group, and chair its teleconferences.
- To convene the Publishing Policy Group of the Cochrane Collaboration Steering Group, and chair its teleconferences.
- To assist the <u>Secretariat</u> [1] in preparing for Steering Group meetings, and Executive and Publishing Policy Group teleconferences.
- To chair the Annual General Meeting of The Cochrane Collaboration.
- To provide advice and guidance to the Chief Executive Officer, Administrator and other Secretariat staff as required.
- To act as appraisers to the Chief Executive Officer and Administrator.
- To assist and guide the Chief Executive Officer in working towards delivery of the Collaboration's Strategic Plan.
- To respond to issues raised by members of The Cochrane Collaboration, outside the remits of the Chief Executive Officer and Administrator.
- To pursue those initiatives and projects agreed by the Cochrane Collaboration Steering Group to be the responsibility of the Co-Chairs.
- To represent The Cochrane Collaboration at meetings with current and potential funders, and other agencies as required.
- To write a letter for publication in each issue of Cochrane News.

Accountability

The Co-Chairs are accountable to the Steering Group, and to the members of The Cochrane Collaboration.

Oualifications

The Co-Chairs are expected both to have leadership skills and to be fully consultative, to have vision, to be adept at dealing with people, to be able to solve problems and resolve conflicts effectively, to communicate well, and to have the self-confidence to represent The Cochrane Collaboration in a variety of different settings. Experience of membership of the Steering Group is advantageous but not essential (see below).

Recruitment process

- 1. The Steering Group agreed in October 2004 that in future there should be a formal process of nominating existing members of the Steering Group for the position of Co-Chair, and the members of the Steering Group would vote. Nominations should normally be made nine months in advance of the Annual General Meeting of The Cochrane Collaboration, and discussed at the mid-year Steering Group meeting. Candidates should have their nominations proposed and seconded by other members of the Steering Group. They should provide a written summary of their suitability for taking on this responsibility by answering the following questions. Should a Co-Chair resign before the end of their term of office, or leave office for some other reason, the recruitment process would be activated as soon as possible.
 - 1. The Secretariat would be responsible for issuing the call for nominations for the position of Co-Chair, and for presenting the names of nominated candidates, their summaries, and the names of their proposers and seconders to the Steering Group.
- 2. If no member of the Steering Group comes forward for selection, or if the person/people who come(s) forward are judged unsuitable by the Steering Group (by vote if necessary), a person from outside the Steering Group would be sought, six months before the position of



Co-Chair becomes vacant. A selection committee would be established by the Steering Group, comprising 3-5 members of the Steering Group (including at least one Co-Chair) and, if the Steering Group wishes, up to two people who are not members of the Steering Group (for example, previous members of the Steering Group). It would be the responsibility of this committee to identify candidates for the role of Co-Chair and to recommend one person for the position to the Steering Group. The Steering Group would then vote on whether or not to accept this recommendation. If the recommendation is not accepted, the process would be repeated.

1. In accordance with the Articles of <u>Association</u> [24] of The Cochrane Collaboration, the Steering Group would make the selected person a member of the Steering Group and, at the next Annual General Meeting, the Cochrane <u>entities</u> [20] would be asked to approve her/his membership.

Time commitment

There is a need for an absolute minimum of eight hours per week for the Co-Chairs combined (or for a single Chair if the Steering Group ever reverts to that), but with an expectation that a combined total of up to thirty hours per week might sometimes be needed (not including the full-time requirements at the times of the Steering Group meetings).

Term of position

The Co-Chairs hold office for two years. If the need arises, they may continue to hold office for a further two-year term, with the majority approval of the Steering Group.

Questions for intending candidates for election as Co-Chair of the Steering Group

[Responses not to exceed two A4 pages in length, in Arial font, size 11.]

- 1. How long have you been contributing to the work of The Cochrane Collaboration, and how did you first become involved?
- 2. Have you helped to prepare or bring into practice a <u>Cochrane review</u> [22]? If so, what was vour involvement?
- 3. What experience do you have of committee work (particularly at the policy-setting level) nationally, internationally, and within The Cochrane Collaboration?
- 4. What do you think would make you an effective Co-Chair?
- 5. What would you like to change about the Collaboration and/or the Steering Group, and why?
- 6. What would you wish to achieve as Co-Chair of the Steering Group?
- 7. For individuals seeking re-election as Co-Chair: What do you think you have contributed to the work of the Steering Group during your previous two-year term of office?
- 8. Please state any potential conflicts of interest that might limit your participation in Steering Group discussions and decision-making:
 - 1. Core conflicts of interest:
 - 2. Internal conflicts of interest:
 - 3. External conflicts of interest:

1.1.2.10 Methods Board and Methods Executive

In 2009, a proposal to establish a Methods Board (section 1.1.2.10.1) and a Methods Executive (section 1.1.2.10.2) was accepted by The Cochrane Collaboration Steering Group [13] (CCSG [23]). The Methods Board is an inclusive group of people with key methods roles in the Collaboration, and



has adopted formal responsibility for methodological recommendations to CCSG. The Methods Executive acts as a conduit for communication and information flow between the Methods Board and the CCSG, the Editor in Chief and other Cochrane entity executives. It is co-chaired by the Methods Groups' representative on the CCSG. The Methods Executive is accountable to the Methods Board and reports to the Board on activities, with a written report presented at the Methods Board meeting during the annual Cochrane Colloquium and incorporated into the final minutes.

1.1.2.10.1 Methods Board - remit and membership

Purpose of Methods Board

The purpose of the Methods Board is to provide a broad forum for discussion and recommendations on methods for Cochrane Reviews and other methodological issues faced by The Cochrane Collaboration.

Objectives

- Provision of consolidated advice to the Cochrane Collaboration <u>Steering Group</u> [13] (<u>CCSG</u> [23]), intended for implementation in the Cochrane Handbooks, <u>Review Manager</u> [25] and other major documents and software, on the content and structure of Cochrane Reviews, in particular by gathering opinion from Methods Groups and the Methodology Review Group;
- Provision of consolidated advice to the CCSG, the Editor in Chief, the Methods Executive, the RevMan Advisory Group, and others as appropriate, on methodological issues faced by The Cochrane Collaboration, in particular by gathering opinion from Methods Groups and the Methodology Review Group;
- A forum for general discussion and <u>interaction</u> [26] among Methods Groups, and between Methods Groups and the Methodology Review Group;
- Co-ordination and provision of a programme of training workshops (and possibly other meetings) at Cochrane Colloquia, in collaboration with the local organizers;
- Sign-off of training materials for the Training Working Group;
- Provision of members to the Opportunities Fund committee, the Thomas C Chalmers Award committee, and other committees as appropriate.

Decision-making

- The Methods Board will aim to reach full consensus but where this is not possible decisions will be taken based on a majority vote of its voting members. In the case of a tied vote, the CCSG Methods representative will have the deciding vote.
- For decisions to be taken at Methods Board meetings, a quorum of 10 voting members is necessary. For decisions to be taken by e-mail correspondence, it is expected that all eligible members of the Methods Board will vote but if this is not possible the above quorum stands.
- Wherever possible, decisions will be based on consultation with the full Methods Board and the memberships of the groups they represent.

Meetings and communications

• One face-to-face meeting per year which will generally be held at the annual Cochrane



Colloquium.

- E-mail discussion.
- Ad hoc telephone conferences when required.
- The Methods Board minutes will be made publicly available electronically.

Membership of the Methods Board

The Board will consist of a general membership and a voting membership (which is a subset of the general membership).

General membership

- Methods Group representative(s) on the CCSG.
- Co-convenors of all Methods Groups.
- Editor in Chief of <u>The Cochrane Library</u> [18] (or representative).
- Editors of all Cochrane Handbooks.
- Co-ordinating Editors (and key staff) of the Methodology Review Group.
- Key personnel for methods of diagnostic test accuracy reviews.
- Key personnel for methods of overviews of reviews.
- Co-Convenors of Methods Application and Review Standards (MARS) Working Group.
- Key personnel from networks [27] of CRG [15]-based methods individuals.
- Editors of Cochrane Methods (formally the annual Methods Groups' newsletter).
- Methods representative on the Colloquium Policy Advisory Committee (CPAC).
- Methods representative on the Information Management System Group (IMSG [28]).
- Other people holding roles to represent methods perspectives, including all members of the Methods Executive not otherwise eligible for membership of the Board.

Voting membership

- One representative from each Methods Group (registered as a Methods Group with the Monitoring and Registration Committee).
- One representative from the Cochrane Methodology Review Group.
- One representative from each network of CRG-based methods individuals.
- One representative from the Cochrane Handbook for Systematic Reviews of Interventions.
- One representative from the Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy.
- One Methods Group representative from the CCSG.

Size, composition and representation

- The Methods Board is not limited in number and aims to be inclusive.
- There will be two Co-Convenors of the Methods Board.
- The Co-Convenors will be chosen from amongst the general membership of the Methods Board, but at least one Co-Convenor must be a member of the Methods Executive.
- The specific individuals who are acting as voting representatives will be elicited at the start of each meeting or teleconference, if a vote is anticipated.



1.1.2.10.2 Methods Executive - remit and membership

Purpose of Methods Executive

The purpose of the Methods Executive is to be a conduit for communication and information flow between the Methods Board and The Cochrane Collaboration Steering Group [13] (CCSG [23]), the Editor in Chief, CRG [15] Executives and the Fields' Executive.

Accountability and reporting

- The Methods Executive will be accountable to the Methods Board.
- The Methods Executive will report to the Methods Board on activities, with a written report presented at the Methods Board meeting held at the annual Colloquium, and incorporated into the final minutes.
- The Methods Executive will produce written reports or papers for the CCSG and other stakeholder groups as required.

Objectives

- To advise the CCSG, via the Methods Group representative(s) on CCSG, on all aspects relating to the role and function of Methods Groups in a timely and effective manner.
- To advise the Editor in Chief on all aspects relating to methodology and Methods Groups as relevant to editorial content in a timely and effective manner.
- To facilitate effective and timely communications between the Methods Groups, Managing Editors (MEs), Trials Search Co-ordinators (TSCs), the Co-ordinating Editors' Board, Centres, Fields, the Training Working Group, the Editor in Chief, and any special working groups as appropriate. The Methods Executive will work particularly closely with the Co-ordinating Editors' Executive, through involvement in the Methods Application and Review [29] Standards (MARS) Working Group.
- To consider any relevant decisions or discussions from the CCSG and its various sub-committees and advisory committees, and from the Editor in Chief, to share these as appropriate with the Methods Board, and to delegate appropriate actions to individuals or Methods Groups.
- To approve and evaluate membership of the Methods Board.
- To work with the Monitoring and Registration Committee (MaRC [30]) on issues related to appointing Methods Groups Convenors, setting core functions for Methods Groups, assessment of Methods Groups' performance against core functions, and performance appraisal mechanisms for Methods Groups Convenors.
- To assist if necessary the filling of methods-related positions on the CCSG's sub- and advisory committees, or other special projects or working groups, and to ensure appropriate methods representation where none currently exists.
- To identify collective Methods Groups concerns and issues and bring them forward to the appropriate arena with the view to achieving the mission of The Cochrane Collaboration.

Decision-making

- Wherever appropriate and feasible, decision-making will be delegated to the Methods Board.
- For decisions taken by the Methods Executive (such as minor decisions or urgent decisions), members of the Methods Executive will aim to reach full consensus. Where this is not possible,



- decisions will be taken based on a majority vote. In the case of a tied vote, the CCSG Methods Group representative will have the deciding vote.
- For decisions to be taken at Methods Executive meetings, a quorum of more than half of the membership of the Methods Executive is necessary. For decisions to be taken by e-mail correspondence, it is expected that all members of the Methods Executive will vote but if this is not possible the above quorum stands.

Meetings and communications

- One face-to-face meeting per year which will generally be held at the annual Cochrane Colloquium.
- Regular (approximately bi-monthly) telephone conferences.
- Representation at the mid-year Cochrane meetings as appropriate.
- E-mail discussion.
- The minutes of the Methods Executive meetings will be made publicly available.

Membership of the Methods Executive

- Membership will be on a voluntary basis.
- Any general member of the Methods Board can nominate themselves to be a member of the Methods Executive.
- Volunteers will be expected to have the time to devote to the position, the skills required, and the trust of their colleagues.
- All terms will be for three years (with the exception of some of the initial members). To ensure continuity, terms will be staggered to ensure that approximately one third of the Group is replaced in a given year. No limit is set on the number of terms that may be served, but reappointment is contingent upon the Co-Convenors' approval.

Size, composition and representation

- The Methods Executive is limited to eight people, including the Methods Group representative(s) on the CCSG.
- Ideally, the Methods Executive members will reflect the diversity of methods activities in the Collaboration, in particular their geographical <u>distribution</u> [31], type of activity (e.g. theoretical research vs <u>empirical</u> [32] research vs development of guidance vs implementation) and type of methodology (e.g. <u>intervention</u> [33] vs diagnostic test accuracy; statistical vs non-statistical; generic vs specific).
- There will be two Co-Convenors of the Methods Executive.
- The Methods Executive will choose the Co-Convenors from amongst its members.
- The Methods Executive will choose a representative for the Monitoring and Registration Committee amongst its members.

1.1.2.2 Members of the Steering Group

General description

The Cochrane Collaboration Steering Group [13] (CCSG [23]) is the Board of Directors of The



Cochrane Collaboration, a registered charity. The CCSG sets policy for The Cochrane Collaboration, in consultation with the members of the organisation.

Responsibilities

People are elected to represent a type of Cochrane entity (a <u>Cochrane Review</u> [22] Group, a <u>Centre</u> [34], a Field, a Methods Group, or the Consumer Network) or a type of role (Author, Co-ordinating Editor, Managing Editor, Trials Search Co-ordinator) within a Cochrane entity.

Responsibilities include:

- 1. Canvassing the opinion of members of one's constituency on issues of central importance to The Cochrane Collaboration.
- 2. Informing members of one's constituency of the development of new, or the modification of existing, policy.
- 3. Communicating decisions made at CCSG Group meetings and other matters of interest to members of one's constituency on a regular basis, usually by e-mail.
- 4. Attending the two face to face CCSG meetings each year, one of which takes place during the Colloquium, the other of which takes place approximately six months later. The latter ('mid-year' meetings) are hosted by a Cochrane entity, often in conjunction with a conference for people in the region. CCSG members are invited to make presentations at these conferences, which provide an opportunity to raise awareness of The Cochrane Collaboration and to give prominence to the work of the hosting entity. In accordance with charity law, CCSG members cannot receive payment for fulfilling their role as members of the CCSG, but all travel and accommodation costs of these meetings are reimbursed to them from core Collaboration funds (in accordance with the Collaboration's policy on reimbursement of expenses see section 2.1.2 [35] below).
- 5. Attending the Annual General Meetings (AGMs) of the Charity and its trading subsidiary. The AGMs are held during the annual Cochrane Colloquia.
- 6. Participating as a member of one of the committees of the CCSG (the Operations and Finance Committee [OFC], or the Monitoring and Registration Committee [MaRC [30]]). The OFC conducts its business by monthly teleconference; the MaRC conducts its business mostly by e-mail, and also holds a face to face meeting once or twice a year. The Co-Chairs of the CCSG decide which of these committees it would be most suitable for newly elected members to join, according to both the gaps left on each committee by outgoing members, and the particular skills and interests of the incoming members.
- 7. Representing the CCSG on one of its advisory committees. These committees are comprised mostly of non-CCSG members, but each committee has two CCSG members to facilitate communication. Some of the advisory committees meet face to face occasionally, but most of them meet by teleconference or during the annual Colloquium if possible, and otherwise conduct their business by e-mail. The workload varies from committee to committee, and funding is available to each of them (via an annual budget approved by the CCSG) to enable members to communicate with each other. The document 'Structure, remit and membership of groups accountable to the Steering Group' on the Collaboration website (www.cochrane.org/admin/structure.htm [36]) describes the responsibilities and membership of these committees.

Accountability

CCSG members are accountable to it and to the constituents who elected them.

Oualifications

No specific qualifications are required for being a member of the CCSG other than being an active member of the relevant constituency. It is important that people who join the CCSG are prepared to take an active part, and to share the workload with the other members.



Recruitment process

The members of The Cochrane Collaboration elect people to the CCSG annually. The <u>entities</u> [20] (or the relevant constituents, where relevant for some posts) are the 'members' of The Cochrane Collaboration, and each entity contributes a single aggregated vote. People are elected to the CCSG for three years, with effect from the first Annual General Meeting (AGM) after the annual election in which they were elected.

Term of position

CCSG members serve for a period of three years. At the end of three years, they are eligible to stand for re-election for a further three years. With the exception of the Co-Chairs (see section 1.1.2.1 [37]), no-one may be a member of the CCSG for more than two consecutive terms (i.e. six years), but may stand for re-election after a subsequent gap of three years.

Questions for intending candidates for election to the CCSG

[Responses not to exceed two A4 pages in length, in Arial font, size 11.]

- 1. How long have you been contributing to the work of The Cochrane Collaboration, and how did you first become involved?
- 2. Have you helped to prepare or bring into practice a Cochrane review? If so, what was your involvement?
- 3. What experience do you have of committee work (particularly at the policy-setting level) nationally, internationally, and within The Cochrane Collaboration?
- 4. What do you think would make you an effective member of the Steering Group?
- 5. What would you like to change about the Collaboration and/or the Steering Group, and why?
- 6. What would you wish to achieve as a member of the Steering Group?

1.1.2.3 Company Secretary

General description

The Cochrane Collaboration is a registered charity in the UK. The Collaboration is required to have a company secretary under UK law.

Responsibilities

The information in this section is taken from an official document issued by Companies House in the UK:

The duties of a Company Secretary are not specified by the [Companies] Act [1985], but are usually contained in her/his contract of employment. Special duties

As the Company Secretary is an officer of the company under section 744 of the Act, he/she may be criminally liable for defaults committed by the company, e.g. failure to file, in the time allowed, details of any change in the company's directors' and secretary's details and the company's annual return.

The Company Secretary may also have to make out a statement of the company's affairs if an administrative receiver or a provisional liquidator is appointed, or if a winding up order is made (sections 47 and 131 of the Insolvency Act 1986).

Other duties

In addition, the Company Secretary usually undertakes the following duties



- 1. Maintaining the statutory registers. These are the:
- 1.
- Register of members (section 352)
- Register of directors and secretaries (section 288)
- Register of directors' interests (section 325)
- Register of charges (section 407)
- Register of interests in shares (for public companies only)
- 1. Ensuring that statutory forms are filed promptly. The Company Secretary cannot simply send a letter to notify the Registrar of Companies of the wish to change the situation of the company's registered office, or about changes have been made among directors or secretaries or their particulars. Forms 287 and 288a/b/c should normally be used as appropriate. The annual return form 363s may also be used in some circumstances if due at the convenient time. Changes of details of directors and secretaries must be notified within 14 days. There are many other forms that need to be delivered to the Registrar of Companies.
- 2. Providing members and auditors with 21 days' written notice of an annual general meeting, and 14 days' written notice of a meeting other than an annual general meeting, or a meeting to pass a special resolution. For an unlimited company, the written notice required is seven days.
- 3. Sending the Registrar of Companies copies of every resolution or agreement to which section 380 applies, e.g. special and extraordinary resolutions.
- 4. Supplying, not less than 21 days before a meeting at which the company's accounts are to be presented, a copy of the accounts to every member of the company, every debenture holder and every person who is entitled to receive notice of general meetings: section 238 of the Act.
- 5. Keeping, or arranging for keeping, minutes of directors' meetings and general meetings.
- 6. Supplying copies of the company's accounts and other documents to those entitled to them, and ensuring that people entitled to do this can inspect company records. For example, members of the company and members of the public are entitled to a copy of the company's register of members, and members of the company are entitled to inspect the minutes of its general meetings and to have copies of these minutes.
- 7. Although it is no longer a requirement for a company to use a company seal, if it does so the Company Secretary is usually responsible for its custody and use.



The Act does not give the Company Secretary any specific powers, but it does allow her/him to sign the following re-registration applications:

- the re-registration of a limited company as unlimited: section 49(4) of the Act;
- the re-registration of an unlimited company as limited: section 51(4);
- the re-registration of a public company as a private company: section 53(1)(b); and
- the re-registration of a private company as a public company: section 43(3).

The Company Secretary is also allowed to sign most of the forms prescribed under the Companies Act.

The rights of a Company Secretary depend on the terms of her/his contract with the company. The Company Secretary has no special rights under the Companies Act.

Accountability

The Company Secretary is accountable to the <u>Steering Group</u> [13] and to The Cochrane Collaboration as a whole, as well as having legal responsibilities in the UK.

Qualifications

No specific qualifications are required for being the Company Secretary.

Recruitment process

The Steering Group selects the person to be Company Secretary, usually in consultation with the Directors of the Trading Company (since it may be more convenient for the same person to be Company Secretary for both The Cochrane Collaboration and The Collaboration Trading Company).

Term of position

The Company Secretary relinquishes these responsibilities at her/his own request or at the request of the Steering Group.

1.1.2.4 Funding Arbiter

Introduction

The Cochrane Collaboration policy on commercial sponsorship dictated that the position of <u>Funding Arbiter</u> [38] be established, analogous to the <u>Publication Arbiter</u> [39]. The Funding Arbiter convenes a panel of five members (including him/herself) to give guidance on difficult issues which have been referred to the Panel with respect to the policy on commercial sponsorship.

Membership of the Funding Arbitration Panel

The Funding Arbitration Panel is comprised of five people. The Convenor (i.e. the Funding Arbiter) is appointed by the Cochrane Collaboration Steering Group [13] from among its members. The other Panel members are identified by the Funding Arbiter in consultation with the Co-Chairs of the Steering Group, and are approved by the whole Steering Group. The Funding Arbiter must be a member of the Steering Group, and at least one of the Panel members must be from outside it. The third Panel member must be from outside the Collaboration; the fourth and fifth members may or may not be Steering Group members. The current members of the Funding Arbitration Panel can be found in the Contact [40] section.



Process for referrals to the Funding Arbitration Panel

Where it is believed that an issue of funding contravenes the current policy, or where there is some doubt, these matters will be referred to the Funding Arbiter. Referrals may also be made by those seeking advice on interpretation of the current commercial sponsorship policy.

Arbitration process

Administrative support and co-ordination are provided as a special function by the Cochrane Collaboration Secretariat [1]. People can communicate directly with the Funding Arbiter by e-mail (fundingarbiter@cochrane.org [41]).

Referrals to the Funding Arbiter should be made by registered Cochrane entities [20], on behalf of individuals or groups, using the appropriate online forms [42]; submission of such a form will automatically generate an e-mail to the Funding Arbiter's e-mail address, which will automatically be forwarded to the Secretariat, where each referral is checked to ensure that it contains the necessary information (see below). If the referral information is complete it is then forwarded to the Funding Arbiter; if incomplete, it is returned to the sender with a request for the missing information. Once the referral information is complete, the Secretariat forwards it to the Funding Arbiter.

The Funding Arbiter decides whether an enquiry is for him/her only or for the full Funding Arbitration Panel. The Funding Arbiter may determine that the referral is clearly not in breach of the current commercial sponsorship policy, and may give a ruling to such an effect without referring to the full panel. The Funding Arbiter may consider that more information is required before referral to the full Funding Arbitration Panel.

If the Funding Arbiter determines that the issue is equivocal, or if the issue will result in refusal of funding or the cancelling of a <u>review</u> [29] or <u>protocol</u> [43], or is otherwise contentious, then the full Funding Arbitration Panel will consider the matter. This will be communicated to the Secretariat which will be responsible for distributing the referral to the full Funding Arbitration Panel. Therefore, the Funding Arbiter will classify each individual referral as an enquiry, which can be dealt with by the Funding Arbiter, or as a matter requiring a decision which will be dealt with by the full Funding Arbitration Panel.

The Funding Arbitration Panel will decide on each referral after individual panel members have considered it, and then reach a consensus (either by e-mail discussion or teleconference). The final decision must have the agreement of at least three (of the four) panel members. If the panel members are unable to reach a consensus then the Funding Arbiter will request the Co-Chairs of the Steering Group to nominate a third party to mediate. The nominated person could be either a member of the Steering Group, one of the Co-Chairs, or an active contributor to the work of The Cochrane Collaboration who is not a member of the Steering Group. In circumstances in which one member of the panel is unable to participate (e.g. due to a conflict of interest) the final decision must have the agreement of at least two (of the remaining three) panel members.

If a teleconference is required, the Secretariat will arrange this. All decisions will be determined by the Funding Arbiter and Funding Arbitration Panel after referring to the current Cochrane Collaboration policy on commercial sponsorship. All deliberations will be documented. The Secretariat maintains a database of all referrals and decisions, which forms part of the case law. This information forms the basis of the Funding Arbiter's reports to the Steering Group for consideration at its biannual meetings.

Should the Funding Arbitration Panel find it necessary to recommend withdrawal of a review from <a href="https://doi.org/10.2016/nc.20

1. The contact author and review group should be informed of the Panel's decision.



- 2. The contact author and review group should be given the opportunity to appeal to the Steering Group if they wish.
- 3. The appeal should be made within one calendar month.
- 4. The Steering Group should respond within two calendar months.

Appeals

Appeals against decisions made by the Funding Arbiter should be made directly to the Steering Group, using the following procedure:

- 1. Written appeals should be submitted through the Funding Arbiter e-mail address (fundingarbiter@cochrane.org [41]).
- 2. The written appeal and all relevant correspondence are forwarded to all the members of the Steering Group who are given a deadline by which to provide feedback. Any Steering Group members who are also members of the Funding Arbitration Panel will excuse themselves from discussion of the appeal.
- 3. The Co-Chairs of the Steering Group (or another member of the Group if there is a conflict) review the collated feedback, and come to a decision as to the most appropriate response to the appeal. They communicate this decision directly to the appellant(s).

Term of office

The term of the Funding Arbiter is limited by her/his term on the Steering Group, i.e. three years, with the possibility of another three-year term, to a maximum of six years. The term for the other panel members is three years, with the possibility of another three-year term, to a maximum of six years. No two panel members should leave the panel at the same time or within twelve months of each other, i.e. panel membership should be staggered so that there is continuity within the panel.

Information to be included in referrals to the Funding Arbiter

Is the question about a published review or protocol?

If so, please give full details of the protocol or review, including contact details for all authors, and list all sources and amounts of funding. Please give full details of the funder to which this matter refers (i.e. name of funder, contact details, type of organisation, website), details of what the funds were used for, and whether the funds went to specific individuals or groups.

Is the question about a review title or protocol yet to be published?

If so, please give full details of the title or protocol, including contact details for all authors, and list all sources, amounts and conditions of funding. Please give full details of the funder to which this matter refers (i.e. name of funder, contact details, type of organisation, website); details of what the funds were used for, and whether the funds went to specific individuals or groups.

Is the question about current funding of a Cochrane entity?

If so, please give full details of the entity and its current funding sources and amounts; the contact details of the entity convenor or director; full details of the funder to which this matter refers (i.e. name of funder, contact details, type of organisation, website) and any conditions placed on the funding; details of what the funds were used for, and whether the funds went to specific individuals or groups.

Is the question about proposed funding of a Cochrane entity?

If so, please give full details of the funder to which this matter refers (i.e. name of potential funder, contact details, type of organisation, website) and any conditions placed on the funding; details of the amount of funding and what the funds will be used for and to whom the funds will go (i.e. a



named person or group). Also provide full details of the other sources and amounts of funding of the entity/group/person.

Job description

- 1. General description
- 1.1 The position of Funding Arbiter was established in 2004 following the release of the new policy on commercial sponsorship in April 2004 by The Cochrane Collaboration.
- 1.2 The Funding Arbiter gives guidance on difficult issues referred to him/her with respect to the policy on commercial sponsorship. Where it is believed that an issue of funding contravenes the current policy, or where there is some doubt, these matters are to be referred to the Funding Arbiter. Referrals may also be made by those seeking advice on interpretation of the current commercial sponsorship policy. The Funding Arbiter convenes a Funding Arbitration Panel to consider difficult issues and to report to the Cochrane Collaboration Steering Group.
- 2. Responsibilities
- 2.1 To convene the Funding Arbitration Panel. The Funding Arbitration Panel will be made up of four persons: the Convenor (i.e. the Funding Arbiter) will be appointed by the Steering Group and will be a member of it. The other three members of the Funding Arbitration Panel will be identified by the Funding Arbiter in consultation with the Co-Chairs of the Steering Group, and will be approved by the whole Group. One of these panel members will not be a member of the Group. Therefore the Funding Arbiter must be a member of the Steering Group, and at least one of the panel members must not be a member of it. The third panel member may or may not be a member of the Group. The fourth member of the panel will be from outside The Cochrane Collaboration.
- 2.2 To determine if referred questions are either:
- 2.2.1 An inquiry, which can be dealt with by the Funding Arbiter (for example, the Funding Arbiter may determine that the referral is clearly not in breach of the current commercial sponsorship policy, and may give a ruling to such an effect without referring to the full panel), or
- 2.2.2 A matter requiring a decision, which will be dealt with by the full Funding Arbitration Panel (for example, if the Funding Arbiter determines that the issue is equivocal, or if the issue will result in refusal of funding or the cancelling of a review or protocol, or is otherwise contentious, then the full Funding Arbitration Panel will consider the matter).
- 2.3 To give advice to members of the Collaboration who make an inquiry (see 2.2.1 above).
- 2.4 To rule on matters requiring a decision (see 2.2.2 above) after consultation with the Funding Arbitration Panel. The decision of the Funding Arbiter must have the agreement of the majority of panel members.
- 2.5 To report to the Steering Group see 3.1 below.
- 3. Accountability

The Funding Arbiter is accountable to the Steering Group and will report twice a year to the Group at its biannual meetings.

- 4. Qualifications
- 4.1 The Funding Arbiter must be a current member of the Cochrane Collaboration Steering Group.
- 4.2 No specific qualifications are required.
- 4.3 The Funding Arbiter must have sufficient education, experience, and previous involvement



with the Collaboration to warrant selection by the Steering Group.

5. Recruitment process

The Funding Arbiter will work with the Co-Chairs of the Steering Group and the Chief Executive Officer to identify a suitable replacement from existing Steering Group members. Potential candidates should be nominated and seconded by existing members of the Steering Group, and the nomination should be approved by a majority of the Steering Group including the Co-Chairs.

- 6. Term of position
- 6.1 The term of the Funding Arbiter is limited by their term on the Steering Group, i.e. three years, with the possibility of another three-year term, giving a maximum of six years.
- 6.2 The term for the other panel members is three years, with the possibility of another three-year term, giving a maximum of six years.

No two panel members should leave the position at the same time or within twelve months of each other, i.e. panel membership should be staggered to ensure continuity.

1.1.2.5 Ombudsmen

The Steering Group [13] established the position of Cochrane Collaboration Ombudsman [44] in October 1998. Since October 2000, there have been two Ombudsmen, so as to share the workload and to provide an alternative, should one of the Ombudsmen have too strong a conflict of interest in an issue on which they are asked to help. The role of the Ombudsmen is to help resolve areas of conflict that arise between people or entities [20] within The Cochrane Collaboration, for which the usual process of involving the Directors of the reference Cochrane Centre [34](s) has not been sufficient. The Ombudsmen are appointed by the Steering Group, and must not be current members of the Steering Group. They submit an annual, written report to the Steering Group. The report includes details of their activity during the year but does not identify specific details if, in the opinion of the Ombudsmen, there is a need for these details to remain confidential. If the Ombudsmen are unable to resolve an issue, it can be referred to the Steering Group. If the dispute or conflict is related to the publishing of a Cochrane review [22], it should be referred to the Publication Arbiter [39].

Chris Silagy was appointed the first Ombudsman in October 1998. Gill Gyte became the second Ombudsman in October 2000, sharing the role with Chris Silagy until his death in December 2001. In August 2002 Peter Langhorne took on this role, sharing it with Gill Gyte. Gill resigned in October 2005 after five years, and was replaced by Kathie Clark (former member of the Cochrane Collaboration Steering Group and former Co-Director of the Canadian Cochrane Network and Centre). Peter and Kathie have fulfilled this role for eight and five years respectively, and are both now stepping down. The Steering Group will select replacements at its face-to-face meeting in Keystone in October 2010.

The Steering Group approved the following job description for the Ombudsmen in April 2005:

General description

- ECCEPTION TO Mediate in conflicts when asked to do so, mediation being to help people in conflict to resolve their differences in order to work out a mutually acceptable agreement. This may be done face-to-face or by telephone. The mediator's role includes helping the parties move from their entrenched positions to the recognition of their respective interests, from which they can negotiate a workable agreement.
- EEEEEEEE To produce guidelines for handling conflict and mediation.
- EEEEEEEE To support others providing mediation when it is not possible for one of the Ombudsmen to



be there.

•εεεεεεε To run workshops on handling conflict, mediation, etc.

Responsibilities

- EEEEEEEE To guide people to find ways of resolving their own conflicts when requested.
- ECCCCCCC To think who else is affected by the conflict and include these parties when guiding the devising of solutions, e.g. to think of the impact on the Collaboration.
- EEEEEEEE To be available when needed.

Accountability

To the Collaboration through the Steering Group.

Oualifications

Substantive previous involvement with the Collaboration.

Recruitment process

To be chosen by the Steering Group. Nominations to be sought from members of the Collaboration, and the decision to be made by the Steering Group through a standard voting process, based upon a paragraph provided by each candidate summarising their relevant expertise and experience in relation to the remit of the position.

Term of position

Five years.

1.1.2.6 Publication Arbiter

General description

The <u>Steering Group</u> [13] established the role of <u>Publication Arbiter</u> [39] during its meeting in Stavanger, Norway, in 2002, and subsequently agreed that there should be two Publication Arbiters, in order to provide coverage if one was unable to fulfil the responsibilities at any time or where one had a conflict of interest. The role of the Publication Arbiter relates specifically to the publication of Cochrane reviews, and was established to help people to reach a mutually acceptable agreement in areas of dispute between the editorial teams of Cochrane Review Groups (e.g. of the appropriate home for a specific Cochrane review), and between review authors and their editorial team (e.g. when review authors are unwilling to make changes suggested by the editors). Since March 2004, Kay Dickersin, Director of the US Cochrane Center, has been Co-Publication Arbiter, initially with David Henderson-Smart of the Cochrane Neonatal Group until October 2006, and subsequently with Richard Hughes of the Cochrane Neuromuscular Disease Group. Professor Hughes resigned in February 2009, and in April 2009 the Steering Group approved Professor Rick Nelson, Deputy Co-ordinating Editor of the Cochrane Colorectal Cancer Group, as Professor Hughes' replacement.

The Steering Group approved the following job description for the Publication Arbiters in October 2005:

Responsibilities

To respond to requests for arbitration about conflict concerning publication of reviews from authors, entities [20], or The Cochrane Collaboration's Ombudsmen.

To report to the Steering Group on the numbers and types of conflict being reported, the arbitration process used, and the outcomes.

Accountability



The Publication Arbiters are accountable to the Cochrane Collaboration Steering Group, and report in writing to the Group annually at its mid-year meetings.

Qualifications

One of the Publication Arbiters must be a former member of the Cochrane Collaboration Steering Group; the other need not be. No specific qualifications are required, but the Publication Arbiters are expected to have a background and skills to address the above responsibilities. The Publication Arbiters must have sufficient knowledge, experience, and previous involvement with the Collaboration to warrant selection by the Steering Group. They should have a good understanding and experience of the <u>editorial process</u> [45] for preparing and maintaining a Cochrane review, and to have co-authored at least one Cochrane review.

Recruitment process

The Publication Arbiters are chosen by the Steering Group from among its former members, authors and entities. Potential candidates should be nominated and seconded by current members of the Steering Group, and a nomination should be approved by the majority of the Steering Group with the approval of its Co-Chairs.

Term of position

There is no set term for the position of Publication Arbiter, but a maximum of five years would be appropriate. The two Publication Arbiters should step down at different times in order to provide continuity.

1.1.2.7 Trading Company Directors

General description

The Cochrane Collaboration Steering Group is the board of directors of The Cochrane Collaboration, a charity registered in the UK on 10 April 1995 (company no. 3044323). The Steering Group sets policy for The Cochrane Collaboration, in consultation with the members of the organisation. On 27 October 1998 a Trading Company was established (company no. 3657122) as a wholly-owned subsidiary of The Cochrane Collaboration, with the primary purpose of receiving the royalties on sales of the Charity's main output, The Cochrane Library [18], on behalf of the Charity. The Directors of the Trading Company (of whom there are currently three) hold the following responsibilities:

Responsibilities

- 1. Attending two meetings of the Trading Company Directors per year, chiefly to monitor the accurate payment of royalties by the publishers, and to ensure that all surplus funds are paid over to The Cochrane Collaboration annually by Gift Aid. Also, to ensure that the Charity's legal responsibilities are fulfilled and in a timely manner.
- 2. Communicating any concerns to the Steering Group about the contractual relationship with the publishers, payment of royalties, tax and VAT issues, etc.
- 3. Checking and signing off on the Annual Report and Financial Statements of the Trading Company, before their <u>distribution</u> [31] to the <u>entities</u> [20] of The Cochrane Collaboration, and acceptance at the Charity's and Trading Company's Annual General Meetings.
- 4. Ensuring the Trading Company Directors are represented at the Annual General Meetings, which are usually held during the annual Cochrane Colloquia.
- 5. Dealing with employment matters pertaining to the staff of the Cochrane Collaboration Secretariat [1], in collaboration with the Co-Chairs of the Steering Group [13].

Accountability

The Trading Company Directors are accountable to the Steering Group.



Oualifications

No specific qualifications are required for being a Trading Company Director; however, these positions have been filled by ex-members of the Steering Group who are also ex-Treasurers, because this provides them with the relevant knowledge and experience.

Recruitment process

On the resignation of a Trading Company Director, the remaining Directors consider a suitable replacement from among the past members of the Steering Group. If no-one could be identified who would be willing to take on this role, a volunteer would be called for from amongst the contributors to The Cochrane Collaboration.

Term of position

Trading Company Directors have no fixed term of office, but one-third of the Directors resign each year at the AGM and can be reappointed.

1.1.2.8 Treasurer

The following job description for the Treasurer of The Cochrane Collaboration was approved by the <u>Steering Group</u> [13] Executive in July 2004, and updated in December 2010.

General Description

The Treasurer is an Officer of the Collaboration. The role of the Treasurer is one of oversight, defined by the Charity Commission for England (the Collaboration's regulatory body) as being "to ensure that proper accounts are kept, and to help set financial and investment policies".

The Treasurer of The Cochrane Collaboration (the charity) and the Collaboration Trading Company Limited (the trading company) must be an elected member of the Cochrane Collaboration Steering Group, and be appointed by that Group to be Treasurer. The Treasurer usually assumes office at the Annual General Meetings of the two companies during the annual Cochrane Colloquia.

Responsibilities

The Treasurer is expected to:

- Discuss the budget and cash flow forecast with the Co-Chairs of the Steering Group, the CEO and the <u>Secretariat</u> [1] Administrator, as and when required.
- Speak to the Profit and Loss Statements and Balance Sheets showing the Collaboration's financial position, during Operations and Finance Committee telephone conferences, and face-to-face meetings of the Steering Group, and respond to related queries.
- Advise the Secretariat on the authorisation of expenditure if the Secretariat is in doubt.
- Participate in telephone conferences of the Trading Company Directors as and when required.
- Give input to the annual audit of accounts, and participate by telephone conference in the 'audit clearance' meeting with the accountants, CEO and Secretariat Administrator, if necessary.
- Attend the Annual General Meetings of The Cochrane Collaboration and the Collaboration Trading Company Limited, at which their Report and Financial Statements are presented to the membership for adoption, and be prepared to answer queries about these.
- Sign off on the Report and Financial Statements of The Cochrane Collaboration and the Collaboration Trading Company Limited, on completion of the annual audit, after these have been approved at the Annual General Meetings.



Accountability

The Treasurer is accountable to the Cochrane Collaboration Steering Group and the Directors of the Collaboration Trading Company Limited.

Background/Qualifications

The Treasurer must be an elected member of the Cochrane Collaboration Steering Group, with budgeting, financial and spreadsheet skills.

Recruitment Process

On the resignation of the Treasurer, the Co-Chairs of the Cochrane Collaboration Steering Group will assess the current membership of the Steering Group, and approach the person they consider has the most appropriate skills to take over the responsibilities of Treasurer.

Term of Position

The Treasurer relinquishes these responsibilities on leaving the Cochrane Collaboration Steering Group.

1.1.2.9 CRG executives

In 2008 the three main groups of people within <u>CRG</u> [15] editorial teams, the Co-ordinating Editors, Managing Editors and Trials Search Co-ordinators, formed their own sub-groups or 'executives'. These executives consult with those they represent on issues relating to their role and function within the organisation. They also provide a communication channel between each other and with the <u>Steering Group</u> [13] and its various sub- and advisory groups, and advise the Steering Group on all aspects relating to the executives' functions within Cochrane <u>entities</u> [20]. For the detailed remits of these executives, contact the appropriate representative on the Steering Group.

Subheadings in this section

1.1.2.9.1 Co-ordinating Editors' Executive - terms of reference

- 1. To provide advice and communicate the concerns of Co-ordinating Editors to the Editor in Chief;
- 2. To provide advice and support to the CCSG [23] representatives (both of whom will be members of this group);
- 3. If required, to make decisions between meetings, with an expectation of consulting the entire Board;
- 4. To provide advice to Co-ordinating Editors' Executive members who have cross membership with the CoEds-Methods Working Group and other advisory groups;
- 5. To communicate with members of the Co-ordinating Editors' Board on a regular basis, particularly on decisions that affect Co-ordinating Editors directly.



1.1.2.9.2 Managing Editors' Executive - remit

Purpose of the Managing Editors' Executive [This section was updated by the MEs' Executive and inserted into the Manual on 25 January 2011.]

The purpose of the MEs' Executive is to be a conduit for communication and information flow to and from the MEs, the Cochrane Collaboration Steering Group [13] (CCSG [23]) and the Editor in Chief (EiC).

Accountability and reporting

The MEs' Executive will be accountable to MEs as a whole.

- The MEs' Executive will report to all MEs on activities, with a written report presented at the MEs' Colloquium meeting and incorporated into the final minutes.
- The MEs' Executive will produce written reports or papers for the CCSG and other stakeholder groups as required.

Objectives

- To advise the CCSG via its ME representative on all aspects relating to the role and function of MEs in a timely and effective manner.
- To advise the EiC on all aspects relating to the function of MEs within the <u>Cochrane Review</u> [22] Groups (CRGs) in a timely and effective manner.
- To facilitate effective and timely communications between the MEs, Trials Search Co-ordinators (TSCs), the Co-ordinating Editors' Board and the EiC.
- To feed back any relevant decisions or discussions from the CCSG and its various subgroups and advisory groups, and from the EiC.
- To assist if necessary the filling of ME positions on The Cochrane Collaboration sub-groups and advisory committees and to ensure ME representation where none currently exists.
- To consult with and assist if necessary the CCSG and relevant sub-committees and advisory committees on the appointment of ME 'liaison' positions when any such positions arise, e.g. in the context [46] of special projects or the formation of temporary working committees.
- To plan and organise the MEs' meetings at annual Cochrane Colloquia.
- To assist with the planning and organising of regional and other MEs' meetings as appropriate.
- To consult MEs on issues relating to their role and function within the organisation.
- To identify collective MEs' concerns and issues and bring them forward to the appropriate arena.

Decision-making

- The MEs' Executive will aim to reach full consensus but where this is not possible decisions will be taken based on a majority vote. In the case of a tied vote, the CCSG ME representative Chair will have the deciding vote.
- For decisions to be taken at MEs' Executive meetings a quorum of more than half the membership of the MEs' Executive is necessary. For decisions to be taken by e-mail



correspondence, it is expected that all members of the MEs' Executive will vote but if this is not possible the above quorum stands.

Wherever possible decisions will be based on consultation with all MEs.

Meetings and communications

- At least one face-to-face meeting per year, which will generally be held at the annual Cochrane Colloquia; an additional meeting may be held at the CCSG mid-year meeting.
- E-mail discussion.
- Ad hoc telephone conferences when required.
- The MEs' Executive minutes will be accessible on Archie in the MEs' Forum.
- Minutes of meetings and conference calls will adhere to the following timeline: first draft to be circulated within two weeks and finalised within one month of the meeting date.

Membership of the MEs' Executive

- Membership will be on a voluntary basis. A general call for volunteers will initially be made via the MEs' discussion list (mes@lists.cochrane.org [47]) whenever there is a vacancy.
- MEs can nominate themselves or a colleague[1] [48] to be a member.
- Nominated MEs will prepare a short personal statement outlining why they are interested in the position and what they feel they would add to the Executive.
- In the event that more than one nomination is received for a vacancy the candidates will be discussed amongst the members of the Executive and the final decision will be made by the Co-Convenors.
- Volunteers will be expected to have the time to devote to the position, the skills required, and the trust of their colleagues.
- All terms will be for three years. To ensure continuity, recruitment of new members will be staggered to ensure no more than one-third of the Group is replaced in a given year. No limit is set on the number of terms that may be served, but reappointment is contingent upon the Chair's approval. The ME representative on the CCSG will rotate with the incumbent in the position.

Size, composition and representation

- The MEs' Executive is limited to eight people comprising the ME representative on the CCSG and seven other MEs. Ideally the MEs will reflect the diversity of CRGs, in particular the size of a CRG in terms of review portfolio, experience of the ME, and geographical region.
- There will be two Co-Convenors of the MEs' Executive who serve as Chairs the ME representative on the CCSG and another MEs' Executive member. The latter position will be rotational and will be appointed by the Chair who is the ME representative on the CCSG, after consultation with the MEs' Executive.

Responsibilities of MEs' Executive members

- To participate actively by e-mail, teleconference meetings, and if possible, face-to-face meetings at Cochrane Colloquia.
- To raise and respond to issues of importance to MEs via papers presented to the CCSG, its sub-groups and advisory groups, the Co-ordinating Editors' Board, the annual MEs' and joint



editorial meetings.

To take minutes on a rotating basis at the MEs' Executive meetings.

Responsibilities of MEs' Executive Co-Convenors

- To liaise on a regular basis to ensure issues of relevance to MEs are taken forward to the MEs' Executive in the first instance, and to determine how these should be managed (e.g. by e-mail, teleconference).
- To organise and collate feedback from members of the MEs' Executive on documents sent to the Co-convenors of the Exec or the full MEs' Executive from the EiC or other members of the Cochrane Editorial Unit [49].
- To agree and sign, whenever possible, messages sent to the MEs' Executive/MEs.
- Once agreed upon by the MEs' Executive/MEs, messages will be sent out with both signatures.

Communication

- To liaise with the Cochrane Editorial Unit by communicating with the EiC and copying information to the Programme Development Manager at the EiC's office.
- To ensure that ME representatives on Cochrane advisory groups and committees provide feedback to the MEs' Executive in a timely manner for consideration at MEs' Executive meetings (and teleconferences).
- To ensure appropriate communication through the MEs' mailing list and discussion forum.

[1] [50] Colleague refers to those who hold the post of Managing Editor, Assistant or Satellite Managing Editor across Cochrane Review Groups

1.1.2.9.3 Trials Search Co-ordinators' Executive - remit

(Updated by the TSCs' Executive - 11 February 2011)

Purpose of the Trials Search Co-ordinators' Executive

The purpose of the Trials Search Co-ordinators' (TSCs') Executive is to facilitate open communication between TSCs, the Cochrane Collaboration Steering Group [13] (CCSG [23]) and the Editor in Chief (EiC).

Objectives

To advise the CCSG and the EiC through its TSC representative on the CCSG on all aspects relating to the role and function of TSCs.

To consult TSCs on issues relating to their role and function within the organisation.

To provide an effective and timely communication channel between TSCs and Information Specialists, the CCSG, its various committees, the EiC, Managing Editors and Co-ordinating Editors. The TSCs' Executive will invite non-member TSCs (for example, TSC representatives on committees) to give specialist advice where appropriate.



To provide feedback to TSCs on any relevant decisions or discussion from the CCSG, its various committees and the EiC.

To ensure that TSCs are appropriately represented on CCSG committees.

To consult with the CCSG, its committees and the EiC on the appointment of TSC 'liaison' positions when any such positions arise, e.g. in the context of special projects or the formation of temporary working groups.

Accountability and reporting

The TSCs' Executive will:

be accountable to the CCSG through the TSC representative on the CCSG;

provide advice to the Cochrane Editorial Unit [49] (CEU);

be accountable to TSCs as a whole:

produce written reports or papers for CCSG meetings during Colloquia and mid-year meetings, and at other times as necessary;

provide a workplan each year, including for the agenda for its mid-year meetings, for which its members' attendance is funded by the CCSG; and

provide a summary of the outcomes of the TSCs' Executive's workplan; the content of this summary will form the basis of the TSCs' report for the Collaboration's Annual Report.

Membership

Membership will be on a voluntary basis. A general call to TSCs for volunteers will be made whenever there is a vacancy. Volunteers will be asked to submit a short paragraph (no more than 250 words) stating why they wish to join the TSCs' Executive and what skills, experience or qualities they would bring as a member.

TSCs can nominate themselves or colleagues to be a member.

The TSCs' Executive is limited to eight people: the TSC representative on the CCSG and seven other TSCs, one of whom will be the TSC representative on the Monitoring and Registration Committee (MaRC [30]). The TSC representative on the CCSG and the TSC representative on the MaRC will rotate with the incumbent in the position.

TSCs' Executive members serve for a period of three years. At the end of three years, members are eligible to volunteer for membership for another three years. No-one may be a member of the TSCs' Executive for more than two consecutive terms (i.e. six years), but may volunteer again after a subsequent gap of three years. An exemption to the above would occur in the case of a TSC who, having served on the TSCs' Executive for three or six years, was elected as the TSC representative on the Steering Group.

There will be two Co-Convenors of the TSCs' Executive: the TSC representative on the CCSG and another member of the TSCs' Executive. The latter position will be rotational and will be appointed by the Co-Convenor who is the TSC representative on the CCSG, after consultation with the TSCs' Executive.

Decision-making

The TSCs' Executive will aim to reach full consensus amongst its members, but where this is not possible decisions will be taken based on the majority vote. In the case of a tied vote the TSC CCSG representative Convenor will have the deciding vote.



For decisions to be taken at meetings a quorum of more than half the membership of the TSCs' Executive is necessary. For decisions to be taken by e-mail it is expected that all members of the TSCs' Executive will vote, but if this is not possible the above quorum stands.

Wherever possible decisions will be based on consultation with all TSCs.

Meetings and communications

Two face-to-face meetings each year, during the annual Colloquium and at the time of the CCSG mid-year meetings.

A dedicated e-mail discussion list (<u>tsc-exec@cochrane.org</u> [51]).

Telephone conferences when required.

Minutes of TSCs' Executive meetings will be accessible on Archie in the TSCs' Forum.

Responsibilities of TSCs' Executive members

To participate actively by email, teleconference meetings and, if possible, face to face meetings during Colloquia and mid-year meetings.

To attend a face-to-face meeting supported by funds from the CCSG during its mid-year meeting; those members who are part- or fully funded to attend this meeting will participate actively in the strategic session.

To co-ordinate meetings and workplans with other <u>CRG</u> [15] Executives (e.g. the Managing Editors' Executive and the Co-ordinating Editors' Executive) to ensure an appropriate level of joint work on goals and issues of common interest.

The TSCs' Executive will raise and respond to issues of importance to TSCs via papers presented to the CCSG and relevant committees. All members of the TSCs' Executive will be expected to draft papers for internal consultation and to provide timely feedback on such drafts.

Responsibility for minute-taking at teleconferences and face-to-face meetings will be shared on a rotating basis by all members of the TSCs' Executive.

1.2 Strategic Plan

In 1979, Archie Cochrane, a British physician, criticised the medical profession for not having established a system for producing up-to-date summaries of the results of reliable research about the effects of health care. The Cochrane Collaboration was founded in 1993 to respond to Cochrane's challenge, and evolved rapidly over the subsequent three years.

Building on this initial experience, The Cochrane Collaboration's <u>Steering Group</u> [13] developed a <u>Strategic Plan</u> [14] to guide The Cochrane Collaboration's evolution over the next five years, which was accepted at The Cochrane Collaboration's annual Colloquium in October 1996. This Plan, which guided The Cochrane Collaboration's evolution over the subsequent six years, was revised in the light of the evolving nature of the organisation. An updated version was prepared at the April 2002 meeting of the Cochrane Collaboration Steering Group, and all Cochrane <u>entities</u> [20] were involved in a wide consultation that ended in September 2002.



The new Strategic Plan was approved by the Cochrane Collaboration Steering Group in May 2003, and a list of its new features is appended to the minutes of the Steering Group meeting held in Melbourne, Australia, on 31 March 2003 (www.cochrane.org/ccsg/ccsgmeetings [52]).

All versions of the Strategic Plan, including the most recent of 2005, can be found on the <u>Collaboration's website</u> [53].
[53]

Subheadings in this section

1.2.1 Goals and objectives

- Goal 1: To ensure high <u>quality</u> [5] Cochrane systematic reviews available across a broad range of healthcare topics.
- Goal 2: To promote access to Cochrane reviews and the other products of The Cochrane Collaboration.
- Goal 3: To ensure an efficient, transparent organisational structure and management system for The Cochrane Collaboration.
- Goal 4: To achieve sustainability of The Cochrane Collaboration.

1.2.2 Activities

 $\textbf{GOAL 1: To ensure high } \underbrace{\textbf{quality}}_{\textbf{[5]}} \textbf{[5] Cochrane systematic} \quad \textbf{reviews are available across a broad range of healthcare topics.}$

ACTIVITY 1.1

To ensure high quality in Cochrane reviews by:

- 1.1.1 Producing, maintaining and keeping up to date a <u>handbook</u> [54] describing the methods to be used in producing systematic reviews based on current methodological evidence.
- 1.1.2 Ensuring that the standard of Cochrane reviews corresponds to guidelines about how to produce high quality up to date reviews contained in the *Cochrane Handbook [55] for Systematic Reviews of Interventions*.
- 1.1.3 Improving access to reports of studies (including non-English language reports and unpublished data).
- 1.1.4 Providing training and specific support to the preparation and maintenance of Cochrane reviews for authors, methodologists, managing editors, co-ordinating editors, editors, trials search co-ordinators, handsearchers, referees, consumers and others.
- 1.1.5 Ensuring effective mechanisms for broad consumer participation.
- 1.1.6 Ensuring Cochrane reviews are easy to understand.
- 1.1.7 Developing and implementing appropriate pre-publication refereeing mechanisms.
- 1.1.8 Developing, implementing and encouraging mechanisms for broad post-publication consultation including feedback.



- 1.1.9 Ensuring that Cochrane reviews are up-to-date.
- 1.1.10 Ensuring that Cochrane reviews are relevant to users including those from low- and middle-income countries
- 1.1.11 Ensuring potential conflicts of interest are disclosed.
- 1.1.12 Encouraging excellent methodological research to improve the science of systematic reviewing.
- 1.1.13 Ensuring the continuous improvement of software to help those preparing and maintaining Cochrane reviews.
- 1.1.14 Ensuring that all Cochrane <u>entities</u> [20] contribute to improving the quality of Cochrane reviews

ACTIVITY 1.2

To ensure broad coverage of healthcare topics in Cochrane reviews by:

- 1.2.1 Identifying, prioritising and filling gaps in the coverage of reviews across and within Cochrane Review Groups.
- 1.2.2 Sustaining the current <u>rate</u> [56] of growth in the number and breadth of Cochrane reviews.
- 1.2.3 Developing and implementing mechanisms to avoid unnecessary duplication of effort.
- 1.2.4 Developing mechanisms to expand low and middle income country participation in Cochrane reviews.

GOAL 2: To promote access to Cochrane reviews and the other products of The Cochrane Collaboration.

ACTIVITY 2.1

To ensure that Cochrane reviews are easy to understand by:

- 2.1.1 Identifying and responding to the needs of those using Cochrane reviews.
- 2.1.2 Enhancing editorial practices and standards.
- 2.1.3 Developing plain language summaries of Cochrane reviews.
- 2.1.4 Presenting Cochrane reviews in a range of languages.
- 2.1.5 Fostering education and training in understanding Cochrane reviews.

ACTIVITY 2.2

To improve retrieval of information from Cochrane databases by:

- 2.2.1 Ensuring the flexibility of searching and browsing.
- 2.2.2 Developing a range of modes and media of dissemination.
- 2.2.3 Exploring options to enhance accessibility of databases for people with special needs.
- 2.2.4 Improving mechanisms for reporting data and system errors and monitoring implementation of solutions by publisher and entities.

ACTIVITY 2.3



To ensure that Cochrane reviews are widely available by:

- 2.3.1 Creating excellent <u>distribution</u> [31].
- 2.3.2 Developing pricing options for The Cochrane Collaboration's products.
- 2.3.3 Ensuring cost is not a barrier to use.
- 2.3.4 Offering the outputs of The Cochrane Collaboration to different types of potential customers (including as components of specialised databases).

ACTIVITY 2.4

To ensure the work of The Cochrane Collaboration is promoted by:

- 2.4.1 Developing a marketing strategy for Cochrane reviews that includes promotion and public relations.
- 2.4.2 Enhancing the corporate identity of The Cochrane Collaboration by preparing appropriate materials for potential funders, users, and supporters.
- 2.4.3 Promoting The Cochrane Collaboration's name and logo as a trademark.
- 2.4.4 Identifying and responding to the requirements of users and potential users.
- 2.4.5 Raising awareness and demand within potential user groups including those communities for whom English is not the first language.

GOAL 3: To ensure an efficient, focussed transparent organizational structure and management system for The Cochrane Collaboration

ACTIVITY 3.1

To ensure that the organisational focus of The Cochrane Collaboration supports the core function of preparing, maintaining and promoting accessibility of Cochrane reviews by:

- 3.1.1 Requiring the <u>Steering Group</u> [13] to stay focused on the core function of preparing, maintaining and promoting accessibility of Cochrane reviews.
- 3.1.2 Requiring each entity to identify specific targets related to the preparation and maintenance of Cochrane reviews.
- 3.1.3 Monitoring the progress of each entity in achieving its targets and advising and supporting entities where targets are not met.
- 3.1.4 Reviewing the registration status of entities that consistently do not meet agreed targets.
- 3.1.5 Devising a satisfactory way of conducting the Annual General Meetings during Colloquia.

ACTIVITY 3.2

To ensure that all decision-making processes within The Cochrane Collaboration are transparent and explicit by:

- 3.2.1 Identifying and defining the relationships among the various entities and advisory groups within The Cochrane Collaboration.
- 3.2.2 Minimising the decisions that need to be made centrally by the Steering Group compared with those that can be made more efficiently at entity level.



- 3.2.3 Developing clear and open processes for taking forward new ideas.
- 3.2.4 Establishing clear lines of reporting between the entities, the Steering Group and its advisory groups.
- 3.2.5 Ensuring that entities adhere to the practices and policies of The Cochrane Collaboration.
- 3.2.6 Developing mechanisms to resolve conflicts within The Cochrane Collaboration.

ACTIVITY 3.3

To promote effective communication within The Cochrane Collaboration by:

- 3.3.1 Ensuring that the focus of the Cochrane Collaboration's <u>Secretariat</u> [1] is effective and efficient communication.
- 3.3.2 Enhancing usability of The Cochrane Collaboration's publications.
- 3.3.3 Preparing and making available documents describing key responsibilities of The Cochrane Collaboration's Secretariat staff, Steering Group members, the different roles of entity members and contact people within The Cochrane Collaboration.
- 3.3.4 Developing appropriate information management systems.
- 3.3.5 Establishing and maintaining an up-to-date, evidence-based, user-friendly website.
- 3.3.6 Ensuring accurate dissemination of information about The Cochrane Collaboration via CCInfo and Cochrane News.

ACTIVITY 3.4

To promote effective communication with people outside The Cochrane Collaboration by:

- 3.4.1 Ensuring that all decision-making processes and relationships between The Cochrane Collaboration and other organisations are transparent and explicit.
- 3.4.2 Requiring each entity to be responsible for external communication relating to its sphere of activity.
- 3.4.3 Encouraging each entity to collaborate with each other in promoting the work of The Cochrane Collaboration as a whole.
- 3.4.4 Maintaining the post of Chief Executive Officer.
- 3.4.5 Developing and implementing a strategy for establishing alliances with major international organisations.

GOAL 4: To achieve sustainability of The Cochrane Collaboration.

ACTIVITY 4.1

To ensure an adequate income stream for The Cochrane Collaboration by:

- 4.1.1 Developing the business management capacity of The Cochrane Collaboration.
- 4.1.2 Drawing up a management plan for the marketing and sales of the products of The Cochrane Collaboration in collaboration with its publishers.
- 4.1.3 Establishing efficient mechanisms for licensing and sales of Cochrane Collaboration products (including The *Cochrane Database of Systematic Reviews*, specialised sub-sets of it, The Cochrane Central Register of Controlled Trials (CENTRAL), The Cochrane Database of Methodology



Reviews and the Cochrane Methodology Register.

- 4.1.4 Setting performance targets and monitoring sales of Cochrane Collaboration products.
- 4.1.5 Approaching a range of agencies for longer term funding.
- 4.1.6 Continuing to develop the role of the <u>Funders' Forum</u> [57] to improve links with funders, potential funders and other important alliances.
- 4.1.7 Developing a sustainable funding model.

ACTIVITY 4.2

To develop a business plan for the central activities of The Cochrane Collaboration by:

- 4.2.1 Costing the central administrative services for The Cochrane Collaboration and its Steering Group, including the Secretariat, the *Cochrane Handbook for Systematic Reviews of Interventions*, other printed information, and training materials prepared on behalf of The Cochrane Collaboration.
- 4.2.2 Planning and budgeting for communication activities.
- 4.2.3 Planning and budgeting for training activities.
- 4.2.4 Developing a plan and budget for software development.
- 4.2.5 Developing a sustainable process for assembling and maintaining the Cochrane Central Register of Controlled Trials [58] (CENTRAL).
- 4.2.6 Developing a plan for the management of annual colloquia.

ACTIVITY 4.3

To recognise and support the efforts of individuals in The Cochrane Collaboration by:

- 4.3.1 Developing mechanisms to enhance training and career development.
- 4.3.2 Developing additional mechanisms to recognise excellent contributions by individuals and entities.
- 4.3.3 Ensuring that the preparation and maintenance of Cochrane reviews receives full academic recognition.
- 4.3.4 Developing mechanisms to foster and maintain enthusiasm for work within The Cochrane Collaboration.
- 4.3.5 Celebrating achievement at the annual Colloquium and other fora.
- 4.3.6 Evaluating and reviewing the <u>Strategic Plan</u> [14] every three years.

1.2.3 Proposed planning milestones

The following table was devised in 2002, outlining several proposed milestones for achieving the mission of The Cochrane Collaboration. It was established at that time that at least 10,000 comprehensive reviews would be required to provide broad coverage of most healthcare topics that had been subject to controlled trials (Mallett and Clarke, Proceedings of the 10th Cochrane



Colloquium, Stavanger 2002). A mature, devolved management structure and stable funding system are essential to achieving this. The next steps in the strategic planning process involved a) establishing short-term priorities, b) identifying measurable objectives, and c) identifying responsibilities for progress.

| Date (time) | Reviews | | | Organisation | |
|-----------------------|---|--|--|--------------|--|
| | Number | Quality [5] | Access | Structure | Sustainability |
| 2005 | 3,000 | Comprehensive copy editing procedures | Free at point of use (FPU) in low-income | | Model developed for sustainable core |
| (3 years) | (plus 2,000 protocols for reviews in | in place | countries. | structure | funding |
| | | Plain language summaries for all reviews | Reviews included in major clinical guidelines | | CEO developing |
| | | 80% of reviews up-to-date (updated within 2 years) | | CEO in post | central assistance with entity fundraising |
| 2010 (8 years) | 6,000 (plus 2,000 protocols for reviews in | procedures in place | Cost not a barrier to use (FPU in all countries) | | Stable, sustainable funding model (mixed income from sales, government |
| | preparation) | 90% of reviews up-to-date | Several derivative products | | agencies, Trust funds) |
| 2015 | 10,000 | As above | Multiple derivative products | As above | As above |
| (13 years) | (plus 1,000 protocols for reviews in preparation) | 100% of reviews up-to-date | | | |
| | | | | | |

Notes:

- Predicted growth of reviews assumes <1000 new reviews per year (similar to current growth).
- CEO refers to Chief Executive Officer, responsible for business functions, including funding.
- FPU indicates that access to reviews is free at the point of use.

1.3 Memorandum and Articles of Association

These documents can be obtained either from the office of The Cochrane Collaboration <u>Secretariat</u> [1] at <u>secretariat@cochrane.org</u> [2] or downloaded from the <u>Collaboration's website</u> [60]. [60]

1.4 Communication

Subheadings in this section

1.4.1 Websites



The Cochrane Collaboration's website is available at the following locations:

Worldwide www.cochrane.org [17]

Back-up server

failover.cochrane.org [61]

All Cochrane Centres, and most of the other <u>entities</u> [20], have their own website. These websites vary from hundreds of screens to sites consisting of one or two screens with a few links to other Cochrane sites. The Cochrane Collaboration website (<u>www.cochrane.org/contact</u> [62] should be checked for the most up-to-date list of site addresses, as they are subject to change from time to time.

The German Cochrane Centre is responsible for maintaining the organisation's website. An increasing number of Cochrane documents (for example, The Cochrane Collaboration's Memorandum and Articles of <u>Association</u> [24], its <u>Strategic Plan</u> [14], minutes of the meetings of its <u>Steering Group</u> [13], and the text of its introductory leaflets) are available on this site. Many pages include content that may be edited online by an individual or group accountable to the Publishing Policy Group (a sub-group of the Steering Group), and implemented by the German Cochrane Centre. This responsibility is for substantive changes in content (not for copy editing or adding standard items that have already been approved on a generic basis, such as entity newsletters).

John Wiley and Sons Limited offer The Cochrane Library [18] on the Internet on a subscription basis (www.thecochranelibrary.com [21]). Residents of Australia, Denmark, Finland, India, Ireland and the Island of Ireland, New Zealand, Norway, Poland, Sweden and the United Kingdom are now able to access The Cochrane Library for free, thanks to funding for a national provision (www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/AccessCochraneLibrary.html). See this site also for information on several low-income country initiatives. Canadian health professionals in academic or healthcare centres have free access in the provinces of New Brunswick, the Northwest Territories, Nova Scotia, Nunavut, Saskatchewan and Yukon. Also Wyoming in the United States has free access. There are also several special schemes providing free access to higher and further education institutions in the UK, to residents of Latin and Central America and the Caribbean (via BIREME), and a limited number of free registrations in South Africa.

1.4.2 FTP servers

FTP servers allow Cochrane <u>entities</u> [20] to make large files available for downloading by their members. For example, the UK FTP server allows uploads into an 'Uploads' directory (but without the right to delete). Uploaded files are automatically removed after 48 hours.

Server: <u>ftp.cochrane.c</u>

o.uk [63]

User: ftp

Password: Your email

address or ftp://ftp.cochra ne.co.uk [63]

1.4.3 Mailing lists

The Cochrane Collaboration's website provides details of all the unrestricted Cochrane mailing lists, and instructions on how to subscribe to them. Following are details of most of the Cochrane lists currently in existence, some of which are restricted to a specific group of people, who have to be added to the list by a 'list moderator', and some of which may be subscribed to directly:



Restricted membership

If you believe you should be added to/removed from one of these lists, please contact The Cochrane Collaboration Secretariat [1] (secretariat@cochrane.org [2]). Anyone in the organization may e-mail the following list(s), regardless of whether or not they are themselves subscribers. Many of these lists are moderated, i.e. messages to them are screened by a list 'moderator' to avoid junk and obscene e-mail reaching the list subscribers.

Cochrane list Mailing list address

Archie Development Advisory Committee (ADAC) _ [64]adac@lists.cochrane.org [65]

Centre Directors' Executive cdsexec@lists.cochrane.org [64]

Cochrane Centres (all staff) centres@lists.cochrane.org [66]

Cochrane Centre and Branch Directors cbds@lists.cochrane.org [67]

Cochrane Collaboration Steering Group [13] (ccsg@lists.cochrane.org [68]

CCSG [23])

Cochrane Register of Studies Project Board [69]crspb@lists.cochrane.org [70]

Colloquium Policy Advisory Committee (CPAC) cpac@lists.cochrane.org [69]

Consumer Network (worldwide) consumers@lists.cochrane.org [71]

Consumers' Executive consumersexec@lists.cochrane.org [72]

CRGs - Co-ordinating Editors (CoEds) coeds@lists.cochrane.org [73]

CRGs - Co-ordinating Editors' Executive coedsexec@lists.cochrane.org [74]

CRGs - Managing Editors (MEs) mes@lists.cochrane.org [75]

CRGs - Managing Editors' Executive mesexec@lists.cochrane.org [76]

Evidence Aid (formerly Tsunami Support) <u>EvidenceAid@lists.cochrane.org</u> [77]

Field contact people fields@lists.cochrane.org [78]

Fields' Executive fieldsexec@lists.cochrane.org [79]

Handbook [54] Editorial Advisory Panel heap@lists.cochrane.org [80]

(HEAP)

Information Services Operations Committee _ [81]isoc@lists.cochrane.org [81]

Information Services Strategy Committee issc@lists.cochrane.org [82]

Methods Group contact <u>methods-groups@lists.cochrane.org</u> [83] people

Methods Executive methods-exec@lists.cochrane.org [84]

Monitoring and Registration Committee (MaRC marc@lists.cochrane.org [85]

[30]



Operations and Finance Committee (OFC) ofc@lists.cochrane.org [86]

ReviewManager Advisory <u>rac@lists.cochrane.org</u> [87]

Committee (RAC)

Trials Search Co-ordinators (TSCs) <u>tscs@lists.cochrane.org</u> [88]

Trials Search Co-ordinators' Executive <u>tscs-exec@lists.cochrane.org</u> [89]

Websites Committee (WSC) _ [89]wcs@lists.cochrane.org [90]

The lists in bold typeface above are the 'entity lists': these are the addresses to be used when e-mailing the **main contact people** of all <u>entities</u> [20]. In addition, when relevant, messages to 'all entities' should be copied to the Co-ordinating Editors' list (<u>coeds@lists.cochrane.org</u> [73]), the Trials Search Co-ordinators' list (<u>tscs@lists.cochrane.org</u> [88]); also to the editor of CCInfo and Cochrane News (<u>cochrane@uottawa.ca</u> [91]).

Unrestricted membership

To find out how to subscribe to these lists, visit The Cochrane Collaboration website (www.cochrane.org/admin/maillist.htm [92]).

List address E-mail list address

AusInfo: People interested in The Cochrane

ausinfo@lists.cochrane.org [93]

Collaboration in Australasia and South-East Asia

CCInfo: People interested in The Cochrane ccinfo@lists.cochrane.org [94]

Collaboration (worldwide)

RevMan software users revman@lists.cochrane.org [95]

1.4.4 The Collaboration's Information Management System - Archie

The contact details (name, address, telephone and fax numbers, and e-mail address) of Cochrane entities [20] and individuals are held in The Cochrane Collaboration's Information Management System (IMS). Access is via the Internet (www.cochrane.org/archie [96]), and restricted mainly to the contact person of each Cochrane entity, each of whom is provided with a personal user name and password. The data for entities and their members are maintained by the entities themselves. Since Archie runs on a central server, all changes that are made are instantly available to other users.

Modules of all types of entity (not only those of <u>Cochrane Review</u> [22] Groups) are published in each issue of <u>The Cochrane Library</u> [18]. For this reason it is important for Super Users of Fields, Methods Groups and Centres to take responsibility for updating their entity's module at regular intervals (preferably quarterly, if there have been changes in personnel or other information since the previous issue of *The Cochrane Library*). This involves keeping the names of entity staff up to date, and also their declarations of interest (see section <u>1.5.2</u> [97] above); removing details of past events such as workshops; removing duplicate entries; and updating other information as necessary.

It is possible to export data from Archie for use in local systems, but all updating is done centrally.



The software has been developed and is maintained by the IMS team at the Nordic Cochrane Centre, who provide technical help and advice with updating entity modules. The table below indicates who has responsibility for managing the different types of data stored in Archie. Details of other responsibilities, such as user support or system management and backup, are not included here.

| People | Responsibilities | Questions about data should go to: |
|---|---|--|
| Individuals who do not have access to 'Archie' | keep their primary Cochrane entity informed about any changes to their contact details | Primary Cochrane entity |
| Standard users (individuals who have access and can edit their own contact details) | update their own contact details verify that entity affiliation is correct | Primary Cochrane entity |
| Entity administrators | update their own contact details update their entity's record (including its module, if a non-CRG [15]) update the entity's membership/role information update members' records (if primary), or notify relevant administrator (if not primary) respond to questions/requests from other entity administrators respond to questions/requests from entity members | Individuals in question, or other entity administrators |
| Data administrator ¹ (staff of the Collaboration Secretariat [1]) | tries to ensure that contact details of the contact people of all entities are available and up-to-date updates these contact details if necessary² directs questions/requests to the appropriate Entity | Particular individuals, Entity administrators, or System administrator |
| System administrator ¹ (staff of the IMS team at the Nordic Cochrane Centre) | has no data responsibilities performs imports and bulk editing tasks, and generates reports from the Database responds to questions/requests | n/a |

- 1. Data and System administrators may also independently be Entity administrators for specific entities.
- 2. The type and number of contact persons required will depend on the type of entity, and should be



agreed with the Cochrane Collaboration Secretariat.

1.4.5 Archie - Terms of use

1. Introduction

Individuals should be able to trust that their contact details are treated responsibly and are only shared between those who have a valid reason for accessing them. This is especially important in a time in which e-mail addresses are being traded as a commodity. Therefore, it should be understood that these terms of use are for protection purposes, and not meant to imply distrust.

2. Accounts are personal

Each user account must be used by one individual only. Any sharing or 'lending out' of logins and passwords is not allowed.

3. No bulk mailing

Archie should never be used to generate mass mailings. The Cochrane Collaboration has a series of voluntary e-mail lists that should be used whenever a large number of people need to be contacted.

4. No sharing with other parties

Individual users are not allowed to share data from Archie with parties outside The Cochrane Collaboration.

5. Actions are logged

The system can log all actions performed by users. The system administrators retain the right to conduct any analysis of the logs deemed necessary for security or optimisation purposes.

6. Sanctions

It is the responsibility of the system administrators to terminate immediately any user accounts that are used in violation of these terms. Any disputes over terminated accounts will be handled by the Cochrane Collaboration Secretariat [1].

1.4.6 Criteria for inclusion in Archie and/or access to the Entity Website Builder

The Cochrane Collaboration Secretariat [1] (secretariat@cochrane.org [2]) is responsible for dealing with requests for inclusion of new entities [20], special and temporary groups in Archie, for dealing with requests for access to the entity website module of the Collaboration's content management system (CMS), and for considering exceptions that do not meet the criteria below.

Requests from 'Possible' entities should be put forward by the Director of the relevant reference Cochrane <u>Centre</u> [34], in accordance with established practice. This does not apply to the Steering Group's advisory and working groups, which should be given an entry in Archie and/or access to the entity website module of the Collaboration's CMS on request.

A. Criteria for inclusion in Archie

- 1. The contact details of intending Cochrane entities that have held at least one exploratory meeting (attended by a member of the Monitoring and Registration Committee) should be included in Archie, should be labelled 'Possible', and their Super User(s) should have access to Archie.
- 2. The contact details of intending Cochrane entities that have not held at least one exploratory meeting (attended by a member of the Monitoring and Registration Committee) should not be



- included in Archie, and they should not have access to Archie.
- 3. Collaboration-wide working groups reporting to the Steering Group (such as the CENTRAL Vision Group, the Umbrella Reviews Working Group, the Updating Working Group, etc.) should be included in Archie in the 'Other' category, if they request it, and their Super User(s) should have access to Archie.

B. Criteria for access to the Entity Website Builder

- All Cochrane entities officially registered with The Cochrane Collaboration should be given access to the entity website module of the Collaboration's content management system (CMS) (web@cochrane.org [98]).
- 2. Collaboration-wide working groups reporting to the Steering Group (such as the CENTRAL Vision Group, the Umbrella Reviews Working Group, the Updating Working Group, etc.) should have access to the entity website module of the Collaboration's CMS if they request it.
- 3. 'Possible' Cochrane entities (i.e., groups of people who have held an exploratory meeting attended by a member of the Monitoring and Registration Committee) should have access to the entity website module of the Collaboration's CMS if they request it, so that they can prepare a website for use post-registration. The template for their site would contain a disclaimer stating that the site is 'in preparation' and that the group is not yet officially registered with The Cochrane Collaboration. The 'Possible' entity should not be given its final site address until after it has achieved official registration with The Cochrane Collaboration via the Monitoring and Registration Committee.
- 4. Any group of people not officially registered with The Cochrane Collaboration should not have access to the entity website module of the Collaboration's CMS, as the Cochrane logo is an integral feature of this software, and people would be misled into thinking that the group is officially part of The Cochrane Collaboration.
- 5. The Cochrane Collaboration Secretariat (secretariat@cochrane.org [2]) is responsible for considering exceptions that do not meet the above criteria, put forward by the Director of the relevant reference Cochrane Centre.

1.4.7 Newsletters

Cochrane News is the international newsletter of The Cochrane Collaboration. It is edited and produced several times a year by the Canadian Cochrane Centre [34], and distributed worldwide by the other Cochrane Centres. Deadlines for receipt of articles and information for each issue are publicised in the News. In addition, some Cochrane Review [22] Groups and other entities [20] produce their own newsletters as a means of communicating with their members. The Canadian Cochrane Centre puts current copies of Cochrane newsletters on The Cochrane Collaboration website: electronic copy of newsletters should be e-mailed to cochrane@uottawa.ca [91] in Word format (not HTML).

1.4.8 Guidelines for sending e-mail attachments

Modern computers can create and handle huge files, and the use of graphics and photo images boosts file size dramatically. This can cause problems when files are sent as e-mail attachments, especially for recipients with slow dial-up access.

Here are some guidelines for sending e-mail attachments:

- 1. Be aware of the size of the files you are sending. In Microsoft Windows you can check these details in 'Windows Explorer' or 'My Computer'.
- 2. As a very arbitrary guide, think twice before distributing files bigger than 1Mb via e-mail. For people who use a dial-up connection to collect their e-mail, an attachment of this size can take between five and ten minutes to download.



- 3. If a document is less than a page and consists of text where formatting is not overly important, copy it into the body of the e-mail message rather than sending it as an attachment. An MS Word document attachment containing only one word is about the same size as 3000 words of e-mail text. This will also reduce recipients' concerns about the virus risks associated with email attachments.
- 4. Only send very large attachments (over 1Mb) by previous arrangement with the intended recipient(s).
- 5. Consider using WinZip (or some equivalent) to compress large files before sending them. This can reduce the size of files by up to 80%, but make sure the recipient(s) can handle that format.
- 6. If you have large files to make available to a number of people, consider placing them on one of the Cochrane File Transfer Protocol [43] (FTP) servers; then you need only send people the details of the file name and how to access the server. The UK FTP server, for example, has an 'Uploads' directory that can be used for this purpose (ftp://ftp.cochrane.co.uk/uploads [99]). As well as dedicated FTP programs, web browsers such as Netscape and Internet Explorer can be used to send and retrieve such files.

1.4.9 Cross-cultural team working within The Cochrane Collaboration

The document by psychologist Michele Deeks (see www.cochrane.org/docs/crossculturalteamwork_000.doc [100]) reviews some of the key issues relating to international team working within The Cochrane Collaboration. It provides an insight into the challenges and benefits of this aspect of the Collaboration. Anyone who works with individuals from different cultural backgrounds, either in a face-to-face content.org/content/working, should find it useful. The aim of the document is to help members of the Collaboration to develop a better understanding of the factors that influence successful cross-cultural communication and international team working. It also provides guidelines on how to maximise effectiveness [101] when working in an international team.

1.5 Support

Subheadings in this section

1.5.1 Principles governing sources of support

It is a fundamental principle of The Cochrane Collaboration that the responsibility of finding the resources required should be shared. No single country has sufficient resources to sift through the daunting piles of accumulated evidence about the effects of health care that await synthesis in systematic, up-to-date reviews, and efficient international co-ordination of this task is essential. Support from a variety of organisations worldwide is both essential and to be expected.

The Cochrane Centres share the responsibility for seeking resources to co-ordinate and support The Cochrane Collaboration; co-ordinating editors must seek the resources to co-ordinate Cochrane Review [22] Groups, prepare edited modules of reviews, and compile specialised databases; authors must find resources to prepare and maintain systematic reviews; Field Co-ordinators and Convenors of Methods Groups must also find the resources they require.

1.5.2 Declarations of interest

Managing conflicts of interest on the Steering Group [13]



Steering Group members are asked at the beginning of Steering Group meetings to identify whether they have any conflicts of interest specific to Steering Group agenda items. When a Steering Group member discloses a conflict of interest relevant to a decision that is on the agenda of a Steering Group meeting, that member should excuse him/herself from the part of the meeting during which the decision is made; however, the conflicted member may be present during discussion of the relevant item. For example, if the Steering Group is making a decision about funding an entity to do a specific task, and a Steering Group member is a member of that entity, then that Steering Group member has a conflict of interest. The conflicted Steering Group member may be present and contribute to the discussion of the proposal, but must leave the room when the final decision is made. Managing conflicts of interest is the responsibility of the entire Steering Group, under the guidance of the Co-Chairs. All Steering Group members are expected to disclose potential conflicts, and any Steering Group member may raise a concern about a conflict of interest.

In April 2005, the Steering Group approved the following template for making their declarations of interest, both before each of their face-to-face meetings and also in their module [102] which is published quarterly in The Cochrane Library [18]. A year later, the Steering Group agreed that the following people should also be required to publish declarations of interest in their module: editorial base [103] staff and editors of CRGs; Convenors, Co-Convenors and administrative staff of Methods Groups; Directors, Convenors, Co-ordinators and Administrators of Fields; and the staff of Centres and Centre Branches who are involved in the review [29] process (Directors, scientific staff, administrative staff, and Trials Search Co-ordinators/ Information Specialists). The Steering Group clarified at its meeting in April 2007 that it should be at the discretion of individual Centre Directors as to whether declarations of interest should be made by non-director scientific staff; the Group agreed that it was unnecessary for administrative staff to make such declarations.

The template is intended to capture any secondary interest that would conflict with the primary interest of conducting an unbiased review:

Template for structured declarations of interest

What is a 'conflict' of interest? A conflict of interest exists when a secondary interest (e.g. personal financial gain) can influence, or have the appearance of influencing, judgements regarding the primary interest (e.g. service on the Cochrane Collaboration Steering Group). Steering Group members and others (see above) are asked to disclose all relationships with commercial organisations that could pose a conflict of interest that would reasonably appear to be related to the primary interest. The term 'related organisation' below means any organisation related to health care or medical research. These declarations of interest are updated regularly.

A. Financial interests

In the last five years, have you:

- 1. Received research funding: any grant, contract or gift, commissioned research, or fellowship from a related organisation to conduct research? If yes, list.
- 2. Had paid consultancies: any paid work, consulting fees (in cash or kind) for an organisation? If yes, list.
- 3. Received honoraria: one-time payments (in cash or kind) from a related organisation? If yes, list.
- 4. Served as a director, officer, partner, trustee, employee or held a position of management with a related organisation? If yes, list.
- 5. Possessed share-holdings, stock, stock options, equity with a related organisation (excludes mutual funds or similar arrangements where the individual has no <u>control</u> [59] over the selection of the shares)? If yes, list.
- 6. Received personal gifts from a related organisation? If yes, list.
- 7. Had an outstanding loan with a related organisation? If yes, list.
- 8. Received royalty payments from a related organisation? If yes, list.

B. Non-financial interests

Do you have any other competing interests that could pose a conflict of interest that would reasonably appear to be related to the primary interest? If yes, explain.

1.5.3 Discretionary Fund

In October 2000 the Cochrane Collaboration <u>Steering Group</u> [13] decided to allocate monies to set up a small discretionary fund. This was initially limited to a total expenditure of £10,000 per year, with a ceiling of £2000 to any one applicant; the total expenditure was raised to £15,000 per year, with a ceiling of £3000 to any one applicant, in October 2003. At its meeting in April 2009, <u>the Steering</u>



Group agreed to raise the limit on any one application from £3000 to £5000, keeping the overall limit at £15,000 per annum. Members of The Cochrane Collaboration are eligible to apply for small amounts of funds to facilitate important activities within the organisation. Applications will only be accepted from the person or people responsible for a particular registered entity, and Convenors of the Steering Group's advisory committees. The following criteria will guide the Steering Group's decision as to whether or not to approve an application:

- 1. Focus on 'core' functions The proposal should: (a) focus on core functions of Collaboration activity, particularly the production, maintenance and dissemination of high <u>quality</u> [5] reviews, and (b) be made by a Cochrane entity. (Advisory committees to the Steering Group may also apply to this Fund.)
- 2. Gain to the Collaboration The proposal should promise significant gain to all or part of the Collaboration.
- 3. Collective benefit The potential benefit of the proposal should not focus on a single entity but apply across a number of <u>entities</u> [20] (for example, by co-ordinating activities).
- 4. Likelihood of success The proposal should have a high likelihood of meeting its aims within the agreed budget.
- 5. Alternative sources of funding The proposal should not have an obvious and readily accessible alternative source of funding available.
- 6. Cost of not funding There should be judged to be a significant loss of advantage to the Collaboration if the proposal is not funded.
- 7. Long-term continuity Because discretionary funds will not be available on a recurrent basis, there should be some plan for continuity of funding and support if this will be necessary.

It is accepted that applications will rarely meet all these criteria; however, applicants are asked to consider all seven criteria when applying, and to use the criteria as the paragraph headings in their application.

Applications

- A brief application for funding should be sent to the Cochrane Collaboration <u>Secretariat</u> [1] (<u>secretariat@cochrane.org</u> [2]), using the seven criteria listed above as the paragraph headings, to ensure completeness and consistency across all applications. The application should include details of the timeline and a description of the deliverables. The Secretariat is responsible for forwarding applications to the Steering Group.
- 2. Applications should state clearly the amount of money being requested.
- 3. The Operations and Finance Committee will take the final decision, requesting additional information from the applicant(s) as necessary.
- 4. Successful applicant(s) will be required to provide a report of a maximum of 500 words to The



Cochrane Collaboration Secretariat (<u>secretariat@cochrane.org</u> [2]) within three months of spending their award. This report will be shared with the Steering Group and might be made available to other people if judged appropriate by the Steering Group.

5. Patterns of application and expenditure will be reported to the Steering Group every six months.

Cochrane Collaboration Discretionary Fund Expenditure to date [21 February 2011]

| Date | Amount | Entity | Purpose of application |
|-----------------|---------|---|--|
| June 2010 | £2939 | Cochrane Eyes and Vision Group | Development of a guide for authors on involving consumers in Cochrane Reviews |
| September 2010 | £5000 | Non-Randomised Studies Methods Group | Travel costs to Ottawa for workshop leaders on including non-randomised studies in systematic reviews |
| February 2011 | £3000 | Comparing Multiple Interventions Methods Group | Travel costs to Milan of several meeting participants, 12-14 March 2011, to address the handling of multiple interventions in Cochrane reviews |
| 2010-11 to date | £10,939 | | |
| August 2009 | £2058 | Australasian Cochrane Centre [34] | Summaries on the management of burns |
| August 2009 | £2346 | Travel expenses of trainers (P Bossuyt, P Macaskill and T Stijnen) + conference calls | Trainers on DTA reviews course, University of Birmingham, UK |
| November 2009 | £3000 | Bec Hanley | External review of the Cochrane Consumer Network (<u>CCNet</u> [12]) |
| Total (2009/10) | £7404 | | |
| November 2008 | £400 | UK Cochrane Centre (Thomas Clarke) | Analysis of content of Cochrane Central Register of Controlled Trials, by <u>CRG</u> [15] specialized register |



| Total (2008/09) | £400 | | |
|-----------------|---------|--|---|
| April 2007 | £586 | Colloquium Policy Advisory Group (Jonathan Ipser) | Putting Colloquium abstracts onto Collaboration website |
| December 2007 | £2934 | Nigerian Effective Health Care Alliance | Nigerian Consumer Network meeting |
| February 2008 | £144 | Colloquium Policy Advisory Group (Jonathan Ipser) | Completing putting Colloquium abstracts onto Collaboration website |
| Total (2007/08) | £3664 | | |
| October 2006 | £2590 | South African Cochrane Centre | Joint project with Cochrane Consumer Network |
| December 2006 | £3088 | Consumers and Communication Group | PCE editorial board |
| February 2007 | £3049 | South African Cochrane Centre | Exploratory meeting to establish an African Cochrane Network |
| March 2007 | £3039 | Chinese Cochrane Centre | Traditional Chinese Medicine project |
| Total (2006/07) | £11,766 | | |
| September 2005 | £2503 | The entities of the following Managing Editors: June Cody, Jane Cracknell, Tina Leonard, Ruth Mitchell, Megan Prictor, Narelle Willis | CRG Procedures Collection Working Party (for provision of 'good practice' examples of editorial process [45]) |
| November 2005 | £1355 | South African Cochrane Centre | Evaluation of the HIV/AIDS Mentoring Programme |
| November 2005 | £3070 | Acute Respiratory Infections Group | Updating the evidence on interventions for avian 'flu |
| November 2005 | £500 | UK Cochrane Centre | Research project on 'Implications for research' in Cochrane reviews |
| January 2006 | £596 | Colloquium Policy Advisory Group (Jonathan Ipser) | Pilot project to make Colloquium presentations available |



| | | | on the Collaboration website |
|----------------------------------|---------|---|--|
| March 2006 | £425 | South African Cochrane Centre | Additional funds for evaluation of the HIV/AIDS Mentoring Programme. (Note: Only applied for £1355 initially.) |
| March 2006 | £3000 | Statistical Methods Group | Dissemination of statistical and methodological expertise to individuals and entities in South and Central America and South Asia |
| March 2006 (claimed in May/June) | £2394 | Co-ordinating Editors' executive | Strategic planning session on prioritisation, Khon Kaen, April 2006 |
| March 2006 | £1520 | Argentinean branch of Iberoamerican Cochrane Centre | Global meeting to discuss free access to The Cochrane Library [18] in Latin America |
| Total (2005/06) | £15,363 | | |
| September 2004 | £3019 | Christian Medical College, Vellore | Exploratory meeting to establish a South Asian Cochrane Network in India |
| Total (2004/05) | £3019 | | |
| September 2003 | £633 | Consumer Network | Contribution towards legal fees |
| February 2004 | £1520 | Acute Respiratory Infections Group | Dr Sreekumaran Nair's attendance at Statistics and Meta-Analysis [104] in Cochrane reviews course, Melbourne, and visit to ARI Group's editorial base [103], Brisbane |
| March 2004 | £1056 | Canadian Cochrane Centre and Network | France Légaré's expenses to attend the French-speaking network meeting in Paris, France |
| Total (2003/04) | £3209 | | |
| April 2002 | £750 | Nordic Cochrane Centre | Testing of RevMan Analyses software by the University of Liverpool |



| June 2002 | £2000 | Cancer Network | Legal fees to establish 'AidCancer' |
|-----------------|-------|-----------------------------------|--|
| February 2003 | £1339 | Consumer Network | Laptop computer and mailing to all CN members |
| March 2003 | £2000 | Pregnancy and Childbirth Group | Evaluation of the work of the Pregnancy and Childbirth Group Consumer Panel |
| Total (2002/03) | £6089 | | |
| May 2001 | £1000 | Statistical Methods Group | Statistical Issues course, Oxford, July 2001 (2 nd instalment) |
| July 2001 | £744 | French Cochrane Centre | Françoise Martin's work for the Lyon Colloquium |
| Total (2001/02) | £1744 | | |
| November 2000 | £2060 | Nordic Cochrane Centre | Printing RevMan 4.1 |
| March 2001 | £1000 | Statistical Methods Group | Statistical Issues course, Oxford, July 2001 (1 st instalment) |
| Total (2000/01) | £3060 | | |

NOTE: This table shows the total costs to the Collaboration, including bank charges on international transfers of funds.

2. COCHRANE COLLABORATION POLICIES

Subheadings in this section

2.1 General policies

Subheadings in this section

2.1.1 Code of conduct for avoiding potential financial conflicts of interest

Subheadings in this section

2.1.1.1 General principle

The essential activity of The Cochrane Collaboration is co-ordinating the preparation and maintenance of systematic reviews of the effects of healthcare interventions performed according



to procedures specified by The Cochrane Collaboration. The performance of the review must be free of any real or perceived <u>bias</u> [6] introduced by receipt of any benefit in cash or kind, any hospitality, or any subsidy derived from any source that may have or be perceived to have an interest in the <u>outcome</u> [105] of the review. All <u>entities</u> [20] that constitute The Cochrane Collaboration must accept this general principle as a condition of participation in the organisation.

2.1.1.2 Policy

- 1. Receipt of benefits from any source of sponsored research must be acknowledged and conflicts of interest must be disclosed in the *Cochrane Database of Systematic Reviews* and other publications that emanate from The Cochrane Collaboration.
- 2. If an author is involved in a trial included in his/her review, this must be acknowledged, as it could be perceived as a potential conflict of interest.
- 3. If a proposal raises a question of serious conflict of interest, this should be forwarded to the local Cochrane Centre [34] for review (and the Steering Group [13] notified accordingly). If the issue involves a Cochrane Centre, the issue should be referred to the Steering Group.
- 4. It is not mandatory to send funding proposals to the local Cochrane Centre or Steering Group before accepting them. However, such reviews would be desirable in cases of restricted donations, or any donation that appears to conflict with the general principle. Any funding that may be in conflict with The Cochrane Collaboration's policy on commercial sponsorship (see section 2.3 [106]) should be reviewed by the <u>Funding Arbiter</u> [38] (see section 1.1.2.4 [107]).
- 5. The Steering Group (via the Monitoring and Registration Committee) should receive (and review at least annually) information about all external funds accepted by Cochrane entities [20]. All such funds should comply with The Cochrane Collaboration's policy on commercial sponsorship (see section 2.3 [106]).

2.1.2 Avoidance of conflict of interest in reimbursing Steering Group expenses

The following policy was discussed by the Cochrane Collaboration Steering Group [13] at their meeting by teleconference on 9 July 2001, and ratified at their meeting on 8 October 2001:

- 1. Steering Group members are eligible for financial assistance with travel and accommodation expenses to attend Steering Group meetings, providing that such expenses are not normally funded as part of their regular duties.
- 2. The Cochrane Collaboration is a charity and all expenses incurred must be transparent (supported by receipts) and easily justifiable (if necessary to the Annual General Meeting).
- 3. Steering Group members should expect to be eligible for sufficient financial assistance to cover a standard economy airfare (or equivalent travel expense). Any significant departure from this principle should be cleared in advance with the <u>Secretariat</u> [1].
- 4. Steering Group members should expect to be eligible for sufficient financial assistance to cover reasonable accommodation and subsistence expenses (i.e. consistent with the successful completion of their Steering Group business).
- 5. The Secretariat Administrator can pay travel agents directly, on behalf of Steering Group members, and can also reimburse travel costs in advance, on request, to those Steering Group members without an institutional base

Clarification added in March 2004: Expenses incurred in attending a seminar/conference arranged in conjunction with a Steering Group meeting, either mid-year or during the Colloquium, should be met from Collaboration funds. This means accommodation costs, transport costs (train/bus/taxi fares) and living expenses (meals). The accommodation costs of all nights during the annual Cochrane



Colloquium should be met from central funds, not just the days when there are Steering Group meetings. Extra hotel accommodation in order to attend a meeting during the Colloquium which causes a Steering Group member to stay an extra night should also be met from central funds.

2.1.3 Criteria for choosing venues for Steering Group and Centre Directors' meetings

Since all Cochrane Centres have hosted a mid-year meeting of the <u>Steering Group</u> [13] and the Centre Directors, or have hosted (or agreed to host) a Colloquium, the Steering Group agreed at its 2002 meeting in Stavanger, Norway, on the following criteria for choosing the location (i.e. the city) and the venue (i.e. the hotel and meeting rooms) for the mid-year meetings of the Steering Group and the Centre Directors:

- **1. Benefit to the proposed host**: The host should provide information on the expected benefit to them and to Cochrane Collaboration activity in their country. Hosts in countries where The Cochrane Collaboration currently has a lower profile than desirable should be encouraged.
- **2. Convenience of travel**: The location of the meetings should be within two hours' travelling time of an international airport.
- **3. Cost of travel**: This includes the cost to The Cochrane Collaboration of travel by the Steering Group, and of people asked to make a special journey to attend the Steering Group meeting, and the cost to individual Cochrane Centres for their Director(s).
- **4. Cost of accommodation**: The accommodation provided should be consistent with the rules agreed by the Steering Group in relation to expenditure on subsistence (see section <u>2.1.2</u> [35]).
- **5. Cost of meeting facilities**: This needs to be considered if the host cannot cover the costs of the meeting facilities, or if the meeting is organised and funded by The Cochane Collaboration centrally.
- **6. Reliable e-mail access**: It is important for the host to have reliable e-mail access, to facilitate making arrangements for, and communicating about, these meetings.

2.1.4 Cochrane Colloquia

Subheadings in this section

2.1.4.1 Standard operating procedures for Cochrane Colloquia

A document describing the Collaboration's annual conferences (Colloquia) is available at www.cochrane.org/colloquia/cpag/ [108]. This document contains advice for people both organising and attending Colloquia. Any suggestions for amendments to this document should be sent to the Co-Convenors of the Colloquium Policy Advisory Committee, Steve McDonald (steve.mcdonald@med.monash.edu.au [109]) and Jordi Pardo (jpardo@santpau.es [110]).

2.1.4.2 General criteria for Cochrane Colloquia sponsorships

[The Steering Group [13] approved this revised policy on 22 October 2006.]

<u>Context</u> [46]

This policy document was first drafted by the Colloquium Policy Advisory Committee (CPAC) and



approved by the Cochrane Collaboration Steering Group in 2003. The policy was updated in 2005-06 in light of The Cochrane Collaboration's general policy on commercial sponsorship, which had been tightened up in 2004. The impetus for revising the Collaboration's sponsorship policy had been "to provide still greater reassurance that the conclusions of Cochrane reviews were not biased through the influence of funding by commercial entities [20] that stood to benefit financially from the results of reviews". The tightened up policy was also designed to safeguard the Collaboration's carefully nourished reputation for impartiality and scientific rigour.

In 2005, the Steering Group asked the CPAC to reassess the policy on sponsorship for Cochrane Colloquia in light of the updated general policy on commercial sponsorship. (The existing policy permitted commercial sponsorship of Colloquia in limited circumstances.) The CPAC debated the issues and put forward recommendations to the Steering Group, including the option to prohibit commercial sponsorship.

At its meeting in Khon Kaen in April 2006, the Steering Group considered the CPAC's revised policy and noted that "to amend the policy on sponsorship of Colloquia in line with the Collaboration's overall policy on commercial sponsorship did not necessarily mean [111] a blanket ban on commercial sponsorship, as the Collaboration's policy did allow commercial sponsorship under some circumstances (e.g. via donations to the Foundation Fund, and funding of Methods Groups)." [minute item 21.2]

In light of these sentiments, the CPAC has once more considered the policy on sponsorship of Colloquia. The following policy does not therefore recommend a ban on commercial sponsorship, but seeks to make explicit the circumstances under which all forms of sponsorship, whether from public or commercial sources, are permitted.

Background

Cochrane Colloquia are the annual scientific and business meetings of The Cochrane Collaboration. The scientific and academic content of Colloquia, as well as their organisation and philosophy, must be consistent with the general principles of the Collaboration. In particular, when planning a Colloquium the principles of independence, transparency, promotion of worldwide access and encouragement of diversity must be kept in mind.

Previous Colloquia have had a diversity of funding sources, depending on local needs and opportunities. Sponsorship has largely come from public sources (e.g. government and other public sector agencies), although commercial sponsorship, including from pharmaceutical companies, has been used by some Colloquium organisers.

Although the local autonomy of Colloquium organisers must be preserved (since they bear the enormous financial risks associated with the organisation of such events), it is useful to have general criteria for sponsorship that provide clear guidance for the circumstances under which all forms of sponsorship, whether from public or commercial sources, are permitted.

Sponsorship criteria

As a guiding principle, commercial sponsors (as defined in the Collaboration's general policy on commercial sponsorship) should be approached only after other avenues for sponsorship (e.g. governments and other public sector agencies) have been exhausted.

Generic sponsorship

Generic sponsorship, in which sponsorship from several sources is pooled to increase the overall income of the Colloquium, is preferred because sponsorship is not linked to any specific event or activity but rather to the Colloquium as a whole. As well as being easier to manage, potential conflicts of interest that may arise from having single sponsors for particular activities are more likely to be avoided. Generic sponsors can be acknowledged by name in the list of sponsors in the Colloquium programme. Under this model, commercial sponsorship is permitted since it is not tied to specific sessions or events.



Targeted sponsorship

Some organisations, however, may be reluctant to be grouped with others, especially if their financial contribution is greater, or if sponsorship is only feasible if it is directly tied to an event or activity (e.g. pre-Colloquium symposium, plenary session or social event). If this is the case the following guidelines apply:

6.1 Scientific sessions

Sponsorship of scientific sessions is only permitted by non-commercial, public sector or not-for-profit agencies (e.g. governments, other public sector agencies, charities, etc.) and by commercial organisations that do not come under the Collaboration's definition of a commercial source. Furthermore, the content of all scientific sessions must be at the sole discretion of the Scientific Committee and no sponsor should have any decisive influence over the content.

Commercial sources (as defined in the Collaboration's general policy on commercial sponsorship) are not permitted to sponsor any scientific sessions.

6.2 Social events and general services

Sponsorship of social events and the provision of general services (e.g. translation, printing) is permitted from both commercial and non-commercial sources.

6.3 Satellite events

All satellite events that occur outside the main Colloquium programme but which come under the control [59] of Colloquium organisers are subject to the same policies as outlined in sections (i) and (ii) above. This includes events that are advertised through the Colloquium website; events that appear on the Colloquium registration form; and events that are notified to Colloquium participants through bulk emails.

Advertisements in the Colloquium programme

Commercial organisations (i.e. those that come under the commercial sponsorship definition) are not permitted to advertise in the Colloquium programme. Other commercial organisations (e.g. publishers, software companies) and non-commercial or public sector agencies are permitted to advertise.

Sponsors, whether commercial or non-commercial, should be listed under 'Sponsors' in the Colloquium programme and may have the organisation's logo displayed alongside. The nature of the sponsorship (i.e. what the sponsorship has been used for) should be made clear (see Melbourne Colloquium programme, below).

Satchel inserts and gifts

Commercial organisations (i.e. those that come under the commercial sponsorship definition) are not permitted to provide or distribute pens, notepads, flyers or other gifts in delegate satchels.

Exhibits

Commercial organisations (i.e. those that come under the commercial sponsorship definition) are not permitted to exhibit as part of any Colloquium exhibition, or to distribute free gifts.

Non-commercial, public sector or not-for-profit agencies and other commercial organisations (e.g. publishers, software companies) may exhibit, provided the following restrictions are applied:

• €Publishers and educational companies whose products are of direct educational interest (i.e. they are not healthcare products or technologies) are permitted to promote their products at their stands, provided these are of direct relevance to the Colloquium (i.e. related to evidence-based health care).



 Organisations that have exhibits at the Colloquium may publish details in the programme about their stands that inform delegates about the activities of the company in the field of evidence-based health care and education only, and should not directly advertise healthcare products or technologies.

Compliance with this policy is the direct responsibility of Colloquium organisers. Organisers should work together with their Colloquium Advisory Board and/or Scientific Committee to make sure that the best decisions are made within the policies specified above. The Colloquium Policy Advisory Committee should be consulted when clarification is required.

Steve McDonald and Claire Glenton

Co-Convenors of the CPAC in August 2006

Excerpt from Melbourne Colloquium 2005 programme



2.1.4.3 Process for selecting the location of Cochrane Colloquia

Background

Annual Cochrane Colloquia are held to promote and develop the work of The Cochrane Collaboration and to help shape its future direction. A list of previous and future Cochrane Colloquia can be found at http://www.cochrane.org/colloquia/ [112].

From the very first Cochrane Colloquium in 1993, the Collaboration has relied on the enthusiasm and commitment of various Cochrane Centres and Branches to take on the responsibility of hosting and organising its annual scientific and business meeting.

In October 2006, on the advice of the Colloquium Policy Advisory Committee (CPAC), The Cochrane Collaboration Steering Group [13] implemented a selection process for determining the location of future Colloquia. This new process replaced a largely ad hoc process which didn't account for dealing with competing offers.

Proposals

A Cochrane Centre or Branch wishing to host a Colloquium is required to complete a proposal form (http://www.cochrane.org/colloquia/cpag/ProposaltohostColloquium.doc [113]). The purpose of the form is to help in the selection of future Colloquia by setting criteria for assessing proposals and to ensure there is a balance over time with respect to international locations.

Additionally, by completing the short proposal form, potential Colloquium organisers will be made



aware of the main practical issues to be addressed when thinking about organising a Colloquium, and be directed to the existence of relevant Colloquium guidelines and policies.

Potential organisers should read the document prepared by the CPAC, 'A comparison of models for Cochrane Colloquia', available from the Cochrane website at http://www.cochrane.org/colloquia/cpag/ [108]. Reports of previous Colloquia are available on request from the Co-Convenors of the CPAC who can also be contacted for help or guidance on completing the form.

Timelines and assessment of proposals

A call for proposals to host Cochrane Colloquia is made in June each—year for the Colloquium to be held in three years' time. For example, the call for proposals to host the 2013 Colloquium will be made in June—2010. The CPAC is responsible for assessing proposals, clarifying any—issues or uncertainties with the potential organisers, and making a recommendation—to the Steering Group for consideration at its October meeting.

Centres or Branches tentatively considering hosting the Colloquium are encouraged to notify their intention to the CPAC Co-Convenors informally at the earliest opportunity.

Link to form: http://www.cochrane.org/colloquia/cpag/ProposaltohostColloquium.doc [113]

2.1.5 Registering surveys with the Secretariat

(that are being sent to Cochrane mailing lists)

A <u>survey</u> [114] constitutes a set of questions posted to a Collaboration mailing list by someone who is not a member of that list in order to collect statistical or other information. A survey can be:

- Core or non-core Cochrane business (e.g. the 2006 review [29] of the Steering Group [13] would be classified as core Cochrane business, while a survey about travel arrangements to Cochrane Colloquia is non-core business); and
- Internal (i.e. from a member of a Cochrane entity) or external (i.e. not from a member of a Cochrane entity).

Questions posted to a Collaboration mailing list by a member of that list do not constitute a survey, and fall outside this process (including those to the Cochrane Consumer Network list by members of that list).

Brief details of all surveys conducted since the beginning of 2006 are documented (at www.cochrane.org/ccsg/qag/SurveyList [115]). People planning to conduct surveys are encouraged to check this list to ensure the information has not been obtained by a previous survey.

Core information for surveys and covering e-mails

Surveys, and their covering e-mails, must contain the following core information:

- Survey title.
- Who the survey is from.
- Why the survey is needed.
- The benefit of the survey to The Cochrane Collaboration.
- What the results will be used for.
- How and when the results will be disseminated.
- Whether or not the respondents will be de-identified.
- The statements:



"Responding to this survey is entirely optional." and

"The Cochrane Collaboration Secretariat [1] has been notified of this survey, according to the policy laid out in *The Cochrane Policy Manual*, but neither the Secretariat nor the Steering Group take responsibility for the survey's content."

The surveys should also be web-based where possible, so that the cover e-mail need only include the internet link and core information.

- The Administrator of the Cochrane Collaboration Secretariat (secretariat@cochrane.org [2]) should be notified in advance about the intention to conduct a survey. This notification should include the survey title, intended survey date, target mailing lists, and the survey's cover e-mail. If someone sends a survey directly to one of The Cochrane Collaboration's entity lists without notifying the Secretariat, the Secretariat will send a follow-up [116] message to that list, advising them of this fact. Once someone has notified the Secretariat that they intend to conduct a survey of members of The Cochrane Collaboration, the [117] fact that the Secretariat has been notified should be indicated clearly on the survey itself.
- Surveys should only be sent to official Collaboration mailing lists and not to individuals accessed through The Cochrane Collaboration's Information Management System (Archie).
- The person or group conducting the survey is responsible for ensuring that the survey does not contain offensive or inappropriate language.
- Completion of surveys is not compulsory, and surveys should clearly indicate this.
- Dissemination of surveys should not coincide with a <u>module</u> [102] (publication) deadline (see
 - www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/SubmissionDeadlines.html).

Policy

- The Administrator of the Cochrane Collaboration Secretariat (secretariat@cochrane.org [2]) should be notified in advance about the intention to conduct a survey. This notification should include the survey title, intended survey date, target mailing lists, and the survey's cover e-mail. If someone sends a survey directly to one of The Cochrane Collaboration's entity lists without notifying the Secretariat, the Secretariat will send a follow-up [118] message to that list, advising them of this fact. Once someone has notified the Secretariat that they intend to conduct a survey of members of The Cochrane Collaboration, the [119] fact that the Secretariat has been notified should be indicated clearly on the survey itself.
- Surveys should only be sent to official Collaboration mailing lists and not to individuals accessed through The Cochrane Collaboration's Information Management System (Archie).
- The person or group conducting the survey is responsible for ensuring that the survey does not contain offensive or inappropriate language.
- Completion of surveys is not compulsory, and surveys should clearly indicate this.
- Dissemination of surveys should not coincide with a <u>module</u> [120] (publication) deadline (see www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/SubmissionDeadlines.html).

2.1.6 Country names in Cochrane publications

The country names which are published as part of author affiliations in Cochrane reviews in The Cochrane Library [18], and contact details for Cochrane entities [20] on www.cochrane.org [17] and potentially other derivatives of Cochrane output, follow the ISO 3166 country list (www.iso.org/iso/country_codes/iso_3166_code_lists/english_country_names_and_code_elements.htm [121]), with a few exceptions. The ISO 3166 country list is published and maintained by the International Standards Organization (ISO) (Codes for the representation of names of countries and their subdivisions - Part 1: Country codes).

The country names on the ISO 3166 list are implemented as selectable, non-editable fields in the Collaboration's software, RevMan and Archie. It is not possible to publish country names which do not exist on the ISO list, with the following approved exceptions:

| Entry on ISO 3166 country list | Approved exception implemented in RevMan |
|--------------------------------|--|
| | and Archie |



| Iran, Islamic Republic of | Iran |
|--|-----------------------|
| Korea, Democratic People's Republic of | Korea, North |
| Korea, Republic of | Korea, South |
| Macedonia, Former Yugoslavia | Republic of Macedonia |
| Micronesia, Federated States of | Micronesia |
| Palestinian Territory, Occupied | Palestinian Territory |
| Tanzania, United Republic of | Tanzania |
| United Kingdom | UK |
| United States of America | USA |
| | |

Suggestions for additional exceptions should be emailed for approval to The Cochrane Collaboration's Chief Executive Officer, Nick Royle (nroyle@cochrane.org [122]), before they can be implemented in the Collaboration's software.

2.1.7 Policy on indirect overhead costs

The following policy was approved by the Executive of the <u>Steering Group</u> [13] on 26 July 2004:

As a registered charity (UK registration number 1045921), The Cochrane Collaboration can only undertake activities in pursuance of its charitable objectives and as such does not contribute to indirect costs for activities located in third-party institutions.

In cases where contribution to indirect overheads is requested and refusal to pay these costs would impact negatively on The Collaboration's ability to function effectively, each case should be referred to the Steering Group for consideration by its Executive, which would make a recommendation.

2.1.8 Policy on the granting of endorsements

Background

1. From time to time The Cochrane Collaboration is asked to give its endorsement to activities, training programmes, work groups, policies, organisations, conferences, journal articles and such like. Such endorsement might range from use of the Collaboration's logo to a statement of support. In the past the Cochrane Collaboration Steering Group [13] has granted endorsements on an ad hoc basis, following no explicit criteria or guidelines. Following the promulgation of the Collaboration's tightened policy on commercial sponsorship (April 2004, as amended, to be found at www.cochrane.org/docs/commercialsponsorship.htm [123]), the Steering Group at its April 2005 meeting in Providence, USA, approved the following policy, criteria and guidelines by which applications for endorsement should be processed and assessed.

Aim

2. This paper sets out the policy, criteria and guidelines for processing and assessing applications for endorsement made to The Cochrane Collaboration. (Individual entities [20] may wish to follow similar procedures for entity endorsements where these do not impinge on the Collaboration's over-arching responsibility.) It does not replace the policy for the use of the Cochrane logo (www.cochrane.org/logo/ [124]), but the checklist will be used when assessing



requests to use the logo.

3. The Steering Group has adopted the policy, criteria and guidelines as set out below, and as summarised in the checklist attached at Annex 2.1.8.A.

Definitions

4. Endorsement – the act of giving moral support to or approval of something, generally involving the use of a statement, logo, or recognised symbol. Expression of support: an act of support or approval falling short of full endorsement, and which might entail the setting by The Cochrane Collaboration of specific conditions or limitations.

Policy, criteria and guidelines

- 5. The policy of The Cochrane Collaboration is that:
 - 1. Endorsements and expressions of support, including affiliations, ('endorsements') may serve the best interests of The Cochrane Collaboration and its members where the aims of the activities or organisations to be endorsed are aligned with its aims and purposes; and as such endorsements may be sought for such activities and organisations.
 - 2. Endorsements may relate, but need not be limited, to activities, conferences, meetings, training events and programmes, published material, and to organisations or groups as specific entities.
 - 3. Not-for-profit groups or organisations may seek endorsements.
 - 4. Except in exceptional circumstances (such as co-sponsorship of an event with not-for-profit or charitable purposes) no application for endorsement will be accepted from for-profit groups or organisations, by political parties and related interest groups, or by organisations or groups whose endorsement might contravene The Cochrane Collaboration's charitable purposes, as defined in its Memorandum and Articles of <u>Association</u> [24] (www.cochrane.org/admin/artassoc.htm [125]).
 - 5. Individuals may not seek personal endorsement of themselves, except in pursuance of The Cochrane Collaboration's aims and purposes and for a specific intent (such as endorsing an individual's candidature to represent The Cochrane Collaboration on an external working group or committee).
 - 6. Where endorsement is sought and the proposal does not meet the full criteria, but nonetheless is felt to have merit, an expression of support may be offered that does not imply full endorsement, and may entail the setting of specific conditions or limitations (such as not approving use of the Cochrane logo).
 - 7. Endorsement where given will usually be for specific articles, events or activities that are by definition time-limited. However, consideration will be given to endorsements for longer periods up to three years, after which the endorsement will automatically lapse and renewal if required must be sought.
 - 8. The Cochrane Collaboration may impose a non-returnable fee for administering endorsement requests.
 - 9. The final decision to give endorsement rests with the Cochrane Collaboration Steering Group (as delegated in this policy document); where an endorsement is rejected The Cochrane Collaboration gives no undertaking to provide feedback.

Criteria for assessing applications for endorsement

- 6. The following criteria will be used when assessing applications for endorsement:
 - 1. Policy: Does the requested endorsement breach any point of The Cochrane Collaboration's policy for endorsement? For example, a proposal from a for-profit medical devices company would normally be rejected.
 - 2. Alignment: Are the aims of the proposed activity, and of the responsible body, aligned with those of The Cochrane Collaboration? For example, if an evidence-based healthcare workshop is proposed for endorsement, and the aims and principles of the organisation running and/or



- promoting the workshop, and the material that is to be endorsed are aligned with The Cochrane Collaboration's aims and purposes, approval would normally be given.
- 3. Relevance: The item for which endorsement is requested should be relevant to the place in which The Cochrane Collaboration's endorsement will appear. For example, if an evidence-based healthcare workshop is proposed for endorsement, the Cochrane logo may appear on the workshop's advertising and course materials, but not in some other place such as on an unrelated part of the promoter's website homepage, or the workshop's sponsors' materials, or other unrelated material, without explicit permission.
- 4. Conflict: Endorsement will not be given to organisations or activities where this would create conflict with The Cochrane Collaboration's commercial sponsorship policy. For example, if a not-for-profit university medical school was to seek endorsement for an evidence-based healthcare conference this might be approved, but if the conference had a for-profit pharmaceutical company as a major sponsor this would usually lead to the request being rejected.
- 5. Positioning: The positioning of The Cochrane Collaboration's endorsement in relation to other logos, brand or company names, photographs, etc. should not infer any implied endorsement. For example, if the Cochrane logo were to be placed next to the name of a for-profit pharmaceutical company the request would be rejected.
- 6. Publicity: What type of publicity is The Cochrane Collaboration's endorsement likely to generate, and for whom? For example, if publicity arising from endorsement would be likely to harm The Cochrane Collaboration's reputation, such endorsement would be rejected.

Guidelines for processing applications for endorsement

- 7. Requests for endorsement will be processed as follows:
 - 1. Requests for endorsement should be submitted through the e-mail address of the Cochrane Collaboration Secretariat [1] (secretariat@cochrane.org [2]).
 - 2. Requests should contain sufficient material to allow a proper assessment to be made. Material showing the way in which the endorsement is to be used should be provided. Clarification may be requested.
 - 3. The Cochrane Collaboration's Chief Executive Officer (CEO) will undertake initial assessment of requests using the criteria shown above. In the CEO's absence for protracted periods (such as annual leave), and when there is urgency to the request, the Secretariat Administrator may make the initial assessment.
 - 4. If a request substantially meets the criteria, it will be submitted to the next appropriate meeting of the Steering Group's Operations and Finance Committee, whose teleconferences are normally held every four to six weeks. If a request relates solely to the use of the Cochrane logo, and in straightforward circumstances, the decision may be made by the CEO alone.
 - 5. The Operations and Finance Committee may approve or reject the request, seek further information, or refer it to the full Steering Group for consideration.
 - 6. The originator of the request will be informed of the Operations and Finance Committee's decision within ten working days of its meeting, and within fifteen working days of the Steering Group's meeting, should the request have been referred to it.
 - 7. Feedback will not be provided.
 - 8. A decision table for considering requests is shown at Annex 2.1.8.B.

Use of the 'Cochrane Inside' logo

8. A form of endorsement suitable for material containing or derived from Cochrane Collaboration outputs is the 'Cochrane Inside' logo. People or organisations wishing to use this logo should follow the same procedure as outlined in this document, with the additional criterion as to whether the item to be endorsed with the 'Cochrane Inside' logo contains or substantially derives from Cochrane Collaboration output'. Where this criterion is not met, use of the 'Cochrane Inside' logo will be denied. Unlike the 'Cochrane' logo, the 'Cochrane Inside' logo will not be available for use from the Cochrane website, but should be requested from the Secretariat (secretariat@cochrane.org [2]).



9. A licensing fee and further conditions may be imposed for use of the 'Cochrane Inside' logo.

Contact for further information

10. If you wish to discuss the issues outlined in this paper, or an application for endorsement, please contact the Chief Executive Officer, nroyle@cochrane.org [122], or telephone +44 (0)1865 310138.

Annex 2.1.8.A - checklist for assessing applications for endorsement

| Criteria | Is the criterion met? | | |
|--|-----------------------|----|---------|
| | Yes | No | Unclear |
| 1. Policy: Does the requested endorsement breach any point of The Cochrane Collaboration's policy for endorsement (1.1 to 1.7 below)? | | | |
| 1.1 Endorsements and expressions of support, including affiliations ('endorsements'), may serve the best interests of The Cochrane Collaboration and its members where the aims of the activities or organisations to be endorsed are aligned with The Cochrane Collaboration's aims and purposes; and as such endorsements may be sought for such activities and organisations. | | | |
| 1.2 Endorsements may relate, but need not be limited, to activities, conferences, meetings, training events and programmes, published material, and to organisations or groups as specific entities [20]. | | | |
| 1.3 Not-for-profit groups or organisations may seek endorsements. | | | |
| 1.4 Except in | | | |



| exceptional | | |
|---------------------------|--|--|
| circumstances (such as | | |
| 1 | | |
| co-sponsorship of an | | |
| event with not-for-profit | | |
| or charitable purposes) | | |
| no application for | | |
| | | |
| endorsement will be | | |
| accepted from for-profit | | |
| groups or | | |
| organisations, by | | |
| 1 - | | |
| political parties and | | |
| related interest groups, | | |
| or by organisations or | | |
| groups whose | | |
| | | |
| endorsement might | | |
| contravene The | | |
| Cochrane | | |
| Collaboration's | | |
| charitable purposes, as | | |
| | | |
| defined in the | | |
| Memorandum and | | |
| Articles of Association | | |
| [24] (| | |
| | | |
| www.cochrane.org/admi | | |
| n/artassoc.htm [125]). | | |
| | | |
| 1.5 Individuals may not | | |
| seek personal | | |
| | | |
| endorsement of | | |
| themselves, except in | | |
| pursuance of The | | |
| Cochrane Collaboration's | | |
| | | |
| aims and purposes and | | |
| for a specific intent | | |
| (such as endorsing an | | |
| individual's candidature | | |
| | | |
| to represent The | | |
| Cochrane Collaboration | | |
| on an external working | | |
| group or committee). | | |
| group or committee, | | |
| 1.6. Whoma and a | | |
| 1.6 Where endorsement | | |
| is sought and the | | |
| proposal does not meet | | |
| the full criteria, but | | |
| 1 | | |
| nonetheless is felt to | | |
| have merit, an | | |
| expression of support | | |
| may be offered that | | |
| does not imply full | | |
| | | |
| endorsement, and may | | |
| entail the setting of | | |
| specific conditions or | | |
| limitations (such as not | | |
| 1 | | |
| approving use of the | | |
| Cochrane logo). | | |
| | | |
| 1.7 Endorsement where | | |
| II./ ENGOISEMENT WHERE | | |
| given will usually be for | | |



| specific articles, events or activities that are by definition time-limited. However, consideration will be given to endorsements for longer periods up to three years, after which the endorsement will automatically lapse and renewal if required must be sought. | | |
|--|--|--|
| 2. Alignment: Are the aims of the proposed activity, and of the responsible body, aligned with those of The Cochrane Collaboration? | | |
| 3. Relevance: The item for which endorsement is requested should be relevant to the place in which The Cochrane Collaboration's endorsement will appear. | | |
| 4. Conflict: Endorsement will not be given to organisations or activities where this would create conflict with the Collaboration's commercial sponsorship policy. | | |
| 5. Positioning: The positioning of The Cochrane Collaboration's endorsement in relation to other logos, brand or company names, photographs, etc. should not infer any implied endorsement. | | |
| 6. Publicity: Likely publicity generated by the endorsement should not be harmful to The Cochrane Collaboration. | | |
| 7. The requests should contain sufficient material to allow a | | |

| 4 | | |
|---|----------|------|
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| L | (= | Ţ // |
| 1 | | |

| proper assessment to be made. Material showing the way in which the endorsement is to be used should be provided. | | |
|--|--|--|
| 8. ('Cochrane Inside' logo only): Does the item to be endorsed with the 'Cochrane Inside' logo contain or substantially derive from Cochrane Collaboration output? | | |

Annex 2.1.8.B - Decision table

| | Yes | No |
|--|---|---|
| | Action: | |
| 1. Is this a simple request for the use of the Cochrane logo? | CEO process, no further referral. | Continue, refer to Executive |
| 2. Does the request substanti ally meet the criteria? | Executive; recomme nd | Refer to Executive ; recomme nd rejection. |
| 3. For referrals to the Executive Group, did the Executive approve the request, seek further informati on, or refer it to the full Steering Group [13] for | If approved, inform originator of acceptan ce within ten working days of Executive meeting. | originator |



| considera | 1 | and/or | | |
|---------------------------|---------------------|-------------------|--|--|
| tion? | | | | |
| | | Referred | | |
| | | to full | | |
| | | Steering | | |
| | | Group. | | |
| 4. For | lf | Otherwise | | |
| referrals | approved, | | | |
| to the | inform | originator | | |
| Steering | originator | | | |
| Group, | of | decision | | |
| did the | acceptan | within | | |
| Steering | ce within | fifteen | | |
| Group | fifteen | working | | |
| approve the | working | days of | | |
| request, | days of Steering | Steering Group | | |
| or seek | Group | meeting, | | |
| further | meeting. | either: | | |
| informati | inceding. | citirer. | | |
| on? | | Rejection; | | |
| | | or | | |
| | | | | |
| | | Further | | |
| | | informati | | |
| | | on | | |
| | | required | | |
| | | (repeat | | |
| | | process | | |
| | | as | | |
| | | required). | | |
| Feedback regarding the | | | | |
| application, its | | | | |
| consideration and the | | | | |
| decision(s) made will not | | | | |
| be available. | | | | |

2.2 Publishing policies

Subheadings in this section

2.2.1 Guiding principles for disseminating Cochrane reviews

The guiding principles for disseminating the reviews prepared by The Cochrane Collaboration are:

- To obtain the widest possible distribution [31] and accessibility at a reasonable price
- To maintain the integrity of the individual reviews
- To give credit where credit is due to authors, editors, funders, and others.



In November 2004, the Steering Group's Publishing Policy Group agreed that <u>The Cochrane Library</u> [18] should continue to be limited to the publication of reviews dealing with **human** health issues.

2.2.2 Cochrane reviews (converting protocols, updating/withdrawing)

A <u>Cochrane review</u> [22] is a systematic, up-to-date summary of reliable evidence of the benefits and harms of health care. Cochrane reviews are intended to help people make practical decisions. For a review to be called a "Cochrane review" it must be in the Parent Database, maintained by The Cochrane Collaboration. The Parent Database is composed of modules of reviews submitted by Cochrane Review Groups (CRGs) registered with The Cochrane Collaboration. The reviews contributed to one of the modules making up the Parent Database are refereed by the editorial team of the CRG, as described in the <u>CRG module</u> [102]. The specific methods used in a Cochrane review are described in the text of the review. Cochrane reviews are prepared using <u>Review Manager</u> [25] (RevMan) software provided by The Cochrane Collaboration, and adhere to a structured format that is described in the <u>Cochrane Handbook</u> [54] for Systematic Reviews of Interventions. In brief, this format consists of:

- A 'cover sheet', giving the title and citation details of the review; the names, addresses and other contact details, both of the authors and of the editorial team responsible for the Cochrane Review Group to which the authors belong; and the sources of support for preparing and updating the review.
- A structured report of the review, consisting of background information, the objective, the materials and methods used, the results of the review, discussion and conclusions about implications for practice and research.
- Full citations of reports of the studies incorporated in the review, and of reports of those studies that were potentially eligible, but which the authors decided to exclude (with reasons for the exclusions).
- Tabulations of the characteristics of the trials included in the review, including information relevant to an assessment of the <u>methodological quality</u> [126] of each of the studies included.
- Tabulation of the results of the review, with presentation of statistical syntheses (meta-analyses), when these were both possible and appropriate.

To ensure that the results of their work can be widely and freely disseminated, authors prepare and maintain their reviews for inclusion in The *Cochrane Database of Systematic Reviews* on the understanding that they will not be subject to any exclusive copyright arrangements, and that they may be used in one or more of the specialised databases compiled using a selection of reviews contained in the Parent Database.

Subheadings in this section

2.2.2.1 Who is the audience for Cochrane reviews?

The target audience for Cochrane reviews is people making decisions about health care. This includes healthcare professionals, consumers and policy makers with a basic understanding of the underlying disease or problem.

It is a part of the mission and a basic principle of The Cochrane Collaboration to promote the accessibility of systematic reviews of the effects of healthcare interventions to anyone wanting to make a decision about health care. However, this does not mean [111] that Cochrane reviews must be understandable to anyone, regardless of their background. This is not possible, any more than it would be possible for Cochrane reviews to be written in a single language that is understandable to everyone in the world.



Cochrane reviews should be written so that they are easy to read and understand by someone with a basic sense of the topic who may not necessarily be an expert in the area. Some explanation of terms and concepts is likely to be helpful, and perhaps even essential. However, too much explanation can detract from the readability of a review. Simplicity and clarity are also vital to readability. The readability of Cochrane reviews should be comparable to that of a well-written article in a general medical journal.

2.2.2. Policy on updating reviews and converting protocols

It is Collaboration policy that reviews should either be updated within two years or should have a commentary added to explain why this is done less frequently. It is also Collaboration policy that protocols that have not been converted into full reviews within two years should generally be withdrawn from the *Cochrane Database of Systematic Reviews*.

[Note: The two-year term should commence from the date of first publication.]

2.2.2.3 Policy on withdrawing protocols and reviews

The decision to withdraw a <u>protocol</u> [43] <u>or</u> [127] <u>review</u> [29] should generally be made between the review team and the <u>Cochrane Review</u> [22] Group (<u>CRG</u> [15]), and the reason for the withdrawal should be given in the Published Notes section of the protocol or review. The facility to withdraw a protocol or review is included in the software that CRGs use to submit their <u>module</u> [102] for publication in each issue of the *Cochrane Database of Systematic Reviews* (<u>CDSR</u> [128]). When a protocol or review is withdrawn, it will be flagged in the next issue of the *CDSR* as 'withdrawn' and only the title, coversheet and reason for withdrawal will be published.

A CRG may withdraw a protocol and then remove it from the issue of the *CDSR* after which it was first withdrawn. However, a review should never be removed from the *CDSR*, since review Abstracts are published in MEDLINE, where users are referred to the latest issue of The Cochrane Library [18] for details of the current status of the review. A review may be withdrawn temporarily (suspended) and can be reinstated once it is considered satisfactory by the authors and CRG; otherwise it should remain withdrawn.

Reasons for withdrawing protocols and reviews from The Cochrane Library

Protocols

- The authors have requested this protocol to be withdrawn. The reason/s is/are (GIVE LIST OF REASONS).
- The protocol is out of date and does not meet the current methodological standards of The Cochrane Collaboration.
- Authors have made no progress with this protocol in xxx months/years. New authors are being sought to take over this protocol.
- The protocol has been republished as a diagnostic test accuracy protocol (GIVE FULL REFERENCE).
- The protocol has been split into these protocols (GIVE FULL REFERENCES).
- The protocol has been merged with another protocol (GIVE FULL REFERENCE).
- Title reassignment. New protocol will be published by review authors (GIVE NEW AUTHORSHIP).
- The Review Group was unable to maintain contact with the contact author. The co-authors are unable to take over this protocol. New authors are being sought to take over this protocol.

Reviews

• The Editor/CRG withdrew this review as of Issue X, 200X. The review will be reinstated following

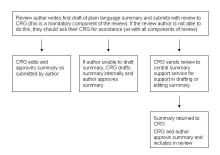


- a substantive update.
- Potentially relevant studies MAY HAVE been excluded from this review and it has been withdrawn pending further investigation.
- The statistical analysis MAY HAVE BEEN inappropriate and this review has been withdrawn pending further investigation.
- There MAY BE errors with data presentation and this review has been withdrawn pending further investigation.
- Major errors in the review have been identified (e.g. through the Feedback mechanism). These
 errors are: (LIST THEM). The review will be re-published following revision and peer review [129]
- Non-compliance with the Cochrane Collaboration's Commercial Sponsorship Policy.
- The review has been combined with (STATE NUMBER) other published Cochrane review(s) and the new combined review has been published as (GIVE FULL REFERENCE).
- The review has been split into (STATE NUMBER) reviews that will be/have been published as (GIVE FULL REFERENCES IF KNOWN).
- This review is being updated and replaced following the publication of a new protocol (GIVE FULL REFERENCE). It will remain withdrawn when the new review is published.
- The review has been republished as a diagnostic test accuracy review (GIVE FULL REFERENCE).
- The authors have requested this review to be with withdrawn. The reason/s is/are (GIVE LIST OF REASONS).
- Authors are unable to update the review. This is one of the conditions for publishing the review. New authors are being sought to update this review.
- The review has been withdrawn while the authors update aspects of its methodology (LIST THESE).

2.2.2.4 Plain language summaries

The process of writing plain language summaries: drafting, $\,$ editing, approval and ownership

The first draft of the plain language summary should be written by the review [29] author and submitted with the review to the relevant CRG [15]. The writing of plain language summaries, however, is a specific skill, and review authors and CRGs may need support. Many CRGs have this skill within their editorial team, but where this is not available, a central support service will assist CRGs in writing and editing plain language summaries if they choose to access this support. The following flow chart outlines the use of this service:



The central summary support service will be co-ordinated by the Cochrane Consumer Network (ccnet-contact@cochrane.de [130]). CRGs wishing to access this service should send the review to this address. The ownership and final approval of the plain language summary, as a mandatory part of the review, remains with the CRG and the review author.

2.2.2.5 Process in the event of serious errors in published Cochrane reviews



The Cochrane Collaboration has robust, open and methodologically mature processes aimed at ensuring that Cochrane reviews provide the best available evidence of the effects of healthcare interventions. These include documented methodologies, good training, internal and external peer review [131], an open comments and criticisms system, and a willingness to embrace continuous improvement. However, it can be expected that, despite these best endeavours, flaws may appear in Cochrane reviews from time to time. Most of these flaws will be relatively minor, but may occasionally be more severe (and this process arises from a single incident in the first eleven years of the Collaboration's history). The procedure to be followed in the event of a serious error being found in a Cochrane review can be found on the Collaboration website at www.cochrane.org/docs/process for serious errors in Cochrane reviews.htm [132]

2.2.2.6 Access to archived reviews

All previously published reviews (including protocols) are stored in The Cochrane Collaboration's central server, Archie, which supports the running of the editorial bases and satellites of the Cochrane Review [22] Groups (CRGs) and enables the publication of Cochrane reviews. In preparation for the launch of Archie during 2005-2006, all previously published versions of Cochrane reviews were restored from source material for all published issues of the Cochrane Database of Systematic Reviews [1994-1996] and The Cochrane Library [18] from the year 1996, providing easy access to these earlier published versions. All new reviews and updated versions of previously published reviews are stored in Archie, and cannot be deleted. Archie also contains versions of draft reviews that are not published. These can be deleted.

The archive of published Cochrane reviews is only available to editorial bases of CRGs (as well as system and data administrators for Archie), and can help editorial bases to answer queries about previously published versions which are not available in the public archive through *The Cochrane Library* (see below). However, it is at the discretion of the CRGs as to whether they choose to provide copies of reviews to people who have asked for them. For information about how to contact CRGs, see www.cochrane.org/contact/entities.htm#CRGLIST [133].

Researchers can also apply for permission from the Executive of the Cochrane Collaboration Steering Group [13] for access to previously published reviews by contacting Monica Kjeldstrøm, the Director of the Cochrane Information Management System (IMS) (mk@cochrane.dk [134]). If permission is granted, the IMS team at the Nordic Cochrane Centre [34] can provide these data, but there may be a cost for this service.

The Cochrane Library on the Wiley InterScience online platform archives all citation versions of previously published reviews (including protocols) starting from Issue 4, 2003 (www.thecochranelibrary.com [21]). Where previous versions of a record exist, these can be accessed via the 'Other Versions' link on the menu in the left-hand frame of the review. Only users with a subscription to The Cochrane Library can access archived reviews.

Deleted protocols are also archived online on Wiley InterScience. These are not visible to the user via the Search or Browse functions, but will appear if the user types in the exact URL for the deleted protocol.

2.2.3 The Cochrane Database of Systematic Reviews

There are obvious advantages of electronic publication for systematic reviews that require maintenance as new evidence emerges and as mistakes are discovered; thus the principal medium for disseminating Cochrane reviews is through The *Cochrane Database of Systematic Reviews*. This is disseminated on line via the Internet and on CD-ROM. Electronic publication involves the preparation of software for interrogating and displaying the reviews in The *Cochrane Database of Systematic Reviews*. This is not the direct responsibility of The Cochrane Collaboration, but of publishers and others.



2.2.4 Rationale for requiring Cochrane authors to publish in the Cochrane Database of Systematic Reviews first

The generic Title Registration Form for registering a new <u>Cochrane review</u> [22] was amended to include the following statement:

'The support of the <u>CRG</u> [15] in preparing your review is conditional upon your agreement to publish the <u>protocol</u> [43], finished review and subsequent updates in the <u>Cochrane Database of Systematic Reviews</u>. By completing this form you undertake to publish this review in the <u>Cochrane Database of Systematic Reviews</u> (concurrent publication in other journals may be allowed in certain circumstances with prior permission from the CRG).'

2.2.5 Publication of versions of Cochrane reviews in print journals

Authors may wish to seek co-publication of Cochrane reviews in peer-reviewed medical journals, particularly in those journals that have expressed enthusiasm for co-publication of Cochrane reviews (see Appendix 1 [135] for correspondence from specific journal editors on this matter). For The Cochrane Collaboration, there is one essential condition of co-publication: Cochrane reviews must remain free for dissemination in any and all media, without restriction from any of them. To ensure this, Cochrane authors grant The Cochrane Collaboration worldwide licences for these activities, and do not sign over exclusive copyright to any journal or other publisher. A journal is free to request a non-exclusive copyright that permits it to publish and re-publish a review, but this cannot restrict the publication of the review by The Cochrane Collaboration in whatever form The Cochrane Collaboration feels to be appropriate.

A Cochrane systematic review should be published either before, or at the same time as, its publication in other journals. Authors should not publish Cochrane reviews in journals before they are ready for publication in The *Cochrane Database of Systematic Reviews* (CDSR [128]). This applies particularly to Centre [34] directors and editors of Cochrane Review Groups (CRGs). However, journals will sometimes insist that the publication of the review in *CDSR* should not precede publication in print. When this is the case, authors should submit a review for publication in the journal after agreement from their CRG editor and before publication in *CDSR*. Authors should remember to include the statement, "This is a version of a Cochrane review, which is available in The Cochrane Library [18]." Publication in print should not be subject to lengthy production times, and should not delay publication of a Cochrane review in *CDSR* (either because of delays from a journal or in order to resubmit their review to another journal). Journals can also request revision of a review for editorial or content reasons. External peer review [131] provided by journals may enhance the value of the review and should be welcomed.

Journals generally may require shorter reviews than those published in *CDSR*. Selective shortening of reviews may be appropriate, but there should not be any substantive differences between the review as published in the journal and in *CDSR*. If a review is published in a journal, it should be noted that a fuller and maintained version of the review is available in *CDSR*. Typically, this should be done by including a statement such as the following in the introduction: "A more detailed review will be published and updated in the *Cochrane Database of Systematic Reviews*. Reference". The reference should be to the <u>protocol</u> [43] for the review published in *CDSR*. A similar statement should be included in the introduction if a review is published in *CDSR* prior to publishing a version of the review in a journal. After a version of a Cochrane review has been published in a journal, a reference to the journal publication must be added under the heading 'Other published versions of this review'.

Authors are also encouraged to add the following statement to versions of Cochrane reviews that



are published in journals: "This is a version of a Cochrane review, which is available in *The Cochrane Library*. Cochrane systematic reviews are regularly updated to include new research, and in response to feedback from readers. If you wish to comment on this, or other Cochrane reviews of interventions for XXX, please send it to XXX." Cochrane Review Groups may wish to establish a policy on the person to whom comments should be sent.

Authors whose primary affiliation is a Cochrane entity should include the following sentence when publishing an article that is not about The Cochrane Collaboration or does not reflect official policy: "The views expressed in this article represent those of the authors and are not necessarily the views or the official policy of The Cochrane Collaboration."

In addition, the following modification of the disclaimer published in *The Cochrane Library* should be added to Cochrane reviews published in journals: "The results of a Cochrane review can be interpreted differently, depending on people's perspectives and circumstances. Please consider the conclusions presented carefully. They are the opinions of review authors, and are not necessarily shared by The Cochrane Collaboration."

The following passage can be provided to journal editors upon submission of a review for publication, and the letter of submission should be copied to the CRG editors for information. This policy and procedure may be new to some journal editors and may require direct discussion with the journal editor. The CRG editors should be informed of any problems encountered in this process.

"This systematic review has been prepared under the aegis of The Cochrane Collaboration, an international organisation that aims to help people make well-informed decisions about healthcare by preparing, maintaining and promoting the accessibility of systematic reviews of the effects of healthcare interventions. The Cochrane Collaboration's publication policy permits journals to publish reviews, with priority if required, but permits The Cochrane Collaboration also to publish and disseminate such reviews. Cochrane reviews cannot be subject to the exclusive copyright requested by some journals."

Subheadings in this section

2.2.5.1 Statement for paper publication

The following statement should accompany reviews submitted for publication in paper journals:

'This paper is based on a <u>Cochrane review</u> [22] published in <u>The Cochrane Library</u> [18] YYYY, Issue X (see <u>www.thecochranelibrary.com</u> [21] for information). Cochrane reviews are regularly updated as new evidence emerges and in response to feedback, and *The Cochrane Library* should be consulted for the most recent version of the review.'

2.2.5.2 Derivative publications

This section was prepared by Deborah Dixon, Editorial and Business Development Director, John Wiley & Sons Ltd; updated in November and December 2004, and June 2005, and approved by the Publishing Policy Group (PPG [136]) of the Cochrane Collaboration Steering Group [13] on 12 July 2005. It was updated by Deborah Pentesco-Gilbert, Publisher of The Cochrane Library [18], in February 2007 to include a list of derivative publications and to amend the wording to include other derivatives other than the spin-off libraries.

Background

Wiley is keen to evaluate derivative publications including journals and spin-off libraries that fulfil the following criteria:



- It is an excellent stand-alone product with a robust business plan that generates revenues for the Cochrane entity and overall profit.
- It is a high quality [5], high profile product that enhances the brand of The Cochrane Library.
- It is a product that complements our sales strategy for *The Cochrane Library*.
- There is sufficient 'added value' in terms of content compared with that in *The Cochrane Library* that it warrants separate publication.

The contract between The Cochrane Collaboration and Wiley gives Wiley first option to publish derivative products from *The Cochrane Library*. If Wiley refuses this option then Wiley will set a fee for the licensing of Cochrane reviews for the derivative product. This fee is to be approved by The Cochrane Collaboration.

Evaluation process

Wiley proposes the following process to be adapted by Cochrane <u>entities</u> [20] with proposals for derivative publications:

The Cochrane entity describes, in a written proposal, the precise content to be included.

- If any of the content to be included has not been created by the Cochrane entity (e.g. third-party material such as that produced by the York Centre [137] for Reviews and Dissemination, or Cochrane reviews created by other groups) the Cochrane entity needs to obtain written permission from the owners of the content to include it in the derivative product. They need to be aware that a fee or royalty may be requested for the inclusion of this material, which will need to be paid by the Cochrane entity or out of the royalties payable by Wiley to the Cochrane entity.
- The Cochrane entity needs to send its proposal, including information on the plans for payment of royalties to other content providers, simultaneously to Wiley and to The Cochrane Collaboration (i.e. to the Publishing Policy Group (PPG), and thence to the Steering Group).
- Wiley will evaluate the financial viability of the derivative product by conducting peer and market review of the proposal.
- If in agreement to explore the proposal further, Wiley will propose a royalty payment or licence fee. The Cochrane Collaboration (the Publishing Policy Group and thence the Steering Group) needs to respond as to whether a payment or a proportion of the royalty should be paid to The Collaboration Trading Company, and if so what the payment should be.
- Cochrane entities need to have a plan that outlines the supplying of the content to Wiley in a form that is ready to publish, and the responsibilities for all parties involved are to be described in the proposal.

Production costs

If it is agreed that Wiley will publish the derivative product, Wiley will bear the costs of production of the derivative product.

Marketing, sales, and $\underline{\text{distribution}}$ [31] of the spin-off Library

Wiley will have the full responsibility for marketing, sales and distribution of the derivative product. Wiley will make it available for sale on the open market to individuals, institutions and consortia. Sales staff from Wiley will also approach companies to buy large quantities of the product at discount (this strategy was agreed at the Steering Group meeting in Bergamo in March 2004). Wiley will set all prices.

Licensing of Cochrane reviews to an alternative publisher

If Wiley declines the first option to publish the derivative product and the Cochrane entity finds an alternative publisher, the publisher needs to apply to Wiley for a non-exclusive licence to publish the Cochrane reviews included in the derivative product. Provided that the number of reviews published in the derivative product does not exceed a number considered by Wiley to jeopardise sales of *The Cochrane Library*, Wiley will apply a fee for the licence, and revenue generated will be included in



the royalty calculation for The Cochrane Collaboration. Wiley will seek advice from the Publishing Policy Group if the number of reviews to be included in a particular derivative product exceeds the number that Wiley consider would jeopardise sales of *The Cochrane Library*. Wiley would provide a rationale for setting the limit for the number of included reviews. This fee will be set on a case-by-case basis supported by a business rationale. A separate fee will be set for a CD-ROM version and an Internet version. Fees will be presented to The Cochrane Collaboration (via the Publishing Policy Group and thence the Steering Group) for approval. A full acknowledgement to The Cochrane Collaboration and to Wiley would need to be made for the use of the reviews. Derivative products cannot, however, carry the branding of *The Cochrane Library*.

If anyone has an idea for a derivative product, they should contact Deborah Pentesco-Gilbert, Publisher, *The Cochrane Library*, John Wiley & Sons Ltd, The Atrium, Southern Gate, Chichester, West Sussex, PO19 8SQ, UK (Tel +44 (0)1243 770693; Fax +44 (0)1243 770460; E-mail dpentesc@wiley.co.uk [138]).

Current derivative publications

Evidence-based Child Health: A Cochrane Journal (<u>www.evidence-basedchildhealth.com</u> [139]).

The WHO Reproductive Health Library (www.rhlibrary.com [140]).

Cochrane reviews - mobile version (www.skyscape.com/cochrane [141]).

2.2.5.3 Responding to feedback

It is essential that efficient arrangements are available for amending reviews in the light of new evidence and valid feedback. To achieve this, The Cochrane Collaboration's working methods include a commitment to timely updating and concurrent reporting of feedback and other responses. The Cochrane Collaboration has established an iterative system through which successive versions of each review reflect not only the emergence of new data, but also valid feedback, solicited or unsolicited, from whatever source. Successive versions of a particular review, together with any intervening feedback, are being archived.

The Cochrane Collaboration's commitment is made clear on the cover sheet for each review contained in The *Cochrane Database of Systematic Reviews*, which gives the names, addresses and other contact details (telephone, fax, and electronic mail) both of the contact author and of the editorial team responsible for co-ordinating the <u>Cochrane Review</u> [22] Group to which he or she belongs.

These requirements of The Cochrane Collaboration, taken together with the practical experience acquired by a group of authors in preparing and maintaining systematic reviews of controlled trials in pregnancy and childbirth, lie behind The Cochrane Collaboration's adoption of electronic media as a primary means of assembling and disseminating Cochrane reviews. Complementary arrangements will be needed to ensure that other publication forms that use Cochrane reviews are aware of substantive updates.

2.2.5.4 'House rules' for responding to feedback on the Internet

COCHRANE LIBRARY FEEDBACK - HOUSE RULES

The Cochrane Library [18] Feedback tool allows users to provide comments on and feedback of Cochrane reviews and protocols in *The Cochrane Library*. If accepted, the feedback will be published in a scrolling list of comments in reverse chronological order, with the most recent submission at the top of the page. In submitting your feedback, you agree with the following:



- In submitting feedback, you grant The Cochrane Collaboration a non-exclusive licence to publish the feedback, and to identify you as its author, as part of the feedback feature and also to include it, if required, as part of the next update of the review commented on.
- 2. John Wiley & Sons Ltd (the Publisher) and The Cochrane Collaboration <u>Steering Group</u> [13] will decide in their sole discretion whether to publish the feedback and reserve the right to cease publication at any time and without notice.
- 3. The Publisher will not accept feedback which may be libellous, abusive, in breach of any obligation of confidentiality or otherwise unlawful.
- 4. You must have copyright ownership of all material that you post. No articles or graphics may be posted without the express written consent of the copyright holder. Publication of the feedback will not infringe the copyright, trademark, trade secret, right of privacy or publicity, or any other rights of any third party.
- 5. You must respect the privacy of individuals. This means no posting of others' telephone numbers, addresses, or any other private information.
- 6. The Publisher will accept only feedback which is relevant and appropriate to the review commented on.
- 7. No solicitations or advertisements are allowed.
- 8. Please keep your comments brief and to the point, and check them before you submit. Please also remember to declare any potential conflict of interest that you may have.
- 9. Online etiquette means that you don't post the same feedback more than once. If you receive no acknowledgement of your comment please contact the Publisher at cochrane_feedback@wiley.co.uk [142]; please include your email address if possible so that the feedback editor can make contact with you.
- 10. You take responsibility for postings under your identification and use the information provided here at your own <u>risk</u> [143]. The Publisher will not be liable for the content of comments posted here.
- 11. The Publisher cannot reply to requests for clinical or personal advice sent through the Feedback tool.
 - 12. Comments which report only typographical errors, spelling mistakes or punctuation should be sent to the author of the review or the Review Group Coordinator.

2.2.6 Royalties

The Cochrane Collaboration is a registered charity (registered company number 1045921). Profits from the sale of The Cochrane Library [18] are used to support the work of The Cochrane Collaboration. In recent years, The Cochrane Collaboration has been very successful in various ways. Being registered as a charity under English law brings certain tax and other benefits. However, having charitable status does limit the amount of commercial trading that can be done by The Cochrane Collaboration. Because a price is charged for *The Cochrane Library*, and because The Cochrane Collaboration might want to consider limited business activities in the future, it became clear that there was a need for a trading company to take care of such activities. The Cochrane Collaboration Trading Company Limited was therefore established in October 1998 (registered company number 3657122).

The Steering Group [13] decided that ideally the company directors should be ex-members of the Steering Group, and preferably ex-Treasurers. The main responsibility of The Collaboration Trading Company is to receive the royalties on sales of *The Cochrane Library*. The Trading Company is a wholly-owned subsidiary of The Cochrane Collaboration (i.e. The Cochrane Collaboration is the sole shareholder). The Trading Company is obliged to hold annual general meetings to approve the accounts and to re-elect directors if necessary: these meetings take place during the annual Cochrane Colloquia.

2.2.7 Copyright (Licence for Publication forms)



Copyright of Cochrane reviews remains with the authors. They, however, grant to The Cochrane Collaboration an irrevocable, paid-up, exclusive, worldwide licence (with right to sub-license) to incorporate in The *Cochrane Database of Systematic Reviews* all material that they have provided to, and shall in future provide to, The Cochrane Collaboration.

All authors of Cochrane reviews are required to give their permission for publication before their review is published on The *Cochrane Database of Systematic Reviews* in <u>The Cochrane Library</u> [18]. From late February 2011, the author will automatically be sent an email with a link taking her/him to the 'Archie' login page and then on to the Licence for Publication web form. The email will also have, as an attachment, a PDF of the proof of the review. Once the author has accessed the web form, s/he will be asked to accept the licence, type her/his name, and click a button. The author will also be able to read the final version of the review from within the form.

Authors may wish to seek co-publication of versions of Cochrane reviews and Cochrane Methodology reviews in other journals, particularly those that have expressed enthusiasm for this. Such co-publication is welcomed by The Cochrane Collaboration, as long as it is done in accordance with the guidance in Section 2.4 of the *Cochrane Handbook [54] for Systematic Reviews of Interventions* and with the copyright requirements summarized here. In this case, authors should call it "a version of a Cochrane review".

Subheadings in this section

2.2.7.1 Copyright on Cochrane reviews published in The Cochrane Library, including translated versions

All original documents published in <u>The Cochrane Library</u> [18] are the copyright of The Cochrane Collaboration and may not be reproduced or published elsewhere, in whole or in part, without the written consent of John Wiley & Sons on behalf of The Cochrane Collaboration.

This copyright applies to all parts of Cochrane reviews and Cochrane Methodology reviews, including abstracts and graphs. This copyright also applies to all translated versions of reviews and parts of reviews, including translations of abstracts of Reviews.

Authors wishing to submit versions of Cochrane reviews for publication in other journals should contact John Wiley & Sons for permission.

Background and rationale

The Cochrane Library is a recognised healthcare journal, and articles published in The Cochrane Library should be treated in the same way as articles published in other healthcare journals. With the exception of those situations covered by 'fair use' or 'fair dealing' provisions, permission must be obtained from John Wiley & Sons in advance of reproducing all or part of a Cochrane review (including abstracts, graphs, etc.).

The copyright referred to in this policy statement is literally 'the right to copy'. Although authors retain ownership of the content of Cochrane reviews, each author has licensed publication rights to The Cochrane Collaboration, which in turn has licensed all electronic publication rights exclusively to John Wiley & Sons.

Under current contractual arrangements, if an author wishes to submit a paper based on a Cochrane review for publication in a print journal, they must first obtain permission from John Wiley & Sons Limited.

Note also that authors may not give permission for the electronic publication of articles submitted to print journals that are based on Cochrane reviews. If journals wish to include copies of published



reviews on their Web pages, they must first obtain permission from John Wiley & Sons Limited.

Abstracts and plain language summaries of Cochrane reviews are available without charge on the Internet. Abstracts and their plain language summaries are nonetheless subject to copyright and may not be used or reproduced without permission. While freely available, abstracts and plain language summaries are not in the public domain and are subject to copyright restrictions.

There are several reasons for requiring permission to publish reviews and parts of reviews. The first is that this is the only way that The Cochrane Collaboration can keep track of where Cochrane reviews and parts of reviews are being published. The second reason is that it is not possible to gauge the impact of Cochrane reviews without knowing where they appear. The third reason is that any income from the publication of Reviews should be used to help sustain The Cochrane Collaboration and the dissemination process.

Decisions about who is allowed to reproduce Reviews are made in accordance with policy agreed with The Cochrane Collaboration Steering Group [13].

Authors should note that they are allowed to distribute up to 25 reprints of their Cochrane review, but that they may not sell reprints.

Responsibility for content of Cochrane reviews

Responsibility for the content of a Cochrane review rests with the authors, not the <u>CRG</u> [15] editors. The Licence for Publication form does not change this. Although the CRG editors have the authority not to accept a review for publication, the author(s) take responsibility for what they give to the editors. Section 4.2.2 of the <u>Cochrane Handbook</u> [54] for Systematic Reviews of Interventions describes the importance of the authors in relation to their accountability for the review.

Priority of Permissions (i.e. which takes precedence: the date that something is published or the date of signing the Licence for Publication form?)

The date of signing the form is more important than the date that the Cochrane review (or a version of it) is published. The date on the form is the date on which the rights mentioned in it are transferred. As a reminder, The Cochrane Collaboration's policy in relation to 'co-publication' of versions of Cochrane reviews in other journals is in Section 2.4 of the *Cochrane Handbook [55] for Systematic Reviews of Interventions*. This outlines the importance of not delaying the publication of the Cochrane review in order to wait for a journal to publish a version of the review.

2.2.7.2 Clarification from John Wiley & Sons Limited regarding permission to republish material

There has been some confusion and concern regarding the policies and processes for obtaining permission to republish material published in The *Cochrane Database of Systematic Reviews* elsewhere, most particularly in print journals. We hope that the following explanations will help to clarify the situation.

New Licence for Publication Form

Firstly, it is important to realise that the new Form does not require authors to assign any extra rights to The Cochrane Collaboration than the previous form. In fact, the new form states additional authors' rights for what they can do with their review.

As previously, authors are required to assign an exclusive licence to The Cochrane Collaboration to publish their review in electronic editions of <u>The Cochrane Library</u> [18], and to prepare reprints of that review in print form.

The new Form also offers authors the opportunity to assign worldwide print rights to The Cochrane Collaboration for publication in print publications. The reason that this option has been included is



that Wiley is currently investigating the possibility of launching at least one Cochrane Journal. We think that the Collaboration having its own journal(s) will offer authors the opportunity to gain print citations and even higher profile for their reviews. We would hope that the Journal(s) would fast become the preferred option for republication of Cochrane reviews in print form. This will also be an effective way of increasing the profile of the work of the Cochrane Review Groups. However, we recognise that some authors might wish to continue submitting versions of their Cochrane review for print publication elsewhere and this is why the new Form allows them to retain the print rights if they so wish.

Permission to Republish in Print

If authors wish to republish their review, in complete or shortened form, elsewhere in a print journal they are required to seek permission from Wiley. This is the same procedure as for the previous publishing arrangement, when authors had to seek permission from Update Software.

To make such a request to John Wiley & Sons Limited, please complete the following Copyright Permission Request Form and send it to the Permissions Department at the address shown on the form. Permission will be granted provided that reference will be made in the republished version to the original publication source (*The Cochrane Library*). There will be no charge for such a request.

If another publisher requests permission to republish a Cochrane review then they will be instructed to seek also the permission of the authors. A charge will be levied on the other publisher for such a request to cover administrative costs. This is a routine arrangement within publishing and we think it is justified because the publisher is acquiring valuable content to publish, and the expectation should be that some financial value should be assigned to the right to republish. The charge levied is lower than the true value of the content because we recognise that the extra dissemination provided by the republication is a positive outcome [105].

A similar charging policy will be adopted if another publisher requests permission to translate and republish a Cochrane review in another journal.

Deborah Dixon

John Wiley & Sons Ltd

2 July 2003

2.2.7.3 Copyright permission request form



Permissions Department

John Wiley & Sons Limited

The Atrium, Southern Gate

Chichester, West Sussex

PO19 8SQ, UK

Tel: +44 (0)1243 843356

Fax: +44 (0)1243 770620

E-mail: PermissionsUK@wilev.com [144]



| Review [29] Title: |
|--|
| Author(s): |
| Issue Number & Year: |
| Material requested (e.g.: whole review, <u>abstract</u> [145], graphs, plain language summary, figures - state which): |
| Details, format and language of re-use: |
| Number of copies to be made (if applicable): |
| Name and Title of Requester: |
| Name of Requesting Organization: |
| Postal Address: |
| |
| Telephone: Fax: |
| E-mail: |

Permission requests are handled by John Wiley & Sons Limited on behalf of the Cochrane Collaboration, and should be submitted to the address above.

PLEASE NOTE THAT IN ADDITION TO RECEIVING PERMISSION FROM WILEY, REQUESTERS MUST ALSO OBTAIN THE PERMISSION OF THE AUTHOR(S) BEFORE REPUBLISHING ANY COCHRANE MATERIAL.

2.2.7.4 Licence for Publication - Cochrane Reviews

This section updated on 21 February 2011 by Rasmus Moustgaard, Acting Director, IMS.

Cochrane Database of Systematic Reviews

Licence for Publication:

Cochrane Review [22] ("Review")



When all authors have signed and dated this form, it should be sent by post or fax, or scanned and e-mailed electronically, to the Managing Editor of the appropriate Cochrane Review Group.

| Cochrane Review ID: | |
|------------------------|--|
| Cochrane Review title: | |
| Cochrane Review Group: | |
| Author(s): | |

Authorship – I/we have made a substantial contribution to the conception and design, or analysis and interpretation of the data in this Review. I/we have drafted the Review or commented on it critically for intellectual content. I/we have reviewed the final version of the Review and approve its <u>validity</u> [9] for publication.

Updating – I/we agree to maintain this Review in light of new evidence, feedback, and other developments, and to update the Review at least once every two years, or, if requested, transfer responsibility for maintaining the Review to others as agreed with the editorial team of the <u>CRG</u> [15].

Cochrane Review Group approval – I/we acknowledge that, to be published in the Cochrane Database of Systematic Reviews, the Review must be approved by the CRG's Co-ordinating Editor or nominated deputy. The CRG's editorial team has the right to transfer responsibility for this Review to another CRG. The CRG has the right to withdraw the Review if it is not kept up to date or otherwise does not meet the standards of the CRG and/or The Cochrane Collaboration.

For Diagnostic Test Accuracy Reviews only – I/we acknowledge that, to be published in the Cochrane Database of Systematic Reviews, the Review must be approved by the Cochrane Diagnostic Test Accuracy Editorial Team.

Licence for publication – I/we hereby grant to The Cochrane Collaboration for the full period of copyright and all extensions and renewals, an exclusive licence of the rights of copyright in and to the Review, including but not limited to the right to publish, re-publish, transmit, sell, distribute, and otherwise use the Review and the material contained therein in electronic editions of the Cochrane Database of Systematic Reviews, and print reprints thereof, and in derivative works, in all languages throughout the world, and to license or permit others to do so.

I/we represent that the Review is my/our original work. I am/we are the copyright owners of the Review or I am/we are expressly authorised by the copyright holder to grant this licence for publication. I/we warrant that the Review contains no libellous or unlawful statements and does not infringe the rights or privacy of others. I/we confirm that we have sought and obtained written permission from the copyright holders to use in the Review any excerpts from copyrighted works owned by third parties and have shown credit to the sources in the Review.

Authors' rights - In return for the grant of the licence, the author(s) shall have the following rights:

- The right to post the Review as an electronic file on the author's own website and/or the author's institution's website, using the PDF version of the Review available in the Cochrane Database of Systematic Reviews.
- The right to photocopy or to transmit online or to download, print out, and distribute a reasonable number of copies of the published Review in whole or in part, for the author's personal or professional use including teaching purposes, but not for commercial purposes.
- The right to re-publish without charge all or part of any published Review authored or contributed to by the author in a book written or edited by the author.



• The right to use selected figures and tables, and selected text, including the <u>abstract</u> [145] and/or plain language summary from the Review, for the author's own teaching purposes.

The author agrees that any and all copies of the Review or any part thereof distributed or posted by the author in print or electronic form will include the following form of acknowledgement and the relevant citation:

"This Cochrane Review is published in the Cochrane Database of Systematic Reviews 20XX, Issue X. Cochrane Reviews are regularly updated as new evidence emerges and in response to feedback, and the Cochrane Database of Systematic Reviews should be consulted for the most recent version of the Review." Please include reference to the Review and hyperlink, to the original version using the following format: Authors. Title. Cochrane Database of Systematic Reviews 20XX, Issue X. Art. No.: CD00XXXX. DOI: 10.1002/14651858.CD00XXXX (insert persistent link to the article by using the URL: http://dx.doi.org/10.1002/14651858.CD00XXXX [146]). (This statement should refer to the most recent version of the Cochrane Database of Systematic Reviews in which the Review appears.)

Permission to re-publish in forms not covered by the rights granted above may be sought from The Cochrane Collaboration's Publisher, John Wiley & Sons, Ltd (www.thecochranelibrary.com/view/0/PermissionsReprints.html [147]); for example, permission to publish a version or excerpt of a Review in a print journal, online journal, or book.

Declaration of interest statement, as included in the Review

[Statement is inserted automatically from same section in the Review.]

Author(s)

| [The contact details are i | nserted automatically.] |
|----------------------------|-------------------------|
| Date: | Signature: |

[This section is repeated for each author.]

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This section updated on 21 February 2011 by Rasmus Moustgaard, Acting Director, IMS.

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Protocol [43] for a Cochrane Review [22] ("Protocol")

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The text below sets out The Cochrane Collaboration's policy on the use of the logo (the symbol and phrases containing the word 'Cochrane') in connection with activities that might relate to the work of The Cochrane Collaboration.

2.2.9.2 Who can use the logo without explicit permission?

Registered entities [20] in The Cochrane Collaboration have always been entitled to use the Cochrane logo on their headed stationery, newsletters and other material related to their work within The Cochrane Collaboration. This entitlement continues, and all entities are encouraged to use the official logo. If an entity uses its own version of the logo (for example, a modified version of the symbol or the symbol with words such as 'AUSTRALASIAN COCHRANE CENTRE' underneath it), they are strongly recommended by the Steering Group [13] also to display the official logo (see below for policy on modified versions of the logo). Official Cochrane Collaboration publications (such as the Internet sites) should display the complete, official logo (symbol plus text plus registered trademark symbol) and not the symbol on its own.

2.2.9.3 Who should seek permission before using the symbol (with or without text)?

2.2.9.4 Use of modified version of the logo

Several Cochrane entities [20] use a modified version of The Cochrane Collaboration's logo (for example, by changing the diamond into a local item when advertising Cochrane Colloquia, or putting the name of their entity under the symbol). This is permitted, but the ® must not be used on modified versions, and sponsors' names must not be included within the words under the symbol. In addition, the Cochrane Collaboration Steering Group [13] strongly recommends that the official logo (i.e. the symbol and THE COCHRANE COLLABORATION ® underneath it) is also included on all documents using any modified version of the logo. This policy should be implemented by entities



when replenishing their current stock of materials bearing a modified version of The Cochrane Collaboration logo. If offence is caused to anyone by the use of a modified logo, or if an official document does not bear the official logo, The Cochrane Collaboration's Publishing Policy Group should be informed. Other aspects of The Cochrane Collaboration's policy on the use of the logo and downloadable files containing the logo are available from www.cochrane.org/logo [153]

2.2.9.5 What if someone seems to be using the symbol (with/without text) or name inappropriately?

The Cochrane Collaboration Secretariat [1] should be informed as soon as possible of any apparently inappropriate use of the logo, symbol or name. If offence is caused to anyone by use of a modified logo, or if an official document does not bear the official logo, the Publishing Policy Group (PPG [136]) should be informed. Such instances will be discussed by the PPG, together with the relevant Cochrane entity (if there is one). If the PPG decides that the use is inappropriate, the Convenor of the PPG or the Chair of the Cochrane Collaboration Steering Group [13] will write to the organisation or person responsible, asking that they stop using the logo, symbol and/or name. If they do not comply, appropriate action will be taken to enforce this request.

2.2.10 Translation policies

These policies are for three types of material: Cochrane reviews (including abstracts), other material published in <u>The Cochrane Library</u> [18], and material about The Cochrane Collaboration that is in the public domain. Specific policies for each of these types of material follow general policies that apply to all three types of material.

2.2.10.1 General translation policies

- 1. The primary objective of these policies is to ensure high <u>quality</u> [5] translations, recognising that insisting on high quality might delay access. However, providing access to low quality translations is of questionable value.
- 2. Translations must clearly indicate the version of the English material that was translated.
- 3. John Wiley & Sons Limited will maintain a list of all approved translations of Cochrane reviews and abstracts.
- 4. Duplicate translations of the same material in the same language by different groups should be prevented through the following mechanisms:
 - 1. Translation plans should be registered with John Wiley & Sons Limited:
 - 1. If there is more than one proposal to translate the same material into the same language, the proposal that ensures the highest quality translation and continuity should be approved. If there is no substantial difference in the proposals, the first proposal received should be approved, unless there are clear reasons for not doing so. In cases where these decision rules are not followed, the reason for not doing so should be explicit and public.
 - 2. If unauthorised or duplicate translations occur, this should be brought to the attention of the Convenor of the Publishing Policy Group. The Publishing Policy Group should then attempt to negotiate with the translators, bringing in a mediator, if necessary. If the issue cannot be resolved in this way, legal action will be considered.

2.2.10.2 Translation policies for Cochrane reviews and abstracts of Cochrane reviews

Translation policies for Cochrane reviews and abstracts of Cochrane reviews are currently under



review. In the meantime, the existing policies should continue to be adhered to in the following respects:

- The production of Cochrane reviews must be entirely in English.
- Translations of reviews should be called 'Translations of Cochrane reviews' rather than 'Cochrane reviews', and translations should carry a disclaimer to exonerate The Cochrane Collaboration from any responsibility for their accuracy.
- Translations must clearly indicate the organisation that is responsible for the translation.
- The people who did the work and provided funding for translations must be properly acknowledged.
- The Cochrane Collaboration's policy on copyright for Cochrane reviews applies to both the English versions and their translations.
- Rights to publish, distribute or sell translations of Cochrane reviews must be negotiated with John Wiley & Sons.

2.2.10.3 Translation policies for other material published in The Cochrane Library

The following policies apply to the *Cochrane* Handbook [54] for Systematic Reviews of Interventions and other Cochrane material published in The Cochrane Library [18]. They do not apply to material published in The Cochrane Library that is not produced by The Cochrane Collaboration, such as the Database of Abstracts of Reviews of Effects.

- 1. The Cochrane Central Register of Controlled Trials [19] (CENTRAL) cannot be translated.
- 2. Proposals to translate abstracts and other output of The Cochrane Collaboration should be submitted to the Publishing Policy Group.
- 3. Any proposal to sell translations of Cochrane material other than Cochrane reviews must be negotiated with the Publishing Policy Group.
- 4. There must be a written agreement with the Publishing Policy Group.

2.2.10.4 Translation policies for Cochrane Collaboration material in the public domain

- 1. Promotional material and information about The Cochrane Collaboration, such as the Cochrane Collaboration brochure, may be translated by Cochrane entities [20], or by others with the approval of a Cochrane entity.
- 2. These translations should be registered with John Wiley & Sons.

(These policies were approved by the Publishing Policy Group of the <u>Steering Group</u> [13] on 6 October 1999, and amended by them on 14 December 2000.)

2.2.10.5 Non-English translations of documents published in The Cochrane Library

The following template should be completed as far as possible before undertaking the translation of any document published in <u>The Cochrane Library</u> [18] into a language other than English, so that it can be registered with The Cochrane Collaboration via John Wiley & Sons (<u>dpentesc@wiley.co.uk</u> [138]). When the translation has been finished, the cover sheet should be revised if necessary. The



cover sheet should also be made available with the translated document, in both the language of the translation and in English. There is a separate policy for the translation of abstracts of Cochrane reviews.

- 1. What document (or part of a document) has been translated, and into what language? Please include sufficient information to identify the version of the document that was translated.
- 2. How can someone obtain an English language version of the most up-to-date version of the official document?
- 3. Who is responsible for this translation (e.g. a Cochrane <u>Centre</u> [34])? This person or entity should also be the point of contact for people who wish to report errors in the translation.
- 4. Who did the translation (i.e. a named person or group of people) and on what date did they complete it?
- 5. How was the *quality* [5] of the translation checked?
- 6. What plans are there to ensure that the translation keeps up-to-date with changes to the official document?

2.2.10.6 Non-English translations of official Cochrane Collaboration documents

The following template should be completed as far as possible before undertaking the translation of an official Cochrane Collaboration document (such as the introductory leaflet) into a language other than English, so that it can be registered with the Cochrane Collaboration Secretariat [1] (
secretariat@cochrane.org [2]).

- 1. What document (or part of a document) has been translated, and into what language? Please include sufficient information to identify the version of the document that was translated.
- 2. How can someone obtain an English language version of the most up-to-date version of the official document?
- 3. Who is responsible for this translation (e.g. a Cochrane Centre [34])? This person or entity should also be the point of contact for people who wish to report errors in the translation.
- 4. Who did the translation (i.e. a named person or group of people) and on what date did they complete it?
- 5. How was the <u>quality</u> [5] of the translation checked?
- 6. What plans are there to ensure that the translation keeps up-to-date with changes to the official document?

2.2.11 How to cite our products

The Cochrane Library [18]:

The Cochrane Library, Issue X, 200X. Chichester: Wiley.

A module [102] in The Cochrane Library:

Authors [to be determined by the entity but to be written using the style: Smith J, Jones M, or the entity name]. Name of Cochrane entity. In: *The Cochrane Library*, Issue X, 200X. Chichester: Wiley. Updated monthly.

A Cochrane review [22] in The Cochrane Library:

Authors. Title of review. *Cochrane Database of Systematic Reviews* 200X, Issue X. Art. No.: CD00XXXX. DOI: XX.XXXX/XXXXXXXXXX.CD00XXXX.pubX.



Example:

Gates S, Anderson ER. Wound drainage for caesarean section. *Cochrane Database of Systematic Reviews* 2005, Issue 1. Art. No.: CD004549. DOI: 10.1002/14651858.CD004549.pub2.

The Cochrane Style Guide has detailed instructions on how to replicate this citation style when entering citations in RevMan.

Cochrane reviews should be cited as published in the *Cochrane Database of Systematic Reviews*, with the issue of publication rather than the current issue of *The Cochrane Library*.

Cochrane Handbook [54] for Systematic Reviews of Interventions:

To cite the whole Handbook [55], use:

Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions*, Version [version number] (updated [month] [year]). The Cochrane Collaboration [year]. Available from www.cochrane-handbook.org [154] (accessed [day] [month] [year]).

Details for citing individual chapters of the Handbook are provided at the end of each chapter.

The Cochrane Policy Manual:

The Cochrane Collaboration. *The Cochrane Policy Manual* Issue X, 200X [updated [date]]. www.cochrane.org/admin/manual.htm [155] (accessed [date]).

This information is available to the public at http://www.cochrane.org/training/authors-mes/citing-our-products [156].

2.2.12 Withdrawal or suspension of complimentary copies of The Cochrane Library

2.2.12.1 Withdrawal

The Contact Person for each published <u>Cochrane Review</u> [22]* will receive a complimentary subscription to <u>The Cochrane Library</u> [18] as long as their review is updated at least every two years. The exact expiry date of the Contact Person's subscription is two and a half years from the date when the published review was 'assessed as up to date'.

*This does not apply to Protocols.

The policy of withdrawal of complimentary copies of *The Cochrane Library* from the Contact Person of a review took effect from Issue 1, 2002 (i.e. for reviews that had not been updated since Issue 3, 1999). This meant that Issue 2, 2002 was the first issue for which complimentary copies could be withdrawn from Contact Persons. Implementation of this policy was subsequently monitored, and the CCSG [23] agreed in November 2008 that the Contact Persons of published reviews should receive a complimentary subscription to *The Cochrane Library* for approximately two years.

2.2.12.2 Suspension

In May 2009 the Editor in Chief notified the contact people, <u>of all published reviews which had been assessed as up to date within the preceding two years</u>, of their eligibility for complimentary online access to The Cochrane Library, with effect from Issue 3, 2009. Alternatively, contact people who wished to continue to receive complimentary access <u>offline</u> could continue to do so, but the CDs would be replaced by DVDs: this was because there were now six CDs for each issue of The Cochrane Library and the environmental cost of producing and distributing them had become a



major issue. As a further alternative, contact people could donate their complimentary subscription to someone else with an entry in Archie. The same message was conveyed to Cochrane entities [20] (other than Review Groups) regarding each entity's entitlement to one complimentary subscription, and to Review Groups regarding their entitlement to the several complimentary copies of each issue that they had been receiving in the past. Suspending unwanted or unused complimentary subscriptions would sensibly release funds to further the Collaboration's goals.

2.2.13 Access to the Parent Database

The current position with regard to access to the Parent Database is that the Collaboration's publisher sends a copy of this before each release of The Cochrane Library [18] to the Information Management System team at the Nordic Cochrane Centre [34]. This is in order to facilitate software development, and to fulfil requests for information from members of The Cochrane Collaboration for either administrative or research purposes. If someone wants access to such information, they should use the following template to request the approval of the Steering Group [13] Executive via the Director of the Information Management System:

- · Request for data from the Parent Database
- Name of person requesting the data:
- Cochrane entity:
- Date of request:
- Information being requested:
- Is this a one-off request or a request for information on a regular basis?
- How will the information be used?
- How will the findings be disseminated?
- By when do you need these data?

To be answered by the IMS team:

- How many resources is this request likely to require?
- Can the data be provided by the requested date?

People given access to data from the Parent Database will be expected to provide a brief (no more than two pages) report to the Executive of the Steering Group, indicating the purpose to which the data were put, within two months.

2.2.1.4 Cochrane-Wiley book series proposals

The aims of the approved Cochrane-Wiley book series are to:

- (i) Increase global awareness and recognition of the Cochrane 'brand' in the books marketplace, and thus awareness, recognition and uptake of The Cochrane Collaboration's activities and outputs, and so increase <u>review</u> [29] production and influence global healthcare decision-making;
- (ii) Improve the accessibility and usefulness of Cochrane output for specific audiences;
- (iii) Exploit the synergies of both a multi-title series and of joint publication of <u>The Cochrane Library</u> [18] to increase awareness and sales of both products;
- (iv) Achieve a financial return for individual titles in excess of that which might have arisen from titles in isolation, through both the synergies referred to above, and through a larger negotiating presence; and



(v) To reduce the administrative burden on individual <u>Cochrane groups</u> [20] by removing from them the necessity to negotiate individual contract terms, beyond those specific to individual titles.

With these aims in mind, the <u>Steering Group</u> [13] agreed in April 2010 that once proposals for the Cochrane-Wiley book series have been sufficiently developed for consideration by the Wiley project approval panel, they should be sent to the Operations and Finance Committee (OFC) for approval on behalf of the full Steering Group. At the same time that a book is proposed formally for this book series, the Collaboration should be advised via the Chief Executive Officer, and the OFC would provide feedback to Wiley. The current arrangement for royalties is a matter for the relevant <u>Cochrane Review</u> [22] Group editors as to where they wish the royalties to go. For an individual book title, no decision should be made until a contract has been signed between the Collaboration and Wiley. If the word 'Cochrane' is used in the book title, this would have implications for royalties: the expectation is that they would either go to the Collaboration or to the relevant author(s)/Review Group, but there may be circumstances in which this is not practicable.

Text provided by Nick Royle, Chief Executive Officer, December 2010.

2.3 Commercial sponsorship policy

Introduction

The <u>Steering Group</u> [13] of The Cochrane Collaboration has undertaken a process of consultation on commercial sponsorship. The debate was stimulated by a letter from several members of The Cochrane Collaboration who felt that existing policy ought to be more restrictive - to provide still greater reassurance that the conclusions of Cochrane reviews were not biased through the influence of funding by commercial <u>entities</u> [20] that stood to benefit financially from the results of reviews.

Commercial sponsorship of health-related research is, of course, not an issue of concern uniquely to The Cochrane Collaboration. Many members of The Cochrane Collaboration have pointed out that external perception is also important. Any perception that for-profit commercial organisations, notably but not exclusively, the pharmaceutical industry and medical device manufacturers, were influencing the conclusions of Cochrane reviews would damage a carefully nourished reputation for impartiality and scientific rigour.

This issue was discussed at length at the 11th annual Cochrane Colloquium in Barcelona in October 2003. A consultation document was disseminated during December 2003 with a request for views by 31 January 2004; 156 individuals or groups responded. Most were active members of The Cochrane Collaboration. The Steering Group met in Bergamo, Italy, from 29 February to 2 March 2004 and considered at length the very extensive and detailed documentation. An agreed policy document was disseminated on 6 April 2004. At that time, there was, for some questions, very clear consensus; for others, there was not. The Steering Group discussed unresolved issues at their meetings in Ottawa, Canada, on 1 and 4 October 2004, and in Providence, US, on 2 to 4 April 2005. They were also discussed at the annual general meeting during the 12th Cochrane Colloquium in Ottawa on 3 October 2004. Following these discussions, the policy document was amended in April 2005.

Background

Since the decisions taken by The Cochrane Collaboration are also of interest to others it may be helpful to describe, briefly, the structure of The Cochrane Collaboration. It is a highly devolved organisation that involves more than 10,000 people, in different capacities, worldwide. Most do not receive any payment for the work they do within The Collaboration. They are drawn to The Collaboration through a wish to commit, either as a professional or as a consumer, to a movement to provide more sound evidence on which healthcare decisions can be made. The formal structure of The Collaboration comprises Cochrane Review Groups (which produce systematic reviews), Centres (with responsibilities that include support for Cochrane Review Groups within their area of



geographical responsibility), Methods Groups, Fields, a Consumer Network, an elected Steering Group, and a small Secretariat [1]. The Secretariat, Steering Group and Advisory Group meetings, and key generic developments (e.g. software for information management, production of the Cochrane Handbook [54] for Systematic Reviews of Interventions, and development of The Collaboration's website) are all funded, in part or in whole, through royalties on sales of The Cochrane Library [18]. Everything else (including support of Cochrane Review Groups and Centres) is funded through applications to other sources (often government agencies), and these sources are almost all in the country in which the entity is located.

There is substantial variation internationally in the amount of funding for support of Cochrane activity and, in some parts of the world, it is extremely difficult to access government or charitable funds. In some areas, there has recently been an important decrease in financial support for Review Groups and Centres. Therefore, an alternative option, of seeking funding from commercial sources, could be attractive to, say, Co-ordinating Editors of Review Groups, or Centre Directors, who otherwise face the prospect of curtailing productivity and/or making skilled and experienced staff redundant. Setting policy on issues as sensitive and important as sources of funding in as complex an organisation as The Cochrane Collaboration is never an easy matter, and may be even more difficult at this time.

Definitions

- By 'commercial source' we mean [111] any for-profit manufacturer or provider of health care, or any other for-profit source with a real or potential vested interest in the findings of a specific review. Whilst government departments, not-for-profit medical insurance companies and health management organisations may find the conclusions of Cochrane reviews carry financial consequences for them, these are not included in this definition. Also not included are for-profit companies that do not have real or potential vested interests in Cochrane reviews (e.g. banks).
- By 'sponsorship' of a review, we mean a sum of money given to an author or group of authors to prepare, or update, a Cochrane review. Such sponsorship could include not only commissioning of specific systematic reviews, but also, for example, funding of a sabbatical period to work on a Cochrane review.
- We used the term 'firewall' in the consultation document. By this, we mean, figuratively, a fireproof wall put in place to ensure that, if a fire occurs, it is confined to one area. We used the term to indicate a clear barrier or separation between a source of funding and the use to which that funding is put, so as to prevent any influence by the funding source on the outcome [105] of, say, a Cochrane review.

Conclusions

- 1. There was overwhelming consensus that there should be a clear barrier between the production of Cochrane reviews and any funding from commercial sources with financial interests in the conclusions of Cochrane reviews.
- 2. Thus, sponsorship of a Cochrane review by any commercial source or sources (as defined above) is prohibited.
- 3. Other sponsorship is allowed, but:
 - A sponsor should not be allowed to delay or prevent publication of a Cochrane review. A sponsor should not be able to interfere with the independence of the authors of reviews in regard to the conduct of their reviews.
 - The <u>protocol</u> [43] for a Cochrane review should specifically mention that a sponsor cannot prevent certain outcome measures being assessed in the review.
- 4. These rules also apply to 'derivative products' (containing Cochrane reviews) so that commercial sponsors could not prevent or influence what would be included in such products.
- 5. To ensure the integrity (real and perceived) of the 'firewall', it is also prohibited for a commercial source or sources (as defined above) to sponsor Cochrane entities that produce Cochrane reviews, that is, Cochrane Review Groups.
- 6. It was agreed that these same restrictions should apply to Fields and to the Consumer Network because of the close proximity of these entities to review production.



- 7. The position on commercial funding of Methods Groups' activities was reviewed and reconsidered at the Steering Group mid-year meeting in Khon Kaen in April 2006. It was agreed that funding from a commercial source (as defined above) for the activities of Methods Groups, or of their members, in producing Cochrane reviews of healthcare interventions or tests, or supporting individual review groups, including peer review [131], is not permitted. Methodologists who have personally received remuneration or research funds from a commercial source in the previous five years should ensure that they have no involvement in reviews of interventions or tests in which the commercial source has a vested interest. The receipt and use of commercial funds by Methods Groups for other purposes must be declared in Methods Groups' modules
- 8. The situation with regard to Cochrane Centres is more complex than for other Cochrane entities. For example, Centres can be both close to review production (like Fields and the Consumer Network) but can also engage in methodological work (like Methods Groups). The position on commercial funding of Cochrane Centres' activities was reviewed and reconsidered at the Steering Group mid-year meeting in Providence in April 2005. As a principle, there should be no direct funding of Cochrane Centres (or Branches of Centres) by commercial sources. This includes the funding of core and non-core functions of Cochrane Centres. Direct funding currently in place can continue, but should be phased out over the next five years. Therefore, from April 2010, any direct funding of Cochrane Centres from commercial sources is prohibited. Non-direct funding of non-core activities (such as translation) would, however, be permitted after 2010 from a central fund see 17 below.
- 9. Some entities may find themselves in financial difficulty because of the need to shed current commercial funding. Therefore, although this policy is mandatory now in relation to any new funding, it will become mandatory in relation to existing sources of funding two years after the date of adoption, to allow time for entities to seek alternative sources of funding. If any entity has contractual obligations that mean that they cannot shed current commercial funding within the next two years, they should discuss this urgently with the Funding Arbiter [38].
- 10. The position of Funding Arbiter has been established, analogous to the <u>Publication Arbiter</u> [39]. The Funding Arbiter is a Steering Group member and convenes a standing panel of four to give guidance on difficult cases.
- 11. The responsible Cochrane Review Group should refer any existing Cochrane reviews that have been produced by a process that would no longer be permissible to the Funding Arbiter. A decision will be taken within the first twelve months of the implementation of this policy to consider what should happen to these Cochrane reviews (e.g. whether they should be withdrawn from *The Cochrane Library*).
- 12. Authors of reviews should declare financial support for the review, private clinical practice (if relevant), stocks, legal advice, consultancies, involvement in primary research in the subject area of their review, and any other 'competing interests' that they judge relevant.
- 13. Such declarations will be described in the review. The declarations will not be published outside of the review itself, for example with the <u>abstract</u> [145] or plain language summary.
 - 14. If an author has been actively involved in a study/studies that was/were eligible for their review, they should have, as a co-author, someone who was not involved in the study/studies. The co-author would not necessarily be the contact author for the review, but could act as a 'guarantor'.
- 15. If a review has been done, or is proposed, by people who are employed by a pharmaceutical or medical devices company that relates to the products of that company, it will be referred to the Funding Arbiter. In such circumstances, The Cochrane Collaboration will insist on a multi-disciplinary review team with a majority of the team of authors not being employed by the relevant company.
- 16. People with a direct financial interest in a particular intervention should not be involved in a review of that intervention, either as authors, editors or peer reviewers.
- 17. It was agreed to establish a central fund into which unrestricted donations could be made. It was further agreed that there should not be a prohibition on donations from any single company or type of industry but that all funding of activity in The Cochrane Collaboration should be in keeping with the principles of The Cochrane Collaboration.
- 18. There is an existing Collaboration policy on sponsorship of Colloquia. The Colloquium Policy Advisory Committee have been asked to reconsider this in light of changes to the policy on commercial sponsorship, and to bring any recommendations for changes to this policy to the Steering Group.



- 19. Authors and Cochrane Review Groups should not receive royalties on sales of reprints of their reviews, since these sales are likely to have been made to commercial sources and might, therefore, be assumed to be equivalent to direct sponsorship of the review or Group. Therefore, the current policy that royalties on reprint sales go to The Cochrane Collaboration centrally, via the Collaboration Trading Company, will continue. When a central fund is established, the possibility that such income should go into it will be discussed.
- 20. John Wiley and Sons Limited should continue to be encouraged to make bulk sales of *The Cochrane Library* and derivative products to commercial sources.
- 21. All Cochrane Collaboration policies are kept under continual review, but these decisions will be formally reviewed after three years.

6 April 2004

Amendments made in April 2005

- 1. The position on commercial funding of Methods Groups' activities is being reviewed and will be reconsidered at the Steering Group mid-year meeting in April 2006.
- 2. As a principle, there should be no direct funding of Cochrane Centres (or Branches of Centres) by commercial sources. This includes the funding of core and non-core functions of Cochrane Centres. Direct funding currently in place can continue, but should be phased out over the next five years. Therefore, from April 2010, any direct funding of Cochrane Centres from commercial sources is prohibited. Non-direct funding of non-core activities (such as translation) would, however, be permitted after 2010 from a central fund see 17 above.

Amendments made in April 2006

The position on commercial funding of Methods Groups' activities was reviewed and reconsidered at the Steering Group mid-year meeting in Khon Kaen in April 2006. It was agreed that funding from a commercial source (as defined in this policy) for activities of Methods Groups, or of their members, in producing Cochrane reviews of healthcare interventions or tests, or supporting individual review groups, including peer review, is not permitted. Methodologists who have personally received remuneration or research funds from a commercial source in the previous five years should ensure that they have no involvement in reviews of interventions or tests in which the commercial source has a vested interest. The receipt and use of commercial funds by Methods Groups for other purposes must be declared in Methods Groups' modules.

This information is available to the public at http://www.cochrane.org/about-us/commercial-sponsorship [157].

2.4 Annual prizes and awards

Additional information to that presented below, including the names of committee members and past recipients, can be found on the Collaboration's website at http://www.cochrane.org/about-us/awards-scholarships-funding-initiatives/annual-prizes-and-awards [158].

Subheadings in this section

2.4.1 Thomas C Chalmers Award

Thomas C Chalmers MD



Throughout his career, Tom was an outspoken advocate of randomised trials, whether at the bedside, at professional meetings, in class, or [127] in situations pertaining to his own life. After his diagnosis of prostate cancer in 1993, he insisted that he only receive treatment [8] in the context [46] of a clinical trial [159]. Fortunately, there was an ongoing trial at Dartmouth Hitchcock Medical Center in which he enrolled. Over the course of his illness, he delighted in quizzing and lecturing the residents and physicians caring for him about the evidence for their tests and interventions. He loved to teach, frequently using argument as a device. His creativity spanned his entire career, influencing clinicians and methodologists alike. He is perhaps best known for the notion 'randomise the first patient', his belief that it is more ethical to randomise patients than to treat them in the absence of good evidence.

In his later years, in arguably his most important work, Tom and his colleagues showed that, had information from RCTs been systematically and cumulatively synthesised, important treatments such as thrombolytic therapy for myocardial infarction would have been recognised as useful earlier. In addition, he demonstrated that the advice given in textbooks and review [29] articles published over the same period of time did not correspond to the available evidence, even fifteen years after an intervention's effect had been well characterised.

The Thomas C Chalmers Award

The Thomas C Chalmers Award was established with individual donations to celebrate and recognise Tom's interests, and was awarded for the first time at the 2nd Cochrane Colloquium in Hamilton, Ontario, Canada, in October 1994. The recipients receive a certificate and 1000 US dollars (to be split equally between the two recipients). Any runners-up also receive certificates.

Selection criteria for the Thomas C Chalmers Award

The Thomas C Chalmers Award is given each year to the principal authors of the best oral presentation **and** the best poster presentation at the Colloquium. All accepted posters and oral presentations will be eligible for the Award if they address methodological issues related to systematic reviews and demonstrate:

- 1. originality of thought;
- 2. high quality [5] science;
- 3. relevance for the advancement of the science of systematic reviews;
- 4. clarity of presentation.

The work should be presented by a junior investigator who is currently contributing to a Cochrane entity and who hasn't previously been the recipient of this Award.

Presentations are judged by the Thomas C Chalmers MD Award Committee (chaired in 2010 by Georgia Salanti). The ten members of the Committee are drawn from the Methods Groups of The Cochrane Collaboration. At least two members represent the Screening and Diagnostic Tests Methods Group, two members represent the Statistical Methods Group, and one member represents the Prognosis Methods Group. The Committee also aims to be geographically representative of the Collaboration. The Award is administered by the Cochrane Collaboration Secretariat [1] (secretariat@cochrane.org [2]).

More details can be found on the Collaboration's website at http://www.cochrane.org/about-us/awards-scholarships-funding-initiatives/annual-prizes-and-awards/thomas-c-chalmers-award [160].

2.4.2 Chris Silagy Prize

Chris Silagy, AO, MD



Chris Silagy was the founding Director of the Australasian Cochrane Centre [34] (1994 to 2001), a former Chair of the Cochrane Collaboration Steering Group [13], and instrumental in the development and success of The Cochrane Collaboration. Chris was energetic, positive and inspiring. Before his death on 13 December 2001, Chris expressed a wish for a Fund to be established, to be held by the Monash Foundation. Chris initiated this fund with his own contribution, and requested donations be made to it instead of flowers or other tributes after his death. Chris requested that this Fund be used to recognise contributions to The Cochrane Collaboration in ways that are often insufficiently recognised. For example, providing administration, management, Colloquium organisation, communication and motivation - in short, the 'glue' that helps to keep The Cochrane Collaboration together. At the Cochrane Collaboration Steering Group meeting in April 2002, the establishment and perpetuation of this Prize was approved, with The Cochrane Collaboration agreeing to contribute in kind to the Prize, by supporting the recipient's attendance at the Colloquium to receive the Prize.

The Chris Silagy Prize

The Chris Silagy Prize is awarded at every Cochrane Colloquium to an individual (or team) who has made an extraordinary contribution to the work of The Cochrane Collaboration. The Prize consists of 1000 Australian dollars (drawn from the Chris Silagy Memorial Fund), a certificate which includes the words 'for an extraordinary contribution to the work of The Cochrane Collaboration' (that would not be recognised outside the scope of this prize) and expenses associated with attending the Colloquium (to be met by The Cochrane Collaboration).

Scope

Potential recipients of the Chris Silagy Prize are required to have:

- made an extraordinary contribution to The Cochrane Collaboration;
- made a contribution that exceeds the expectations of their employment;
- made a contribution to The Cochrane Collaboration that would not be recognised outside the scope of this Prize (publishing a piece of research work or preparing a Cochrane systematic review [29] do not fall within the scope of this Prize as they qualify for other awards and methods of recognition);
- been identified by their peers as consistently contributing to a spirit of collaboration.

A call for nominations for the Chris Silagy Prize is made through the Cochrane Collaboration mailing lists in April each year. Nominations should include a nominator, two seconders and a one-page supporting document outlining how the nominee meets the selection criteria. A selection panel of three individuals is appointed each year from past members of the Steering Group and its advisory groups, and the previous year's Prize recipient (if unconflicted). A Governing Committee (see below) oversees this Prize.

Governing committee

Jane Russell (Silagy)

Sally Green

Jini Hetherington (from 2003)

Donations to the Chris Silagy Prize Fund

Donations to this Fund are most welcome. Cheques should be made payable to 'The Silagy Fund, Monash University' and sent to The Development Office, Building 65, Monash University 3800, 246 Clayton Road, Clayton, Victoria 3168, Australia.

Credit card donations (MasterCard, Bankcard and Visa only) can be faxed to +61 3 9905 2944. The



credit card number should be written clearly, and the fax must include the expiry date of the credit card, the name exactly as it appears on the card, and the cardholder's full name and address.

Telephone donations can be made to Sara Kelly, The Development Office, Monash University, University Development and Alumni, on $+61\ 3\ 9905\ 9957$.

Donors to the Chris Silagy Prize Fund

Individual donors: Professor Leon Piterman; Mrs Pamela R Herman; Professor Elsdon Storey; Ms Lyn Roberts; Dr Wendy Rogers; Professor David Hill; Ms Frances Fairman; Professor Amy E Zelmer; Mr Eric L Garner, AM; Mrs Suzanne Strangward; Dr Rosemary L Nixon; Mrs Joan M McPhee; Mr John L McPhee; Professor Stephen J Duckett; Ms Pauline Pellegrini; Mr NG Taylor; Dr JL Linn; Dr JS Linn; Ms Margaret F Broadhead; Professor Godfrey Fowler; Mrs Jeannett L Hall; Mrs R Allen; Mr Ken R Strangward; Mr Julian F Coles; Ms Janet Coles; Professor MP Vessey.

Institutional donors: National Heart Foundation of Australia; Mt Waverley District Scout <u>Association</u> [24].

More details can be found on the Collaboration's website at http://www.cochrane.org/about-us/awards-scholarships-funding-initiatives/annual-prizes-and-awards/chris-silagy-prize [161].

2.4.3 Bill Silverman Prize

William (Bill) Silverman, MD

Bill Silverman (1924-2004) was one of the founders of American neonatal medicine. He was honoured repeatedly as one of the pioneers in his specialty; however, he often evoked somewhat mixed responses amongst his colleagues because he was in the habit of raising troubling questions about the scientific basis and ethics of his and their practices. Like many of the people who have helped to establish The Cochrane Collaboration, Bill Silverman could be regarded as a 'troublemaker'. As he reiterated frequently, however, criticism is a form of troublemaking that can help to drive progress. Furthermore, criticism should not be limited to examining the work of others, but should also include self-criticism.

The Bill Silverman Prize

The Bill Silverman Prize explicitly acknowledges the value of criticism of The Cochrane Collaboration, with a view to helping to improve its work, and thus to achieve its aim of helping people make well-informed decisions about health care by providing the best possible evidence on the effects of healthcare interventions. The establishment of the Prize was approved by the Cochrane Collaboration Steering Group [13] in 2007, and awarded for the first time in 2008.

The Prize is offered annually and the authors of a piece of research published or presented in the preceding twelve months (July 1 to June 30) will be eligible. The criteria for the Prize are that the publication or presentation evaluated any aspect of the preparation, maintenance or dissemination of Cochrane reviews or the work of The Cochrane Collaboration more generally, and:

- was of high <u>quality</u> [5];
- was accompanied by constructive suggestions on how the relevant aspects of the work of The Cochrane Collaboration could be improved;
- has had, or is likely to have, a positive impact on the scientific quality, relevance and use of Cochrane reviews.



The Prize recipients are announced at the Cochrane Colloquium each year. The prize comprises a cash award of 1000 US dollars and a certificate. (Additional funds are not available from the Prize fund for the recipients to attend the Cochrane Colloquium.) The cash award goes to the corresponding author of the selected publication or presentation, and it is this person's responsibility to distribute the award in a fair way to her/his colleagues. The Prize committee will provide details of all nominations that relate to evaluations of any aspect of the preparation, maintenance or dissemination of Cochrane reviews or the work of The Cochrane Collaboration more generally, to the Executive of the Steering Group, so that suggestions for improvements can be considered. The committee will also provide details to the Cochrane Methodology Review Group, so that relevant records can be incorporated into the Cochrane Methodology Register.

Nomination:

The Prize committee calls for nominations for the Prize in May, and issues a reminder in early July. Nominations can be made by anyone, including the authors of the publication or presentation being nominated. Nominations should be e-mailed to secretariat@cochrane.org [2] with 'Bill Silverman Prize' in the subject heading, the citation for the publication or presentation and a brief explanation of how it meets the criteria for the Prize. The deadline for receipt of nominations is August 31.

Bill Silverman Prize committee

The Prize committee comprises five members, at least three of whom do not have an active role within any Cochrane entity (other than, possibly, as an author or referee [162] of one or more Cochrane reviews). One of these people co-chairs the committee. The other co-chair is someone with an active role within a Cochrane entity. Each year, one of the co-chairs will stand down from the committee, to be replaced as co-chair by an existing member. The resulting vacancy on the committee will be filled by the recipient of the most recent Prize (or a person chosen by the recipients).

Funding for the Prize

Bill Silverman's family agreed to the establishment of this Prize, and Iain and Jan Chalmers contributed 5000 pounds sterling of start-up funding. These Prize funds are administered by the Cochrane Collaboration Secretariat. The Cochrane Collaboration Steering Group will determine the future of the Prize when this initial contribution has been exhausted and, if relevant, will seek to identify future funding.

More details can be found on the Collaboration's website at http://www.cochrane.org/about-us/awards-scholarships-funding-initiatives/annual-prizes-and-awards/bill-silverman-prize [163].

2.4.4 Kenneth Warren Prize

Kenneth Warren, MD

Kenneth Warren was a larger-than-life man who was a source of encouragement and support for many young people, particularly those living in developing countries. He was very influential in drawing attention to the 'great neglected diseases' that plague people in the poorer parts of the world. He was one of the first people to draw attention to the need for valid summaries of key research studies and to the way that electronic media could be used to disseminate the results of health research relevant to people in developing countries. Ken was an enthusiastic supporter of the pilot work in pregnancy and childbirth that led to the creation of The Cochrane Collaboration, and, with Fred Mosteller, he co-organised the meeting at the New York Academy of Sciences at which the vision for The Cochrane Collaboration was first made public.

The Kenneth Warren Prize

The Kenneth Warren Prize was established with individual and institutional donations [164] to



celebrate and recognise Ken's interests. It was awarded for the first time at the 8th Cochrane Colloquium in Cape Town, South Africa, in October 2000. The prize is awarded annually to the principal author of whichever systematic review [29], published electronically on The Cochrane Database of Systematic Reviews in The Cochrane Library [18] and authored by a national living in a developing country, is judged to be both of high methodological quality [126] and relevant to health problems in developing countries. The Prize for any given year is open to the principal author of a review published in Issues 1 or 2 of *The Cochrane Library* that year, or Issues 3 or 4 of the previous year. The judgement is made by a panel comprised entirely of nationals of developing countries. The Prize recipient receives a certificate and 1000 US dollars. Also, the travel, accommodation and conference registration costs of the Prize recipient and of the Chair of the selection panel are met to enable attendance at the Cochrane Colloquium to receive/present the Prize.

Donors to the Kenneth Warren Prize Fund

Individual donors: Kenneth Warren's Family, Cyril Akpom, Jan and Iain Chalmers, Dr and Mrs Joseph Cook, Murray and Eleanor Enkin, Phyllis Freeman and Anthony Robbins, Mr and Mrs Alfred Heggie, Adel Mahmoud, Irwin and Marion Schafer, Chris and Jane Silagy.

Institutional donors: Current Controlled Trials Ltd; <u>Eugene Garfield Foundation</u> [165]; <u>Rockefeller Foundation</u> [166]; The LW Frohlich Charitable Trust.

Additional donations to the Kenneth Warren Prize Fund are very welcome. Anyone wishing to consider making a donation should contact secretariat@cochrane.org. [2]

More details can be found on the Collaboration's website at http://www.cochrane.org/about-us/awards-scholarships-funding-initiatives/annual-prizes-and-awards/kenneth-warren-prize [167].

2.5 Fellowships, scholarships and bursaries

This information is available to the public at http://www.cochrane.org/about-us/awards-scholarships-funding-initiatives/fellowships-scholarships-a http://www.cochrane.org/about-us/awards-scholarships-funding-initiatives/fellowships-scholarships-a http://www.cochrane.org/about-us/awards-scholarships-funding-initiatives/fellowships-scholarships-a http://www.cochrane.org/about-us/awards-scholarships-funding-initiatives/fellowships-scholarships-a http://www.cochrane.org/about-us/awards-scholarships-a <a href="http://www.cochrane.org/about-us/awards-scholarships-awards-scholarships-awards-scholarships-awards-scholarships-awards-scholarships-awards-sc

Subheadings in this section

2.5.1 Cochrane Complementary Medicine Field Bursary Scheme

General information

The Bursary Scheme is offered by the Cochrane Complementary Medicine Field, Center for Integrative Medicine, University of Maryland, and made possible through funds from the National Institutes of Health, National Center for Complementary and Alternative Medicine. The purpose of this bursary scheme is to ensure that reviews relevant to complementary and alternative medicine (CAM) (see below) are completed and published in The Cochrane Library [18]. Only Cochrane authors who have already registered CAM-related protocols/reviews with a Cochrane Review [22] Group will be eligible for funding.

Funding offered

Two review proposals in the amount of \$5,000 USD each will be funded annually. The funding must be paid directly to the individual bursary recipient; it cannot be paid to the recipient's institution.

Eligibility requirements



- The review must be registered with a Cochrane Review Group, and the relevant protocol/review must already be published in *The Cochrane Library*.
- The topic of the review must relate to CAM (see below).
- Bursaries will be targeted to reviews for which substantial progress has already been made, and whose completion has been stalled due to a lack of funding.

Proposal outline

Applications should include the following:

- A completed application form (required see below).
- A letter of support from Cochrane Review Group through which the protocol has been registered (optional). Applications will be evaluated based primarily on the submitted application forms (using the assessment criteria below). However, letters of support from Review Groups may also be provided, particularly if such letters would include additional supporting information, not already included in the application form, which might influence assessments.

Assessment

Proposals will be rated on three criteria:

- The importance and relevance to CAM.
- An assessment of the likelihood that the funding would insure completion and publication of the review.
- A perceived need for the funding to complete the review.

Reviews relevant to Traditional Chinese Medicine, a primary focus of research at the Center for Integrative Medicine, University of Maryland, are encouraged.

Each proposal will be rated by two representatives from the Cochrane Complementary Medicine Field, both with a sound knowledge of both CAM and systematic reviews.

Topic parameters

Complementary medicine includes all such practices and ideas that are outside the domain of conventional medicine in several countries and defined by its users as preventing or treating illness, or promoting health and wellbeing. These practices complement mainstream medicine by 1) contributing to a common whole; 2) satisfying a demand not met by conventional practices; and 3) diversifying the conceptual framework of medicine.

The list of Complementary Medicine Field topics comprises the entire spectrum of heath delivery mechanisms, including treatments that a person largely administers to him or herself (e.g. botanicals, nutritional supplements, health food, meditation, magnetic therapy); treatments that providers administer (e.g. acupuncture, massage therapy, reflexology, laser therapy, balneotherapy, chiropractic and osteopathic manipulations, certain types of psychological counselling, naprapathy); and treatments that a person administers to him or herself under the periodic supervision of a provider (e.g. yoga, biofeedback, Tai Chi, homeopathy, hydrotherapy, Alexander therapy, nutritional therapy, Ayurveda).

In addition to the CM treatments listed above, CM interventions also include Qi Gong, Doman Delcato patterning, Anthroposophical medicine, Unani medicine, Traditional African Medicine, Bach flower remedies, clinical ecology, colon cleansing or irrigation, and music or sound therapy. CM diagnostic techniques, a subgroup in the list, include iridology, kinesiology, Vega testing, biofunctional diagnostic testing, electro-acupuncture by Voll, and hair analysis.

Timeline and information for awards

The deadline for completed application forms is 29 October 2010. Application forms are available at http://www.compmed.umm.edu/integrative/cochrane_bursary.asp [169]. Completed application forms and (optional) letters of support should be sent **by e-mail only** to Eric Manheimer (



emanheimer@compmed.umm.edu [170]). (Applications sent by post or fax will not be accepted.)

Successful candidates will be notified by 19 November 2010. Funds will be distributed to successful applicants in a single instalment, after the award notification.

2.5.2 Aubrey Sheiham Public Health and Primary Care Scholarship

Aubrey Sheiham, BDS, PhD, DHC

Aubrey Sheiham is a dental epidemiologist who was inspired and encouraged by Archie Cochrane to question many of the practices in medicine and dentistry. His main commitment is to improving the health of populations in underdeveloped countries and challenging dental establishments to be far more critical. The misuse of healthcare resources has more serious ethical and health implications in underdeveloped countries because resources there for health are generally inadequate. Aubrey considers that supporting and training key health personnel in the concepts of The Cochrane Collaboration will improve the effectiveness [101] and efficiency of primary health care. Aubrey and his wife Helena have been exceptionally generous not only through their financial support of the Aubrey Sheiham Scholarship, but also for making their apartment in Oxford, England, available for the use both of the Scholars and other members of The Cochrane Collaboration visiting Oxford to do Cochrane work.

The Aubrey Sheiham Public Health and Primary Care Scholarship

General information and requirements of the scholarship

The Aubrey Sheiham Public Health and Primary Care Scholarship is a three-month scholarship offered annually by The Cochrane Collaboration to health workers, consumers and researchers living in developing countries. The aim of the Scholarship is to enable the development of skills in preparing systematic reviews of healthcare interventions within The Cochrane Collaboration. The Scholarship is awarded annually for work on a topic related to public health or primary health care.

The Aubrey Sheiham Scholar spends the three-month Scholarship period in Oxford. The Scholar is based at the UK Cochrane Centre [34] in Oxford for the duration of the Scholarship, and resides in free accommodation provided by The Cochrane Collaboration. The Scholar is expected to prepare a Cochrane Review [22] during the tenure of the Scholarship and, upon returning home, to maintain the review and undertake to train other prospective review authors in Cochrane methods.

Preferred recipients will have:

- a good understanding of the English language;
- limited access to relevant training where they live; and
- a review topic that is of significant importance to people living in middle- or low-income countries* (*low- or middle-income countries as defined at www.worldbank.org/data/countryclass/classgroups.htm [171]

The Scholarship recipient will be expected to:

- be previously registered as a review author with the Cochrane Review Group relevant to the proposed research area;
- have agreed a review topic with the relevant Cochrane Review Group before submitting an application;
- work primarily from the UK Cochrane Centre in Oxford, but also work closely with one or more UK-based members of a Cochrane Review Group;
- prepare a Cochrane review during the tenure of the Scholarship;



- maintain the Cochrane review on returning home; and
- teach others how to do systematic reviews on returning home.

The Scholarship will cover:

- travel costs including the cost of ordinary fare travel to and from the UK, as well as reasonable travel within the UK to work on the review topic; and the cost of a visa;
- funds to cover reasonable travel expenses within the UK to visit a relevant Review Group or Co-ordinator;
- a monthly stipend of GBP £500 to cover living costs (free accommodation will be provided in Oxford).

A condition of the scholarship is that Scholars must arrange their own medical insurance for the duration of their visit. Documentation to support this should be provided prior to arrival in the UK. Applications, in English, should include:

- a full curriculum vitae;
- a description of how the applicant would benefit from the Scholarship;
- a description of how the applicant would use the skills gained on returning home;
- the full names and addresses (e-mail address if possible) of three referees;
- an outline of work already done on systematic reviews or clinical trials, including experience with quantitative data;
- the suggested topic for review, with up to 500 words explaining the relevance to public health and primary care; and
- confirmation from the relevant Cochrane Review Group that the topic has been agreed.
- a signed statement from the applicant's head of department, agreeing to release the applicant to take up this Schoalrship, should his/her application be successful.

Application and selection process

The UK Cochrane Centre (UKCC) establishes and administers the yearly timetable for advertising for and selecting the Sheiham Scholar. Once this has been decided, the UKCC circulates information on requirements and application deadlines to Cochrane entities [20] and e-mail lists, and an announcement is posted on the 'Cochrane Opportunities' page of The Cochrane Collaboration's website. Applications are reviewed by the selection panel, whose members are drawn mainly from developing countries.

Timetable for applications

Early September: Call for applications.

NOTE: Applicants MUST have already agreed a review topic with the relevant Cochrane Review Group before submitting their application.

31 October: Deadline for applications.

Early December: Announcement of the following year's Scholarship recipient.

2.5.3 Cochrane Visiting Fellowship

At the beginning of 2004 the Cochrane Collaboration Steering Group [13] introduced a Visiting Fellowship as part of a program to facilitate quality [5] processes surrounding the production of Cochrane reviews. The Fellowship was open to all those working (employed or honorary) in a Cochrane entity towards producing, updating, disseminating or promoting the accessibility of Cochrane reviews. Funds were made available annually for one successful applicant to travel to and



work in another Cochrane entity for a period of up to one month. However, there had been few applications in recent years, some of which had not been aligned to the intent of improving Collaboration processes towards overall quality improvement. The Steering Group therefore agreed in October 2010 that the time for this annual fellowship had passed, and that the monies used to support this initiative would be better directed towards some of the organisation's more contemporary quality improvement initiatives. The Visiting Fellowship therefore ceased.

3. OPERATIONS

Subheadings in this section

3.1 Steering Group

Subheadings in this section

3.1.1 Membership

For the current membership of the <u>Steering Group</u> [13] of The Cochrane Collaboration, see http://www.cochrane.org/contact/steering-group [40]

3.1.2 Election procedure

For a description of the process for conducting elections to the <u>Steering Group</u> [13], see http://www.cochrane.org/intranet/steering-group-elections.

3.1.3 Sub-committees of the Steering Group

The membership of the Steering Group's sub-committees is contained in the appendix to the document, <u>Structure</u>, <u>remit and membership of groups accountable to the CCSG</u> [173]. These committees are as follows:

Operations and Finance Committee

The Operations and Finance Committee is responsible for making interim decisions on behalf of the full Steering Group between its bi-annual face-to-face meetings on issues other than monitoring and registration. It is also responsible for co-ordinating and ensuring good communication among groups responsible for core functions and the Steering Group.

Monitoring and Registration Committee (MaRC [30])

The Monitoring and Registration Committee is responsible for establishing and implementing processes for monitoring and registering <u>Cochrane groups</u> [20] (entities), and for making recommendations to the full Steering Group about their registration/de-registration (see <u>Appendix 2</u> [174]).

Publishing Policy Group (PPG [136])

In March 2010 the responsibilities of the former Publishing Policy Group, for providing advice to the Collaboration's publishers on the contents of The Cochrane Collaboration's products, passed to the



Cochrane Editorial Unit [49].

This section and section 3.1.4 inform the document <u>Structure</u>, <u>remit and membership of groups accountable to the CCSG</u> [173].

3.1.4 Advisory committees to the Steering Group

The membership of the Steering Group's advisory committees is contained in 'Archie'. (See also the Structure, remit and membership of groups accountable to the CCSG [173].) These committees are as follows:

Colloquium Policy Advisory Committee (CPAC)

This advisory committee is responsible for maintaining a record of policy decisions about Cochrane Colloquia, for moving forward new policies after appropriate consultation, and for helping to ensure that hosts of future Colloquia know about and adhere to such policies.

Handbook [54] Editorial Advisory Panel (HEAP)

This advisory committee is responsible for the *Cochrane Handbook [55] for Systematic Reviews of Interventions* (formerly the *Cochrane Reviewers' Handbook*) and other Handbooks as appropriate, for preparing and maintaining Cochrane reviews.

Information Services Strategy Committee (ISSC)

The purpose of the ISSC is to ensure good governance and also to ensure that the technology needs of the Collaboration are considered, delivered and evaluated in the context of a defined and coherent strategy. The ISSC is responsible for developing key performance indicators (KPIs) and modifying these in response to feedback from the Information Services Operations Committee. The ISSC is accountable to the Steering Group, and its role therefore includes ensuring that Steering Group decisions are informed by the provision of high quality information, and that consideration is given to the implementation, co-ordination and communication aspects of technology development.

The ISSC should meet before Steering Group meetings annually/bi-annually in order to be able to report any concerns or issues. This Committee may also need to meet from time to time in order to discuss challenges as they arise.

Membership of the ISSC is as follows:

- Co-Chair of the Cochrane Collaboration Steering Group (CCSG) (Convenor)
- Editor in Chief
- Chief Executive Officer
- An additional member of the Operations and Finance Committee
- Representative of the Co-ordinating Editors' Executive
- Representative of the Centres' Executive
- Representative of the Fields' Executive
- Representative of the Methods Executive
- Representative of the Managing Editors' Executive
- Representative of the Monitoring and Registration Committee
- Project Support and Business Communications Officer

The ISSC is not intended to make operational decisions. It should ensure that it has access to information from a wider community to inform its strategic recommendations. The body with



responsibility for pulling together the broader constituency is the Information Services Operations Committee (ISOC). Crucially, this latter body also includes service providers.

Information Services Operations Committee (ISOC)

The purpose of the ISOC is to provide operational oversight and links between service users and providers. Its objectives include:

- Delivering the strategic objectives identified by the Information Services Strategy Committee (ISSC).
- Providing feedback on resources needed and progress on key performance indicators.
- Ensuring that the ISOC has the information and data necessary to fulfil its functions.
- Ensuring that communication between service users and providers is effective and responsive.
- Ensuring that expertise and experience from within The Cochrane Collaboration is fully utilised in developing strategic and operational approaches.

Remit

The ISOC is accountable to the ISSC, and takes responsibility for ensuring that the strategic approaches determined by the ISSC are implemented effectively and efficiently. It also has a remit which enables it to modify the strategic approach based on feedback from users, awareness of resources and the expertise of its members. It needs to be able to act decisively where its approach is consistent with the direction and resources provided by the ISSC. However, where there is a need for an increase in resources, or where the ISOC advises an important departure from the general direction outlined by the ISSC, there will need to be an escalation procedure to ensure that the issues can be resolved by the ISSC and the ISOC acting together in a timely and efficient manner.

The role of the ISOC includes ensuring that it receives sufficient information from the reporting groups to assure good governance, and that the strategic approaches taken are consistent with Collaboration policies and strategy. It also has a role in ensuring that the reporting groups are moving forward in a co-ordinated fashion, that opportunities for communication and identifying efficiencies of scale are acted on, and that communication by the groups to stakeholders inside and outside the Collaboration is effective.

The ISOC should meet about every three months, preferably by teleconference rather than face-to-face.

Membership of the ISOC is as follows:

- Editor in Chief (Convenor)
- CEU Editors
- Director, Information Management System*
- Two representatives of the IMS Development and Support teams
- Publisher representative*
- Web Operations Manager*
- Representative of the Cochrane Register of Studies provider
- Convenor of the websites committee
- Convenor of the CRS Project Board
- Convenor of the Archie Development Advisory Committee
- Convenor of the RevMan Advisory Committee
- Two representatives of the Managing Editors
- Representative of the DTA Working Group
- Methods Co-ordinator
- Author representative
- Representative of the Centre Directors' Executive
- Representative of the Trials Search Co-ordinators' Executive
- Additional users, to be called on as required



* Has discretion to include colleagues as appropriate.

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Groups reporting to the Information Services Operations Committee

- Web Sites Committee (WSC)
- Cochrane Register of Studies Project Board (CRSPB)
- RevMan Advisory Committee (RAC)
- Archie Development Advisory Committee (ADAC)

This section, and section 3.1.3, inform the document <u>Structure</u>, remit and membership of groups accountable to the CCSG [173]

3.1.4.1 Information Services Operations Committee (ISOC)

The ISOC provides operational oversight and links between service users and providers. Its objectives include:

- Delivery of the strategic objectives identified by the Information Services Strategy Committee (ISSC).
- Providing feedback on resources needed and progress on key indicators.
- Ensuring that the ISSC has the information and data required to fulfil its functions.
- Ensuring that communication between service users and providers is effective and responsive.
- Ensuring that expertise and experience from within The Cochrane Collaboration is fully utilised in developing strategic and operational approaches.

The ISOC is accountable to the ISSC, and responsible for ensuring that the strategic approaches determined by the ISSC are implemented effectively and efficiently. It also has a remit which enables it to modify the strategic approach based on feedback from users, awareness of resources and the expertise of its members. It needs to be able to act decisively where its approach is consistent with the direction and resources provided by the ISSC. However, where there is a need for an increase in resources, or where the ISOC advises an important departure from the general direction outlined by the ISSC, there will need to be an escalation procedure to ensure that the issues can be resolved by the ISSC and ISOC acting together in a timely and efficient manner.

The role of the ISOC includes ensuring that it receives sufficient information from the reporting groups to assure good governance and that the strategic approaches taken are consistent with Collaboration policies and strategy. It also has a role in ensuring that the reporting groups are moving forward in a co-ordinated fashion, and that opportunities for communication and identifying efficiencies of scale are acted on, and that communication by the groups to stakeholders inside and outside the Collaboration is effective. This body should meet about every 3 months and include the following:

| lollowing. | |
|--|--|
| Editor in Chief (convenor) and CEU Editors | |
| Providers | Users (default) |
| Director of IMS team* | Two representative of Managing Editors |
| Publisher representative* | Representative of DTA Editorial Group |



| Web Operations Manager/ Lead of the Cochrane web team* | Methods Co-ordinator |
|---|--|
| Representatives of IMS development and Support teams (2) | Author representative |
| Representative of CRS provider | Representative of Centres' Executive |
| Convenors of the subsidiary committees (except where duplication) | Representative of TSCs' Executive |
| Convenor of the Websites Committee | Additional users (called on as required) |
| Convenor of the CRS project board | Representative of Training Committee |
| Convenor of the ARCHIE development committee | Representative of Consumers' Executive/ Consumer Co-ordinator |
| Convenor of the RevMan development cte | Representative of Fields' Exec |

^{*}indicates that this individual has discretion to include colleagues as appropriate.

The sub-committees reporting to the ISOC are:

The Web Sites Committee (section 3.1.4.1.1).

The Cochrane Register of Studies (CRS) Project Board (section 3.1.4.1.2).

The ReviewManager Advisory Committee (RAC) (section 3.1.4.1.3).

The Archie Development Advisory Committee (ADAC) (section 3.1.4.1.4).

Consideration is being given to merging the RAC and ADAC in the short or medium term. Similarly, the future of the accountability arrangements for the Cochrane Register of Studies might need to be re-evaluated post implementation. We should also explore in the short to medium term the requirements and arrangements to oversee the development of CENTRAL.

Resources:

These committees all meet via teleconference as a default, with face to face meetings reserved for issues/challenges where this is specifically required, and for which specific funding would be requested from the ISSC/CCSG [23]. Therefore, it is likely that there would be cost savings relative to the current IMS projected budget.

3.1.4.1.1 Web Sites Committee (WSC)

The Web Sites Committee reports to the Information Services Operations Committee (ISOC). It includes representatives from the Publisher, the IMS team, the Cochrane Web team and the Cochrane Editorial Unit [49].

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|--------------|---------------|-------------------------|----------------------------|-----------|
| Convenor: to | rotate betwee | n bublisher/ IMS | team/Cochrane | web team. |

Objectives:



- To oversee delivery of the web development project.
- To ensure that web development is co-ordinated between the IMS team, the Cochrane web team and the Collaboration's publishers.
- To ensure efficient and effective communication and delivery of web related projects.
- To ensure that Collaboration resources are used effectively and efficiently and that there is appropriate transparency and accountability.
- To ensure that the reporting and communications required by the Information Services Strategy Committee (ISOC) are produced in a timely and efficient manner.

Remit:

The Web Sites Committee is responsible for ensuring that the delivery of the objectives above. It is tasked with taking decisions efficiently where they are in accordance with previously agreed Collaboration policy, or in pursuit of the approved strategic approaches determined by the Editor in Chief. Escalation to the Information Services Strategy Committee (ISSC) might occur where the ISOC considers that the Web Sites Committee is proposing an important change of strategy. Where the difficulty is one of implementation, issues should be escalated only when necessary and would expect to be resolved by the ISOC.

The Web Sites Committee has a duty to ensure that the ISOC is updated by ensuring good communication and timely reporting.

3.1.4.1.2 Cochrane Register of Studies (CRS) Project Board

Convenor: [To be decided.]

Objectives:

- To ensure effective, timely and efficient implementation of CRS project
- To ensure effective processes and communication in the delivery of the CRS project
- To ensure that Collaboration resources are used effectively and efficiently and that there is appropriate transparency and accountability.
- To ensure that the CRS is exploited with maximum effect in order to meet the requirement to optimise the <u>utility</u> [175] of CENTRAL to systematic reviewers within and outside the Collaboration.

Involvement: (as current project board, to be informed by advisory committee)

Remit:

Currently this is to ensure that the CRS is developed in a timely manner and reflects the requirements document and agreed plan. If this is judged as being at <u>risk</u> [143], this should be escalated to the Cochrane Collaboration <u>Steering Group</u> [13]. The CRS Project Board also has its own Advisory Committee which is comprised of end users and seeks to advise to Information Services Strategy Committee (ISSC) on implementation issues and to co-ordinate testing.

In the future, post introduction of CRS, the CRS Project Board will be expected to dissolve, and will be replaced by the Cochrane Register of Studies Advisory Committee which will be accountable to the ISOC. We should also consider whether another body – tasked with the development of CENTRAL,



would be beneficial, and if so, its relationship with the CRS Advisory Committee.

3.1.4.1.3 ReviewManager Advisory Committee (RAC)

Convenor: [To be decided.]

Objectives:

- To ensure that developments of ARCHIE and RevMan are co-ordinated, prioritised and implemented in a timely manner.
- To take over the activities of the former RevMan Advisory Group.
- To ensure that the needs of <u>review</u> [29] authors and <u>Cochrane Review</u> [22] Groups (CRGs), including methodological inputs to CRGs, are met, and that the systems are developed that reflect the best affordable technical approaches to support review production.
- To develop and maintain a process for prioritising communicated needs.
- To ensure that Collaboration resources are used effectively and efficiently and that there is appropriate transparency and accountability.

Involvement:

- IMS Development and Support team representatives.
- RevMan users: ME representatives x2, Methods Co-ordinator/ Methods Executive representative, DTA Group representative, TSCs' Executive representative, Author representative.
- Cochrane Editorial Unit [49] (CEU) representative.

Remit:

The remit of the RAC is to prioritise requests for enhancements to RevMan and to provide guidance to the IMS Development team. It should consult with the Information Services Operations Committee (ISOC) and others when there is uncertainty relating to the definition of or need for a specific enhancement. The RAC is responsible for ensuring that a report of its activities and the response by the IMS Development team are provided annually to the ISOC, which would normally expect to ratify the decisions taken, assuming they are consistent with previously agreed direction and within budget, but implementing such decisions should not need to await the ratification of the ISOC. At the discretion of the ISOC, it might be necessary to escalate issues to the Information Services Strategy Committee (ISSC) if it believes that a change of strategy or resourcing is required, and in this case it is important that the ISSC is able to act efficiently and in a timely manner.

The RAC has a role in ensuring that resources are used in the most effective manner to improve the service to CRGs and review authors provided by RevMan, and that where new opportunities are identified they are evaluated in a systematic and authoritative manner.

3.1.4.1.4 Archie Development Advisory Committee (ADAC)

Co- Convenor: [To be decided.]



Objectives:

- To ensure that developments of ARCHIE and RevMan are co-ordinated, prioritised and implemented in a timely manner.
- To take over the activities of the former Editorial Management Advisory Group (EMAG [176]), with the exception of the work undertaken by the Editorial Resources Committee.
- To ensure that the perspectives and needs of <u>review</u> [29] authors, CRGs (including methodological input to CRGs) and end users inform the development of ARCHIE.
- To ensure that communication between end users and the IMS Development and Support teams is effective.
- To ensure that Collaboration resources are used effectively and efficiently and that there is appropriate transparency and accountability.

Involvement:

- Representatives from the IMS Development and Support teams.
- ME Representatives x2, Methods Co-ordinator/Methods Executive representative, Training Working Group representative, DTA Group representative, Editorial Resources Committee convenor, Author rep, TSCs' Executive representative.
- Cochrane Editorial Unit [49] (CEU) representative.

N.B. It is yet to be decided whether or not it is appropriate to include the ERC convenor or TWG representatives.

Remit:

The remit of the ADAC is to prioritise requests for developments of ARCHIE and to provide guidance to the IMS Development team. It may consult with the ISOC or others when there is uncertainty relating to the definition of or need for a specific change. For example, the currently agreed approach is to implement workflows for the editorial function of CRGs. The ADAC is able to approve the content of the workflows, although it should consult with users where necessary. A strategically important decision would normally be escalated to the ISOC in order that a wider group of end users can be consulted. The ADAC will be required to oversee production of an annual report to the ISOC, which would normally expect to ratify the decisions taken, assuming they are consistent with previously agreed direction and within budget, but implementing such decisions should not need to await ratification by the ISOC. Issues may need to be escalated to the Information Services Strategy Committee (ISSC), at the discretion of the ISOC, if it believes that a change of strategy or resourcing is required, and in this case it is important that the ISSC is able to act efficiently and in a timely manner.

Like the RAC, the ADAC role is to ensure the most effective use of Collaboration resources in terms of ARCHIE development. The committee also has a role in evaluating new enhancements or opportunities in order that, where necessary, these can be incorporated efficiently into ARCHIE development to the benefit of users.

3.1.5 Attendance at Steering Group meetings

Background

At its meeting in October 2008, the Cochrane Collaboration Steering Group [13] (CCSG [23]) agreed that it should review [29] attendance at its meetings. The issue related to (1) attendance throughout a meeting; (2) attendance just for selected agenda items; and (3) voting rights. This



paper summarises the decisions taken.

Attendance throughout CCSG meetings:

- Elected CCSG members attend throughout meetings (unless they have a significant conflict of interest for a particular item, in which case they leave the room).
- The CEO is an ex officio member of the CCSG because of his key role in Organisational, Business and Finance issues, attends throughout meetings, and participates in discussions as judged appropriate by the CCSG Co-Chairs.
- The Editor in Chief is an ex officio member of the CCSG because of his key role in Methodological, Technical and Scientific issues, attends throughout meetings, and participates in discussions as judged appropriate by the CCSG Co-Chairs.
- The Administrator is an ex officio member of the CCSG because of her key roles in the administration of the Collaboration and (as Company Secretary) in financial issues, attends throughout meetings, takes the minutes, and participates in discussions as judged appropriate by the CCSG Co-Chairs.
- Pending further review, a representative of The Campbell Collaboration is invited to attend CCSG face-to-face meetings as an observer, again participating in discussions as judged appropriate by the CCSG Co-Chairs, on the basis that there is a reciprocal arrangement for representation of The Cochrane Collaboration at meetings of the Campbell Collaboration's Steering Group.
- Other members of the <u>Secretariat</u> [1] are invited to attend CCSG face-to-face meetings on the basis that they are often responsible for taking forward CCSG decisions. The default is that they will sit round the table with the CCSG but may at the discretion of the Co-Chairs be asked to sit separately if there is pressure on space such as might occur, for example, on the first day of the CCSG Colloquium meetings.
- Voting, when necessary, should be limited to elected CCSG members only (excluding those members who have a significant conflict of interest).

Attendance for specific items:

- Other selected people (such as the Director of the IMS, the Website Development Manager, the Directors of the Trading Company, and those submitting papers to the CCSG) should be invited to join CCSG discussion of specific agenda items when the Co-Chairs judge (in advance) that this would enhance decision-making.
- If selected people are invited to attend for more than one agenda item, efforts should be made to arrange the agenda such that a single session covers all the relevant items.
- As a general rule, a CCSG member who has a significant interest in an agenda item leaves the room for discussion and decision-making in respect of that item; however, the Co-Chairs, applying the same criteria (see below), can decide in advance that attendance and participation of the CCSG member in the discussion of that agenda item would improve decision-making; the CCSG member would then stay in the room for discussion, but leave the



room when asked to do so by the Chair for any further discussion and decision-making.

 Criteria on which CCSG Co-Chairs decide that non-CCSG members (or CCSG members with significant conflicts of interest) be invited to the discussion of specific agenda items at CCSG meetings are as follows:

| Criteria | Descriptions |
|--|--|
| Requests for funding over an explicit limit. | Applications for £100k or over. |
| Significant impact on <u>entities</u> [20]. | Applications, even if for modest funds, that have the potential to have a significant impact on a large proportion of entities. |
| Need for specialist knowledge. | Applications where the CCSG lacks specialist knowledge that is necessary for an informed decision. |
| Clarification needed. | Applications where there are pre-identified issues that need clarification before a decision can be reached by the CCSG. |
| Informational sessions. | Agenda items whose main purpose is informational exchange (rather than funding), but where this cannot be done through a written report alone, for example, with groups such as the IMS or Web teams |

• In most cases, the invitee would be the person leading the application, proposal or report to the CCSG. However, in some cases, for example, where specialist knowledge is required, a person may be invited who is <u>independent</u> [177] of a proposal.

3.2 Cochrane Review Groups

Subheadings in this section

3.2.1 Introduction

Subheadings in this section

3.2.1.1 Aims of this section

Cochrane Review [22] Groups (CRGs) embody the central purpose of The Cochrane Collaboration because their members prepare and maintain Cochrane reviews. The longest established Cochrane Review Group is the Pregnancy and Childbirth Group, which evolved over ten years, demonstrating that a Cochrane Review Group can function effectively. Almost all the other currently registered Cochrane Review Groups have developed over a much shorter time, and the way they are brought together in the early stages may be important for their later success. This section focuses on establishing and maintaining Cochrane Review Groups.



3.2.1.2 Principles that make Cochrane Review Groups work

Cochrane Review [22] Groups focus on particular health problems. The Stroke Group (registered with The Cochrane Collaboration in August 1993) is a good example to illustrate the scope and organisation of a Cochrane Review Group. All Cochrane Review Groups are concerned with interventions that help people to avoid the health problem concerned (prevention), to cope with it when it occurs (treatment [8]), and to recover from its effects as fully as possible (rehabilitation). Each Cochrane Review Group considers the health problem from different angles, such as different professional specialties or categories of intervention. The Stroke Group has some 278 active contributors in 21 countries, an administrative base in Edinburgh, Scotland, and 13 editors located in 7 countries. Experience in this and other Cochrane Review Groups that are working well indicates that the following elements are important in their early evolution:

- At least one individual committed to spending energy and time in co-ordinating efforts to set up and develop a Cochrane Review Group.
- People who view a Cochrane Review Group as one small part of a much wider collaborative effort, and who see the work as something in which they wish to participate for the foreseeable future.
- Close liaison between the individuals who are helping to coordinate the formation of a Cochrane Review Group and their reference Cochrane Centre [34].
- An atmosphere of collaboration, with positive efforts made to ensure that the Cochrane Review Group is international and multidisciplinary, with consumer input, and not dominated by one particular individual, interest group, institution or country.
- Efficient, courteous administration, ensuring prompt response to and co-ordination of enquiries from potential contributors.
- Prompt two-way communication between those at the editorial base [103] and the authors.
- Supportive relationship between editors and authors (i.e. similar to that between a good PhD supervisor and postgraduate student).

3.2.1.3 Registration as part of The Cochrane Collaboration

To register as part of The Cochrane Collaboration, a <u>Cochrane Review</u> [22] Group should follow the guidelines outlined in this section. This will <u>mean</u> [111] that Groups applying for registration will have:

- held at least one exploratory meeting
- voluntary participation
- multidisciplinary representation
- international representation, in the editorial team and among the authors
- editors who have already prepared or are preparing a Cochrane review



- plans for supporting its members, such as training workshops
- started to establish a specialized register of trials to help members of the Group
- obtained the endorsement of a reference Cochrane <u>Centre</u> [34] before applying to register as part of The Cochrane Collaboration
- made firm plans to apply for funds to employ a Managing Editor, and accessible computing support for those at the <u>editorial base</u> [103]
- given consideration as to how to ensure that its reviews are of high <u>quality</u> [5], including a process which ensures that reviews are comprehensible to the non-specialist
- obtained consumer involvement at early stages in the development of the Group

3.2.1.4 How Cochrane reviews are published

Each <u>Cochrane Review</u> [22] Group assembles collections of up-to-date systematic reviews with standard Collaboration software (the Information Management System (IMS) and 'RevMan'), and information on the people involved in the Group, its scope, detailed descriptions of the topic areas the Group intends to cover, and of its <u>search strategy</u> [178]. These collections are known as 'modules', and are submitted at guarterly intervals for publication in <u>The Cochrane Library</u> [18].

3.2.1.5 Core functions of Cochrane Review Groups

General statement

A <u>Cochrane Review</u> [22] Group's primary role is to prepare and maintain reviews of ways to prevent and treat health problems, and ways to rehabilitate people who have health problems, within a particular health care area.

Specific core functions

The essential core functions of CRGs are:

- 1. To focus on a particular health problem or healthcare area.
- 2. To prepare and maintain reviews of ways to prevent and treat the health problem, and ways to rehabilitate people who have the health problem.
- 3. To ensure reviews are comprehensible to the non-specialist and use outcomes that matter to people making choices in health care.
- 4. To maximise the quality [5] of reviews.
- 5. For the editorial bases to create, maintain, and submit a CRG module [102] on a quarterly basis.
- 6. For the editorial bases to develop and maintain a Specialized Register, containing all relevant studies in their area of interest, and submit this to CENTRAL on a quarterly basis.
- 7. For the editorial base to contribute to maintaining the Cochrane Contact Database.
- 8. For the editorial base to support the CRG's members (e.g. authors, consumers, editors).
- 9. To avoid duplication of effort across the Collaboration, particularly between other CRGs.
- 10. To enable wide participation in the work of the CRG by reducing barriers to contributing,



- encouraging diversity, and involving people with different skills and backgrounds.
- 11. To ensure effective and efficient communication between CRG members.
- 12. To communicate effectively with the reference Cochrane Centre [34], the Consumer Network, and relevant Fields and Methods Groups.
- 13. To ensure sustainability and continuity of the CRG's programme of work.

3.2.2 How Cochrane Review Groups form

Subheadings in this section

3.2.2.1 What can I do?

Groups need people who are actually going to prepare and maintain Cochrane reviews (which can be anything from a large undertaking to a relatively small one). However, there may be people who want to help in some other way. Some of the possible contributions that individuals might make, apart from doing a review, are to:

- do an electronic search of a specialized database
- help develop and test search strategies
- handsearch a particular journal, or [127] conference proceedings, in any language, for reports of controlled trials
- translate articles for authors
- help authors to identify unpublished data
- help authors by providing additional data about a trial
- peer review [131] a protocol [43] or a completed review
- appraise protocols and reviews to help ensure that they can be understood by non-specialists
- · provide technical advice on analysis
- provide managing editors, editors and authors with methodological and communications support
- help Cochrane Review Groups to obtain financial and other kinds of support
- encourage the involvement of students and professionals in training



- facilitate linkages between individuals throughout the world
- help to remove institutional barriers to people contributing
- use The Cochrane Library [18], and comment on it

3.2.2.2 Exploring areas of common interest

As one of the principles of The Cochrane Collaboration is to avoid duplication of effort, people who are interested in developing a <u>Cochrane Review</u> [22] Group need to get in touch with others already in a Cochrane Review Group where there may be areas of common interest, and with people who have already expressed a similar interest.

The first step is to consult <u>The Cochrane Library</u> [18], which contains information about The Cochrane Collaboration, including details of registered Cochrane Review Groups, and names and addresses of people currently engaged in co-ordinating the formation of new Cochrane Review Groups that are not yet registered. This may provide relevant contact points to follow up.

The Database of Abstracts of Reviews of Effects is a bibliography of published and some unpublished reports of systematic reviews of randomized controlled trials (RCTs), which is maintained by the Centre [34] for Reviews and Dissemination in the UK. People considering establishing a new Cochrane Review Group should consult this to explore areas where systematic reviews already exist, and to identify the people who prepared them: they may be interested in being part of a Cochrane Review Group.

3.2.2.3 Contacting Cochrane Centres

To avoid misunderstandings and confusion, people should contact their reference Cochrane <u>Centre</u> [34] if they think that a new <u>Cochrane Review</u> [22] Group may be justified.

For a Cochrane Review Group to become registered as part of The Cochrane Collaboration, its members have to demonstrate that they have a long-term commitment to the task, and to show that the Group has made every effort to avoid domination by one particular individual, institution, discipline or country. Cochrane Centres help to facilitate the evolution of a Cochrane Review Group, and any application for registration requires a letter of endorsement from the relevant Cochrane Centre to the Cochrane Collaboration Steering Group [13]. Members of staff at Cochrane Centres are involved in the following ways:

- by providing time for one or more representatives of the potential Group to visit a Cochrane Centre for face-to-face discussions with the director and any other people who may be able to help.
- by keeping The Cochrane Collaboration as a whole up to date about developments after the exploratory meeting. This is possible only if the individuals helping to co-ordinate a new Group stay in touch with the Centre.
- by commenting on draft letters, strategy documents, applications for funds, meeting agendas, and so on, to help facilitate the development of the Group in ways that have been shown to work in the past.
- by attending, contributing to, and usually chairing the initial phases of exploratory meetings convened to assess whether the basis and the will exist to establish a new Cochrane Review



Group.

• by running workshops for potential authors on 'How to develop a protocol' and 'How to put a review into RevMan', and by giving advice and training in handsearching.

3.2.2.4 Organizing exploratory meetings

Exploratory meetings may have a number of objectives, for example, to outline the need for systematic reviews, to explain how The Cochrane Collaboration works and what a commitment to The Cochrane Collaboration entails; to assess whether it is feasible and sensible to form a Group, to clarify the scope of a Group, and to formalize any decision to form a Group. Most of the people attending an exploratory meeting may have little or no knowledge or understanding of The Cochrane Collaboration. Someone therefore needs to introduce it, and a demonstration of The Cochrane Library [18] is an effective way of showing people what The Cochrane Collaboration is all about. Exploratory meetings (for examples of an agenda and report of one of these meetings, see sections 3.2.8.1 [179] and 3.2.8.2 [180] respectively) should accomplish the following:

- introduce and make explicit the interests of those attending;
- introduce The Cochrane Collaboration and its working methods;
- review relevant existing work, including any systematic reviews or specialized registers of controlled trials:
- clarify the definition and scope of the health problems to be covered by the Group, and a categorization of these;
- try to avoid possible conflicts and disappointments in the future by ensuring that people who
 may not really want to become involved are given opportunities to support The Cochrane
 Collaboration in other ways, or not directly at all;
- explicitly state that authors are expected both to produce and periodically update their reviews within given time periods;
- generate a list of possible authors in the area;
- consider how to avoid unnecessary overlap with other Cochrane Review [22] Groups;
- assess what resources already exist for developing a Cochrane Review Group, and invite each participant at the meeting to indicate what s/he would be willing to contribute;
- make it clear that members of the Group will be responsible for seeking whatever additional resources may be required;
- agree on an agenda and timetable for action.



In some areas it may take several years to assemble a group of people with similar interests and the ability and resources (particularly the time) needed to take on the responsibilities involved in participating in a Cochrane Review Group. The value of an exploratory meeting may sometimes be to make it clear that, for one or more of a variety of reasons, efforts to establish a Cochrane Review Group are either premature, or possibly misguided.

A representative of the Monitoring and Registration Committee (MaRC [30]) should be invited to attend the exploratory meeting(s). If an MaRC representative cannot attend (either in person, by VOIP or by teleconference), the organisers of the exploratory meeting(s) should ensure they discuss the registration process and a provisional agenda for the meeting(s) with an MaRC representative in advance. The aim of MaRC involvement is to help to ensure that the meeting(s) is/are as useful as possible to inform the proposed CRG [15]'s potential application for formal registration. There should be formal feedback to the MaRC representative, CCSG [23] representative, and Entity Executive, to ensure effective communication, which should include a person-to-person discussion (e.g. by telephone) with the MaRC representative, and circulation of the exploratory meeting(s) minutes to the MaRC representative.

3.2.2.5 Managing the politics

If an exploratory meeting is to provide a reliable basis on which to begin building an enduring Cochrane Review [22] Group, those who convene it and do the background work need to be sensitive to the 'politics' of their task - before, during and after the meeting or meetings. All those who have registered their interest in the relevant topic with The Cochrane Collaboration (and whose names will therefore be included in the directories assembled by The Cochrane Collaboration) should be invited to contribute to exploratory meetings, either by attending in person, or by writing to the Convenor of the meeting, setting out how they would like to contribute to the Group's evolution and work. In addition, participants should come from a number of countries and disciplines, so that the endeavour is internationally based and interdisciplinary from the outset. A member of the Monitoring and Registration Committee should be invited to attend exploratory meetings.

Cochrane Review Groups are expected to produce reviews that are relevant and comprehensible to the public, and should take steps to ensure that health care users as well as providers are identified for consultation and liaison. Groups are encouraged to involve consumer representatives in all aspects of the Cochrane Review Group, including the editorial team.

3.2.2.6 Considering the scope

A common issue at exploratory meetings concerns the boundaries of a <u>Cochrane Review</u> [22] Group. The scope of a Group needs to encompass a wide (preferably the whole) range of treatments available for the disease area for which they are registered, yet be manageable, and of interest to the people involved. Focusing on a particular topic area may be a necessary part of the process. However, it is probably unwise to split subjects in order to accommodate historical conflicts between institutions or specialties. It is much better to try to overcome these, as there are great advantages in such groups working together, and excessive splitting can also increase administrative duplication.

The most useful way of tackling these issues is to discuss the scope of a Cochrane Review Group at the exploratory meeting. The description of the scope of the Group helps to delineate the way in which that Group conceptualizes the topic. As systematic reviews are prepared, this description helps to highlight areas of care where no trials have been identified.

It is important to consider all aspects of a disease process in those Groups that are disease-based, i.e. prevention, acute treatment and chronic treatment/ rehabilitation. Each Group should provide a detailed topic list outlining the areas where reviews are required, and not just the areas where reviews have been produced. Each Group must ensure that the scope of the Group, and the topic list, do not duplicate those of existing Cochrane Review Groups.



3.2.2.7 Making the commitment

Exploratory meetings should give people the opportunity to get to know each other better, as well as to have adequate time as a group to discuss the work and how to do it. A meeting has probably been successful if it has (a) helped participants to understand the size of the task they are considering, (b) given them a chance to reflect on their own possible commitment to the process, (c) helped them to understand the need to work collaboratively, and (d) demonstrated the need for an editorial base [103].

An opportunity should be given for people to go away, think about it, and respond to a deadline, indicating the ways in which they want to contribute. The people who do respond and show an active interest and practical ways to help are likely to form the basis for the Group to develop.

3.2.2.8 The Co-ordinating Editor

It is essential in the development phase of forming a <u>Cochrane Review</u> [22] Group that there is a leader for the project who is potentially prepared to become its Co-ordinating Editor. This person must understand what the job entails, be able to raise the resources necessary to establish a stable <u>editorial base</u> [103], and must have the necessary social, managerial, scientific and editorial skills to maintain the Cochrane Review Group. It is important that they have an institutional base. University and hospital departments are examples of such institutions. A significant time commitment is required. The nature of the work changes through the various stages before and after registration, and then into the active work of the Group – producing and updating reviews. An absolute minimum of one full day per week will be required. The Co-ordinating Editor has particular responsibility for preparing the registration document in <u>association</u> [24] with the potential editorial team. Pulling together an editorial team is another task, and it is essential that representation is both multi-disciplinary and international. Once the Cochrane Review Group has become established, the Co-ordinating Editor will be the member of the editorial team who will retain primary responsibility for ensuring that the Group is productive and efficient, and operates according to the principles of The Cochrane Collaboration.

3.2.2.9 The Managing Editor (formerly 'Review Group Co-ordinator')

The Managing Editor (ME) is a key member of the editorial team who is based at the administrative base. They will have the challenging task of the day-to-day management of a Cochrane Review [29] Group with members all over the world, for many of whom English is not their first language. The Co-ordinating Editor must be available to provide regular help and support to the Managing Editor.

Potential applicants for this post need to know what the job entails. Each Group should decide and make clear for which functions the Managing Editor will be responsible, in advance of the appointment, while allowing for some flexibility according to the particular skills and aptitudes of the person appointed. A clear job description is essential and should be sent to short-listed candidates before the interview, together with additional information about The Cochrane Collaboration. All members of the interviewing panel should be well briefed beforehand about the specific tasks facing the Managing Editor and the skills needed to carry them out. Paragraph 3.2.8.5 gives examples of an advertisement, a job description and a person specification for an Managing Editor.

The Monitoring and Registration Committee should be informed of any new Managing Editors starting with the organization. The <u>Secretariat</u> [1] should also be informed, so that they can send a welcome letter early on when the Managing Editor starts the role. Training is also available for



new Managing Editors in such tasks as co-ordinating handsearching and using The Cochrane Collaboration software. It is helpful to attend one of the workshops run by the Cochrane Centres on protocol [43] development, and on using the Review Manager [25] software. Time spent with the Managing Editor of an established Group is also useful.

Funds should be procured where required to provide computing, medical/specialist and clerical/secretarial support to the Managing Editor, who should not feel that the entire burden of what needs to be done falls on them. Software (Information Management System (IMS) and Review Manager (RevMan)) has been specially developed by The Cochrane Collaboration to automate the process by which Managing Editors prepare their Group's module [102]. Managing Editors can also obtain support from the IMS team at the Nordic Cochrane Centre concerning the RevMan and IMS software.

3.2.2.10 Forming an editorial team

The composition of an editorial team should reflect whatever consensus is reached at exploratory meetings of potential members of the <u>Cochrane Review</u> [22] Group. An endorsement of this kind helps to ensure that the editors share the principles on which The Cochrane Collaboration is based: working together, building on existing enthusiasm and expertise, minimising duplication of effort, avoiding <u>bias</u> [6], keeping up to date, ensuring access, ensuring relevance, and continually improving the <u>quality</u> [5] of its work.

In the light of current evidence, it is important for editors to recognise that they will need to spend the equivalent of approximately one half day a week in fulfilling their commitment to the smooth running of the Group, and in making sure that authors' needs are being adequately met. The Co-ordinating Editor should allot additional time for working with and supporting the Managing Editor. As it is very difficult to help an author without ever having been responsible for a Cochrane review, editors should aim to have prepared at least one Cochrane review as soon as feasible after registration of their Cochrane Review Group. The Group should avoid selecting editors simply because they are well-known or are in command of a large research institution or group. There is no 'limit' on the size of the editorial team, but most Groups have between three and six editors.

Each Group should develop an editorial process through which protocols and reviews must be processed. Authors should be made aware of this process. These are written into each Cochrane Review Group module [102] and published in The Cochrane Library [18]. External peer review [131] is mandatory for all reviews and should be used for protocols where either the editor, co-editor or author feel that it is appropriate. Each CRG [15] editorial team should include a statistical or methodological consultant to deal with methodological issues. This person should be a member of the Statistical Methods Group.

3.2.2.11 The Feedback Editor

The electronic format of The Cochrane Database of Systematic Reviews means that it is possible to respond to and incorporate feedback from users. This will help to increase the quality [5] of Cochrane reviews, but also allow users of the reviews to be brought into the process. The Cochrane Database of Systematic Reviews enables users to make their criticisms in a structured fashion (and submit them electronically, by fax or by electronic mail), and there is a system for enabling the Feedback Editor to coordinate responses from the authors to these criticisms.

Each Cochrane Review Group must select a Feedback Editor to handle post-publication criticism. The Feedback Editor should be selected from outside the members of the editorial team (i.e. should not be one of the editorial team's existing editors or the Managing Editor). The Feedback Editor should be knowledgeable in the relevant subject area of the Cochrane Review Group. In the early days of a Group or in small Groups this ideal may not be achievable because any individual with all the skills needed to be a Feedback Editor will be one of the most valuable and talented members of the Group. Very often the Feedback Editor may have to be recruited from the editorial



board or be an active author. In this situation, the Feedback Editor must not handle criticisms of reviews that they have produced or edited. On such occasions, this duty should fall to another member of the Group, but this individual should be neither the Managing Editor nor the Co-ordinating Editor.

The Feedback Editor organizes and summarizes post-publication criticism of reviews from users, provides guidance to authors about how to respond to the comments from users, and will assist authors in responding to the criticisms, including suggesting changes to be made in the reviews. In the near future the Feedback Editor will automatically receive the criticisms in a structured form. Currently, the Feedback Editor is notified by e-mail when a new criticism is received and then retrieves the criticism from a password-protected website. The Feedback Editor should collate the criticisms and combine those that are duplicative. The Feedback Editor's summary of comments will be inserted in the 'Editorial Notes' section of each review. This section will appear on a screen to identify for the author those criticisms that are of major importance and those that are of minor importance. The Feedback Editor will send the raw criticisms and the editorial notes to the authors. S/he is responsible for ensuring that the responses are timely, and should feed back responses to the editorial team for final approval.

3.2.2.12 Identifying authors

Potential authors need to be clear about the commitment they are making. They are being asked to undertake a substantial amount of work in preparing a systematic <u>review</u> [29] in the first place, and then to keep it up to date as new evidence becomes available and as comments and criticisms are submitted.

The number of authors in Groups varies, and depends on how <u>Cochrane Review</u> [22] Groups decide to organise themselves. It is important that they do not exclude particular groups of people, and that they try to include authors from a mix of professional backgrounds and care perspectives, as well as a variety of countries.

Whilst enthusiasm and time are the first essential qualities in an author, each needs to combine knowledge about the topic in which s/he is interested with a willingness to apply methodological rigour to the review process. This combination of qualities rarely exists within a single individual. More often, it will be necessary to arrange author partnerships, to try to ensure that content and methodological expertise are both applied in preparing reviews. Such partnerships are generally preferable to working alone, even when both partners possess both types of expertise, to ensure the reproducibility of the judgements that are necessary in preparing reviews. One author will sometimes miss something that the other will pick up. It is also very likely that they will complement each other in various ways, and it is often more fun to work with someone else.

Methods of training include:

- workshops on developing protocols and using the <u>Review Manager</u> [25] software that are run by several Cochrane Centres.
- in-house training sessions run by individual Cochrane Review Groups.
- the development of methodological standards by each Cochrane Review Group (e.g. standard proformas for assessing trial <u>quality</u> [5] and extracting data, and standardisation of the data to be included in the Included Studies table). This may be difficult as even within Cochrane Review Groups, individual reviews may have varying data types and quality requirements. These standards are described in each Cochrane Review Group module [102].
- the maintenance of links with relevant Cochrane Methods Groups so that Cochrane Review Groups are guided by the best available methods.
- all reviews will be published on The Cochrane Database of Systematic Reviews in The
 Cochrane Library [18] and therefore need to reach a standard acceptable to the editors of the
 Cochrane Review Group.
- comments on protocols from the editorial team and from others can be extremely helpful in the



ongoing training of authors. The <u>editorial process</u> [45] should be seen as constructive criticism aimed at educating and raising standards.

3.2.2.13 Developing a specialized register of RCTs

Note: The Cochrane Central Advisory Group (referred to below) was disbanded in October 2005.

A prerequisite for systematic reviews of the evidence relevant to the prevention or treatment [8] of a particular health problem is to identify relevant randomized controlled trials (RCTs) as completely as possible, and to assemble them in a specialized register. One of the tasks of a Cochrane Review [22] Group is to maintain and develop a specialized register containing all RCTs in their area of interest. This task is an essential part of the initial efforts to establish a Cochrane Review Group.

Some Cochrane Review Groups expect authors to conduct a handsearch of one journal that is likely to be important to their review as a contribution to the specialized register. Others undertake centrally a systematic handsearch of a core body of relevant journals. In either case, the searcher needs to identify all RCTs, not just those of particular interest to that Group. Someone in the Cochrane Review Group (usually the Managing Editor, a dedicated Trials Search Co-ordinator, or one of the editors) should agree to co-ordinate the search and register processes, and that person should work directly with the US Cochrane Center, which has responsibility for co-ordinating and supporting this activity. (Note: The USCC ceased to be responsible for co-ordinating CENTRAL activities in October 2005.)

Some Cochrane Review Groups may wish to include study designs other than RCTs in their specialized registers. In deciding to do so, they will need to develop inclusion criteria and pilot the application of these in practice. There has so far been relatively little experience in extending inclusion criteria beyond randomized controlled trials. Of the Cochrane Groups [20] now considering other study designs, the Cochrane Effective Practice and Organisation of Care Group (EPOC) is probably most advanced, and advice from that source might help. Those who wish to base reviews on studies that have used methods other than randomization to control selection biases in comparing healthcare interventions should also consider contributing to the relevant Methods Groups exploring this.

A description of how the register was developed and is being maintained must be included in the Cochrane Review Group's module [102]. The following details should be available:

- 1. The inclusion criteria for the register, in particular the type of study included, e.g. randomized and controlled clinical trials only, or other comparative studies as well. There should be no language restriction.
- 2. The <u>search strategy</u> [178] used to generate the register. This strategy might include:
 - 1. handsearching of relevant journals not being searched by other members of The Cochrane Collaboration, with details of which volumes have been searched.
 - 2. handsearching of relevant conference proceedings.
 - 3. electronic searching (if possible using searches validated against handsearching) of electronic databases, such as MEDLINE and EMBASE [181]. Details of the search terms used should be available. Many other electronic databases exist which could be searched, details of which are available from medical libraries.
 - 4. searching reference lists of studies identified.
 - 5. consulting existing trials' registers.
- 3. Unpublished studies are often difficult to identify, but regular discussion with colleagues around the world can help identify them. Authors should also be encouraged to contact pharmaceutical companies where appropriate. Members of the Cochrane Review Group should encourage prospective registration of trials in their field.
- 4. How authors access the register to identify relevant studies (e.g. are authors sent references



- and, if so, how often?).
- 5. Data from the register were, until October 2005, forwarded to the US Cochrane Center for retagging as RCT in MEDLINE and contributing to The <u>Cochrane Central Register of Controlled Trials</u> [19] (CENTRAL), a database of reports of RCTs that is published in *The Cochrane Library*.

The main purpose of CENTRAL is to establish the system for the flow of information of studies within The Cochrane Collaboration to ensure that each Cochrane Review Group is aware of all possible relevant studies that have been identified through the work of The Cochrane Collaboration. CENTRAL contains information that is simple and easily retrieved by Cochrane Review Groups to which it might be relevant. Each Cochrane Review Group must maintain its own specialized register, but CENTRAL provides an additional resource.

Various bibliographic software packages are available for storing references to trials, none of which are ideal for Cochrane specialized registers.

3.2.2.14 Registering a Cochrane Review Group

Registering the <u>Cochrane Review</u> [22] Group is the responsibility of the proposed Co-ordinating Editor with the help of the people who have co-ordinated the exploratory meeting and other potential editors and authors. A report of the Group's deliberations and conclusions needs to be prepared, which will include consideration of the elements expected of a Cochrane Review Group outlined previously. The minutes of the meeting should be drafted with input from those who are going to participate in the Group, and be endorsed by them. Drafts of the report should be sent to the director of the reference Cochrane <u>Centre</u> [34] for comment. An agreed version of the report should then be sent to the Monitoring and Registration Committee (<u>MaRC</u> [30]), together with all the supporting documentation required for registration. The required documents are:

- A covering letter addressed to the MaRC
- A letter of endorsement from the Director of the reference Cochrane Centre
- · A written report of the exploratory meeting
- Letters of support and commitment from those who are going to be members of the Cochrane Review Group
- A draft <u>module</u> [102] entry, including details of the reviews that the editors and other authors intend to supply to <u>The Cochrane Library</u> [18] as soon as feasible after registration
- [A checklist is available to help with Cochrane Review Group registration.]

The letter of application to register the Cochrane Review Group with The Cochrane Collaboration is included as section <u>3.2.8.4</u> [182] to illustrate the type of information that is required. Ideally by this stage, the Group will have identified some financial resources to support it, and may then be able to appoint a Managing Editor.

3.2.2.15 Ensuring computing support

Those at the <u>editorial base</u> [103] need ready access to computing support. The Managing Editor needs advice and help in setting up and maintaining adequate systems for managing the work of the Group, in particular the specialized register of trials, and The Cochrane Collaboration software. Without this support, a lot of time can be lost in struggling to deal with problems that may be outside her/his area of expertise. It is important to consider this factor when applying for funds.

3.2.2.16 Publicising the Group's existence

Methods of telling people of the Group's existence include:



- inserting an information sheet into the registration packs of people attending a relevant conference;
- writing to authors asking for reprints of their articles, and any other articles relating to their trial;
- circulating a newsletter, both within and outside the Group;
- giving talks and presenting abstracts and posters at local and international meetings;
- producing an information pack for people expressing an interest in the Group;
- publishing articles or editorials in appropriate journals.

3.2.3 Producing and updating reviews

Subheadings in this section

3.2.3.1 Fostering collaboration and co-operation

Collaboration and co-operation in a <u>Cochrane Review</u> [22] Group are fostered by giving Cochrane Collaboration work the priority it deserves and needs, and by expressing appreciation of the contributions of authors. Credit should be given where it is due, and it is important to ensure that everyone who contributes shares the accolades that come as a result of their hard work. By far the most important single reason for the success of a Cochrane Review Group is that all its members believe wholeheartedly that they are engaged in an enterprise that can improve the care of people using health services. Good ways to foster such co-operation are by meetings, use of the telephone in addition to electronic and paper mail, and periodic newsletters.

3.2.3.2 Developing protocols

The first stage in preparing a review [29] is the development of a protocol [43] that includes the following: an introduction, objectives (including hypotheses to be tested), inclusion criteria, and methods (including the search strategy [178], comparisons, and specific sub-group analyses and their justification). The protocol is then refereed by the editorial team and external referees and revised as necessary before inclusion in <a href="https://doi.org/10.1001/jhear

- encouraging authors to attend a protocol development workshop, organized by Cochrane Centres and editorial teams;
- providing examples of protocols already produced;
- helping to define the objectives and inclusion criteria for the reviews;
- assembling and maintaining a specialized register of trials as a service to members of the Group;
- helping with translations of articles potentially important to a review;
- obtaining rapid <u>peer review</u> [131] of the protocol from individuals with specialist technical or subject expertise;
- giving the authors a deadline for the final protocol (usually six months).

3.2.3.3 Increasing trials register coverage

Each author should discuss with an editor whether the search strategy [178] described for the



<u>Cochrane Review</u> [22] Group as a whole is sufficient to cover the particular topic the author is working on, and should also look for possible sources of information about unpublished studies (for example, by contacting funding agencies, investigators or pharmaceutical companies).

3.2.3.4 Providing technical support

The <u>editorial base</u> [103] of a <u>Cochrane Review</u> [22] Group has to be able to provide technical support to authors on methods, applying inclusion criteria, statistical and data analysis, use of software, and electronic means of communication. Prompt support of authors helps to maintain momentum and avoids delay. In many circumstances, the Managing Editor will be the first person approached to support authors. The Co-ordinating Editor needs to ensure that systems are in place to ensure prompt response to queries. Editors are unlikely to have the skills or knowledge to be able to answer all the questions an author might raise. In these circumstances editors can consult their reference Cochrane <u>Centre</u> [34], or get in touch with others in The Cochrane Collaboration (for example, a member of one of the Methods Groups), to help solve the problem.

Authors may need technical support with using the RevMan software. If the editorial team has organized proper computing support, they will be able to help and advise authors who raise technical questions.

Each new team should ensure that all authors of the review fulfil the authorship requirements. Authors who have not had direct involvement with the present version of the review should probably not be quoted as authors but should be acknowledged. A form is required to be signed by all authors before final inclusion in The Cochrane Library [18].

Editorial teams must develop systems to monitor the progress of their Group's reviews, from title to protocol [43] stage and from protocol to completed review stage, so that delays in finalising protocols/reviews can be identified. This will allow the editorial team to identify which authors may be in need of help and also to ensure that the users of The Cochrane Database of Systematic Reviews are kept informed of when new reviews will be available.

Authors therefore need to supply a date by which a protocol will become a full review (usually 18-24 months). However, editorial teams should probably avoid imposing rigid deadlines on authors, since there is great variability in the time needed to produce reviews, depending on the subject of the review and the experience and workload of the authors.

Maintaining the review is one of the most important aspects of Cochrane reviews and one that sets them apart from most non-Cochrane systematic reviews. Whilst it must ultimately remain the author's responsibility to update the review in the light of comments from others or new evidence, the editorial team must be able to monitor their Group's reviews and identify those that may be seriously out of date. This will prove extremely difficult once the number of reviews grows, but some potential means of achieving this are:

- reminders to authors
- trials have been added to the reviews, and if so what their status is (i.e. included/excluded, ongoing/awaiting assessment). Software ('Meerkat') to assemble and manage specialist registers was developed by the UK Cochrane Centre and Update Software [183] (www.update-software.com/meerkat/ [184]).

Editorial teams may have to consider removing protocols or reviews from their <u>module</u> [102] if the authors concerned do not turn protocols into reviews or update reviews in a timely manner. Authors may also leave the Group, and unless replacements can be found their reviews will probably have to be 'put to sleep' until a new author is identified. Reviews that become out of date will eventually be removed from The *Cochrane Database of Systematic Reviews* and the <u>abstract</u> [145] submitted to The *Database of Abstracts of Reviews of Effects*.



3.2.3.5 Developing guidelines

Ethical guidelines for The Cochrane Collaboration as a whole have been developed by a working group of the Steering Group [13]. Review [29] Groups need to consider in particular, the role of pharmaceutical/appliance companies in the support of the Group. Industry support for the preparation of specific reviews has been strongly discouraged, both by The Cochrane Collaboration and by representatives of the pharmaceutical industry.

Authors need to take care not to break confidentiality agreements that may cover certain trials in their reviews, especially unpublished ones.

All protocols and reviews produced by the Group are published through its module [102] in The Cochrane Database of Systematic Reviews that is available via the Internet and on CD-ROM. Whilst authors may also wish to publish reviews in paper journals, this must not delay publication in The Cochrane Database of Systematic Reviews. Cochrane resources are principally for the production of Cochrane reviews. Journals cannot be assigned copyright for the CDSR [128] version of the review. Authors who wish to publish their Cochrane reviews in paper journals should contact their editorial team for advice and enter into early negotiations with the appropriate journal (see Section 2.2.4 [185] above).

Most Cochrane Review Groups will need to develop guidelines for authors on assessing trial quality [5], on how various forms of outcome [105] data are chosen and assessed, and on standard descriptive details that are asked for in the 'Trials Included' table. These guidelines could be drafted by the editors in the process of preparing their own Cochrane reviews. Other members of the Group could then be asked to comment on the draft and to suggest modifications. It can be very productive to hold a workshop to discuss prototype materials. This information is then included in the Cochrane Review Group's module in The Cochrane Library [18].

3.2.3.6 Managing areas of common interest

Different <u>Cochrane Review</u> [22] Groups often have areas of interest in common, and this is important to consider when establishing a Group (see section <u>3.2.2.6</u> [186]) and as the Group grows. For example, the <u>treatment</u> [8] of neurocysticercosis is relevant both to the Infectious Diseases Group and to the Epilepsy Group. Such intersecting areas of interest need liaison between Cochrane Review Groups so that effort is not wasted in producing duplicate reviews, and opportunities for collaboration are grasped.

There is great potential for across-group collaboration on a particular review, either informally or by two authors from different Groups working together on one review (which would be incorporated in one or other of the relevant modules for transmission to the Parent Database). Editors need to stay in touch with their Cochrane Centres and other Cochrane Review Groups to receive support and ensure that areas of common interest are managed in a spirit of collaboration. The Cochrane Review Group newsletters are a good way to communicate to others the activity within a Group, both to people within and outside that Group. There are electronic mailing lists for Co-ordinating Editors and Managing Editors which are also useful in these situations.

3.2.3.7 Providing 'space' to conduct systematic reviews

Many authors find it helpful to spend 'protected time' away from their own institutions in order to prepare and update reviews. In these cases, the editorial team can help by offering space in one of their own institutions in order for authors to work on their reviews.



3.2.3.8 Maintaining communication

Electronic mail (e-mail) is accessible to many authors. However, the editors and Managing Editor need to make sure that those without access are not disadvantaged by this and are kept up-to-date with developments within the Group. Paper and electronic methods of communication need to be supplemented with periodic face-to-face meetings, and the editorial team should take every opportunity to meet with authors, providing a welcoming environment at the editorial base [103], visiting them when possible, and supporting their applications for funds and fellowships. An annual meeting of the Cochrane Review [22] Group is important. It allows new people to meet existing members, provides a forum for the exchange of ideas, and an opportunity for the Group to discuss what it has learned from its previous year's experience, to celebrate successes, formulate procedures and discuss new developments. The Managing Editor should ensure that members of the Group are notified of meetings relevant to them, particularly events such as Cochrane workshops and the annual Cochrane Colloquia. These events can be good occasions to which to attach meetings of the Cochrane Review Group as a whole, as combined reasons to meet can save on precious travel budgets. Dedicated collaborators' meetings can be highly beneficial, but are expensive.

3.2.4 Personnel and support

Subheadings in this section

3.2.4.1 Getting started

Many clinicians and health researchers interested in assessing the effects of health care interventions will view systematic reviews as part of their jobs. Individuals who believe they cannot do anything without first obtaining a large grant need to think again about their commitment to the work. Most people have limited experience of performing systematic reviews, and since research funding bodies look for previous achievements in a particular area, grants are more likely to be small sums for pump-priming. A lack of financial resources is unlikely ever to prevent someone from producing a review, particularly if in the initial stages they work with an established Group. That said, grants and other awards made to Cochrane Review [22] Groups and authors are likely to help the process to proceed more quickly and efficiently. When considering financial support it is worth considering that the most precious asset that a clinician has is time to work on a review, uninterrupted by other pressures. Funding for a short period (for example, seven days, possibly spread over three months) devoted entirely to the review, is invaluable. Such time is often best spent at the editorial base [103] where advice and support should be freely available. A number of possible sources for such stipends are emerging.

The resources required by a particular Cochrane Review Group will depend on how it is organized, the breadth of its scope, and the depth of detail to be examined in its reviews, for example, whether or not individual patient data [187] will be analysed. Systematic searches for relevant RCTs can be initiated at low cost, with the help of volunteers if necessary. The organisers of meetings for the Cochrane Review Group may well wish to offer hospitality during the meeting itself, but they should not feel obliged to try to find the funds necessary to meet travel and accommodation expenses of those invited to attend.

3.2.4.2 The resources

The extent to which different countries, and different institutions and individuals within each country, provide resources to support the work of The Cochrane Collaboration will be acknowledged in its electronically published output. No country (or institution within a country) should be expected to shoulder more than its 'fair share' of the costs of preparing the information that is required. Conversely, every country might be expected to contribute, according to its means, to an endeavour



that exists to make available, at minimal access cost, valid information about the effects of health care.

Funders of various kinds are now beginning to recognize the importance of making the best possible use of existing evidence, and the importance of having systematic, up-to-date reviews of this evidence prepared and disseminated. More reliable information is being sought both by organisations needing better information upon which to base decisions about the use of resources within health services, and by research funding bodies wishing to make more informed decisions about new research.

Institutions providing resources, including those paying the salaries of people whose time is being contributed to The Cochrane Collaboration, deserve explicit acknowledgement, both when registering a Cochrane Review [22] Group and in its published reviews, and this information needs to be kept up to date.

3.2.4.3 The authors

Whilst the <u>editorial base</u> [103] of a Cochrane <u>Review</u> [29] Group will need considerable resources, many authors will prepare and maintain reviews as an integral part of their work. Some of them have access to resources to support travel, but for others, particularly those in developing countries, access to funds is more limited. In such cases the editorial team may be able to assist authors in obtaining the necessary support from their own institution or country. This support can be in the form of release from other duties to provide some time to the author, or obtaining funds for such things as computing facilities, photocopying or travel.

Preparing a review involves: designing a protocol [43], with non-specialist involvement to ensure comprehensibility; liaison with the Managing Editor to identify the relevant trials from the specialized register; additional searching for trials, e.g. contacting pharmaceutical companies; deciding which trials to include; extracting the necessary data and contacting the trialists for additional data if required; entering the review into the Review Manager [25] software; adding new data as they become available; responding to comments and criticisms, either from the editorial team or from external peer review [131]. Cochrane Review Groups should avoid having a small number of authors, each of whom is responsible for a large number of reviews. This does not promote diversity of opinion in producing reviews and also may cause problems when it comes to a single author keeping a large number of reviews up to date. Cochrane Review Groups need to set their own limits, but five reviews per author might be a reasonable maximum limit. It is also preferable to have more than one author working on each review.

3.2.4.4 Personnel and structure of a Cochrane Review Group

Each <u>Cochrane Review</u> [22] Group needs a long-term geographical <u>editorial base</u> [103] at which the Managing Editor works, and where the specialized register is held. Editorial teams should be international and multi-disciplinary.

Cochrane Review Groups consist of the following people:

(a) The editorial team

i. The Co-ordinating Editor: The Co-ordinating Editor, who is responsible, in conjunction with the Managing Editor and other editors, for ensuring that the protocols and reviews registered by authors are appropriate to the Group's scope, that they pass through an appropriate editorial process [45] before publication on The Cochrane Database of Systematic Reviews, and that they meet the high standards of The Cochrane Collaboration. S/he may also have



methodological expertise in particular areas of systematic reviewing, and so act as advisor to other authors. The Co-ordinating Editor must provide support to the Managing Editor; and discuss the ongoing progress of reviews and protocols, correspondence and other matters at regular, frequent intervals.

- ii. The Managing Editor: The Managing Editor, who is responsible for the Group's overall organization and the day-to-day running of the Group.
- iii. The Trials Search Co-ordinator: For most Cochrane Review Groups, the Managing Editor has too little time to oversee the journal searching and other trial identification activities of the Group. The work of the Trials Search Co-ordinator will change as the Group matures. Initially, it may involve principally the co-ordination of handsearching and various methods of trial identification to establish a specialized register. Once established, procedures will need to be developed to permit searches to be carried out prospectively as well as retrospectively. As the number of authors grows and the variety of topics expands, Trials Search Co-ordinators will find that their activity becomes even more central to the functioning of the Group. The work changes and in a productive Group will expand progressively, not diminish.
- iv. The Editors: The editors, each of whom is encouraged to produce a Cochrane review within two years of becoming an editor. Editors will be asked regularly to review protocols and completed reviews within a given time-frame (usually less than three weeks).
- v. The Feedback Editor (see section 3.2.2.11 [188]): Each Group is required to appoint a Feedback Editor who is responsible for assisting authors in responding to criticisms.

(b) Other personnel

Many other types of personnel may be required by Cochrane Review Groups to maximise their efficiency, although not all of the following are required in all Groups:

- i. The Secretary: All Cochrane Review Groups require secretarial support at the editorial base; this may be full-time or not, depending on the size of the Group. The role of the Secretary varies between Groups, and not all Groups have sufficient funds to employ such a person.
- ii. Authors: The number of authors in a Cochrane Review Group will vary depending on its stage of development and its scope. The authors are ultimately responsible for producing high <u>quality</u> [5] reviews and keeping them up to date.
- iii. Consumers: All Cochrane Review Groups must aim to develop consumer input. This may take several forms, such as membership of the editorial team, review of protocols/full reviews, authorship of reviews, dissemination of reviews to consumer groups, sub-editing reviews into English understandable by consumers, handsearching, fund raising. All Cochrane Review Groups should liaise with the Cochrane Consumer Network in order to identify the best ways for consumers to contribute to the review process.
- iv. Computing support staff: Computing support is usually required to promote effective communication within the Group via electronic mail and to optimise the use of Cochrane software (Review Manager [25], Module [102] Manager) and other software. Problems with Review Manager fall into two broad categories:
 - (a) technical problems relating to hardware and software requirements (e.g. set-up, memory).



- (b) practical problems in using the program.
- v. The former problems usually require help from someone with technical expertise/computer training that is beyond the scope of most authors. The latter problems can usually be solved by someone who is experienced in entering reviews into Review Manager (RevMan), and each Cochrane Review Group should have a designated editor or author whom others can contact for such help.
- vi. Statistician: A statistician will be required to provide statistical guidance for the Group, e.g. which statistical method to use and when. Statistical help may also be required for particular reviews.
- vii. Handsearchers: People may be required to help with paper journal searching and electronic searching. Local medical libraries can help to run electronic searches.
- viii. Translators: Collaborators will often be needed to help translate reports published in languages in which the members of the Group have no expertise.
 - ix. Research Fellow or Research Assistant: Some Groups have gained significant benefit from having a research fellow or research assistant work alongside the editorial team. This person can provide support to the Managing Editor, help with reviews, and develop methodological expertise.

(c) Internationality

Cochrane Review Groups must do all they can to ensure international representation, particularly amongst authors. This ensures a broad perspective, can help—identify trials reported in languages other than English, and promotes—The Cochrane Collaboration internationally.

(d) Multidisciplinary representation

Health problem based Cochrane Review Groups must ensure that authors represent each of the relevant medical and paramedical disciplines and people who suffer from the problem in question, or those who care for them. For example, rehabilitation may involve physiotherapists or occupational therapists, treatment [8] may involve physicians, surgeons, radiologists, nurses or dietitians, and prevention may involve public health specialists.

(e) Membership of the Group

The membership of each Group is left to the individual Group to decide. Generally it should include those who are actively contributing to the Group, either in terms of preparing and maintaining reviews, identifying or translating trials, providing methodological support, or administration. Amongst other things, an explicit membership list of the Cochrane Review Group is required for Steering Group [13] Election purposes. The Review Group Co-ordinator should ensure that 'Archie' (the Collaboration's Information Management System) is kept up to date with the contact details of the Group's members. She/he should also inform the Cochrane Collaboration Secretariat [1] (secretariat@cochrane.org [2]) of changes in membership of key personnel, so that the appropriate entity mailing lists (for example, the 'adminors' list for RGCs) can be kept up to date.

(f) Recruitment of new members

In order to cover their chosen topics adequately, most Cochrane Review Groups will need to attract new authors and other members after registration. In addition, with time some members may retire or resign from the Group. Some suggestions for recruiting people include:

i. writing journal editorials, or presenting posters at conferences;



- ii. writing to authors of existing (non Cochrane) systematic reviews falling within the scope of the Group;
- iii. heads of department encouraging junior research staff to prepare and maintain systematic reviews;
- iv. collaborating with Cochrane Fields and Centres;
- v. encouraging clinical trialists to review evidence relevant to their trials.

It often helps if the Group has an introductory pack that it can send to interested people, outlining the aims and methods of the Group and the many various ways in which people can help (see section 3.2.2.1). [189]

3.2.4.5 Planning funding

<u>Cochrane Review</u> [22] Groups are responsible for obtaining the necessary funding to carry out their own work. Many Groups exist on minimal funding, partly because there has been little information to guide Groups on what the costs of their work will be. The following are some of the expenses that Cochrane Review Groups should consider:

- 1. Salaries for a Managing Editor, Trials Search Co-ordinator, Secretary, computer specialist. It should be recognized that the ideal minimum effective staff for an <u>editorial base</u> [103] will be at least two full-time staff. A large and productive Group will need a minimum of three staff. As noted earlier, demands of the editorial base increase as the Group grows, so thought should be given to planned growth.
- 2. Computer hardware and software (e.g. to establish a specialized register of studies);
- 3. Consumables (e.g. fees for running electronic search strategies, access to databases and downloading costs); photocopying; inter-library loans; telephone, fax and postage costs; computer disks;
- 4. The costs of a yearly collaborators' meeting or training sessions for authors and/or Managing Editors:
- 5. Expenses of volunteer handsearchers;
- 6. Travel expenses, especially for the Managing Editor (e.g. for travel to the reference Cochrane Centre [34] and annual Colloquia).

The sources of such funding are outside the scope of this document, but should preferably be considered in the original funding application of the Group.

Cochrane Review Groups should supply their members with basic materials free of charge if possible (e.g. the Handsearching manual, and lists of relevant references to studies). However, many Groups are also asked for information by individuals or organisations outside The Cochrane Collaboration, for example, they may be asked for lists of trials. Cochrane Review Groups should decide for themselves whether to respond to such requests and if so whether to charge for such services on the basis that such charges should only cover the costs of such tasks (labour and materials) and should not be profit-making.

3.2.5 Maintaining and managing a Cochrane Review



Group

Subheadings in this section

3.2.5.1 Establishing a refereeing policy

It is the responsibility of the editorial team to establish a refereeing policy for protocols and reviews prior to entry into The *Cochrane Database of Systematic Reviews* (see the *Cochrane Handbook [54] for Systematic Reviews of Interventions*). Issues as to the time frames for protocol and review completion need to be dealt with at the editorial team level. Cochrane Review [22] Groups are also required to respond to comments that come in after the initial version of a review is published (see Section 3.6 in the *Cochrane Handbook [55] for Systematic Reviews of Interventions*). It is also helpful to examine the policies of other Cochrane Review Groups.

3.2.5.10 Producing a newsletter

This is the responsibility of the Managing Editor and the editorial team. Newsletters should include an updated list of the Group's protocols and reviews, as well as notifying members of upcoming workshops. Individuals may like to contribute items such as a 'portrait' of a member of the Group, reports of a recent conference, etc.

3.2.5.11 Reviewing the scope of the Cochrane Review Group

From time to time topics will arise that are not covered in any particular <u>Cochrane Review</u> [22] Group but may be closely aligned to the Group. It may be necessary for the editorial team to consider new topics to be included in the Group's scope. This should be negotiated in conjunction with the director of the reference Cochrane <u>Centre</u> [34].

3.2.5.12 Performance and quality assessment of Cochrane Review Groups

There is no easy way of measuring the performance of <u>Cochrane Review</u> [22] Groups in terms of <u>quality</u> [5]. It is essential to the work of The Cochrane Collaboration that they are productive; preparing and maintaining reviews are the main outputs of The Cochrane Collaboration. Producing a register of trials that can support authors is mandatory for all Cochrane Review Groups. Courteous and efficient communication with authors is also a central focus of all Cochrane Review Groups. The Monitoring and Registration Committee, a committee of the Cochrane Collaboration <u>Steering Group</u> [13], surveys the progress of Cochrane Review Groups every two years by looking at a variety of both quantitative and qualitative outputs.

3.2.5.2 Policy on default statistics

The Cochrane Handbook [54] for Systematic Reviews of Interventions is The Cochrane Collaboration's primary source of statistical advice. Each Cochrane Review [22] Group should state in their module [102] any statistical issues of importance to their Group that are not mentioned in the Handbook [55].



3.2.5.3 Non-performance of authors

Editorial teams are required to develop strategies for dealing with authors who do not produce protocols and reviews within the time-frames agreed, or who fail to communicate adequately with other authors, etc. In some situations the reference Cochrane Centre [34] may be able to assist.

3.2.5.4 Avoiding duplication of reviews and protocols

On occasion, protocols and reviews may be being developed by groups of two or [127] more authors concurrently but independently. This can be avoided if a Group has a good communication system, but occasionally duplication does occur. In this situation the different groups of authors should be encouraged to combine their energies and produce a single review, or alternatively split the topic into two reviews, taking care not to duplicate effort in the process. To help to avoid such duplication, titles of new reviews are registered in 'Archie' (the Collaboration's information management system). Publishing the titles of protocols under development in the Cochrane Review [22] Group's newsletter may also help to avoid duplication.

3.2.5.5 Managing the module requirements

Managing Editors receive training in the software and how to submit the <u>module</u> [102] electronically for publication in <u>The Cochrane Library</u> [18]. This is done four times a year. It is important that the Managing Editor gives adequate warning of the deadline to authors, editors and external referees in order for protocols and reviews to be adequately refereed.

3.2.5.6 Internal Cochrane Review Group policies

Criteria for ongoing membership of the <u>Cochrane Review</u> [22] Group need to be discussed by the editorial team. Some Groups use annual membership forms. Co-operation with the <u>editorial base</u> [103] regarding provision of unpublished data may be considered a membership requirement by some Groups. Editorial processes are set by the editorial team and published in the <u>module</u> [102].

3.2.5.7 Dealing with conflicts within Groups

As The Cochrane Collaboration progresses, conflicts may arise within and between Groups. Editors, authors and Managing Editors may also experience difficulties in sorting out issues within the Group. If internal resolution is not possible, the Director of the reference Cochrane Centre [34] can be approached to mediate.

3.2.5.8 Liaising with Fields and Methods Groups

<u>The Cochrane Library</u> [18] contains information on the contact person of each of the Fields and Methods Groups.

3.2.5.9 Maintaining an active list of authors and other contributors

At regular intervals it is necessary for the Managing Editor and Co-ordinating Editor to ensure that their current list of the members of their group is up to date. This can be done by sending out a 'renewal of membership' form every twelve months.



3.2.6 Conclusion

We have aimed in this section to summarize the collective experience in establishing and maintaining <u>Cochrane Review</u> [22] Groups, to help guide existing and new Groups. This experience provides a baseline for people to work together in achieving the aims of The Cochrane Collaboration. Sharing this experience is something we can all foster through communication among Groups, both to avoid duplication and to enhance the output of Cochrane Review Groups in producing high <u>quality</u> [5] reviews of reliable evidence about the effects of healthcare interventions.

3.2.7 Acknowledgements

The <u>Cochrane Review</u> [22] Group representatives on The Cochrane Collaboration's <u>Steering Group</u> [13] in 1996/97 (Zarko Alfirevic, Cindy Farquhar, Cecilia Hammarquist, and Beverley Shea) revised this section on establishing and maintaining Cochrane Review Groups, and Paul Jones (who was a member of the Steering Group from 1997 to 1999) also provided helpful input. The following people have also contributed to this section in various ways over the last decade: Philip Alderson, Lisa Bero, lain Chalmers, Mike Clarke, Carl Counsell, Paul Garner, Emma Harvey, Jini Hetherington, Ruth Jepson, Steve Milan, Barbara Roberts, Chris Silagy, Lorinda Simms, Mike Smith, Vivenne Topping and Veronica Yank.

3.2.8 Appendices

Subheadings in this section

3.2.8.1 Agenda for an exploratory meeting to discuss formation of a Cochrane Review Group

Exploratory meeting to discuss formation of a Cochrane Heart Group

Dept of Primary Care and Population [190] Sciences,

Royal Free Hospital School of Medicine, London

1000h Sunday 14 December - 1600h Monday 15 December 1997

AGENDA

Sunday 14 December

0900 Registration

Chair: Charles Warlow, Co-ordinating Editor, Cochrane Stroke Group

1000 Welcome and introductions - Everyone

1045 The Cochrane Collaboration - Charles Warlow



1115 Coffee

The work of existing <u>Cochrane Groups</u> [20] in cardiovascular disease

The Stroke Group - Peter Langhome

Peripheral Vascular Diseases Group - Gill Leng

12.30 CVRCT (trials) Register in cardiovascular disease: Nadia Smyrniw

1300 Lunch

1400 Existing systematic reviews not covered by Cochrane groups - Shah Ebrahim

1430 Converting a review published on paper into Cochrane format - Peter Langhorne

1500 Tea and Break into small group discussions to define scope and priorities

a) Ischaemic Heart Disease - (i)Drugs, (ii) Surgery and revascularization,

(iii) Life-style changes and rehabilitation

b) Heart Failure

c) Inflammatory Heart Disease

d) Congenital Heart Disease.

1600 Feedback in Plenary

1730 Close

1900 Dinner at: Weng Wah House, Haverstock Hill, Hampstead

Monday 15 December

Chair: Charles Warlow

0900 Should there be a Cochrane Heart Group? - Everyone

0930 What can people offer?

What can Cochrane Centres offer? - Jain Chalmers

What can the Thames Systematic Reviews Training Unit offer? - Shah Ebrahim

What can others offer? - Everyone

What can those unable to attend offer? - Shah Ebrahim

Does the basis exist for proceeding? - Everyone

1145 Coffee



1215 Action (to be decided in the light of answers to the questions above)

1300 Lunch

1600 Tea at close of meeting

The meeting will close no later than 1600h.

3.2.8.2 Report of an exploratory meeting

Minutes of an

EXPLORATORY MEETING TO CONSIDER FORMING

A COCHRANE SKIN DISEASES GROUP

Held on Friday 17 and Saturday 18 May 1996

At BAD House, 19 Fitzroy Square, London, W1P 6HQ

Present:

Jan Bouwes Bavinck Dermatologist, Leiden, The Netherlands

lain Chalmers UK Cochrane Centre [34], Oxford

Robert Chalmers Dermatologist, Salford

Margaret Corbett Dermatologist, Cambridge

Nicky Cullum Co-ordinating Editor, Wounds Group, York

Thomas Diepgen Dermatologist, Erlangen, Germany

Anne Eady Microbiologist, Leeds

Christina Funnell Director, Skin Care Campaign, London

Andrew Herxheimer Clinical Pharmacologist, London

Christopher Griffiths Dermatologist, Manchester

Alain Li Wan Po Clinical Pharmaceutics, Nottingham

Barbara Meredith National Consumer Council, London

Luigi Naldi Dermatologist, Bergamo, Italy

Steve Shaw Product Manager, Merck/Lipha Pharmaceuticals,

UK

Catherine Smith Dermatologist, Lewisham, London

Phyllis Spuls Dermatologist, Amsterdam, The Netherlands

Marcus Woods Product Manager, Schering Plough, UK



Andrew Whiteside Skin Care Campaign, London

Hywel Williams Dermatologist, Nottingham

Mrs Adrienne O'Donohue British <u>Association</u> [24] of Dermatologists (in

attendance)

Apologies: Apologies were received from Dr Marion White, Aberdeen. Marcus Woods and Christopher Griffiths sent their apologies for the Saturday session.

FRIDAY 17 MAY

Chair - Iain Chalmers

COCHO5-96/01 Welcome and Introductions

Everyone present introduced themselves, giving a brief description of their background and why they felt a Cochrane Skin Group should be set up.

COCHO5-96/02 Introduction to The Cochrane Collaboration and Demonstration of the Cochrane Database of Systematic Reviews

lain Chalmers introduced The Cochrane Collaboration as a network of individuals committed to preparing and maintaining systematic reviews of the effects of health care. He gave a brief history of The Cochrane Collaboration, which was launched formally in October 1993 and proceeded to demonstrate the *Cochrane Database of Systematic Reviews* (now produced as part of *The Cochrane Library* which is updated every 3 months). He demonstrated how reviews are focused on health problems under the headings of prevention, treatment [8] or rehabilitation strategies. Iain emphasised the 6 main principles of The Cochrane Collaboration were:

Collaboration

Collaboration between people worldwide was necessary in order to undertake the massive task of searching journals in different languages for controlled trials and in order to critically appraise and summarize that information in a form that can be used by practitioners and consumers.

Building on individuals existing interests and enthusiasm

Although several of those present were associated with various bodies, Ian emphasised that The Cochrane Collaboration was about contributing to a larger vision.

Minimising duplication of effort

Reducing bias [6]

To reduce bias in reviews by introducing a systematic method of reporting information.

Keeping up to date

Access



COCHO5-96/03 Examples of Systematic Reviews of skin diseases already available/being prepared

Systematic reviews already completed in the field of dermatology are summarized in Section AA.

Four of those present were directly involved in producing systematic reviews, and gave a brief summary of their topic and problems encountered:

Dithranol - Luigi Naldi, Bergamo, Italy

Luigi surveyed clinical trials examining efficacy [191] of short contact dithranol therapy in psoriasis focusing on mainly methodologic issues. Twenty four papers published between January 1982 and December 1989 in English, French and Italian were selected. Nine of the 24 papers contained more than one trial, giving a total of 37 trials to be evaluated. Methodological differences between studies were so vast, that pooling of results was impossible. Most trials suffered from major flaws such as failure to conceal blinding [192] and failure to randomise. Entry criteria were also unclear and dropouts [193] were not analyzed appropriately. Luigi also highlighted some of the problems with within-patient comparisons, e.g. right-left comparisons or comparing 4 different treatments on 4 different quadrants of the body. Luigi called for a review of basic methodological requirements for clinical trials in psoriasis.

Evening Primrose Oil (Epogam) in atopic eczema - Alain Li Wan Po, Nottingham, UK

This review by Alain and Hywel Williams for the Department of Health, highlighted the vast number of outcome [105] measures that were used for evaluating efficacy of treatment for atopic eczema. Each outcome measure - such as cracking, crusting, doctor assessed itch and dryness - used different scales, making standardisation extremely difficult. Although the main results of the study were not available for discussion, the group appreciated the need for standardisation of outcome measures for atopic eczema, especially ones which are important to patients.

Systemic psoriasis treatment - Phyllis Spuls, Amsterdam, Netherlands

Phyllis outlined a detailed review by herself and her colleagues on systemic treatments for psoriasis. This included searching of electronic databases and handsearching of relevant journals. Quality [5] scoring of papers was carried out by 2 investigators. Phyllis pointed out the problems with quality rating studies, eg. only 60% of studies mentioned side effects, whilst only 50% of studies mentioned dropouts and how they were analyzed. Phyllis called for guidelines on conducting controlled trials in dermatology.

Type II error in dermatology trials - Hywel Williams, Nottingham, UK

Hywel reported on a review of 58 clinical trials with negative conclusions published in 3 British dermatology journals 1988-1991. The aim of the study was to determine the <u>risk</u> [143] of these trials of missing important treatment differences. All but one of the 44 evaluable trials had a greater than 1 in 10 risk of missing a 25% relative treatment difference (<u>median</u> [194] risk 81%) and 31 of the trials (70%) were so small that they had a greater than 1 in 10 risk of missing a 50% relevant treatment difference (median risk 42%). Even worse, half of the 'negative' results were incorrectly interpreted as evidence of no difference. Small underpowered studies are a waste of resources and patients' and doctors' time. He suggested that the situation of underpowered small trials in dermatology had not changed very much since his review in 1993, and welcomed the suggestion of updating the review in 1997.

COCHO5-96/04 Progress and developing a register of relevant trials



Hywel Williams emphasised the need to develop a register of relevant trials for systematic reviews of treatments for skin disease. Although reviews on specific topics can and have been done without such a register, a continuation of this policy without assembling a master list of all controlled trials in dermatology would result in duplication of effort and incomplete reviews. It was acknowledged that the best method of compiling such a controlled trials register [58] was to handsearch all the dermatology journals and all conference proceedings in a systematic fashion throughout the world. Preliminary information from the St Johns Dermatology Centre librarian suggested that there were over 100 dermatology journals ever published (excluding conference proceedings where many trials are to be found). The task ahead of dermatology is therefore huge, but one which must be started. Hywel Williams has made a start of handsearching the British Journal of Dermatology.

In order to help in prioritising journals for handsearching Hywel presented the results of a Medline search for dermatology trials using the UK Cochrane Centre search strategy [178]. The search strategy and results of this search are summarized in Section BB. Conclusions to the MEDLINE search were:

In terms of prioritizing journals, most genuine controlled trials are probably in main dermatology journals over last 20 years. Working backwards with the main journals seems a sensible strategy.

In terms of contributing to a Cochrane Skin Group's Trials Register, Medline is limited in its completeness, accuracy and coverage of appropriate journals.

Use of "dermatology" or "skin diseases" as MeSH or free text terms for studying the <u>population</u> [190] of dermatology trials is not very helpful. Specific disease terms are better.

Preliminary electronic searching suggests that there are virtually no CCT/RCT's on the 1000+ least frequent skin diseases.

Hywel closed by emphasising the need to co-ordinate all electronic and handsearching activities centrally in close collaboration with the US Cochrane Center, which had responsibilities for downloading references from the MEDLINE database. This was essential to avoid duplication of effort.

Action -

Individuals interested in contributing to a Cochrane Skin Group should let Hywel know whether they wish to participate in electronic or handsearching of dermatology journals, and if so, which journal/database over what period.

COCHO5-96/05 What might the scope of a Cochrane Skin Group be?

lain Chalmers highlighted the need to consider the scope of a Cochrane Skin Group in order to avoid duplication of efforts with other Cochrane Review [22] Groups. The Wound Healing Group and the Parasitic Diseases Group were examples of groups that could overlap with a Skin Group. Hywel had already been in touch with the co-ordinating editors of these groups to inform them of the skin diseases exploratory meeting and the need to keep in touch about potential areas of overlap. Nicky Cullum, co-ordinating editor of the Cochrane Wounds Group, had come to this meeting with this in mind. The consensus of those present was that so much work was needed in dermatology that it was not necessary to be territorial about which group did what review. Iain Chalmers suggested that for specific reviews, e.g. scabies, there would be nothing stopping someone from a Cochrane Skin Group working under the aegis of the Parasitic Diseases Group. The most important consideration was that the systematic review should be done, and done to a high scientific standard. Nicky Cullum, co-ordinating editor of the Wounds Group, emphasised the need for very close collaboration with their group in view of the large potential area of overlap, eq. leg ulceration. Although the Wounds Group had made a good start at developing a clinical trials register and summarising the effects of health care on pressure ulcers, infrastructure funding remained a major problem. Nicky emphasised the need to consider pooling resources in order to make progress on this.



Action -

Hywel Williams will send a copy of the final minutes to the co-ordinating editors of all Cochrane Review Groups with an area of potential overlap. Nicky Cullum will be invited to all Cochrane Skin Group meetings in order to formulate common strategies on funding and specific reviews.

The question of whether reviews on skin cancer should be included in the scope of a Cochrane Skin Group was discussed. It was felt by most of those present that the amount of work required to review the three major inflammatory disorders, ie. acne, eczema and psoriasis, was already enormous and that taking skin cancer on as a major topic was unwise. Hywel informed the group that there are individuals in Australia who are already considering forming a Cochrane Skin Cancer Group. They could link with the Cancer Network co-ordinated by Chris Williams in Oxford. Jan Bavinck (Netherlands) suggested that a Cochrane Skin Group might consider acting as a contact point and provide support to those wishing to initiate reviews in skin cancer until a Cochrane Skin Cancer Group had been established.

Action -

The main emphasis of a Cochrane Skin Group should be initially on inflammatory skin diseases such as eczema, acne and psoriasis. The group could, however, act as a contact point for reviews on skin cancer until a Cochrane Skin Cancer Group forms.

SATURDAY 18 MAY

COCHO5-96/06 Is there a basis for establishing a Cochrane Skin Group?

All those at the meeting gave an unequivocal 'yes' to this agenda item. The interesting nature of the work, combined with the need for systematic reviews in the field of dermatology and breadth of expertise already represented at the exploratory meeting, provided a very good basis for forming a group.

COCHO5-96/07 What can Nottingham offer?

Hywel Williams summarized the service that he and his colleague Alain Li Wan Po would be able to offer if Nottingham was acceptable to others as the editorial base for a Cochrane Skin Group. These were:

Experience in searching, reviewing and conducting meta analyses.

Good international contacts.

Space for accommodating occasional authors who wish to escape from their normal work surroundings in order to concentrate on a particular review.

Technical (ie. information technology) support.

A courteous and non-empire building attitude towards fostering the Cochrane Skin Group.

COCHO5-96/O8 What can the Cochrane Centres offer?

lain Chalmers described how the Cochrane Centres have been set up to help Cochrane Review Groups to work effectively. Every country throughout the world is linked to a particular Cochrane Centre. Cochrane Centres run free workshops for authors wishing to perform systematic reviews. These are summarized in Section CC.

COCHO5-96/09 What can others offer (including those not present)?



lain asked each individual at the meeting how they wished to be involved with the group's activities. He emphasised the need to appreciate the size of the task ahead before making any commitments, and that people could contribute in many different ways, eg. by organising a handsearch, performing a specific review, as outlined in Section DD.

- ECCEPTION AND STATE OF THE PROPERTY OF THE P
- ECCEPTION CONTINUES TO A CONTINUE SMITH HAD ACCESS to an excellent medical library at St John's Dermatology Centre, St Thomas's Hospital, and was interested in reviewing clinical trials in psoriasis and atopic eczema.
- ECCCCCCC Margaret Corbett offered help with computing, communication, statistical and refereeing skill.
- eeeeeeee Alain Li Wan Po (clinical pharmaceutics) is most interested in methodological problems for inflammatory skin diseases. He has statistical skills and access to PhD students who might be engaged on specific systematic reviews.

- eeeeeeee Andrew Herxheimer would like to prepare a review of cholinergic urticaria and use his experience as an editor to comment on protocols and reviews.
- eeeeeeeee Phyllis Spuls would like to perform reviews with some of her Dutch colleagues, especially on systemic treatments of psoriasis. She will first need to discuss this with her Head of Department before committing herself further.
- eeeeeeee Andrew Whiteside (Skin Care Campaign) offered to help search journals, and with specific reviews and protocol development.
- ECCEPTION OF THE PROPERTY OF



the Germany Language Bureau and has interest in methodological aspects, such as outcome measures, scoring systems, etc. He also co-ordinates the worldwide website for dermatology (Internet site address www.rrze [195]. unierlangen de/docs/FAU/fakultaet/med/kli/derma/), and would be able to assist in publicity for the Group through the Internet.

• ECCEPTION AND ITS PROPERTY OF THE COCHTANE COLLABORATION AND AND THE COLLABORATION AND THE

Action -

Hywel Williams encouraged those present to think about the work of the group before committing themselves any further. He therefore invited them to reflect how they would like to contribute to a Cochrane Skin Group, and to follow this up by writing to him outlining the area and activities that would interest them, by 7 June 1996.

COCHO5-96/10 Written Contributions

i) Those who have expressed a willingness to start helping

Written contributions from people who were committed to preparing and maintaining systematic reviews, but who could not be present at the exploratory meeting, were read out by Hywel Williams:

Name (Country)

Area of Interest and Activity of Interest

Meena Agrawal (UK)

Formulation of pharmaceutical products and

interface audit

Peer reviewing protocols, help with co-ordinating

activities

Chris Commens (Australia)

Non-neoplastic skin diseases

Not specified

Dédée Murrell (Australia)

Non-neoplastic skin diseases, especially autoimmune bullous diseases and autoimmune connective tissue

diseases

Journal searching, or being part of an editorial group or

an author

Lars Petersen (Denmark)

Atopic skin diseases such as atopic dermatitis and

urticaria

Any aspect of Cochrane work

John Newton (UK) Acne

Contribute to acne reviews

Terence Ryan (UK) Scabies, wounds

Facilitating overseas doctors to participate in

systematic reviews

Gordon Searles (Canada) Cutaneous manifestations of internal disease, mucosal

dermatology, autoimmune bullous diseases, toxic

olysis

Searcher and preliminary author

Marion White (UK) Atopic dermatitis Reviewing

ii) Those who wish only to be kept informed of the Group's development:

Dr. John Berth-Jones (Coventry, UK)

Prof. John Burton (Bristol, UK)

Prof. William Cunliffe (Leeds, UK)

Dr. David Gawkrodger (Sheffield, UK)

Prof. Roderick Hay (London, UK)

Prof. Rona Mackie (Glasgow, UK)

Dr. Richard Rycroft (London, UK)

Dr. Thomas Salopek (Canada)

Dr. Keith Steele (UK)

Dr. Jimmy Volmink (S. Africa/UK)

COCHO5-96/11 Action Plan and Timetable

Structure of the editorial group



lain Chalmers invited all those present to serve in an editorial capacity for the Cochrane Skin Diseases Group. All were happy to support Hywel Williams as co-ordinating editor. At that point of the meeting, Iain Chalmers handed over the chairmanship to Hywel. Hywel specifically requested that Professor Alain Li Wan Po join him on the editorial staff in view of Alain's knowledge of methodological aspects of meta-analysis [104] and statistics. The group were happy to support this. Luigi Naldi (Italy) and Thomas Diepgen (Germany) also offered to act in an editorial capacity with the Skin Diseases Group Group and this was accepted by all. Hywel Williams also proposed Dédée Murrell as part of the editorial team in view of her stated desire to work as an editor and in view of the evidence of her commitment by her attendance at Cochrane workshops, etc. in Australia. This was accepted by all. The editorial group will consist of:

- EEEEEEEE Thomas Diepgen (Germany)
- EEEEEEEE Dédée Murrell (Australia)
- € € € € € € € E Luigi Naldi (Italy)
- €€€€€€€€ Hywel Williams (co-ordinating editor, UK)

COCHO5-96/12 Topics for review and possible authors

Topic Possible Authors

Corticosteroids in toxic epidermal necrolysis Luigi Naldi, Jan Bavinck, ?Jean-Claude Roujeau, Moya Mockenhaupt

Long term efficacy of topical corticosteroids and emollients in atopic eczema

Hywel Williams, Cathy Smith, Anne Eady, Andrew Whiteside

Diet and atopic eczema

Cathy Smith, Anne Bady, ?Professor Tim David, Manchester

Antihistamines in atopic eczema

?John Berth-Jones, Hywel Williams

Chinese herbs in atopic eczema

?Andrew Whiteside, Hywel Williams, Alain Li Wan Po

Non-medical interventions in dermatology, eg. family support and education and help for those with learning disabilities



Barbara Meredith

Psychological treatments for psoriasis

Chris Griffiths, ?Chris Main

Treatments for guttate psoriasis

Robert Chalmers

Treatments for palmar plantar, pustular psoriasis and generalised pustular psoriasis

Robert Chalmers, Chris Griffiths, Phyllis Spuls

Systemic Treatments for chronic plaque psoriasis

Phyllis Spuls, Robert Chalmers, Chris Griffiths

Mupirocin for cutaneous infections

Anne Eady

Skin problems in elderly individuals such as treatment of senile pruritus

Barbara Meredith

Treatment of axillary hyper hidrosis

Andrew Herxheimer

Treatment of cholinergic and delayed pressure urticaria

Andrew Herxheimer

Non-steroid treatments for hand eczema

Tina Funnell

Treatment of acne scars

Anne Eady



Hywel noted that some common areas were already beginning to emerge, e.g.

Atopic eczema – Hywel Williams, Alain Li Wan Po, Marion White, Tina Funnell, Andrew Whiteside, Thomas Diepgen, Cathy Smith

Psoriasis - Luigi Naldi, Chris Griffiths, Robert Chalmers, Cathy Smith, Phyllis Spuls

Acne - Hywel Williams, Anne Eady, John Newton

Bullous Disorders - Dédée Murrell and Gordon Searles

It was also pointed out that many of those present had a common interest in methodological issues such as choice of outcome measures to be used in inflammatory skin diseases and that there was considerable skill mix amongst those present to tackle standardisation of these issues in systematic reviews.

COCHO5-96/13 Co-ordination of searching journals and conference proceedings

In addition to the current listing of 102 dermatology journals, Hywel invited all those present to update him with any further journals or conference proceedings where potential trials may be distributed.

Action -

Please send information on conference proceedings/journals to Hywel so that a full list of all journals where potential trials may be located can be compiled.

COCHO5-96/I4 Support for Funding an Administrator

Hywel stressed how important it was to have an administrator/contact base for the work envisaged by the Group. This would be a full time position and would need a person with considerable personal and organisational skills, as suggested by The Cochrane Policy Manual. Such a person would need ongoing funding and the group would need to find their own funds for this activity. Tina Funnell suggested that the Skin Care Campaign organise a fund raising event with presentations to the pharmaceutical companies and other possible funders. Barbara Meredith felt that funding should not be solely pharmaceutical in origin, and others agreed that every attempt should be made to ensure additional sources of funding, such as Government departments, research councils, and other charities, etc., for specific reviews.

Action -

Tina Funnell (Skin Care Campaign) to organise a Cochrane fund raising meeting in London on Monday 23 September 1996. This should include a presentation on the work planned for a Cochrane Skin Group and should include as many members of the editorial team as possible. Once funds are secured, these would be allocated to a separate fund, c/o the Skin Care Campaign. It was agreed by those present that Nicky Cullum of the Wounds Group should also be present at the fund raising meeting so that those from the industry who were interested in wound care products could be approached with a view to supporting the Wounds Group.

COCHO5-96/15 Preparation and Application to Register The Cochrane Collaboration

lain Chalmers circulated an up-to-date checklist for Cochrane review registrations (Section BB). The following targets were agreed by the group:



Application for registration should be submitted end of July/beginning of August 1996.

Date for administrator in post: This would depend on funding from Skin Care Campaign. July 1997 was mentioned as a realistic target.

Submission date for first protocols: Three protocols to be submitted to the editorial group by the end of 1996.

Date for first reviews entered into the Cochrane database: evening primrose oil (Epogam) and atopic eczema by the end of 1996.

Number of reviews in first 5 years: 10 was thought to be realistic.

Dates for completing retrospective handsearches to be negotiated with local Cochrane centre in view of the enormity of the task.

Dates for completing retrospective electronic searches: end of 1997.

lain Chalmers indicated that it would take approximately 6 months before the group was registered if everything proceeded well.

Hywel Williams thanked everyone for attending the meeting and said that he felt that a lot had been achieved. Hywel also emphasised how well the group had worked together over the last couple of days and that the group felt very balanced in terms of skill mix and international and consumer/patient representation. Iain Chalmers echoed these sentiments and felt that the proposed Cochrane Skin Group would be productive and successful.

COCHO5-96/16 Date of the Next Meeting

To be held at BAD House, 19 Fitzroy Square, London WI P 5HQ on 16/17 May 1997.

3.2.8.3 Checklist for application to register a Cochrane Review Group

See Appendix 2: Monitoring and Registration Committee [174], for the latest version.

3.2.8.4 Example covering letter for application to register with The Cochrane Collaboration

Faculty of Medicine and Health Sciences University Hospital Queen's Medical <u>Centre</u> [34] Nottingham NG7 2UH

19th September 1997

Professor Chris Silagy



Chair, Cochrane Collaboration Steering Group [13]
Cochrane Collaboration Secretariat [1]
PO Box 726
Oxford
OX2 7UX

Dear Professor Silagy,

The time has come for the prospective Cochrane Skin Group to apply for formal registration with The Cochrane Collaboration. Developing this new and important group has been done in close consultation from its inception with Iain Chalmers from the UK Cochrane Centre. At my last meeting with Iain in Oxford, we worked through the checklist for CRG [15] registration, and we were of the opinion that all of the criteria had been fulfilled. I would now like to deal with the background and specific issues of the prospective Cochrane Skin Group in more detail:

Background to the Cochrane Skin Group

Interest in forming a Cochrane Skin Group began with a few individuals as far back as 1992. Three meetings have since been held to inform individuals of the nature of The Cochrane Collaboration and to enlist their commitment. The first 'pre-exploratory' meeting was held at the University of Nottingham and was attended by Iain Chalmers, Tina Funnell of the National Eczema Society, Chris Griffiths and Robert Chalmers (both dermatologists at Manchester), Alain Li Wan Po from the Department of Clinical Pharmaceutics at Nottingham, and myself. It was decided at that meeting that there was sufficient enthusiasm to consider holding a formal exploratory meeting, and this was held on Friday 17 and Saturday 18 May 1996 at the British Association [24] of Dermatologist's new office at 19 Fitzroy Square, London. All individuals who had registered an interest in systematic reviews with respect to skin disease with Cochrane Centres throughout the world were invited to this meeting. If they were unable to attend they were asked to give an indication of how they wish to be involved with the work of the group. Minutes of the meeting are enclosed with this application.

During the first day of the exploratory meeting, examples of systematic reviews that had already been prepared in dermatology were discussed. Iain Chalmers demonstrated The Cochrane Library [18] and this was followed by a discussion of how we might develop a register of relevant trials. Potential overlap with other groups was discussed carefully, and Nicky Cullum, co-ordinating editor of the Cochrane Wounds Group, kindly came along to the meeting with this in mind. At the end of that exploratory meeting, there was unequivocal support for moving forward to establish a Cochrane Skin Group. Those present at the exploratory meeting were individuals who were genuinely committed to collaborating in order to produce reviews of important health care problems affecting patients with skin problems.

Consumer involvement has been prominent from the outset of the group, and the group is also truly international and multi-disciplinary. Editorial structure was established at the meeting, with myself as co-ordinating editor and Luigi Naldi (Italy), Thomas Diepgen (Germany), Alain Li Wan Po (Nottingham) and Dédéé Murrell (Australia) as the editorial team. Following the above meetings, I circulated the 47 prospective members of our group an invitation to commit themselves further to getting involved with specific reviews or contributing to the specialised register of controlled trials [58].

At the exploratory meeting, it was suggested that the prospective Cochrane Skin Group might attract funds for a co-ordinator by holding an informing and funding meeting with a range of potential funders, such as the Department of Health, representatives from the drug industry and consumer groups. This awareness and funding meeting was organised closely with patient representatives from the Skin Care Campaign and was held in London on Monday 23 September 1996. A report of this meeting is included with this document. Following the meeting, a number of



influential individuals from the drug industry agreed to get together with view to considering the possibility of corporate funding for a co-ordinator and additional support for the <u>editorial base</u> [103] in Nottingham. We have yet to receive a firm commitment for such corporate funding. We can reassure you that any industry sponsored funding will not be linked under any circumstance to any specific review. It is hoped that the Skin Care Campaign (a UK patient group) will administer the funds for infrastructure to support the Cochrane Skin Group, so that a clear boundary is placed between industry and those conducting specific reviews. We have since been successful in attracting funding for a co-ordinator and infrastructure support from the NHS Executive Trent Region Research and Development Office.

The second meeting of the prospective Cochrane Skin Group was held in London at the British Association of Dermatologists headquarters on May 16/17th 1997. Sixteen individuals attended from a range of countries and professional backgrounds. The theme of the meeting was that of converting the enthusiasm shown at the exploratory meeting into Cochrane output that was realistic and achievable over the next 18 months. Minutes of the meeting and agreed targets are enclosed.

Following the meeting, Professor Kent Woods of the Trent Region Research and Development Office agreed in writing to provide infrastructure support to the prospective Cochrane Skin Group until the end of the next financial year. At that time, he believes that there will be a mechanism open to UK Cochrane entities [20] to request funding from national research and development sources.

Specific items required for CRG registration

- a. Process I can confirm that plans for the Cochrane Skin Group were developed from the outset in close consultations with Iain Chalmers from the UK Cochrane Centre. Alessandro Liberati from the Italian Cochrane Centre has also been involved in supporting Luigi Na1di, and Jos Kleijnen has offered further support to Phyllis Spuls at Amsterdam. All individuals who had expressed an interest in Cochrane work were informed about the meeting. All individuals identified by searching the DARE [197] database using the terms 'skin' and 'dermatology' were identified and circulated accordingly. Further publicity and awareness of the Group has been made possible through a funding and awareness meeting, and also individual presentations such as guest lectures given by myself on the topic of 'The need for systematic reviews in dermatology' given at the international Skin Forum Meeting in Cardiff, October 1996, and at the Annual Meeting of the British Association of Dermatologists (Harrogate 1997), and various meetings attended by Gordon Searles (Canada) and Phyllis Spuls (Amsterdam). Further publicity to the Cochrane Skin Group has been highlighted in a chapter for a recent textbook on dermato-epidemiology [196] and in an article on evidence based dermatology published in the International Journal of Dermatology (1997;36:17-22).
- b. Scope The scope of the prospective skin group has a clear focus on prevention and treatment [8] of skin diseases. Although there was some interest in a separate Cochrane skin cancer group forming in Australia at some stage, this has not been forthcoming. It was agreed at our exploratory meeting that our prospective Cochrane Skin Group would act as a kind of 'foster parent' for any individuals wishing to take the initiative in forming a review related to skin cancer. Dr Jan Bouwes Bavinek from the Netherlands and Dr Ian Harvey (Bristol) have a particular interest in non-melanoma skin cancer. Other individuals have since approached us with an interest in melanoma reviews. All those interested in skin cancer are welcome to work within the Cochrane Skin Group and to liaise with the Cochrane Cancer Network over relevant issues. At our last meeting, it was also the wish of the Group to include reviews of over-the-counter preparations and cosmetics that might be used to treat skin diseases.

Members of the prospective Cochrane Skin Group are clear that reviews relate to the primary



prevention, treatment and prevention of disabilities of skin diseases. A provisional topic list is enclosed in the minutes of the second meeting of the prospective Cochrane Skin Group. Over 20 authors have made a commitment to be involved in such reviews. Potential duplication with other groups such as the Cochrane Wounds Group, the Cochrane Pregnancy and Childbirth Group, the Cochrane Menstrual Disorders Group, the Cochrane Musculoskeletal Diseases Group, the Cochrane Airways Group, the Cochrane Pain, Palliative and Supportive Care Group, the Cochrane Peripheral Vascular Diseases Group, the Cochrane Tobacco Addiction Group and the Cochrane Infectious Diseases Group have been considered. All of the relevant administrators/co-ordinating editors have been contacted by me, and we now regularly keep each other informed about areas of potential overlap. We also help each other with refereeing work such as the recent review on scabies by those interested in parasitic diseases within the Cochrane Infectious Diseases Group.

- c. Editorial base An editorial base has been established at the University of Nottingham with myself as co-ordinating editor and Alain Li Wan Po as co-editor/statistical advisor. Other members of the editorial board include Luigi Naldi (Italy), Thomas Diepgen (Germany), and Dédéé Murrell (Australia). The editorial team is realistic about the time that will need to be invested in the group to ensure its success. Letters of support from editors are enclosed. Each of the editors is involved in preparing and maintaining at least one Cochrane review [22]. Some have attended workshops at their local Cochrane centres. A co-ordinator will be appointed in October 1997.
- d. Collaborators A list of those that have written to me with the intent of helping to produce specific reviews and others who have written to me wishing to be kept informed for the time being is enclosed with this application. Other key individuals, such as Professor Terence Ryan (Oxford), Professor Rod Hay (Guys and St Thomas' Hospital, London), Professor Peter Friedman (Liverpool) and Professor Bill Cunliffe (Leeds) have agreed to act as external peer reviewers for Cochrane reviews pertinent to their fields of interest.
- e. Specialised register Plans for establishing a specialised register for dermatology trials are certainly in progress but I have found it difficult to find the time to prepare and maintain this database myself without any additional help. I have performed some electronic search strategies on the Medline database, and these were outlined at the exploratory meeting; Thomas Diepgen (Germany) has kindly agreed to co-ordinate electronic searching. Until a co-ordinator is appointed, I will co-ordinate hand searching activities in collaboration with the US Cochrane Center, and a plan of handsearching activities is included in the draft module [102] enclosed. A collection of all papers and relevant reports will be held at the editorial base, and. we will provide copies of relevant articles to authors as and when they need them.
- f. Funding A firm response on infrastructure has just materialised through Professor Kent Woods, Director of Research and Development, Trent Regional Health Authority. This commitment will take us to the end of the next financial year when Professor Woods believes there will be a national scheme to support Cochrane entities with a UK co-ordinating base. Opportunities for funding research fellows for specific reviews may be forthcoming in the next round of NHS R&D calls for reviews on treatments for eczema and psoriasis. The teams at Nottingham and Manchester have both submitted institutional curricula vitae in response to these calls. Both groups have since been invited to submit specific proposals to these calls. Professor Chris Griffiths and Dr Robert Chalmers at Manchester University have been successful in gaining funding for a part time clinical psychologist to handsearch two dermatology journals and to produce a systematic review of treatments for guttate and palmoplantar pustular psoriasis. Fay Crawford (York) has also been successful in gaining a grant from the Welsh Office for a systematic review of treatments for common foot infections, such as tinea pedis. It is still unclear whether dermatological pharmaceutical companies will contribute to any form of corporate funding managed by the Skin Care Campaign.



g. Targets for the group - Targets for the group have been set as outlined in the minutes of the 2 nd Prospective Cochrane Skin Group Meeting (enclosed). We anticipate that our co-ordinator will be in post by December 1997. We estimate that around 20 reviews will be produced in the first 5 years, and that our first review will be available December 1997. We anticipate around 4 protocols to be available for the CDSR [128] by October 1997 and 10 by September 1998. We estimate that retrospective handsearching will take us at least 5 years, bearing in mind that there are at least 104 specialised dermatology journals. We estimate that retrospective electronic searches will take us less than one year.

h. Appropriate documentation - A provisional module for *CDSR* and letters of support from my four co-editors and lain Chalmers are enclosed.

Closing remarks

I feel we have a group of enthusiastic individuals genuinely interested in preparing and maintaining systematic reviews in dermatology. The group is truly international and multi disciplinary. Involvement from consumer and patient representatives has been a very strong feature right from the outset of this group, and we think that we will be able to maintain this strong presence throughout the group's existence. We plan to hold our next Cochrane Skin Group meeting on 19/20 June 1998. Like others working in The Cochrane Collaboration, our ultimate aim is to produce high quality [5] reviews of dermatological health care that address questions which are important to patients and their carers. We hope that the Cochrane Collaboration Steering Group will support our application formally to register the prospective Cochrane Skin Group.

Yours sincerely

Dr Hywel C Williams MSc FRCP PhD

Co-ordinating Editor of the Prospective Cochrane Skin Group

enclosures:

Section AA: Provisional module for the CDSR

Section BB: Letters of support from co-editors

Section CC: Prospective Cochrane Skin Group Contact List

Section DD: Minutes of the Second Prospective Cochrane Skin Group Meeting

Section EE: Minutes of the Exploratory Meeting

Section FF: Report of the Funding/Awareness Meeting

3.2.8.5 Recruitment of a Managing Editor

This is a template for Review [29] Groups to use and/or modify as they wish. There is no



'requirement' that this job description be used when advertising a Managing Editor post. This template should not be used without amendment, or at least confirmation that it is appropriate to the local conditions for the Managing Editor of the Review Group in question.

Please also note that this template job description covers the range of responsibilities and tasks that are required to run a Review Group. Depending on the portfolio of reviews and size of the Review Group, these tasks may be assumed by a variety of <u>editorial base</u> [103] personnel (e.g. Assistant Managing Editors, Administrative Assistants, Co-ordinating Editors, Information Specialists, Satellite Co-ordinators, etc). Not all Review Groups may require the entire range of tasks.

3.2.8.5.1 Advertisement

Cochrane XXX Review Group

JOB TITLE: MANAGING EDITOR Salary range: XXX

Based at XXX

Responsible to the Co-ordinating Editor of the Cochrane XXX Review Group

Duration: to be determined by Cochrane XXX Review Group

Reference number: XXX

We would like to invite applications for this interesting and challenging opportunity to contribute to the publication of Cochrane systematic reviews in the field of XXX.

The Cochrane XXX Review Group is part of The Cochrane Collaboration. This is an international network of individuals and organisations committed to preparing, maintaining, updating and disseminating systematic reviews of healthcare interventions to help people make well-informed decisions about health care (see www.cochrane.org [17]). The focus of this Cochrane Review [22] Group is XXX; it is one of XXX Cochrane Review Groups worldwide which contribute to The Cochrane Collaboration.

A Managing Editor is required to ensure the efficient and effective operation of the Review Group's editorial base. The candidate will be responsible for managing the editorial processes for systematic review preparation. This involves providing specialised editorial support to review authors, managing the process of peer review [131], maintaining communication between the Review Group's editorial team members, submitting quarterly modules to the publisher, Wiley-Blackwell, and representing the Review Group to all relevant individuals and agencies.

The ideal applicant will be educated to degree level or above, with managerial, administrative, scientific or publishing experience or equivalent, along with excellent organisational and communication skills. Knowledge of scientific and medical terminology and evidence based health care is desirable. Familiarity with clinical trials, systematic reviews, or The Cochrane Collaboration would be welcomed.

For further details and application form visit: www.XXX [198]

To discuss the post further please contact: XXX

The closing date for receipt of applications is: XXX

Please note that the interviews are scheduled for: XXX



3.2.8.5.2 Job description

JOB DESCRIPTION

MANAGING EDITOR

Cochrane XXX Review Group

Role overview: manages the day-to-day activities and production of the Review Group's reviews up to submission to the publishers for publication in *The Cochrane Library*.

PRINCIPAL DUTIES AND RESPONSIBILITIES

1 MANAGEMENT

- Work closely with the Review Group's Co-ordinating Editor (Co-Ed) on strategic aims and the business plan
- Ensure Review Group complies with The Cochrane Collaboration policies and procedures
- Work with the Co-Ed on setting policies and procedures (not provided by the Collaboration) for the Review Group
- Prepare monitoring reports with input from the Co-Ed and other editorial base personnel, and submit monitoring reports to funders and The Cochrane Collaboration
- Prepare and manage budgets
- €Prepare grant applications as appropriate
- €Manage the editorial workflow of the Review Group's reviews to meet internal Review Group and external Cochrane Collaboration timelines
- €Prepare and submit information and supporting documentation to the Co-Ed for monitoring the editorial base's progress as required
- €Manage the editorial office systems
- ∈Manage the Review Group's staff; (the number of staff will depend on the size, organisation and funding of the individual Review Group)



- €Undertake or participate in recruitment, selection and annual appraisal of staff as necessary (including participation on interview panels)
- ∈Be responsible for own personal and professional development (e.g. learning new software, policies, etc); identify and encourage training for other Review Group members (e.g. editorial office personnel, editors, authors, etc)
- elnitiate quality [5] assurance activities to maintain/improve performance of editorial base
- €Motivate review authors to submit title registration forms, protocols, reviews and update reviews according to agreed timelines
- eHelp to manage relationships between review authors, editors and review teams

2 EDITORIAL TASKS

- €Act as the first point of contact for all correspondence to the Review Group editorial base and filter all submitted material as appropriate
- ∈Register new review titles and liaise with other Cochrane Review Groups to avoid duplication of effort
- ∈Ensure adherence to The Cochrane Collaboration's conflict of interest policy during the production and completion of reviews
- ∈Support and advise review authors on the production of high quality reviews by providing guidance and training in the use of RevMan, The Cochrane Collaboration's software for preparing systematic reviews; collating feedback from editors and peer reviewers; and ensuring the authors respond appropriately to this feedback when re-submitting their reviews
- €Ensure reviews and protocols are of high quality by liaising and utilising the skills of relevant personnel such as the <u>Trials Search Co-ordinator (TSC)</u> [199], the Statistical Editor or statistician
- €Manage the peer review process, identifying appropriate external peer and consumer reviewers with the assistance of the Co-Ed, the editors and relevant professional and consumer bodies
- Proofread and edit protocols and reviews (for content, methodological and technical integrity, adherence to Cochrane standards and format, grammar and use of English) throughout the development stage



- €Prepare, finalise and submit the Review Group's reviews, protocols and module text (including the CRG's contact details and Topics list), using the Information Management System (IMS), to the publishers, Wiley-Blackwell (for quarterly publication in The Cochrane Library [18]), by each quarterly deadline
- €Ensure signed 'permission to publish' forms are submitted by review authors before publication of reviews, and kept at the editorial base, and that back-up copies are sent to The Cochrane Collaboration Secretariat [1]
- ∈Monitor and facilitate the update of reviews according to Cochrane Collaboration policy
- ∈Initiate quality assurance and continuous quality improvement activities to maintain and improve the quality of reviews
- €Act as liaison with the publisher Wiley-Blackwell

3 CO-ORDINATION

- €Co-ordinate activities between the editorial base, review authors, editors and peer reviewers and other members worldwide, and the publishers Wiley-Blackwell
- Make and maintain effective liaison (through e-mail, letter, face-to-face or telephone) with, and where appropriate between, review authors, peer and consumer reviewers, Co-Ed, TSC, other editors and editorial staff, the publisher, other Cochrane entities [20] and international members of The Cochrane Collaboration
- Contribute to the work of The Cochrane Collaboration as a whole by responding to requests for information, completing surveys and contributing ideas and feedback
- Assist with administration of annual elections to The Cochrane Collaboration <u>Steering Group</u> [13]
- In collaboration with the Co-Ed and the Editorial Board, encourage the participation of people from Developing Countries in the work of the Review Group
- Represent the Managing Editor position within The Cochrane Collaboration at committees as appropriate
- Contribute towards publications and reviews as appropriate

4 GENERAL



- Train review authors, editors, peer reviewers and other personnel on policies, procedures and new software as appropriate
- Provide some IT support and mentoring for review authors
- Maintain the Review Group's contact details within the Collaboration's IMS
- Assist with obtaining translations of reports of relevant studies where possible, perhaps in collaboration with the TSC
- Develop and maintain the Review Group website, using the Cochrane website software or other software as appropriate
- Participate in regional meetings of The Cochrane Collaboration and the annual Cochrane Colloquia
- Organise meetings of the Review Group as required, including the international Editorial Board meetings, local conferences and seminars, and meetings between review authors and editors
- Chair Review Group meetings
- Represent the Co-Ed if necessary
- In collaboration with other editorial base personnel, prepare and disseminate newsletters, brochures, team progress reports and information packages for the Review Group
- Give presentations and posters, and disseminate promotional literature at professional and lay meetings
- Produce letters and reports as required (e.g. regular reporting may be required by the host organization, funders, local Cochrane <u>Centre</u> [34] and The Cochrane Collaboration's Monitoring and Registration Committee)
- In collaboration with the Co-Ed, manage any public relations such as dealings with journalists

5 PERSON SPECIFICATION

Essential attributes



- Education to degree level or equivalent skills and experience
- Two years' administrative, scientific or publishing experience
- Two years' managerial or supervisory experience; ability to communicate with staff at all levels
- Ability to produce, monitor and assess estimates/costs and to work within budget
- Excellent time management skills in prioritising workload of self and others, project management and organisational skills; meet fixed deadlines, initiate and follow-up [116] actions, all with minimal or no supervision
- Excellent interpersonal, oral and written communication skills in English, presentation and negotiation skills; able to assist those whose first language is not English
- A working knowledge of scientific and medical terminology and evidence based healthcare
- Excellent computing skills (including word processing, bibliographic databases, spreadsheets, internet and e-mail) and ability to learn new software quickly
- Excellent technical, methodological, copy editing and proofreading skills; attentive to detail
- Adaptable, flexible and willing to undertake additional responsibilities; prepared to work additional hours where necessary in response to Review Group requirements
- Willing and able to travel nationally and internationally

Desirable attributes

- A working knowledge of clinical trial methodology, basic statistical concepts of <u>meta-analysis</u> [104], <u>critical appraisal</u> [200], systematic reviews and epidemiological methods
- Experience with or knowledge of The Cochrane Collaboration and/or The Cochrane Library
- Web design and maintenance skills
- Post-graduate education



• Familiarity with abstracting and indexing services, i.e. <u>PubMed</u> [149], MEDLINE.

3.2.8.6 Recruitment of a Trials Search Co-ordinator

The Trials Search Co-ordinators have discussed and agreed on the wording of a sample advertisement and job description (see below). This was also circulated to Co-ordinating Editors and Managing Editors for comment in December 2006. Comments to be taken into account when it is updated should be sent to Carol Lefebvre, Information Specialist, UK Cochrane Centre [34] (clefebvre@cochrane.co.uk [201]). Please note that this is a template for CRGs to use and/or modify if they wish, i.e. there is no **requirement** for it to be used when advertising a TSC post. Please also note that it is based on the tasks that might reasonably be undertaken by a Trials Search Co-ordinator working full-time. For part-time posts the responsibilities would need to be reduced accordingly.

ADVERTISEMENT

TRIALS SEARCH CO-ORDINATOR

Cochrane XXX Group

Based at [Location]

Responsible to the Co-ordinating Editor of the Cochrane XXX Group

Salary scale: up to circa £32,000 (GBP) (as at April 2006)

Duration: Three years in the first instance with the possibility of renewal

Reference number: XXX

We would like to invite applications for this interesting and challenging opportunity to contribute to the publication of systematic reviews in the field of XXX.

The Cochrane XXX Group is part of The Cochrane Collaboration, an international network of individuals and organisations committed to preparing, maintaining, updating and disseminating systematic reviews of healthcare interventions to help people make well-informed decisions about health care (see www.cochrane.org [17]). You will be a key part of a small team, responsible for assisting review authors through the process of preparing and updating reviews for publication in The Cochrane Library.

The appointee will work closely with review authors in identifying studies for inclusion in their reviews and will take responsibility for maintaining and developing the Group's Specialized Register of trials (currently numbering approximately XXX).

The ideal applicant will have a qualification in librarianship or information science but others with appropriate, equivalent experience are also welcome to apply. Expertise in searching health care databases is essential. Knowledge of medical terminology and experience of <u>critical appraisal</u> [200] and systematic reviews would also be desirable.



For further details and application form visit: XXX

Further details and application forms are also available from: XXX

To discuss the post further please contact: XXX

The closing date for receipt of applications is: XXX

Please note that the interviews are scheduled for: XXX

JOB DESCRIPTION

TRIALS SEARCH CO-ORDINATOR
COCHRANE XXX GROUP

RESPONSIBILITIES

1 SEARCH SUPPORT FOR REVIEW AUTHORS

- design search strategies in collaboration with review authors at both <u>protocol</u> [43] and review stage
- €run searches in MEDLINE, <u>EMBASE</u> [181], <u>The Cochrane Library</u> [18] and other databases as required
- draft the <u>search strategy</u> [178] sections for protocols and reviews
- provide feedback on the trial identification and reference sections of Cochrane reviews and protocols as part of the <u>editorial process</u> [45]
- correspond with review authors to clarify methodological procedures employed in trials
- check reference lists of included studies in completed reviews to ensure that all trials are included in the Group's Specialized Register and that references are correctly cited
- arrange translations of papers where possible to extract information for coding and to enable authors to include/exclude studies from reviews
- alert authors to new trial reports and new trials in their topic area on a quarterly basis

2 ELECTRONIC SEARCHING FOR THE GROUP'S SPECIALIZED REGISTER



- design highly sensitive search strategies as required for a variety of healthcare databases, to identify controlled trials relating to XXX
- execute regular searches of these databases including MEDLINE and EMBASE, and others such as CINAHL, LILACS, PsycINFO and databases of conference proceedings and dissertation abstracts
- extract potentially relevant trial references from overall results of database searches by examination and interpretation of information provided therein and obtain hard copies
- locate references to potentially relevant trials via the Internet
- code trial reports for type of trial, method of randomization and keywords
- record sources searched and evaluate usefulness/relevance
- organise translations of papers where necessary to extract information for coding and to enable authors to include/exclude studies from reviews

3 HANDSEARCHING CO-ORDINATION

- co-ordinate handsearching activities
- determine specialist journals to handsearch
- recruit handsearchers for the Cochrane XXX Group
- manage the handsearching process including providing training and support for handsearchers
- perform regular <u>quality</u> [5]-<u>control</u> [59] checks on handsearchers' work and provide feedback where appropriate
- extract relevant trial reports from results of handsearchers' work by examination and interpretation of trial reports
- code papers for relevance, type of trial, method of randomization and keywords using existing system
- collate and evaluate results of the handsearching initiative



4 GENERAL

- erecord electronic details, downloaded from MEDLINE, of randomized controlled trials not indexed as such on MEDLINE, identified by the electronic and handsearching described above, for re-classification in MEDLINE
- €make quarterly submissions of the Group's Specialized Register and of handsearch results to The Cochrane Collaboration's CENTRAL database in accordance with published quidance
- use the following computer software/databases: MEDLINE (Ovid), EMBASE (Ovid), Microsoft Internet Explorer, Review Manager [25], Microsoft Office packages and reference management software such as Reference Manager [202] or ProCite [203]
- identify potential randomized controlled trials from reference lists in existing trial and review papers by examination of titles and evaluation of the textual context [46] of citations
- prepare materials and presentations for Group meetings
- develop and maintain the Specialized Register in order to track what has been sent to authors and what has subsequently been included in, or excluded from, reviews (and any other relevant information)
- liaise with other Trials Search Co-ordinators (TSCs) in Groups or Fields where there is potential overlap
- work closely with the Managing Editor and liaise with other members of the Group
- contribute to the relevant sections of the Group's module [102] information
- contribute to the Group's newsletter and website
- help to maintain and update the Group's topics list
- etrain others e.g. clerical/support staff to enter data into the Specialized Register
- participate in locally delivered workshops to assist review authors and promote the work of The Cochrane Collaboration
- contribute to writing grant applications, developing the Group's budget and business plan and writing regular reports to funding bodies



• contribute to the Group's Monitoring Report

Person specification

Essential attributes:

- Educated to degree level with a qualification in librarianship or information science, or equivalent
- Careful, analytical and conscientious approach
- Excellent inter-personal skills
- Excellent computing skills and ability to pick up new software quickly
- Excellent time management and organizational skills
- Willingness and ability to travel nationally and internationally

Desirable attributes:

- A knowledge of medical terminology
- Experience of critical appraisal and systematic reviews
- Previous experience or knowledge of The Cochrane Collaboration and /or *The Cochrane Library*

3.3 Centres

Cochrane Centres and their respective Branches act as a regional focus for the activities of The Cochrane Collaboration. Their primary role is to support contributors to The Cochrane Collaboration within a defined geographical or linguistic area.

The core functions of Cochrane Centres are:



- 1. To promote and represent The Cochrane Collaboration.
- 2. To serve as a source of information about The Cochrane Collaboration.
- 3. To provide or facilitate training and support for <u>review</u> [29] authors, editors, handsearchers and other contributors to The Cochrane Collaboration.
- 4. To support regional editorial bases of Review Groups, Methods Groups and Fields by:
 - assisting in finding funding;
 - mediating conflicts, either between Cochrane entities [20] or between individuals and entities.
- 5. To contribute to improving the <u>quality</u> [5] of Cochrane reviews by performing, supporting or promoting methodological research.
- 6. To promote accessibility to <u>The Cochrane Library</u> [18] to healthcare professionals, patients and others, e.g. by pursuing national subscriptions and translations where necessary.
- 7. To handsearch general healthcare journals in the linguistic area of the Centre and to submit the search results to the Collaboration's trial database.

In fulfilling these core functions, Centres are required to:

- ensure effective and efficient communication and mediation between Centre members and members of other entities for which the Centre is a reference centre;
- maintain their details in the Cochrane contact database;
- maintain a description of the Centre's activities in *The Cochrane Library* (Centre <u>module</u> [102]) at least on an annual basis;
- ensure sustainability and continuity of the Centre's programme of work;
- produce a strategic/business plan with targets and an annual report, which reports progress against these targets.

In addition, the Cochrane Centres may perform optional special functions on behalf of the Collaboration, such as development of software for use within the Collaboration or production of Cochrane News. Organising or hosting the annual Colloquium is another important optional function of Centres.

There are currently fourteen Cochrane Centres:

- Australasian Cochrane Centre
- Brazilian Cochrane Centre
- Canadian Cochrane Centre
- Chinese Cochrane Centre
- Dutch Cochrane Centre
- French Cochrane Centre
- German Cochrane Centre
- Iberoamerican Cochrane Centre
- Italian Cochrane Centre
- Nordic Cochrane Centre
- South African Cochrane Centre
- South Asian Cochrane Centre
- UK Cochrane Centre
- US Cochrane Center

Both Centre Staff and Centre Directors meet together annually at Cochrane Colloquia and as needed on other occasions during the year, and are in regular contact through electronic communication. Cochrane Centre and Branch Directors also meet at the time of the Steering Group [13] meetings mid-way between Colloquia.

Centres are required to report on their activities every two years to the Monitoring and Registration Committee, and to provide financial information every year.

Cochrane Centres are responsible for providing their own funding. Most of the Centres receive



infrastructure support from national governments or similar agencies, supplemented by additional project related funds for undertaking specific tasks. Centres usually have small staff who collectively have skills in systematic review methodology, training, research, computing, and administration. Depending on the focus of a Centre's work, other skills may also be present. Whilst most Centres have some full-time staff, many rely heavily on part-time staff who have other commitments. Most Centres have advisory boards that provide advice and support about the strategic direction for activities within the Centre.

All countries have a reference Cochrane Centre. Sometimes a group of people in a country or geographical area may want to establish a formal relationship with The Cochrane Collaboration in order to promote evidence-based health care or to facilitate the production of Cochrane reviews. This can be done either by establishing an informal affiliation with the Centre, or by becoming an official Branch of the Centre. The registration of a Branch does not have to follow the Collaboration's registration process, but the approval of the Monitoring and Registration Committee is needed, based on letters of support from the reference Centre and other Cochrane entities in the region, a structure, workplan, communications strategy and curriculum vitae of the person leading the Branch (see Appendix 2 [174]). The activities of Branches are reported every two years in the monitoring report of the reference Centre, and financial information is reported every year. For a list of existing Branches, see www.cochrane.org/contact/entities.htm#CENTRES [204]. The Monitoring and Registration Committee will approve the establishment of a Branch, but the Branch does not become a 'registered entity' of The Cochrane Collaboration. Its official status is as a Branch of the reference Cochrane Centre, and it is the reference Cochrane Centre which is the 'registered entity' of The Cochrane Collaboration.

An established and financially secure Branch may later wish to become an <u>independent</u> [177] Centre. At that point, and with the support of the reference Centre, the Branch should undertake the formal registration process of the Collaboration described below.

Any group or organisation wishing to consider establishing a new Cochrane Centre within a country should make very early contact with the reference Cochrane Centre that currently exists to support that country. Proposals for new Cochrane Centres need to be circulated early on for discussion amongst existing Cochrane Centres and the Monitoring and Registration Committee. The establishment of a new Centre needs to be closely guided by the reference Cochrane Centre through its Director. Formal registration of a Cochrane Centre is required, as with all other entities within The Cochrane Collaboration. Such registration involves submitting an application to Monitoring and Registration Committee (MaRC [30]) that addresses the checklist in the MaRC section of this Manual. A representative of the Monitoring and Registration Committee (MaRC) should be invited to attend the exploratory meeting(s). If an MaRC representative cannot attend (either in person, by VOIP or by teleconference), the organisers of the exploratory meeting(s) should ensure they discuss the registration process and a provisional agenda for the meeting(s) with an MaRC representative in advance. The aim of MaRC involvement is to help to ensure that the meeting(s) is/are as useful as possible to inform the proposed Centre's potential application for formal registration. There should be formal feedback to the MaRC representative, CCSG [23] representative, and Entity Executive, to ensure effective communication, which should include a person-to-person discussion (e.g. by telephone) with the MaRC representative, and circulation of the exploratory meeting(s) minutes to the MaRC representative.

Where significant changes are expected to a Cochrane Centre (such as change of location, change of Director, or establishment of an additional Branch/Branches) these need to be communicated to the Monitoring and Registration Committee (see Appendix 2 [174]). It is important to recognise that registration of a Cochrane Centre is made to an individual (or group of individuals) conditional upon their agreement to provide the range of support services outlined above. Cochrane Centres do not belong to institutions or funding agencies in perpetuity. Decisions about registration and de-registration of Cochrane Centres are the sole responsibility of The Cochrane Collaboration through its Steering Group.

Monitoring the performance of a Cochrane Centre

Once a Centre has become registered, its performance is monitored fully every two years and



monitored financially in the intervening year, by the Monitoring and Registration Committee of the Steering Group. The process is chiefly one of self-assessment to help the Monitoring and Registration Committee to gain an overall picture of how Centres work and to identify any common or individual difficulties that Centres are experiencing.

The purpose of the monitoring process is to maintain or raise the quality and productivity of Cochrane entities by helping them identify areas in which they excel or in which they have not yet achieved their potential. The Monitoring and Registration Committee includes representatives of the five types of Cochrane entity (Cochrane Review Groups, Centres, Fields, Methods Groups and the Consumer Network), some of whom have been directly elected to the Steering Group.

The Monitoring and Registration Committee does not regard itself as a censorious body, and will strive to help Cochrane entities that are having particular difficulties. However, if a Centre repeatedly fails to perform its core duties adequately, the Monitoring and Registration Committee does have the responsibility for asking the Steering Group to consider de-registering the Centre.

Subheadings in this section

3.3.1 Guiding principles for Centre Directors and Staff

Background

A Cochrane Centre's primary role is to support contributors to The Cochrane Collaboration and to provide a focus for Cochrane activities within a defined geographical or linguistic area. In fulfilling this role, Centre Directors and Staff are expected to:

- uphold the ten principles of The Cochrane Collaboration;
- encourage effective and efficient communication between Centre staff and members of other entities [20] within The Cochrane Collaboration;
- work towards ensuring the sustainability of the Centre in respect of meeting the core functions of a Centre.

Centre Directors and Centre staff are ambassadors of The Cochrane Collaboration, and need to be aware of potential conflicts of interest and issues of representation. Centre Directors and Centre staff should bear in mind that using their Cochrane Centre affiliation may beneficially or adversely affect The Cochrane Collaboration.

The following key points are designed to help guide Centre Directors and Centre staff in their internal and external interactions:

Internal interactions

- Centre Directors should encourage Centre staff to participate in Collaboration-wide activities as a way of developing a sense of belonging to The Cochrane Collaboration (besides being involved in their own Centre work).
- Centre Directors should themselves contribute to The Cochrane Collaboration's activities beyond their own Centre work, and should attend Centre Directors' meetings (or send a representative).

External interactions

- Use of the Cochrane Centre affiliation is appropriate when representing The Cochrane Collaboration or when publishing Cochrane reviews or work related to the Centre's programme of work.
- Centre Directors and Centre staff should consider separating (where appropriate) their Cochrane activities from non-core Cochrane work (such as participation in guideline



- committees, HTA, EBM promotion, etc.).
- In situations where there may be confusion over the capacity in which a Centre Director is writing or acting as a representative, or when discussing or writing about issues which are not covered in official Cochrane documents, use of an alternative affiliation or disclaimer should be considered.
- Official policy within The Cochrane Collaboration is represented by <u>Steering Group</u> [13] minutes, *The Cochrane Policy Manual* and the *Cochrane Handbook* [54] for Systematic Reviews of Interventions.

3.4 Fields

Subheadings in this section

3.4.1 Introduction

Most <u>Cochrane Review</u> [22] Groups are essentially problem-based; they exist to prepare and maintain systematic reviews on specific health care problems. However, there are a number of other dimensions of health care that cannot be usefully conceptualised as 'health problems' such as the setting of care (e.g. primary care), the type of patient/consumer (e.g. older persons), <u>or</u> [127] the type of <u>intervention</u> [33] (e.g. vaccines).

Wishing both to draw upon the support existing in these areas of health care and to ensure that their needs are taken into account when producing and promoting access to Cochrane reviews, The Cochrane Collaboration has another type of entity in order to reflect the interests of these dimensions, or 'fields', of health care more effectively. This concept also applies to those major divisions of health care embracing areas too large to be covered by a single Review Group (e.g. cancer). Entities [20] such as these are called either Fields or Networks [27]; in this section, they are referred to as 'Fields'.

3.4.2 The definition and role of Cochrane Fields

Subheadings in this section

3.4.2.1 Definition of a Cochrane Field

A Cochrane Field is an entity which focuses on a dimension of health care other than a specific healthcare problem - such as the setting of care, the type of consumer, the type of provider, the type of <u>intervention</u> [33], <u>or</u> [127] a major division of health care which embraces an area too large to covered by a single <u>Review</u> [29] Group - and represents its interests.

3.4.2.2 The role of Cochrane Fields

The role of Fields is to facilitate the work of Review [29] Groups and to ensure that Cochrane reviews appropriate to their area of interest are both relevant and accessible to their fellow specialists and consumers. Given the breadth of its area of interest, each Cochrane Field may expect to support, and contribute to, the work of a number of Review Groups. Fields do not prepare or maintain reviews. However, individual members of Fields can, and do, prepare and maintain reviews as members of Cochrane Review Groups.



3.4.2.3 Core functions of Fields

Core functions (updated in October 2010)

Advocacy for evidence-based health care

All Fields must carry out the activities in the following Sections I and II, and at least one activity from Section III.

I. Relation with Field's constituents

In order for Fields to carry out their 'bridging' work, they must have strong relationships in place within their area of specialty. All Fields, therefore, must be able to demonstrate that they are building and maintaining relationships with practitioners, policy-makers, and healthcare users/consumers in the Field's area. The metric to demonstrate the Field's support from its area of health care should be chosen *a priori* by the Field itself in its business plan, and may be one or more of the following: number of members, measurable support from professional organizations, international partnerships, or funding support.

II Recognition of Field's systematic reviews

Each Field is responsible for identifying and tagging in Archie (The Cochrane Collaboration's Information Management System) the reviews, protocols and titles that are relevant to the Field's scope. This work serves three purposes. First, tagging serves as a communication mechanism with Cochrane Review [22] Groups that the Field is interested in, and willing to support as possible, particular reviews. Second, it permits the Field to generate a list of Cochrane reviews, protocols and titles that are relevant to its scope. This list can then be disseminated to stakeholders. Third, it enables the Field to identify gaps in Cochrane evidence readily.

III. Dissemination activities

Activities by which Fields will carry out their mission of advocacy may also include one or more of the following, as chosen by an individual Field based on its scope and resources:

- a) Reformatting or summarizing Cochrane reviews within the Field's scope and disseminating these summaries to stakeholders:
- b) Advising or assisting authors of reviews within the Field's scope with publishing Cochrane reviews in journal article format in specialist journals;
- c) Working with stakeholders to identify priorities for review topics, and bringing these priority topics to the attention of Cochrane Review Groups.



Elective functions

Each Field must carry out at least one activity from this section. Fields will choose one or more of the following areas in which to focus their efforts. This choice will be identified a priori in the Field's business plan, and the Field's work in the area(s) of choice will be recorded in its reports to the Cochrane Monitoring and Registration Committee.

- 1) To promote the production of relevant and high-quality [5] systematic reviews, in conjunction with Cochrane Review Groups, through one or more of the following activities:
- a) Providing resources (time and/or money) for the production of systematic reviews within the Field's scope;
- b) Submitting to the appropriate Review Groups registrations for review titles or review updates on topics within the Field's scope;
- c) Maintaining a register of trials within the Field's scope, and submitting this register to CENTRAL;
- d) Introducing, supporting or linking to Review Groups editors, peer reviewers, or authors with Field-relevant expertise.
- 2) To train those in the Field's area of expertise about Cochrane reviews, and to train those in the Cochrane Collaboration about the Field's content, in conjunction with Cochrane Centres, through one or more of the following activities:
- a) Training stakeholders in the production of systematic reviews within the Field's scope;
- b) Training stakeholders in interpretation of systematic reviews within the Field's scope;
- c) Providing training to persons involved in production of systematic reviews about specific issues (for example, characteristics of the interventions or <u>population</u> [190] represented by the Field) relevant to reviews within the Field's scope.
- 3) To participate in the development of methods for the production or dissemination of evidence-based medicine, in conjunction with Cochrane Methods Groups, through one or more of the following activities:
- a) Conducting methodological work addressing the PICOS (population, intervention, comparison, outcome [105], study design) relevant to the Field's scope;
- b) Developing and disseminating methods for identifying evidence within the Field's scope (e.g. search filters);
- c) Conducting methodological work in development of methods for overviews of reviews within the Field's scope;
- d) Conducting methodological work that will maximise dissemination of information to <u>users of reviews</u> [205] (i.e. knowledge translation research).



3.4.3 How Fields work

Subheadings in this section

3.4.3.1 The functioning of Cochrane Fields

The principal contact person in each Field is its Field Co-ordinator. Given the differences in terrain* between each Field, not all Fields will necessarily allot equal weight to each function. It is the responsibility of a Field Co-ordinator to allocate the Field's time and resources to those functions that most effectively fulfil the Field's role as a support to the Review [29] Groups, and to The Cochrane Collaboration as a whole.

The term terrain is used in this section to denote the range of <u>variable</u> [206] factors operating in a particular area of health care (e.g. levels of awareness, needs, opportunities for action, obstacles to progress, professional considerations etc.) that might influence the direction and/or performance of a Cochrane Field.

3.4.3.2 Identifying trials and developing a Specialised Register

A good <u>review</u> [29] requires the identification of as many studies relevant to its topic as possible. Fields support the review process by searching their specialist sources, identifying reports of studies that appear to meet the Cochrane criteria for controlled trials (irrespective of their subject matter), and making them accessible to The Cochrane Collaboration through CENTRAL. At the same time, Fields also provide a valuable service for their own dimension of health care by establishing and developing a specialised register of randomized controlled trials (RCTs) drawn from CENTRAL, containing all the RCTs relevant to its area of interest that have been identified by The Cochrane Collaboration and others, and by ensuring its publication in <u>The Cochrane Library</u> [18].

Identifying trials

Fields are responsible for co-ordinating the searches within their specialty for studies meeting the Cochrane criteria for inclusion in the <u>Cochrane Central Register of Controlled Trials</u> [19] (CENTRAL).* This entails instigating and co-ordinating:

- full text ('hand searches') of journals
- electronic searches of specialist databases
- searches of specialist <u>grey literature</u> [207] (e.g. conference abstracts and proceedings, pharmaceutical industry, university theses)
- searches for unpublished trials

*For a more detailed account of how to co-ordinate searches, readers are invited to access the Cochrane Handsearch Manual on the Collaboration's website.

Developing a Specialised Register

Identifying reports of trials relevant to its dimension of health care and making them accessible through specialised registers within the Cochrane Central Register of Controlled Trials (CENTRAL) is a core requirement of Fields.

The construction of an authoritative register of randomized controlled trials tailored to the needs of a particular dimension of health care establishes a valuable resource. There is no need for individuals who are in the process of forming a Cochrane Field to wait until the Field has been registered with



The Cochrane Collaboration before assembling a register of randomized controlled trials. This essential task can and should be pursued concurrently with efforts to establish a Cochrane Field in their dimension of health care. A substantial and reliable Register of Trials establishes the Field's credibility amongst its professional peers, legitimises its position as a key source for evidence for individuals and organisations who have an interest in the conduct of literature searches for RCTs and may offer the first material benefit for users of *The Cochrane Library* seeking helpful information related to its particular area of care.

[For a good description of the steps taken by a Field to assemble a specialised register of RCTs, see Silagy C. Developing a register of randomised controlled trials in primary health care. BMJ 1993; 306:897-900.]

3.4.3.3 Ensuring proper representation on Cochrane Review Groups

Ensuring that <u>Cochrane Review</u> [22] Groups covering areas of health care of interest to their Field have sufficient editors or authors, and that their Field is properly represented, are important and ongoing responsibilities of Fields. For example, the Primary Health Care Field has ensured that there is appropriate representation of general practitioners within the Cochrane Pregnancy and Childbirth Group; the interests of the Rehabilitation and Related Therapies Field are similarly represented within the Cochrane Stroke Group. Fields should continuously seek to identify opportunities for individuals working within their area of care, or consumers who have an interest in the area, to become contributors to Cochrane Review Groups. In order to do this effectively, Field Co-ordinators need to be familiar with the Scope statements and Topic Lists of all registered and possible Cochrane Review Groups so that they know which Groups will be producing systematic reviews relevant to their Field.

Where the appropriate Cochrane Review Groups either have not yet been formed, or are in the process of forming, the Field acts as a source of support and encouragement. One of the first acts of a Field is the creation and maintenance of a database of individuals and organisations that have already expressed an interest in supporting the preparation, maintenance or dissemination of Cochrane reviews relevant to the dimension of care the Field represents. This allows the Field to identify like-minded individuals who share a common interest in a particular set of health care problems. By organising, or helping to initiate one or more pre-Exploratory meetings and supplying the necessary materials and guidance, a Field can make a useful contribution to individuals wishing to form a Cochrane Review Group. For example, the Cochrane Cancer Network has helped six Cochrane Review Groups to form in this way. Whenever possible, relevant Fields should be represented at the Cochrane Review Group's Formal Exploratory Meeting.

Once a new Cochrane Review Group is registered with The Cochrane Collaboration, a Field may continue to support its development, using its knowledge of The Cochrane Collaboration and its experience gained with other Groups for the benefit of the new Cochrane Review Group. It may help to identify and meet some of the training needs of members of the new Group. If resources permit, it might also be able to offer office space temporarily to individual authors.

3.4.3.4 Acting as a channel of communication

Fields represent the interests of their particular dimensions of care within The Cochrane Collaboration and promote its aims and work within their dimensions of care.

3.4.3.5 Promoting the health care interests of Fields within The Cochrane Collaboration



Fields can promote the interests of their Field by:

- ensuring proper representation on Cochrane Review [29] Groups
- encouraging comments on Cochrane reviews by inviting individuals and organisations within their dimension of health care to access <u>The Cochrane Library</u> [18] and make use of its Feedback facility
- working with other Fields to help initiate reviews in which they share a common interest.
- initiating meetings or discussions between individuals and organisations within their dimension of health care and The Cochrane Collaboration, directors of Cochrane Centers or co-ordinating editors of Cochrane Review Groups
- eliciting contributions to The Cochrane Collaboration newsletter or other Cochrane publications from relevant individuals and organisations

3.4.3.6 Promoting the aims and work of The Cochrane Collaboration within the Field

Fields promote the aims and work of The Cochrane Collaboration by:

- organising meetings or making presentations at key conferences
- submitting articles about The Cochrane Collaboration and the work of the Cochrane Field to leading journals in their area of health care. [For a good example of this, see Jefferson T. Vaccine trial data systematically assembled, pooled and disseminated by The Cochrane Collaboration. Vaccine 1998; 16:1487-1495]
- using the auspices of organisations in their area of health care to promote the works of The Cochrane Collaboration through meetings or newsletters (e.g. the Primary Health Care Field's regular column in 'WONCA News', the newsletter of the World Organisation of National Colleges and Assemblies of Family Medicine)
- disseminating notices of Cochrane protocols and reviews and news of Cochrane activities through its own newsletter or website
- · maintaining links with individuals and organisations on its contacts database

3.4.3.7 Preparing specialised databases of systematic reviews

Fields help The Cochrane Collaboration to promote the accessibility of its reviews by preparing specialised databases of reviews targeted at users in its particular area of health care.

Note: This section of the Field entry to the *Manual* will be modified as experience in this area of Cochrane Collaboration activity grows.

3.4.3.8 Identifying funding opportunities

By the nature of the activities described above, Fields occasionally find themselves in a position not only to help <u>Cochrane Review</u> [22] Groups identify trials and recruit new authors but also indirectly to provide them with more material support. This may range from supplying letters of support for funding applications, through the establishment of bursaries to sustain authors, to the intentional pursuit of promising opportunities for securing funding. Field Co-ordinators should encourage Co-ordinating Editors of Cochrane Review Groups to keep them apprised of opportunities where Field support would be helpful.



Because they are global <u>entities</u> [20] operating on a wider stage than Cochrane Centres and because, unlike Cochrane Review Groups, they do not have the burden of preparing or maintaining reviews, Fields enjoy a greater capability to investigate funding opportunities not usually available, directly or indirectly, to other Cochrane entities. Field members have a responsibility to be on the lookout for opportunities for funding Cochrane reviews and to communicate these to the appropriate Cochrane Review Groups.

3.4.4 Establishing a Cochrane Field

Subheadings in this section

3.4.4.1 Understanding the differences between Fields and other Cochrane entities

Before establishing a Field it is useful not only to understand the defining characteristics of Fields but also to recognise the difference between Fields and other types of Cochrane entities [20].

Fields and Cochrane Review [22] Groups

Fields provide a range of services (described above) that enable Cochrane Review Groups to provide a product: relevant, high <u>quality</u> [5] systematic reviews.

Most Cochrane Review Groups are essentially problem-based. Their attention is necessarily focused around the relatively narrow band of health care issues defined in their Scope statements. Fields have the responsibility for representing the interests of broad dimensions of health care and promoting the aims and work of The Cochrane Collaboration within these areas. Their objectives, and their approach to achieving them, are therefore necessarily more diffuse than those of Cochrane Review Groups.

Although they are looking at different healthcare problems, all Cochrane Review Groups essentially operate in the same way. They observe an established procedure for preparing and maintaining reviews and work to the same methodological and performance quality criteria. The terrain of its own particular area of health care largely determines the way a Field operates. Not all Fields will give equal weight to the functions described above, nor will they be able to use the same strategies to achieve their objectives. Indeed, goals will differ from Field to Field, dependant on what the Field Co-ordinator feels can realistically be achieved.

Fields and Cochrane Centres

Fields and Cochrane Centres complement and counterbalance each other's work. Like Fields, Cochrane Centres do not produce reviews but provide a range of services designed to support Cochrane Review Groups and facilitate the systematic review process.

One of the many responsibilities of Cochrane Centres is to serve as a source of information about The Cochrane Collaboration and to provide support for Cochrane contributors from all areas of health care within a defined geographical region. Fields serve as sources of information about The Cochrane Collaboration, and provide support to people becoming involved with The Cochrane Collaboration, from all geographical regions, within a defined area of health care.

Similarly, a number of Cochrane Centres are responsible for searching general medical journals published in their geographical region. Fields accept the responsibility for co-ordinating searches of the general specialist journals. These efforts allow the Cochrane Review Groups to refine their search strategies still further and concentrate on searching a smaller number of specialist journals pertinent to their area.

Cochrane Centres are also responsible for the performance and output of Review Groups within their



geographical region and for promoting accessibility to <u>The Cochrane Library</u> [18] to healthcare professionals, consumers and others. Fields have a corresponding responsibility to help ensure that the Cochrane Review Groups prepare and maintain high quality systematic reviews appropriate to their special dimension of health care and that these systematic reviews are accessible to their fellow specialists and consumers.

3.4.4.2 Preparing for and holding a formal exploratory meeting

Individuals interested in developing a Cochrane Field are first advised to consult <u>The Cochrane</u> <u>Library</u> [18], to ascertain whether others have already expressed a similar interest. A search of *The Cochrane Library* will also help them to identify:

- the aims and principles of The Cochrane Collaboration
- the location and contact details of their nearest Cochrane Centre [34]
- the contact details of all registered and possible Cochrane Fields
- whether Cochrane reviews relevant to their area of health care are currently being prepared or maintained
- that those trials relevant to their Field have been identified
- how to access the Master List of Handsearched Journals being searched by The Cochrane Collaboration

The next step should be to identify and contact the reference Cochrane Centre and also the nearest Field (either geographically or as a dimension of health care) which is able to act as a mentor.

A representative of the Monitoring and Registration Committee (MaRC [30]) should be invited to attend the exploratory meeting(s). If an MaRC representative cannot attend (either in person, by VOIP or by teleconference), the organisers of the exploratory meeting(s) should ensure they discuss the registration process and a provisional agenda for the meeting(s) with an MaRC representative in advance. The aim of MaRC involvement is to help to ensure that the meeting(s) is/are as useful as possible to inform the proposed Field's potential application for formal registration. There should be formal feedback to the MaRC representative, CCSG [23] representative, and Entity Executive, to ensure effective communication, which should include a person-to-person discussion (e.g. by telephone) with the MaRC representative, and circulation of the exploratory meeting(s) minutes to the MaRC representative.

The reference Cochrane Centre will support the possible Field by:

- making arrangements for one or more representatives of the potential Field to visit a Cochrane Centre for face-to-face discussions with the director and any other people who may be able to help.
- attending, contributing to, and possibly chairing, the Formal Exploratory Meeting
- informing The Cochrane Collaboration as a whole about developments following the Formal Exploratory Meeting

The mentoring Field will support the Possible Field by:

- commenting on draft letters, strategy documents, applications for funds, meeting agendas
- using their experience to help facilitate the development of the Field, attending (if resources allow)
- contributing to the Formal Exploratory Meeting

If, after their discussions with their reference Cochrane Centre, individuals feel encouraged to proceed with the establishment of a Cochrane Field they should submit their contact details through



the reference Cochrane Centre to The Cochrane Collaboration. An appropriate notice, including the relevant contact details, will appear in the subsequent issue of *The Cochrane Library* advising readers of the emergence of a possible new Cochrane Field.

Formal Exploratory Meetings

Formal exploratory meetings are meetings convened to assess whether the basis and the will exist to establish a new Cochrane Field in a specific area of health care. They may have a number of objectives, depending on the terrain of the area of care under discussion. The following objectives have formed the basis for agendas in the past:

- to introduce and make explicit the interests of those attending
- to introduce The Cochrane Collaboration and its working methods
- to review relevant existing work, including any systematic reviews of RCTs or specialised registers of RCTs
- to make arrangements to organise a systematic search for RCTs in the Field
- to try to avoid possible conflicts and disappointments in the future by ensuring that people who may not really want to become involved (or who may not be suited to working collaboratively with others), are given opportunities to support The Cochrane Collaboration in other ways
- to generate a list of possible authors associated with the Field, and consider how they might contribute to existing or future Cochrane Review Groups
- to assess what resources already exist for developing a Field and to invite each of the participants at the meeting to indicate what he or she would be prepared to contribute
- to make it clear that those who wish to become involved in establishing and maintaining a Field will be responsible for seeking whatever additional resources may be required
- to agree an agenda and timetable for action

If such a meeting is to provide a useful starting point for running a successful Field, the preparatory work must be sensitive to 'the politics' of the particular area of health care in question. It is always advisable to involve participants from a number of countries and from a range of disciplines from the outset, so that the endeavour can be clearly seen to be internationally based and multi-disciplined. Evidence of this breadth of membership and interest will be required later for a successful application to register the Field with The Cochrane Collaboration.

Because of these requirements, it might be tempting to hold a Formal Exploratory meeting as part of a larger international meeting where many potential supporters of the Field may already be gathered. However, experience within The Cochrane Collaboration has shown that this strategy can be counter-productive. The establishment of any Cochrane entity is of enough importance, requires sufficient time and attention to detail, and demands such a high level of commitment from those who ultimately agree to take the entity forward to registration, that it warrants an occasion and a venue which is free from distraction and which allows the attention of the participants to be focused on the single range of issues before them.

For practical reasons one or more smaller pre-Exploratory Meetings may be required to build up the support necessary for a successful <u>outcome</u> [105] of the Formal Exploratory meeting. It is events such as these that might be sensibly held in conjunction with larger national or international gatherings. Such meetings have the benefit of drawing from a large audience and reducing the inconvenience, in terms of cost and time, of those attending. Organizers of a small pre-Exploratory Meeting should call on their reference Cochrane Centre and their nearest Field for advice and practical support.

There is no minimum quorum for a Exploratory Meeting but a turn-out that is lower than might reasonably be expected for the Field, or a meeting of individuals drawn predominately from one country or clinical discipline, generally indicates that insufficient global interest in the Field has been generated to guarantee widespread and continued support.

Certain individuals are required to be present at the Formal Exploratory Meeting:



- the Director, or representative, of the reference Cochrane Centre
- at least one representative from a registered Cochrane Field
- representatives of one or more Cochrane Review Group who have an interest in the establishment of the proposed Field
- one or more consumers or patient representatives from the Field's dimension of care with an interest in establishing consumer representation within the Field
- other people whom the organizers of the Meeting believe have both the interest, commitment and access to resources to take on the role of Field Co-ordinator.
- a member of the Monitoring and Registration Group.

It has become a convention within The Cochrane Collaboration that Formal Exploratory Meetings organized to establish Cochrane Review Groups last for about one and a half days. This is a sensible convention for all new possible Fields to follow. It allows people attending the meeting to hear the case for establishing a new Field, mix socially over dinner, take their rest and the following morning give their considered decision whether or not they are able to contribute to such a the Field.

If the Formal Exploratory Meeting has identified sufficient expressions of support and the case has been made to establish the Field, the organisers of the Meeting should inform their reference Cochrane Centre of this in writing. The Centre will pass this news on and the status of the entity in *The Cochrane Library* will be changed to 'Probable Field'.

Sometimes, however, Formal Exploratory Meetings reveal that efforts to establish a Field would not be worthwhile. In such instances, people can contribute to The Cochrane Collaboration in other ways such as by contributing to Review Groups, by helping to co-ordinate work in other Fields, and by exploring ways of ensuring that Cochrane reviews reach those who need them.

3.4.4.3 Registering with The Cochrane Collaboration

Having held a successful Formal Exploratory Meeting, the last stage in the establishment of the Field is to become registered with The Cochrane Collaboration.

The following describes the preparation of the application for Registration and the documenting of what has already been achieved, is being done, and has yet to be done in the key areas of a Field's activity. This will entail:

- writing a <u>search strategy</u> [178] for the CENTRAL and other relevant databases and regularly updating it
- identifying trials relevant to the Field
- producing a ranked listing of journals to be searched
- establishing contact with all relevant registered and probable Cochrane Review [22] Groups
- drawing up a list of review topics relevant to the Field
- describing the proposed structure of the Field
- where possible, identifying people who might fill key roles in the Field
- obtaining sufficient resources to support the Field
- collecting letters of support from probable contributors and users (e.g. Review Groups, Methods Groups and other Fields)
- preparing the minutes of the Formal Exploratory Meeting
- drawing up a document defining the area of health care being represented
- drafting a covering letter to the Chair of the <u>Steering Group</u> [13] of The Cochrane Collaboration responding to the points raised in the Checklist for registering a new Field (see <u>Appendix 2</u>: <u>Monitoring and Registration Committee</u> [174]).

3.4.4.4 Designing the structure of the Field



The structure of the Field will depend on the terrain of the Field and the direction set by the Field Co-ordinator. Experience suggests that the success of a Field will depend upon a number of different factors, but particularly on the commitment of the individuals prepared to act as Field Co-ordinators, and their determination to ensure that the Field has sufficient resources to achieve its objectives. Field Co-ordination, because of the challenge to achieve cohesion, may require determined and firm leadership, but this should be exercised sensitively. A brief description of the responsibilities of some of the key players that might be involved is included below. Not all Fields will have the need for all these posts.

The Field Co-ordinator

The Field Co-ordinator has the following responsibilities:

- to set and maintain the direction and scope of the Field
- to allocate the Field's resources in the way most appropriate to the achievement of its goals
- to promote the aims and work of The Cochrane Collaboration within the Field's area of care
- to develop and maintain links with organisations outside The Cochrane Collaboration
- to develop and maintain links with the co-ordinating editors of all relevant <u>Cochrane Review</u> [22] Groups
- to develop and maintain links with all Cochrane Centres and Cochrane Fields
- to attend Cochrane Colloquia and regularly report progress and developments in the Field to The Cochrane Collaboration
- to seek and secure sufficient funding to enable the Field to function effectively

The Field Administrator

The Field Administrator may have the following responsibilities:

- to provide the Field Co-ordinator with administrative support
- to help organise meetings and promotional workshops
- to prepare and maintain the Field module [102] in The Cochrane Library [18]
- to co-ordinate the submission of the Field Monitoring document
- to prepare and produce a Field newsletter and/or maintain a Field website
- to maintain the Field database of contacts



• to liaise with the Managing Editors to ensure that the Field is properly represented in the appropriate Cochrane Review Groups

The Field Trials Search Co-ordinator

The Field Trials Search Co-ordinator may have the following responsibilities:

- to identify studies trials relevant to the Field and makes them accessible through CENTRAL
- to co-ordinate searches of the general Field literature, based on a ranked listing of sources to be searched
- to draw up search strategies for CENTRAL and other electronic databases
- to maintain a specialised register [58] of trials

The Specialised Database Co-ordinator

The Specialised Database Co-ordinator may have the following responsibilities:

- to liaise with all Cochrane entities [20] linked to the Field
- to co-ordinate the inclusion of data from the entities associated with the Field
- to establish links with other relevant organisations providing information for the database
- to work with electronic publishers to develop, produce and maintain the database
- to collaborate with others to disseminate the database

Regional representatives

It might be desirable to have one or more regional representatives to assist the Field Co-ordinator, by spreading the workload of the Field more evenly around the world. Regional representatives can undertake some of the responsibilities outlined above on behalf of the Field Co-ordinator at a national or regional level (for example, liaising with relevant national or regional organisations) and perform the role of Acting Field Co-ordinator in times of illness or crisis. Funding would also be required to assist regional representatives to meet their responsibilities.

Field Advisory Board

A Field might also find it useful to form an Advisory Board to advise and assist the Field Co-ordinator. Although composition of such a group is likely to vary from Field to Field, an Advisory Board should consist of individuals who are committed to the aims and principles of The Cochrane Collaboration, and reflect the international nature of The Cochrane Collaboration and the broad area of the field. They should include at least one consumer representative and one representative from a Review Group with active links to the Field.



3.4.4.5 Obtaining resources for Fields

The support needed for Fields is likely to vary, depending on the priorities set by the Field Co-ordinator. The Co-ordinator of a fully functioning Field may require the support of the 2-4 people described above, as well as possible part-time secretarial support.

Office space and equipment will be required, as well as some supplies and services (e.g. telephone and e-mail services, stationery, photocopying, computer supplies, database searching, purchase of key journals, printing newsletters). Travel funds will be needed for meetings, workshops and conferences.

Funding may also be required to assist regional representatives to meet their responsibilities and to allow members of a Field Advisory Board to attend meetings.

3.4.5 The registration process

All applications for registering a new Field are considered by the Monitoring and Registration Committee (MaRC [30]). A Checklist for Registration with The Cochrane Collaboration has been developed to help members of the MaRC to assess the quality [5] and strength of a Field's application (see Appendix 2: Monitoring and Registration Committee [174]) on behalf of the Steering Group [13]. Once the Steering Group has approved its application for registration, the Field becomes a fully-fledged Cochrane Field.

3.4.6 Managing the module

Part of the registration process will necessitate the drafting of a <u>module</u> [102] to be published in <u>The Cochrane Library</u> [18]. This module provides details of the Field, including its composition and scope. This module is contained within The Cochrane Collaboration's Contact Database, and should be kept up to date at all times, since it is via the Contact Database that information about the <u>Field</u> [27](its 'module') is published in *The Cochrane Library*. The Information Management System team at the Nordic Cochrane <u>Centre</u> [34] provides technical advice with updating modules.

3.4.7 Monitoring the performance of a Cochrane Field

Once a Field has become registered, its performance is monitored fully every two years and monitored financially in the intervening year, by the Monitoring and Registration Committee of the Steering Group [13]. The process is chiefly one of self- assessment to help the Monitoring and Registration Committee gain an overall picture of how Fields work and to identify any common or individual difficulties Fields are experiencing. The Monitoring form for Fields is included in Annex A2.D.

The purpose of the monitoring process is to maintain or raise the <u>quality</u> [5] and productivity of Cochrane <u>entities</u> [20] by helping them identify areas in which they excel or in which they have not yet achieved their potential. The Monitoring and Registration Committee includes representatives of the five types of Cochrane entity (Cochrane <u>Review</u> [29] Groups, Centres, Fields, Method Groups and the Consumer Network), some of whom have been directly elected to the Steering Group.

The Monitoring and Registration Committee does not regard itself as a censorious body, and will strive to help Cochrane entities that are having particular difficulties. However, if a Field repeatedly fails to perform its core duties adequately, the Monitoring and Registration Group does have the responsibility of asking the Steering Group to consider de-registering the Field.



3.4.8 The Consumer Network

The Cochrane Consumer Network (<u>CCNet</u> [12]) supports consumer participation within The Cochrane Collaboration. Registered with The Cochrane Collaboration in October 1995, the Consumer Network encourages consumer involvement within The Cochrane Collaboration's range of activities.

People with consumer perspectives play an integral and unique role in many aspects of The Cochrane Collaboration's work. Their perspectives particularly influence:

- 1. Descriptions of the full range of benefits, problems and ethical issues of healthcare interventions and the clinical trials that determine the usefulness of these interventions;
- 2. The ready accessibility and ease of understanding of Cochrane reviews for a wide range of readers, particularly the general public;
- 3. The role that consumer advocacy organisations can play in promoting the use of Cochrane reviews by the general public

The aims of the Consumer Network are:

- 1. To support both consumers and the Cochrane <u>entities</u> [20] who seek the participation of consumers;
- 2. To make Cochrane reviews easy to understand and accessible to the general public;
- 3. To increase public awareness about the importance of: synthesizing evidence from clinical trials, as in Cochrane reviews; registering ongoing clinical trials so that the information is readily accessible to consumers and review authors who synthesise the findings; being transparent about the protocols of clinical trials and enrolment status.

Current activities of the Consumer Network include:

- 1. The development of support materials to enhance general public and consumer advocate participation in The Cochrane Collaboration;
- 2. The running of training programs for active consumer involvement;
- 3. The preparation of short, easy-to-read plain language summaries of all Cochrane reviews, which are accessible in
 The Cochrane Library [18]">The Cochrane Library [18], on the Cochrane website (www.cochrane.org/reviews [208]) and via the Consumer Network.

The Consumer Network operates in a largely voluntary capacity, within a membership governance structure, under the umbrella of The Cochrane Collaboration. It relies on its members to provide the time, energy, enthusiasm and new ideas. The Network has two representatives on The Cochrane Collaboration's international <u>Steering Group</u> [13], elected from the membership of the Consumer Network. Steering Group members' term of office is three years.

For detailed information about the Consumer Network, please refer to the Network's web pages at www.cochrane.org/consumers [209], its module [102] in The Cochrane Library (under 'About The Cochrane Collaboration'), or e-mail ccnet-contact@cochrane.de [130].

3.4.9 Acknowledgements

First and foremost, we acknowledge the invaluable contribution made by Chris Silagy (deceased), former Director of the Australasian Cochrane <u>Centre</u> [34], and the first Field Co-ordinator of the Primary Health Care Field. For an appreciable time this was the only Field registered with The Cochrane Collaboration. That the Collaboration continues to be active in dimensions of health care broader than those problem areas described by the refined scope statements of its <u>Cochrane Review</u> [22] Groups was, to a great extent, due to Chris.



Chris was the editor of 'Representing the Interests of Fields', Section 3 of the original *Cochrane* Handbook [54] (a weighty tome published c.1994 which preceded the current *Manual*). The ideas and material he presented there form the basis of much of the above text.

Thanks are also due to all the members of the registered Cochrane Fields who were kind enough to take time to comment on the initial draft of this document, to members of the <u>Steering Group</u> [13] who suggested improvements to earlier drafts and, lastly, to the continuous encouragement from other sectors of The Cochrane Collaboration that we should answer the question "What exactly do Fields do?"

3.5 Methods Groups

Methods Groups have evolved as a means of meeting The Cochrane Collaboration's need for methodological advice. Initially, groups of experts were called together for workshops on an ad hoc basis to provide guidance on specific questions such as which statistical methods to use in Cochrane Reviews, what information regarding costs should be included in reviews, and how to collect and use individual patient data [187] in reviews. The first of these workshops was convened by the UK Cochrane Centre [34] before The Cochrane Collaboration came into existence. It quickly became apparent that there was a need for ongoing methodological advice and support. Moreover, groups of people with common methodological interests came together in various ways and expressed a desire to contribute to The Cochrane Collaboration on an ongoing basis. Methods Groups were initially registered informally and driven almost entirely by existing enthusiasm and interests. Since then, steps have been taken to help Methods Groups to contribute in effective and efficient ways towards the aims of The Cochrane Collaboration, and they have evolved from informal networks [27] to formal Cochrane entities [20]. In 2009, the Collaboration began implementing a recommendation of its 2008-09 Strategic Review to formalise training and methods development, as additional purposes of the Collaboration. Methods Groups have a key role in producing activities and outputs associated with this training and methods development.

Subheadings in this section

3.5.1 The role of Methods Groups

All Methods Groups have the following three core functions:

- Providing policy advice.
- Serving as a forum for discussion.
- Ensuring that the Methods Group functions as part of The Cochrane Collaboration.

Furthermore, each Methods Group may adopt one or more of the following elective core functions, subject to agreement with the Methods Executive:

- Providing training.
- Hosting a network of <u>CRG</u> [15]-based methods individuals.
- Providing peer review [131].
- 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 <u>quality</u> [5] of Cochrane Reviews.
- Conducting methodological research.
- Communicating Cochrane methodology to external organizations.

Elective core functions should be selected to reflect the needs of the Collaboration and the aims, scope and resources of each Methods Group. Each Methods Group reviews its elective core functions biennially (to coincide with the biennial monitoring process - see Appendix 2 'Monitoring and Registration Committee', Section A2.6 'Monitoring') and the list of elective core functions adopted by each Methods Group is likely to evolve over time. If a Methods Group does not adopt a particular elective core function, this does not necessarily imply that no related activities and outputs will be produced by the Methods Group (indeed, the list of elective core functions may be used by a Methods Group to guide activities and outputs undertaken outside of applicable core functions). Rather, non-adoption of an elective core function simply means that there is no expectation or requirement to fulfil minimum expectations relating to the core function or to produce related activities and outputs.

Each of the core functions are described in more detail below. The relative importance of these core functions varies between Methods Groups, but each Methods Group is required to set targets and report on its activities and outputs against the three common core functions and its elective core functions to the Monitoring and Registration Committee (MaRC [30]) and the Methods Executive every two years.

3.5.1.1 Providing policy advice

Demand for policy advice needed from individual Methods Groups is likely to vary, depending on the extent to which Methods Groups address methodology currently in use in every <u>review</u> [29] (or of potential relevance to every review).

The editors of the Cochrane Handbook [54] for Systematic Reviews of Interventions (hereafter, 'Interventions Handbook') and the Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy (hereafter, 'DTA Handbook') require advice when these Handbooks are being revised. Much of this advice should come from Methods Groups, in response to requests made by the Handbook Editorial Advisory Panel (HEAP) or the Methods Board. Methods Groups are responsible for Handbook material relevant to their aims and scope. Currently, some Methods Groups contribute material to single chapters of the Handbooks, whilst others contribute to several chapters, and others do not currently contribute any material. All Methods Groups are expected to be prepared to respond to requests from the HEAP and Methods Board to produce new or updated material relevant to their aims and scope within a reasonable timeframe.

Methods Groups might also be asked for methodological advice by the Methods Board, the Methods Executive or <u>Cochrane Review</u> [22] Groups (CRGs), which is intended for use to inform collaboration policy (including editorial policies of CRGs). Methodological advice may be used to inform two types of policy decision: decisions about the methodology used to prepare and maintain reviews (e.g. statistics), and decisions about the methods used by the Collaboration to meet its aims (e.g. information retrieval). The role of Methods Groups for both types of decision is to provide guidance for those responsible for decisions, not to take decisions for them.

Requests for methodological advice may originate from a number of sources, including the Methods Application and Review Standards Working Group (MARS), the Cochrane Collaboration Steering Group [13] (CCSG [23]) or its sub- and advisory committees, those responsible for core activities such as developing software or training materials, or those with editorial responsibilities for review production (e.g. the Co-ordinating Editors Executive, the Cochrane Editorial Unit [49]). Requests originating from those sources named above should be channelled via the Methods Board (on which several of the named groups are represented) or the Methods Executive (for requests from the CCSG



or the Cochrane Editorial Unit).

Requests for methodological advice intended for use to inform the editorial policies of CRGs may be made to individual Methods Groups directly by individual CRGs. However, where the advice needed is substantive, likely to draw on more than one area of methodology, and/or likely to be of relevance to a several CRGs, it is appropriate to channel both the request and advice via the Methods Board, to ensure appropriate delegation and co-ordination of activity and to consider potential implications for substantive methods policy and implementation in software.

3.5.1.2 Serving as a forum for discussion

The extent to which individual Methods Groups will need to lead discussions of substantive methodological issues may vary, depending in part on the extent to which Methods Groups address methodology currently in use in every Cochrane Review [22] (or [127] of potential relevance to every review) and the frequency with which issues warranting such discussions arise. However, all Methods Groups are expected to be prepared to respond to the need to lead such discussions as and when they arise.

The Methods Board is the main forum for discussion of cross-cutting methodological issues in the Collaboration, but Methods Groups are expected to establish mechanisms and provide opportunities for discussion of substantive methodological issues relevant to the aims and scope of their Group. At minimum, each Methods Group is expected to implement an e-mail discussion or distribution [31] list for their members. Methods Groups may also hold face-to-face meetings for their members and others interested parties to discuss such issues during Cochrane Colloquia or other events. There is also a growing range of web-based virtual meeting environments that may be exploited for this purpose. Where a methodological issue cuts across two or more Methods Groups but does not impact on the majority of Methods Groups, organization of joint meetings may sometimes be appropriate outside the forum of the Methods Board.

Output from discussions within Methods Group should be communicated to relevant Cochrane entities [20] and groups as appropriate and also used to inform new or updated policy advice, guidance in the Cochrane Handbooks, training materials etc. Outputs may also need to be communicated to external organizations, networks [27] and individuals.

3.5.1.3 Ensuring that the Group functions as part of The Cochrane Collaboration

The Methods Board is the main forum for discussion of cross-cutting methodological issues in the Collaboration, and all Methods Groups are expected to take part in this Board. The inclusive membership and remit of the Methods Board (see Section 1.1.2.10.1) is specifically designed to facilitate Methods Groups' functioning as part of the wider Cochrane Collaboration, within the overall infrastructure that supports methodological input to Collaboration activities and outputs. As part of its remit, the Methods Board provides a forum for discussion and interaction [26] among Methods Groups personnel. It also has responsibility for facilitating links between the Methods Groups and the Cochrane Methodology Review [29] Group. Each Methods Group is expected to designate representatives of their convenors' panel to participate as members of the Methods Board, and to designate one convenor to vote on behalf of the Methods Group at each meeting of the Methods Board, if required (the 'voting convenor' may change for each meeting).

Each Method Group is expected to establish and maintain additional mechanisms and processes to facilitate effective communications with other Cochrane entities [20] (including other Methods Groups). At minimum, each Methods Group is required to update their entity modules at least annually and to keep details of their convenors, other key personnel and members up to date in



Archie (the Collaboration's Information Management System).

Methods Groups are also expected to implement planning to ensure the sustainability and continuity of the Group as long as there is a programme of work to be completed. Evidence of planning to ensure the sustainability and continuity of the group includes: having continuity in leadership and new leaders in training; having the resources needed and, if not, making efforts to find them; ensuring the Methods Group representative on the CCSG [23] is campaigning for the needs of the Group.

Methods Groups are required to participate fully in biennial monitoring of Methods Groups (conducted by the MaRC [30] in collaboration with the Methods Executive) and to provide sufficient information in monitoring forms to allow a complete assessment of self-set targets for activities and outputs against core functions, and performance against these targets. Persistent failure to provide sufficient information in evidence of core function activities could eventually lead to deregistration of the Group as a Cochrane entity (see Appendix 2 'Monitoring and Registration Committee', Section A2.7 'De-registration of an entity').

3.5.1.4 Providing training (elective core function)

Methods Groups may play a central role in the development and provision of methods training materials (including training for trainers) within their particular areas of expertise. Methods training materials may take the form of face-to-face workshops at Colloquia and other meetings, web-based materials (e.g. web-based learning modules, online PowerPoint presentations, 'webinars' etc), or other formats. Methods training may be provided to contributors to The Cochrane Collaboration or to other organizations and individuals external to the Collaboration (who may sometimes be potential contributors to Cochrane Reviews).

Methods Groups that select 'Providing training' as a core function are expected, at a minimum, to:

- Submit proposals to provide methods training workshops at colloquia.
- Respond to requests made by the Training Working Group (TWG), Cochrane Centres and/or the Methods Board to develop, provide and contribute to methods training materials aimed at contributors to The Cochrane Collaboration.

Such requests will need to take into account levels of funding and resources available to individual Methods Groups to support development and provision of such materials; if development and provision of specific training materials is warranted, the Collaboration may need to provide (or help facilitate access to) funds to Methods Groups to support this activity.

So far as possible, all methods training materials provided to contributors to the Collaboration should be consistent with the Interventions Handbook [54] and/or the DTA Handbook [55], and other relevant collaboration policies. Methods Groups will also need to judge the appropriate balance between different forms of training materials (e.g. web-based versus face-to-face), within available resources, in consultation with the TWG, Centres and/or the Methods Board.

The aims and scope of some Methods Groups focus on methodology that falls within the scope of current types of Cochrane Review (i.e. intervention reviews and diagnostic test accuracy reviews). Those Methods Groups whose aims and scope cover methodology included in the Interventions Handbook and/or the DTA Handbook are more likely to select 'Providing training' as a core function and/or to develop or provide training materials outside of core functions, within available resources and in line with training needs within the Collaboration. However, this does not exclude those Methods Groups whose aims and scope cover methodology outside the scope of current types of Cochrane Reviews from selecting 'Providing training' as a core function (subject to agreement with the Methods Executive), or from developing or providing training materials outside of core functions, since there may still be demand for such training within and/or outside the Collaboration.



3.5.1.5 Hosting a network of CRG-based methods individuals (elective core function)

Within each <u>CRG</u> [15], there should be one <u>or</u> [127] more identified individuals with responsibility for enabling CRGs to ensure that their policies and methods used in protocols and reviews correspond with methodology specified in Parts 1 and 2 of the Interventions <u>Handbook</u> [54]; specifically: question formulation, information retrieval, statistics, <u>bias</u> [6] assessment (including use of the 'Risk of bias' tool) and interpretation (including preparation of 'Summary of findings' tables). Identified CRG methods individuals should be networked (within topic areas) and <u>networks</u> [27] of CRG methods individuals should be part of the corresponding Methods Group(s).

Therefore, the following Methods Groups are expected to host networks of CRG-based methods individuals as a core function:

- Applicability [11] and Recommendations Methods Group.
- Bias Methods Group.
- Information Retrieval Methods Group.
- Statistical Methods Group.

In addition, each CRG is encouraged to identify one or more individuals with responsibility for enabling it to ensure that their policies and methods used in protocols and reviews correspond with methodology specified in Part 3 of the Interventions Handbook [55] and in the DTA Handbook, particularly when such methods are frequently used within the CRG. Therefore, other Methods Groups whose aims and scope correspond to methodology specified in Part 3 of the Interventions Handbook and the DTA Handbook may also host a network of CRG-based methods individuals as a core function.

Methods Groups hosting a network of CRG-based methods individuals as a core function are expected, at a minimum, to:

- Enlist at least one individual from each CRG to be part of the network.
- Maintain an up-to-date list of CRG-based methods individuals in Archie.
- Provide a discussion forum such as an e-mail list or blog.
- Provide backup for methods questions that are not resolved by CRGs (resolution of unanswered questions).
- Ensure that training material and Handbook guidance is understood by CRG-based methods individuals.
- Provide feedback on work undertaken within CRGs if requested (e.g. 'Is this Summary of Findings table acceptable?').

3.5.1.6 Providing peer review (elective core function)

Provision of specialist <u>peer review</u> [131] for Cochrane Protocols and Reviews may be delivered primarily by <u>networks</u> [27] of <u>CRG</u> [15]-based methods individuals (in consultation with Methods Groups, as appropriate) for some areas of methodology. However, other areas of methodology may not be covered by networks of CRG-based methods individuals. Therefore, some Methods Groups (and their members) may choose to offer peer review support to CRGs or author teams directly (within available resources), as an alternative or complement to that delivered via networks of CRG-based methodologists.



Methods Groups that select 'Providing peer review' as a core function are expected, at a minimum, to:

- Implement a mechanism to identify members willing to provide peer review of relevant components of Cochrane Protocols and Reviews on behalf of the Methods Group.
- Implement a process to offer timely peer review of relevant components of Cochrane Protocols and Reviews.
- Communicate the availability of peer review and the process to be used to access this service to CRGs.
- Set target response times for provision of peer review of relevant components of Cochrane Protocols and Reviews.
- Provide peer review within target response times.

3.5.1.7 Providing specialist advice (elective core function)

As with peer review [131] support, provision of specialist advice may be delivered primarily by networks [27] of CRG [15]-based methods individuals (in consultation with Methods Groups, as appropriate) for some areas of methodology. However, other areas of methodology may not be covered by networks of CRG-based methods individuals. Therefore, some Methods Groups (and their members) may choose to offer specialist advice and expertise to author teams and/or CRGs directly (within available resources), to support the production of specific components of individual Cochrane Protocols and Reviews, as an alternative or complement to advice and expertise delivered by networks of CRG-based methods individuals. This form of support may range from provision of advice on how to implement a specific methodology in a specific review, to 'hands-on' work to complete elements of the review process.

Methods Groups that select 'Providing specialist advice' as a core function are expected, at a minimum, to:

- Implement a mechanism to identify members willing to provide specialist advice on behalf of the Methods Group to support production of relevant components of Cochrane Protocols and Reviews.
- Implement a process for members to offer timely specialist advice to support production of relevant components of Cochrane Protocols and Reviews.
- Communicate the availability of specialist advice and the process to be used to access this service to CRGs and/or individual authors.
- Set target response times for provision of specialist advice on a case-by-case basis.
- Provide specialist advice within target response times.

3.5.1.8 Contributing to new products or lines of activity (elective core function)

'The Cochrane Collaboration: A Strategic Review' included recommendations that the Collaboration should: use uncommitted income strategically to develop new products or lines of activity; identify principles for developing new products or lines of activity; and invest in a development function for new products or lines of activity. Two specific new products/lines of activity that the Strategic Review recommended for further investigation were 'Cochrane Education' (a broad based educational program focussing on dissemination and use of Cochrane Reviews to various stakeholders) and 'Cochrane Response' (a rapid response review program). Methods Groups may be well-positioned to contribute to the development of these and other new products or lines of activity. In some cases



such contributions may be requested or offered via the Methods Board, the Methods Executive or both.

Methods Groups that select 'Contributing to new products or lines of activity' as a core function are expected, at a minimum, to:

- Identify specific new products or lines of activity to which a contribution will be made in consultation with the Methods Board, the Methods Executive and other stakeholder groups within the Collaboration (e.g., CCSG [23], the Cochrane Editorial Unit [49]), as appropriate.
- Set targets and deadlines for deliverables (outputs) on a case-by-case basis.
- Meet targets and deadlines for deliverables (outputs).

3.5.1.9 Contributing to software development (elective core function)

The Methods Board is responsible for decisions on substantive methods policy and guidance for implementation in software and Handbooks, and for provision of advice to the RevMan Advisory Group and the CCSG [23] on the content and structure of Cochrane Reviews (in particular by gathering opinion from Methods Groups). Methods Groups may therefore be invited by the Methods Board to provide advice on software development issues relating to methodology relevant to their aims and scope. Alternatively, Methods Groups may propose methodology related developments for implementation in software. Additionally, Methods Groups may have a lead role in the development of software independent [177] of the Methods Board (e.g. the Applicability [11] and Recommendations Methods Group has a lead role in the development of GRADEpro (GRADEprofiler), the software used to create Summary of Findings (SoF) tables in Cochrane Reviews).

Methods Groups that select 'Contributing to software development' as a core function are expected, at a minimum, to:

- Identify specific software to which a contribution will be made.
- Set targets and deadlines for deliverables (outputs) on a case-by-case basis.
- Meet targets and deadlines for deliverables (outputs).

3.5.1.10 Conducting Cochrane methodology reviews (elective core function)

Methods Groups and their members can play an important role in facilitating, producing and disseminating the results of Cochrane Methodology Reviews on topics relevant to their aims and scope. For further information about Cochrane Methodology Reviews and the Cochrane Methodology Review Group (CMRG), see the CMRG Module [102] in The Cochrane Library [18].

Methods Groups that select 'Conducting Cochrane methodology reviews' as a core function are expected, at a minimum, to:

- Set targets for registration of titles for new Cochrane Methodology Reviews with the CMRG.
- Set targets for publication of new CMRG Protocols in the Cochrane Database of Systematic Reviews (<u>CDSR</u> [128]).
- Set targets for publication of new or updates of CMRG Reviews in the CDSR.



• Meet targets for registration of titles with the CMRG and publication of CMRG Protocols and new, or updates of, CMRG Reviews in the CDSR.

3.5.1.11 Contributing to the Cochrane Methodology Register (elective core function)

The Cochrane Methodology Register (CMR) is a searchable database of studies relevant to the methods of systematic reviews of healthcare and social interventions. CMR includes journal articles, book chapters, conference proceedings, conference abstracts and reports of ongoing methodological research. It aims to include all published reports of empirical [32] methodological studies that could be relevant for inclusion in a Cochrane methodology review, along with comparative and descriptive studies relevant to the conduct of systematic reviews of healthcare interventions.

Methods Groups that select 'Contributing to the Cochrane Methodology Register' as a core function are expected, at a minimum, to:

- Implement a mechanism (in consultation with the CMR) to identify studies relevant to the methods of systematic reviews of healthcare and social interventions that fall within the aims and scope of the Group.
- Contribute details of methodology studies relevant to the aims and scope of the Group to the CMR on at least a quarterly basis (deadlines to be agreed with the CMR).
- Implement a process (in consultation with the CMR) to tag CMR records of articles by Group members.

3.5.1.12 Helping to monitor and improve the quality of Cochrane Reviews (elective core function)

The Editor in Chief and his office (Cochrane Editorial Unit [49]) are responsible for the overall quality [5] of The Cochrane Library [18] and as such are working with Review [29] Groups to improve the quality of reviews. It will be important for Methods Groups to have a strong relationship with the Cochrane Editorial Unit to support this activity and have input to quality initiatives. This has begun through the work of the Methods Application and Review Standards (MARS) Working Group (formerly the CoEds-Methods Working Group). The MARS Working Group facilitates high-level interaction [26] between the Editor in Chief, the Co-ordinating Editors (and hence Review Groups) and the HEAP / Methods Groups, with a focus on implementation of Handbooks and improving review quality. Part of the remit of the Methods Board is to receive input from the MARS Working Group and to ensure appropriate delegation of tasks arising from it, including Methods Groups' input to quality monitoring and improvement initiatives.

Methods Groups that select 'Helping to monitor and improve the quality of Cochrane Reviews' as a core function are expected, at a minimum, to:

Respond to requests channelled via the Methods Board/ Methods Executive for specialist input
to active monitoring of aspects of the quality of Cochrane Reviews and/or initiatives aiming to
improve the quality of Cochrane Reviews.

Such requests will need to take into account levels of funding and resources available to individual Methods Groups to support these activities; if active monitoring/ contribution to specific initiatives is warranted, the Collaboration may need to provide (or help facilitate access to) funds to Methods Groups to support this. In addition, Methods Groups may choose to initiate active monitoring and/or quality improvement initiatives themselves, independent [177] of any request from the MARS



Working Group or other source.

3.5.1.13 Conducting methodological research (elective core function)

So far as possible, the policy advice, training materials, <u>peer review</u> [131] and specialist advice etc. that Methods Groups provide within the Collaboration should be based on good evidence, and not solely on opinion. Methods Groups may achieve this by collating, evaluating, consolidating and recommending methods, as well as by developing methods themselves. The body of evidence that Methods Groups may draw upon includes evidence from <u>empirical</u> [32] methodological research studies, where such studies may be conducted under the auspices of one or more Methods Groups (see below), by leaders and/or members of Methods Groups, by methodologists within the Collaboration but outside Methods Groups, or by methodologists outside the Collaboration.

Most research output is from individuals within Methods Groups rather than Methods Groups themselves (i.e. in the absence of funding for most Methods Groups, methodological research is typically an indirect rather than a direct output). Also, whilst research undertaken by methodologists in the Collaboration may be motivated, sometimes very strongly, by events or observations in the Collaboration, intellectual property generally lies with employers rather than the Collaboration (even for funded projects).

There is consensus amongst Methods Groups that the Collaboration cannot expect methodological research output from Methods Groups other than specific projects funded by the Collaboration. However, this does not exclude the possibility that, in some instances, Methods Groups may obtain funding for empirical methodological research studies to be conducted (wholly or partly) under the auspices of the Methods Group itself (as opposed to individuals or their employer institution). It is only the latter that falls under the definition of the core function 'Conducting methodological research'.

Methods Groups are also encouraged to maintain an agenda for research relevant to their aims and scope that reflects the kinds of policy advice, training materials, peer review and specialist advice etc. they provide within the Collaboration. Some Methods Groups are happy to place such research agendas in the public domain, whilst others are less eager to do this, motivated by a need to protect intellectual property. Additionally, Methods Groups are encouraged to exploit opportunities to facilitate and support needed empirical and theoretical methodological studies, so far as possible. Members of Methods Groups are also encouraged to list their Methods Group affiliations on publications if appropriate.

Methods Groups that select 'Conducting methodological research' as a core function are expected, at a minimum, to:

- Maintain (publicly or privately) an agenda for research relevant to their aims and scope that reflects the kinds of policy advice, training materials, peer review and specialist advice etc. they provide within the Collaboration.
- Seek funds for empirical or theoretical methodological research studies to be conducted (wholly or partly) under the auspices of the Methods Group.

3.5.1.14 Communicating Cochrane methodology to external organizations (elective core function)

An increasingly important function for some Methods Groups may be to interact with external organizations and networks [27] to provide their members with advice on and/or explain



methodology (relevant to the aims and scope of the Group) that is used in the preparation and maintenance of Cochrane Reviews.

Methods Groups that select 'Communicating Cochrane methodology to external organizations' as a core function are expected, at a minimum, to:

- Respond to requests from external organizations and networks to provide advice on and/or explain methodology (relevant to the aims and scope of the Group) that is used in the preparation and maintenance of Cochrane Reviews (within available resources).
- Maintain a private register of external organizations and networks whose members would benefit most from advice on and/or explanation of methodology (relevant to the aims and scope of the Group) that is used in the preparation and maintenance of Cochrane Reviews.
- Offer advice or explanation of methodology (relevant to the aims and scope of the Group) that is used in the preparation and maintenance of Cochrane Reviews to external organizations and networks whose members would benefit most from this (within available resources).

3.5.2 Registration and accountability

In the early years of The Cochrane Collaboration, Methods Groups developed mainly around the desire to provide a forum for discussion, and the majority of Methods Groups were initially registered through an informal process. However, it became clear that it was important to register Methods Groups formally and to ensure that they address their responsibilities adequately. New Methods Groups are expected to register in much the same way as other Cochrane entities [20]. That is, exploratory meetings are held, there are explicit criteria for assessing the applications for new Methods Groups (see Appendix 2: Monitoring and Registration Committee [174], Section A2.5 and Annex A2.A), and registration is achieved only after approval by The Cochrane Collaboration Steering Group [13] (CCSG [23]).

A representative of the Monitoring and Registration Committee (MaRC [30]) should be invited to attend the exploratory meetings. If a MaRC representative cannot attend (either in person, by VOIP or by teleconference), the organisers of the exploratory meetings should ensure they discuss the registration process and a provisional agenda for the meetings with a MaRC representative in advance. The aim of MaRC involvement is to help to ensure that the meetings are as useful as possible to inform the proposed Methods Group's potential application for formal registration. There should be formal feedback to the MaRC representative, Methods Groups representative on CCSG, and Methods Executive [210], to ensure effective communication, which should include a person-to-person discussion (e.g. by telephone) with the MaRC representative, and circulation of the exploratory meeting's minutes to the MaRC representative.

The Methods Groups' representative on the CCSG is responsible for assisting with the preparation of an application to register as a Methods Group, in consultation with the Methods Executive. This includes advice on the preparation of a draft module [102] for the Group, the collection of indications of support from relevant individuals and entities within The Cochrane Collaboration, and clarity about the role of the proposed Methods Group in supporting the preparation of high quality [5] Cochrane Reviews. When preparing an application for registration, a proposed Methods Group must decide which elective core functions they will fulfill during their first two years (Section 3.5.1). Methods Groups, like other entities, are expected to set targets against which their contribution to the aims of The Cochrane Collaboration can be measured. Their progress is monitored fully every two years, and financially on an annual basis, in order to identify potential and actual difficulties and provide support to help them achieve their objectives and meet their targets.



Methods Groups prepare and maintain modules in Archie (the Collaboration's Information Management System) for inclusion in <u>The Cochrane Library</u> [18]. These modules contain contact details and information about the scope, membership and activities of each Methods Group. Workshop reports and other documents of general interest can also be incorporated in Methods Group modules.

To date, few Methods Groups have held direct funding to support the activities they undertake and outputs they produce for the benefit of The Cochrane Collaboration. They rely on the voluntary efforts of their members and, usually, administrative and other 'in kind' support from the host organizations of their convenors. Each Methods Group is required to have at least two convenors and, if possible, these should be from different countries. It is the responsibility of the convenors to provide a point of contact for members of the Methods Group and for Cochrane entities that need help from the Group.

As well as organizing training workshops at the annual Cochrane Colloquia, some Methods Groups also use Colloquia as an opportunity to organize business or scientific meetings for their members and others. Furthermore, because the pressure of other meetings at the Colloquia can make it difficult to arrange meetings that last more than a few hours, Methods Groups may arrange longer meetings at other times to discuss specific issues in sufficient detail.

3.5.3 Co-ordination of Methods Groups

Decisions about the scope and boundaries of Cochrane Methods Groups have sometimes rested solely on the existing interests of the individuals involved. When establishing Methods Groups, a balance needs to be struck between The Cochrane Collaboration's principles of "building on people's existing enthusiasm and interests" and "minimising duplication of effort". In the first few years of The Cochrane Collaboration, enthusiasm and established interests were generally allowed to dominate over the prevention of duplication, so that those with specific interests relevant to the aims of The Cochrane Collaboration were encouraged to pursue them. This sometimes resulted in more overlap than is desirable, and more consideration is now being given to avoiding unnecessary duplication and proliferation of Methods Groups with overlapping interests. This had implications for new Methods Groups wishing to register (i.e. they must address needs that are not already being addressed), for existing groups and for co-ordinating the activities of Methods Groups.

Responsibility for co-ordinating Methods Groups rests with their representative on The Cochrane Collaboration Steering Group [13] (CCSG [23]) and the Methods Executive. This responsibility includes facilitating communication among Methods Groups, responding to expressions of interest in forming new Methods Groups, serving as a conduit to the Monitoring and Registration Committee and the CCSG for applications to register Methods Groups, and facilitating the development and maintenance of modules for Methods Groups. One specific aspect of this co-ordination is the organization of a meeting of the Methods Board at each Cochrane Colloquium.

Methods Groups are expected to contribute to the work of the Methods Board. A key responsibility of



the Methods Board is the provision of formal recommendations to the CCSG on methods to be used for Cochrane Reviews on the effects of interventions. This guidance will largely originate from the Methods Groups. The guidance is disseminated through the *Interventions* Handbook [54] and DTA Handbook [55], and through implementation in software, both of which also rely on specific input from Methods Groups. The Handbook [55]s aim to help authors make good decisions about the methods they use in their systematic reviews of healthcare interventions and diagnostic tests. The guidelines in the *Handbooks* are intended to help authors to be systematic and explicit about the questions they pose in Cochrane reviews and how they derive answers to those questions.

3.5.4 Improving methodological support in The Cochrane Collaboration

In October 2003, The Cochrane Collaboration <u>Steering Group</u> [13] (<u>CCSG</u> [23]) approved the inclusion of the following text in the Policy Manual:

- New Methods Groups may need to focus their efforts on conducting research and producing advisory material before they can be in a position to provide useful one-to-one advice to <u>Cochrane</u> <u>Review</u> [22] Groups (<u>CRGs</u> [22]), Centres and Fields. Methods Groups will state in their <u>module</u> [102] their current ability to provide advice.
- 2. When preparing funding applications for health research projects it is expected that CRGs, Centres and Fields should consider including budget lines to fund the methodological and statistical support that they require to complete those projects.
- 3. CRGs should ensure that their named methodological or statistical consultant is able to commit regular time to the work of the CRG.
- 4. The CCSG endorsed the model of methodological and statistical consultants being editors of CRGs, to enable them to play a greater role in ensuring and improving <u>methodological quality</u> [126] of Cochrane Reviews.
- Everyone involved in CRGs, Methods Groups, Centres and Fields should look for opportunities to involve new methodologists in the work of the Collaboration, and ensure that they are linked into the relevant Methods Group(s).

In 2009, the core functions of Methods Groups were revised better to reflect both the diversity of the types of methods that they addressed, and the associated needs of the Collaboration with regard to those methods. The revised core functions had an increased emphasis on the role of Methods Group in providing policy advice, serving as a forum for discussion, and ensuring that the Group functions as part of The Cochrane Collaboration. Methods Groups were also given the option to adopt one or more elective core functions, which include providing training, hosting a network of CRG-based methods individuals, providing peer review [131] and specialist advice, helping to monitor and improve the quality of Cochrane Reviews, and conducting methodological research; it is recognised and accepted that not all Methods Groups will take on all these functions.



Annex: Annual survey of members

(based on the <u>survey</u> [114] used by the Individual Patient Data Methods Group)

- 1. Are you still interested in being listed as a member of the Methods Group?
- 2. Are you planning to attend this year's Colloquium?
- 3. If so, do you think there should be a meeting of the Methods Group at the Colloquium?
- 4. Would you be willing to help with the conduct of a <u>Cochrane review</u> [22] that had to tackle issues relevant to the Methods Group? If so, which areas of health care would you be willing to help with?
- 5. Which areas of methodological research are you interested in?
- 6. Have you completed any empirical [32] studies of methodology in the last year?
- 7. If so, please send details (including reprints if available) to us.
- 8. Are you involved in any empirical studies of methodology at the moment?
- 9. If so, please send details (e.g. a study <u>protocol</u> [43]) to us.

APPENDIX 1: Co-publication agreements/ correspondence with journal editors re publishing Cochrane reviews

Subheadings in this section

A1.1. Co-publication agreements

Journals with which Cochrane Review [22] Groups have co-publication agreements

As at 10 June 2009

American Journal of Gastroenterology

Anesthesia and Analgesia [see correspondence in section A1.2 [211]]

Archives of Dermatology

British Journal of Dermatology

British Journal of Surgery [see correspondence in <u>section A1.2</u> [211]]

British Medical Journal

BMJ Publishing Group's specialist journals (all)

Canadian Medical <u>Association</u> [24] Journal [see correspondence in <u>section A1.2</u> [211]]

Cancer <u>Treatment</u> [8] Review (CTR) [see editorial in CTR 2003;29:149]

Climacteric [see correspondence in section A1.2 [211]]



Cochlear Implants International [see ENT Group correspondence in section A1.2 [211]]

Colorectal Disease [see correspondence in <u>section A1.2</u> [211]]

Diseases of Colon and Rectum

European Journal of Vascular and Endovascular Surgery (EJVES)

Health Education Journal [see correspondence in section A1.2 [211]]

Human Reproduction

HNO [see ENT Group correspondence in section A1.2 [211]]

International Journal of Epidemiology [196] [see correspondence in section A1.2 [211]]

International Journal of Pediatric Otorhinolaryngology [see ENT Group correspondence in <u>section A1.2</u> [211]]

JAMA [see correspondence below]

Journal of Audiological Medicine [see ENT Group correspondence in section A1.2 [211]]

Journal of General Internal Medicine [see correspondence in section A1.2 [211]]

Journal of Health Services Research and Policy [see correspondence in section A1.2 [211]]

Journal of Human Hypertension [see correspondence in section A1.2 [211]]

Journal of Laryngology and Otology [see ENT Group correspondence in section A1.2 [211]]

Journal of the American Academy of Dermatology

Journal of the National Cancer Institute [see correspondence in section A1.2 [211]]

Journal of Neurology, Neurosurgery and Psychiatry [see correspondence in section A1.2 [211]]

Journal of Rheumatology [see correspondence in section A1.2 [211]]

Journal of Wound, Ostomy and Continence Nursing (Journal of WOCN)

Obstetrics and Gynecology [see correspondence in section A1.2 [211]]

South African Medical Journal [see correspondence in section A1.2 [211]]

Stroke

A1.2. Correspondence from journal editors re publishing Cochrane reviews

From: jane cracknell [mailto:jane cracknell@yahoo.com] [212]

Sent: 13 October 2004 11:31

To: Jini Hetherington



Cc: Tom Pedersen; Ann Møller

Subject: Re: [Adminors [213]] Co-publication agreements with paper journals

CARG has a dual publication arrangement with Anesthesia and Analgesia. The arrangement is as follows: All newly published CARG abstracts are sent to Anesthesia and Analgesia by CARG. The editor in chief then decides whether to accept the shortened version of the review [29] (which will appear in the new A&A Cochrane Corner) or to invite the author to submit the full version of the review. Full versions of the review still need to go through A&A's editorial process [45]. Reference is made to the original Cochrane review [22].

Best wishes, Jane Cracknell, RGC, Cochrane Anaesthesia Review Group (CARG)

From: DStark@wiley.co.uk [214] [mailto:DStark@wiley.co.uk] [215]

Sent: 15 January 2004 11:51

To: mclarke@cochrane.co.uk [216]

Subject: British Journal of Surgery and Cochrane

Dear Mike,

I am writing to extend an invitation to submit Cochrane reviews to the British Journal of Surgery for publication. We anticipate that the arrangements would be similar to those of Lancet in that we would be interested in parallel publication of course, but also submission of completed and approved Reviews published in *The Cochrane Library* or not. We would also require the manuscript to transit our peer-review process and be revised accordingly. In addition, BJS reviews are heavily edited to ensure their content reads well. Therefore the final paper might be quite different from the original manuscript and Cochrane review, to which we would of course make full reference. Please feel free to contact me should you have any questions, and I look forward to helping to share relevant Cochrane reviews with the larger surgical community.

Kind regards, David Stark, Managing Editor, British Journal of Surgery, John Wiley and Sons Ltd, The Atrium, Southern Gate, Chichester, PO19 8SQ, UK (tel: + 44 (0)1243 770 384; fax: + 44 (0)1243 770 460). Visit the British Journal of Surgery online at www.bjs.co.uk [217]

From: Mike Clarke (mclarke@cochrane.co.uk [216])

Sent: 15 January 2004

To: David Stark (<u>dstark@wiley.co.uk</u> [218])

Subject: British Journal of Surgery and Cochrane

Dear David,

Thanks very much for this email. I am copying it to Jini Hetherington in The Cochrane Collaboration Secretariat [1] so that the British Journal of Surgery can be included in the list of journals that have offered this. In addition, if you have no objection, I would like to include your email alongside the related ones from other journals, in the relevant appendix of The Cochrane Manual. This is



available on the Internet (www.cochrane.org/admin/manual.htm [155]) and provides an easy way for Cochrane authors to see what the requirements of your journal would be.

Thanks again. Best wishes, Mike.

From: <u>DStark@wiley.co.uk</u> [214] [mailto:DStark@wiley.co.uk] [215]

Sent: 15 January 2004 16:38

To: Mike Clarke

Subject: British Journal of Surgery and Cochrane

Dear Mike, Many thanks for your prompt reply. Please feel free to use my email in this way, and I look forward to relaying your news to all the members of the British Journal of Surgery Society. Kind regards, David.

To: CCInfo, 31 October 2008

From: MaryEllen Schaafsma [mschaafs@uottawa.ca]

Subject: Invitation to submit reviews for co-publication

The Canadian Cochrane Network and <u>Centre</u> [34] has reached a co-publishing agreement with the Canadian Medical <u>Association</u> [24] Journal for shortened versions of Cochrane reviews. CMAJ is accepting submissions of versions of Cochrane reviews for simultaneous publication with the release of each issue of <u>The Cochrane Library</u> [18]. These versions should be about 3000 words and will give full reference to the original review published in *The Cochrane Library*.

We encourage authors from all Review Groups to submit reviews of interest to general practitioners for consideration for publication. Please contact Paul Hebert, Editor in Chief, CMAJ, or Jeremy Grimshaw, Director CCNC, with the topic and timelines for your review.

To: CCInfo, 6 February 2003

From: Thilo Kober thilo.kober@medizin.uni-koeln.de [219]

Subject: Cancer <u>Treatment</u> [8] Review (CTR) Invites Cochrane reviews

The Editorial Base [103] of the Cochrane Haematological Malignancies Group (CHMG) has been approached by the biomedical journal 'Cancer Treatment Review' (CTR) to invite authors to publish their Cochrane reviews that have already appeared in *The Cochrane Library*. CTR has a long tradition of publishing and has a decent impact factor (~3.5). CTR and a previous oncology journal, Evidence-based Oncology (EBO), have merged late last year. The previous editor of EBO, Ben Djulbegovic, is now responsible for commissioning/reviewing systematic reviews for CTR. Ben is also an editor and author of the CHMG. As there is no biomedical journal specialising in systematic reviews to date, this would be a great opportunity to showcase Cochrane reviews and to enhance



promoting the accessibility of systematic reviews of the effects of health care interventions. For more information please contact Dr Djulbegovic per Email on: <u>DjulbeBM@moffitt.usf.edu</u> [220]

From: Alastair MacLennan [mailto:alastair.maclennan@adelaide.edu.au] [221]

Sent: Monday, 11 October 2004 3:14 p.m.

To: Michelle Proctor

Subject: Co-publication agreements with paper journals

Dear Michelle.

Climacteric, The Journal of the International Menopause Society, will regularly publish relevant abstracts from Cochrane reviews when submitted by the authors or review group co-ordinators with authors permission.

Climacteric also invites authors of reviews on topics related to women's long term health to submit electronically for early publication abridged reviews under 3000 words.

Climacteric is an <u>Index Medicus</u> [222] listed, peer reviewed scientific journal with the widest international circulation of any scientific journal on the menopause and related issues.

Articles are usually peer reviewed within one month and when accepted usually can have early publication.

Kind regards, Alastair

Professor Alastair H. MacLennan

Co-Editor-in-Chief CLIMACTERIC,

Department of Obstetrics & Gynaecology

Women's and Children's Hospital

Adelaide University, AUSTRALIA 5005

Extract from CCCG newsletter, 2003:

Subject: The Cochrane Library and the journal, Colorectal Disease

During the summer (2003), members of the CCCG editorial team, Andrew Renehan and Peer Wille-Jørgensen, have been in dialogue with the editors of the journal, Colorectal Disease, which in turn, unanimously voted to embrace the Cochrane philosophy, and now includes among its central aims the promotion and distribution [31] of high-quality [5] clinical evidence through systematic reviews. This initiative will be launched through an editorial in the journal early in 2004. From January 2004, Colorectal Disease will include a sub-editorial group dealing specifically with the promotion of systematic reviews and meta-analysis [104]. Peer Wille-Jørgensen, currently co-ordinating editor for CCCG, and Andrew Renehan, CCCG editor, will take the roles of senior and junior Cochrane/meta-analysis sub- editors, respectively, within the journal's editorial team.



Submissions are encouraged of reviews using various methodologies including individual patient based data; RCTs (the "usual" Cochrane review type); interventional non-randomized studies; reviews of observational studies; and reviews of studies of diagnostic test and screening. Specifically, authors of ongoing or updated Cochrane reviews within CCCG are encouraged, through the CCCG Editorial Board, to submit their reviews (in modified format) for duplicate publication in Colorectal Disease. Well-conducted systematic reviews and meta-analyses will be considered as original research and published as such. We urge CCCG editors to keep an eye out for and/or submit potential reviews.

Peer Wille-Jørgensen, Andrew Renehan

COCHRANE COLORECTAL CANCER GROUP (CCCG)

Bispebjerg Hospital,

Building 11B, 1st floor/CCCG

#23 Bispebjerg Bakke

DK 2400, Copenhagen NV

DENMARK

Telefax: (+45) 35 86 18 31

Website: <u>www.cccg.dk</u> [223]

From: Jodie Doyle, Health Promotion and Public Health Field

Sent: 4 March 2002

Subject: Health Education Journal Offers to Publish Cochrane reviews

The Cochrane Health Promotion and Public Health Field has just received a letter from the editor of the Health Education Journal, extending an invitation to Cochrane authors to publish in this journal. The editor acknowledges the copyright issues surrounding our reviews and offers the HEJ as a vehicle of dissemination rather than a holder of the copyright. This move follows in the footsteps of other well-respected journals and serves to increase the public profile of Cochrane reviews of health promotion and public health interventions.

Jodie Doyle, Field Administrator

The Cochrane Health Promotion and Public Health Field

Victorian Health Promotion Foundation

PO Box 154, Carlton South, VIC 3053, AUSTRALIA

tel: +61 3 9667 1336, fax: +61 3 9667 1375

email: jdoyle@vichealth.vic.gov.au [224]

website: www.vichealth.vic.gov.au/cochrane/ [225]



From: Taryn Young, South African Cochrane Centre

To: Jini Hetherington, Cochrane Collaboration Secretariat

Date: 17 March 2005

I wish to inform you of the Cochrane Column in the International Journal of Epidemiology [196] (IJE). I have been approached by the editors of the IJE to coordinate a 'Cochrane Column'. The aim of the Column is to highlight Cochrane systematic reviews, especially those with public health implications, and stimulate debate and comments on the relevance, feasibility (availability, accessibility, acceptability, technical skill required, etc.), how it might change practice, or barriers to changing practice. The product will be 1-2 pages in the IJE with the summary of a Cochrane review and comments by experts (clinicians, economists, policy makers) side by side. I thought that it would be good if this could be included with the list of co-publications in the Cochrane Manual.

From: Drummond Rennie, Deputy Editor, JAMA

Sent: February 2001

To: Mike Clarke, Cochrane Collaboration <u>Steering Group</u> [13]

Subject: Publishing Cochrane reviews

Dear Mike.

I have drawn your recent correspondence with Richard Horton, of the Lancet, to the attention of Dr Cathy DeAngelis, editor in chief of JAMA, and the other JAMA editors.

We, too, recognize that there is good evidence that Cochrane reviews are better than other systematic reviews and we wish to attract the best of these. We have examined our journal policies and feel that they provide very few barriers to good new Cochrane reviews at the cutting edge of medicine.

As before, JAMA welcomes systematic reviews and manuscripts from The Cochrane Collaboration, and has published these in the past. Our policy concerning such manuscripts is that, in general, we like to publish the message in JAMA before it appears in the Cochrane Library. However, we handle all manuscripts on an individual basis and are certainly prepared to consider for publication manuscripts describing reviews that have already appeared in the Library. Obviously, the message of the two reports will be the same but the two documents would have many differences. We would, of course, get peer review and usually require revision.

JAMA has an excellent record of publishing systematic reviews and we intend to continue this.

I send my best regards, Drummond.

Further information provided by Drummond Rennie on 14 January 2004:

JAMA will require that its version of the Cochrane review be published before the companion full Cochrane review is published in *The Cochrane Library*, even if this is only a few days before. JAMA will consider updates of existing Cochrane reviews only if the update contains what the journal editors would classify as very substantial new information."



Extract from CCInfo, 20 January 2005, Item D:

Sender: Victor M Montori, MD (Montori. Victor@mayo.edu [226])

Subject: JGIM Call for Cochrane reviews

I think the editorial published in the December issue of the Journal of General Internal Medicine may be of interest to all Cochranites. In this editorial (see full text below), we call for Cochrane authors to submit versions of their reviews for publication in JGIM:

Montori, Victor M., Saha, Somnath & Clarke, Mike (2004) A Call for

Systematic Reviews. Journal of General Internal Medicine 19 (12),

1240-1241. doi: 10.1111/j.1525-1497.2004.41001.x

More information about IGIM is at

www.blackwellpublishing.com/journal.asp?ref=0884-8734&site=1 [227]

Cheers, Victor.

Victor M. Montori, MD, MSc

Assistant Professor of Medicine

Division of Diabetes, Endocrinology, and Medicine

Knowledge & Encounter Research Unit

SPARC Innovation Program - Mayo E17

Mayo Clinic College of Medicine

200 First Street SW, Rochester MN 55905

Voice 507 284 2617

Fax 507 284 5745

Journal of General Internal Medicine 2004;19 (12), 1240-1241.

Blackwell Publishing, Ltd.

EDITORIAL: A Call for Systematic Reviews

In this editorial, we discuss the <u>power</u> [228] of systematic reviews and their central role in evidence-based practice, and we encourage authors of systematic reviews to submit them for publication in Journal of General Internal Medicine.

Most clinical care research studies enroll patients who represent only a narrow spectrum of those to



whom clinicians may wish to apply the results.1 Also, most studies are not large enough on their own to measure precisely all relevant patient-important outcomes, for instance, both benefits and harms of therapy. Small studies often produce indeterminate or contradictory results. One potential solution is to conduct large clinical studies enrolling a wide variety of patients and measuring all patient-important outcomes with <u>precision</u> [10].2 An alternative is to summarize and synthesize existing evidence in a systematic review.

In contrast to a nonsystematic review (i.e., the majority of narrative reviews and book chapters), a systematic review typically allows readers to appraise how the review was conducted and the evidence synthesized. Rather than being all encompassing, systematic reviews focus on a single question or a small set of closely related questions. In offering an answer, authors might decide to pool the results of individual studies using statistical techniques, a procedure called meta-analysis. Not all systematic reviews allow for such pooling. Also, not all meta-analyses pool the results of studies identified systematically. In this communication, we refer to both systematic reviews and to the meta-analyses conducted across studies included in systematic reviews.

Clinicians can trust the <u>validity</u> [9] of a systematic review to the extent that it was conducted rigorously using protocols to implement safeguards against <u>bias</u> [6] in assembling, critically appraising, and synthesizing the evidence. High quality reviews also systematically explore and explain between-study differences. Such systematic reviews may yield valid, precise, and widely applicable answers to focused clinical questions. 3 Thus, systematic reviews have come to play a central role in 1) informing clinical decisions and guidelines and 2) identifying knowledge gaps for researchers and funding agencies. Because of their power to aid both clinicians and researchers, JGIM encourages authors of systematic reviews to submit them for publication in our journal.

The idea of systematically synthesizing research evidence began to emerge in the 18th and 19th centuries. In their historical account of evidence synthesis, Chalmers, Hedges, and Cooper noted that work published as early as 1904 in England and 1907 in the United States shared features with modern meta-analyses.4 Meta-analytic techniques evolved and matured in agriculture and the social sciences and preceded the identification of mechanisms to prevent bias in research synthesis. It was in the late 1980s and early 1990s that research documented the shortcomings of narrative reviews (and of the recommendations included in them).5–7 Consequently, the number of systematic reviews and meta-analyses increased, and methodologists published criteria by which the quality of a systematic review could be judged.8,9

In 1993, an international group of authors and methodologists established the Cochrane Collaboration. 10 In 1995, they produced the first issue of the *Cochrane Database of Systematic Reviews* containing the full text of the first 36 Cochrane systematic reviews. Since the mid-1990s, the Cochrane Collaboration has promoted the methods of systematic reviews and has now prepared and disseminated more than 2000 systematic reviews of the effects of health care interventions and is endeavoring to keep all of these up to date. Researchers at York University in the United Kingdom have assembled the *Database of Abstracts of Reviews of Effects* (DARE [197]) to list all systematic reviews in health care, not just those produced by the Cochrane Collaboration.11 Both DARE and the *Cochrane Database of Systematic Reviews* are published in *The Cochrane Library* (www.thecochranelibrary.com [21]).

In 1997, the Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality; AHRQ) began funding Evidence-based Practice Centers (EPCs) to conduct systematic reviews, collected in evidence reports, to answer specific questions about clinical conditions that are common, expensive, and relevant to the Medicare and Medicaid population [190] of the United States.12 Over 100 evidence reports have resulted from this effort, conducted in 13 EPCs across North America. The summaries and complete evidence reports are available on the EPC program's website (www.ahrq.gov/clinic/epc/ [229]).

Full Cochrane reviews and EPC evidence reports are published online. The electronic publication of these reviews facilitates their maintenance by allowing authors to update them as new relevant evidence emerges. And while the Cochrane reviews are available in full text with a subscription to the Cochrane Library (or through national licenses in some countries) and the EPC evidence reports are available for free on the AHRQ website, most clinicians never access these reviews. Moreover,



clinicians who do access these reports may have difficulty using them, as they are typically very detailed and lengthy documents written for a wide audience and formatted in a way that may hinder clinicians' ability to efficiently and quickly appraise and apply their results in practice. The findings of Cochrane reviews and EPC evidence reports therefore typically reach the practicing general internist's awareness only when summarized and published in peer-reviewed clinical journals.

Why should authors submit systematic reviews to JGIM? We believe that when authors of systematic reviews (including Cochrane reviews and EPC evidence reports) prepare reports for publication in peer-reviewed clinical journals such as JGIM and adhere to journal instruction and reporting guidelines (such as QUORUM13 for systematic reviews of randomized trials or MOOSE 14 for systematic reviews of observational studies), their reviews gain in readability and their message disseminates with greater ease among the target audience. Systematic reviews published in JGIM may get additional dissemination through press releases, circulation of our table of contents by e-mail, access online via the JGIM website, and publication in secondary journals that scan and highlight high-quality articles published in JGIM (e.g., ACP Journal Club). Furthermore, JGIM authors and deputy editors may assist authors in optimizing the quality and clarity of their reports for the Journal's target audience.

In 2000, 80% of all systematic reviews were published in 11% of all clinical journals (including the Cochrane Library, which published 56% of these): 5 of the 9 reviews published in JGIM that year were rigorous systematic reviews.15 Systematic reviews published in these journals received significantly more citations than narrative reviews published in the same journals.15 Thus, both authors and journals can benefit from the publication of systematic reviews.

To further facilitate the publication of Cochrane reviews and EPC evidence reports, we have ensured that our policies regarding copyright and duplicate publication are consistent with those of the Cochrane Collaboration (www.cochrane.org/admin/manual.htm [155]) and AHRQ (personal communication, Kenneth Fink, MD, MGA, MPH, September 7, 2004). Publication in JGIM will not limit dissemination of the Cochrane review or EPC evidence report in any way. Specifically, publication of full Cochrane reviews in the Cochrane Library and EPC evidence reports by AHRQ will not disqualify manuscripts derived from those reviews from consideration by JGIM. Authors of Cochrane reviews will retain copyright. Furthermore, to the extent that a protocol or the complete review is available in the Cochrane Library, the JGIM publication will point readers to this repository, noting that this is where the full review and any updates will be available. We will encourage authors of Cochrane reviews to cite the JGIM publication in the text of their Cochrane reviews, thereby drawing the attention of readers of the Cochrane review to a publication that might be more suited to some clinicians. A similar practice of cross-citation, when possible, will alert JGIM readers to the complete EPC evidence reports in the AHRQ website.

Journal of General Internal Medicine aims to be a premier general medical journal and to continue to meet the needs of all our readers. We believe we can further our mission by publishing rigorous and useful systematic reviews of important topics relevant to our areas of focus: clinical care and health services research, patient-clinician communication, and medical education.16 Systematic reviews submitted to JGIM do not need to be limited to the assessment of effectiveness [101] of interventions; reviews of diagnosis and screening (test performance, clinical manifestations of disease, disease probability [230], and clinical prediction rules), harm and prognosis, and other aspects of potential relevance to our readers are welcome. We look forward to the opportunity to consider your systematic reviews for publication in JGIM.

VICTOR M. MONTORI, MD, MSc, Mayo Clinic College of Medicine, Rochester, Minn; SOMNATH SAHA, MD, MPH, Portland VA Medical Center and Oregon Health & Science University, Portland, Ore; and MIKE CLARKE, DPhil, UK Cochrane Centre, Oxford, England.

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From: Jeremy Grimshaw, Co-ordinating Editor, EPOC Group

Sent: 23 June 2000

To: CCInfo

Subject: Agreement for co-publication in JHSRP and *The Cochrane Library*



The editors and publisher of the Journal of Health Services Research and Policy (www.lshtm.ac.uk/php/hsru/jhsrp/j-aims.htm [232]) have agreed to co-publication of Cochrane reviews (as outlined in section 2.3 of the Cochrane Handbook [54]).

Best wishes, Jeremy

From: Gregory Lip [mailto:g.y.h.lip@bham.ac.uk] [233]

Sent: 20 October 2004 13:53

To: mclarke@cochrane.co.uk [216]

Cc: h.g.maxwell@ed.ac.uk [234]; Gareth Beevers (E-mail)

Subject: Journal of Human Hypertension and Cochrane

Dear Mike,

I am writing to extend an invitation to submit Cochrane reviews to the Journal of Human Hypertension for publication. Gareth Beevers (Editor in Chief) and I (as Editor) anticipate that the arrangements would be similar to those of Lancet in that we would be interested in parallel publication of course, but also submission of completed and approved Reviews published in *The Cochrane Library*.

We would also require the manuscript to transit our peer-review process and be revised accordingly. In addition, JHH reviews are edited to ensure their content reads well. Therefore the final paper might be quite different from the original manuscript and Cochrane review, to which we would of course make full reference. Please feel free to contact me should you have any questions, and I look forward to helping to share relevant Cochrane reviews with the larger hypertension community.

For JHH website, see www.nature.com/ihh [235]

King regards, Greg.

Gregory YH Lip

Consultant Cardiologist and Professor of Cardiovascular Medicine

Director - Haemostasis Thrombosis & Vascular Biology Unit

Editor - Journal of Human Hypertension

University Department of Medicine

City Hospital

Birmingham B18 7QH

England UK

From: Barnett S Kramer, Editor-in-Chief, Journal of the National Cancer Institute



To: Prof Andreas Engert

Date: 1 October 2003

Prof Andreas Engert

Cochrane Haematological Malignancies Group

Klinik I für Innere Medizin

Universitätsklinikum Köln

50924 Köln

Germany

Dear Prof. Engert:

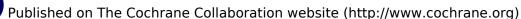
Thank you for your letter of 12 September proposing a collaboration between the Cochrane Haematological Malignancies Group (CHMG) and the JNCI. Indeed, we are very interested in the collaboration you propose and would be happy for the CHMG to submit completed and approved Cochrane reviews to JNCI for possible publication. As you note, the actual publication decision would depend on the outcome of the review process. However, I would commit to sending all such submissions for full peer review - that is, they would not be subject to editorial board rejection in advance of peer review.

I do have several questions about the process you envisage. First, I want to be sure that a review that is submitted to JNCI will not be submitted to any other journal at the same time that it is under consideration at JNCI. Second, I believe that full versions of Cochrane reviews are available online only through the Cochrane library, and I want to be certain that online publication of the JNCI version of any Cochrane review (and, as you note, these will differ) will not violate any of Cochrane's provisions. Third, could you clarify the relative timing of publication—would the Cochrane review appear before the JNCI version, or would mechanisms be established to publish the two versions simultaneously?

We would also be interested in the biannual report of recent ongoing and published randomized controlled trials from the CHMG Specialised <u>Trials Register</u> [58]. Are there any restrictions on what we can do with this report? For example, it might be something that we would include online only as part of JNCI Cancer Spectrum (which includes not only the online version of JNCI but also many other contents as well—including, as you may know, abstracts of Cochrane reviews relevant to cancer). Would this approach to publishing the report be acceptable to CHMG and the Cochrane Collaboration?

We agree that a collaboration between JNCI and CHMG will be beneficial to both the Journal, in giving it access to high-quality systematic reviews, and the CHMG, in disseminating the reviews as widely as possible. Thank you for proposing the collaboration, and I look forward to working with you.

Yours sincerely, Barnett S Kramer, Editor-in-Chief, Journal of the National Cancer Institute





From: Debbie Morton, Cochrane Neurological Network

Sent: 10 October 2002

To: CCInfo

Subject: Publishing policy revised in response to Cochrane efforts

The Journal of Neurology, Neurosurgery and Psychiatry (JNNP) was approached by a team of neurological Cochrane collaborators in June with a proposal aimed at persuading the Journal to revise its publishing policy to allow for the acceptance of Cochrane reviews. In July, the Journal notified Dr. Carl Clarke, reader in clinical neurology and consultant neurologist for the University of Birmingham, that his efforts in spearheading the campaign together with the Cochrane Neurological Network and other Cochrane collaborators had been successful. The Journal's editorial board agreed to revise its policy to allow Cochrane reviews to be considered for publication, provided they be edited for length and readability.

Additionally, the Journal took interest in the concept of a 'Cochrane Corner'*** proposed by Professor Peter Sandercock, co-ordinating editor of the Cochrane Stroke Group. The Journal agreed to a revised 'evidence-based corner' to be published in each month's issue, similar to the one recently introduced in the journal, 'Stroke'. The evidence-based corner will provide a brief summary of an evidence-based review along with critical comments by an author. It will appear in each month's issue and will span two pages.

Debbie Morton, Cochrane Neurological Network, Milan, Italy

***Extract from Neurological Network Newsletter - September 2006:

Each corner will consist of a summary of a neurological review from *The Cochrane Library*, to be selected by Neurological Network member Maria Grazia Celani, who will co-edit the corner together with Peter Sandercock, another member of the Neurological Network and the Co-ordinating Editor of the Cochrane Stroke Group. Graeme Hankey, an advisory board member of the Neurological Network, will provide editorial consultation. Once a selection is made on which review to summarise for a given issue, the corresponding review author will be invited to write the summary. The co-editors will be in charge of editing the summary and submitting the final version to the JNNP for publication.

From: Peter Tugwell, Co-ordinating Editor, Musculoskeletal Group

Sent: 18 September 2002

To: DA Gordon, Journal of Rheumatology, 920 Yonge Street, Suite 115, Toronto, On,

Canada M4W 3C74

Re: Simultaneous publication of Cochrane reviews

in The Journal of Rheumatology

Thank you for the confirmation of your support of the arrangements to submit our Cochrane reviews simultaneously to The Journal of Rheumatology and the Cochrane Library. This letter is to ensure that we are clear on the process.

As discussed, upon submission we will send you:



- 1) A cover letter endorsing the Cochrane review
- 2) Copies of two external referees' assessments of the Cochrane review
- 3) Four copies of the Cochrane review, including tables and graphs, as well as an electronic copy on disk as per The Journal of Rheumatology author guidelines.

We understand that Cochrane reviews submitted by this process will not normally be peer-reviewed again, and the time frame for publication may vary from time of submission but will usually be between three to six months. In *The Cochrane Library* the Cochrane review will cite The Journal of Rheumatology as a co-publication when posted (or cited as "in press" if posted prior to print publication). We anticipate that The Journal of Rheumatology might receive approximately 8 Cochrane reviews for publication a year.

Many thanks for your ongoing support of The Cochrane Collaboration and, in particular, the Cochrane Musculoskeletal Review Group.

Sincerely, Peter Tugwell.

From: James Scott, MD, Editor, Obstetrics and Gynecology

Sent: February 2001

To: Mike Clarke, Cochrane Collaboration Steering Group

Subject: Publishing Cochrane reviews

I am writing to extend an invitation to submit Cochrane reviews to Obstetrics & Gynecology for publication. The arrangements would be similar to those of Lancet and JAMA. We would be very interested in any reviews that involve any aspect of women's health care. I am the new Editor of Obstetrics and Gynecology that has the largest readership of any journal in our specialty. If you have any questions, I would be happy to talk with you at any time.

You can contact me at: Obstetrics & Gynecology, 420 Chipeta Way, Suite 100, Salt Lake City, UT 84108.

Jim Scott

From: Joy Oliver, South African Cochrane Centre

Sent: 11 January 2002

To: CCInfo

Subject: South African Medical Journal

We are delighted to announce that the Editorial Board of the South African Medical Journal (SAMJ) has agreed to co-publication of Cochrane reviews (new and updates) in the journal, an arrangement that is similar to the Lancet editorial policy that was announced in the middle of last year. The SAMJ announcement is contained in the January issue of the journal (SAMJ 2002 January;



92(1): 1). We encourage all authors to consider submitting their reviews for publication in the SAMJ in order to promote dissemination of reviews to a wider audience in South Africa and beyond.

From: Dr Graeme J Sankey, Associate Editor, Stroke

To: Professor Peter Sandercock

Date: 25 August 2000

Subject: Cochrane feature in 'Stroke'

Professor Peter Sandercock

Professor of Medical Neurology

Coordinating Editor, Cochrane Stroke Group

Department of Clinical Neurosciences

Western General Hospital NHS Trust

Crewe Road

Edinburgh EH4 2XU

Dear Peter

Thank you for your letter dated 6th June, 2000 in which you follow-up [116] on our initial discussion at the European Stroke Conference in Vienna about the proposal to publish a regular quarterly feature in the Stroke Journal entitled "Cochrane Library Update". It is proposed new reviews or substantive updates of existing reviews that have been published in full by the Cochrane Stroke Group as part of the Cochrane Library Update could also be published in short form in Stroke, with the content being either the abstract, implications for practice and implications for research, and a single figure (generally the effect of the intervention on the primary measure of outcome) or alternatively a short newsletter-style piece with a short report or commentary on recent new reviews or updates.

We will also consider whether any spare space on the Cochrane Library Update page in the Journal could be allocated for giving notice of forthcoming activities (e.g. workshops) and relevant website addresses.

Of course, full text articles derived from the Cochrane reviews, but abbreviated, may also be submitted for publication in Stroke as original articles and follow the usual peer review process.

Finally, as the Stroke Journal is one of a family of journals under the direction of the American Heart Association, we will liaise with our editorial colleagues from the journal Circulation and explore whether the Cochrane Heart Group may be able to seek a similar arrangement with Circulation.

Yours sincerely, Dr Graeme J. Hankey, Associate Editor/Stroke



From: Jenny Bellorini, Review Group Co-ordinator, Cochrane ENT Group

To: All Cochrane ENT Group authors and co-authors

Date: 26 November 2001

Subject: Co-publication of reviews in ENT journals

Dear colleagues

Further to my e-mail message of 15th June regarding the interest of the Lancet and JAMA in receiving manuscripts of Cochrane reviews for consideration for co-publication, I am pleased to be able to tell you that the following ENT journals have now also indicated their interest in co-publishing Cochrane reviews:

The Journal of Laryngology and Otology

The International Journal of Pediatric Otorhinolaryngology

HNO

The Journal of Audiological Medicine

Cochlear Implants International

The Cochrane Collaboration actively encourages wider dissemination of its reviews through co-publication in print journals. The only requirement is that Cochrane reviews must remain free for dissemination in any and all media, without restriction from any of them and therefore Cochrane authors may not sign over exclusive copyright to any journal or other publisher. If a review is published in a journal, it should also be stated that a fuller and maintained version of the review is available in the Cochrane Library. Other than these requirements, it is expected that any Cochrane review submitted to a journal would be subject to that journal's full peer review process and, for editorial or content reasons, may differ from the version published in *The Cochrane Library*.

Instructions for authors for most of the above journals can be obtained from me at the Cochrane ENT Group editorial base.

I will keep you informed of similar expressions of interest from other ENT journals.

Best wishes

Jenny Bellorini

NOTE: The editor of Clinical Otolaryngology and Allied Sciences has since expressed an interest.

APPENDIX 2: Monitoring and Registration Committee

Subheadings in this section

A2.1. Introduction

The Cochrane Collaboration is an international charity with a largely decentralised organisational structure including over 90 entities [20] on five continents. Observing a set of ten principles, it has



established an international reputation for <u>independent</u> [177], unbiased, high <u>quality</u> [5], systematic reviews of healthcare interventions, and collectively receives funding that annually runs into millions of pounds.

As the Charity's board of directors, the members of the <u>Steering Group</u> [13] need to ensure that:

- The Cochrane Collaboration's objectives as a charity are being met;
- The income and expenditures of its entities are accounted for;
- Each entity is operating effectively, efficiently and is capable of fulfilling its core functions;
- Each entity is operating in accordance with established principles and procedures;
- The high standards of The Cochrane Collaboration are maintained as it grows;
- The members of the board of directors are kept informed of the current status and capacity of the entities comprising The Cochrane Collaboration, enabling them to make evidence-based policy decisions.

In order to do this a Monitoring and Registration Committee was established in 1999 as a sub-group of the Steering Group, to whom it is accountable.

A2.2. Core functions of the Monitoring and Registration Committee

The Monitoring and Registration Committee has five core functions:

Establishing and implementing processes for registering entities [20].

Establishing and implementing processes for monitoring entities.

Establishing and implementing processes for notification and approval of changes in entities.

Making recommendations to the full <u>Steering Group</u> [13] about the registration, monitoring and de-registration of entities.

Facilitating <u>quality</u> [5] improvement through the recognition and encouragement of 'best practices'.

A2.3 Composition of the Monitoring and Registration Committee

The Monitoring and Registration Committee (MaRC [30]) consists of two Co-Convenors and seven or eight members. One of the Co-Convenors must be a member of the Steering Group [13]. Both Co-Convenors must be nominated by the Co-Chairs of the Steering Group and approved by the full Steering Group. Members of the MaRC are proposed by the entity Executives to the MaRC Co-Convenors and approved by the full Steering Group. (If the MaRC member proposed is not a member of the entity Executive, a good communication plan should be in place.) The MaRC consists of at least two Cochrane Review [22] Group (CRG [15]) representatives, a Field representative, a Methods Group representative, a Centre [34] representative, and a Consumer Network representative (some of whom will be members of the Steering Group). Non-elected members will be appointed as required; these appointments also require the approval of the full Steering Group. The Editor in Chief is a non-elected member of the MaRC because of the potential for overlap relating to CRG issues.



A2.4 Objectives of the Monitoring and Registration Committee

The Monitoring and Registration Committee has six objectives:

- 1. To provide the <u>Steering Group</u> [13] with reliable information on an annual basis concerning the development, performance, achievements, productive capacity, financial status and morale of the <u>entities</u> [20] in The Cochrane Collaboration.
- 2. To help ensure adherence to the core principles of The Cochrane Collaboration.
- 3. To help maintain agreed standards in the organisation, methods and output of registered Cochrane entities.
- 4. To help prevent foreseen difficulties faced by, or facing entities and to identify entities which might be experiencing difficulties.
- 5. To identify entities to the Steering Group which are faced by or will be facing difficulties, and help to forestall potential problems
- 6. To provide feedback to the Steering Group related to common issues which are faced by or will be facing entities.

A2.5 Registration

Subheadings in this section

A2.5.1 Objective of the registration process

The objective of the registration process is to determine the viability and eligibility of each new entity applying for registration with The Cochrane Collaboration against a set of agreed criteria.

A2.5.2 Registration criteria

The criteria for registration reflect the core principles and objectives of The Cochrane Collaboration, as outlined in its <u>mission statement</u> [3]. The criteria are that:

- The proposed entity is relevant to health care.
- The proposed entity will further The Cochrane Collaboration's objectives.
- The proposed entity has the capacity and resources to fulfil its core functions.
- The proposed entity will not be duplicating the efforts of existing Cochrane entities [20].
- The proposed entity will have the full support of relevant Cochrane entities.
- The proposed entity is not dominated by a single individual, discipline, profession or national group.
- The individuals involved have the skills and resources likely to ensure the success of their entity.
- The individuals involved recognise the high level of personal commitment and enthusiasm needed to ensure the success of their entity.
- The individuals involved undertake, on behalf of the entity, to abide by the principles of The Cochrane Collaboration.



A2.5.3 Registration process

The Monitoring and Registration Committee has agreed to evaluate the current registration requirements (Annex A2.A [236]). The way that entities [20] prepare for registration is different for each type of entity, and the steps necessary for preparation of a registration application are described in the relevant entity chapters (section 3 [237]) in the Manual. The current process for new registrations, after the initial preparation has taken place, is outlined and illustrated in Annex A2.B [238].

A2.5.4 Ongoing registration issues

Once an entity has been registered, its representative on the Monitoring and Registration Committee facilitates any further developments in the entity's status. This includes, for example, dealing with relocation of entity bases, changes of Directors/Co-ordinating Editors/Convenors or significant reductions in resources. Major changes require either the approval of the Monitoring and Registration Committee or (where this is inappropriate) that the Monitoring and Registration Committee is informed without delay. Entities [20] are requested to inform the Monitoring and Registration Group of minor changes through the monitoring process. A guide to changes that are classed as 'major' or 'minor', and the notification status of these changes, is provided in Annex [239].

A2.6 Monitoring

Subheadings in this section

A2.6.1 Objectives of the monitoring process

The monitoring process has the following objectives:

- 1. To provide the <u>Steering Group</u> [13] with reliable information on an annual basis concerning the performance, achievements, capacity, financial status and morale of the <u>entities</u> [20] constituting The Cochrane Collaboration.
- 2. To identify and assist entities which seem to be having particular difficulties in meeting their objectives.
- 3. To identify common barriers and facilitators faced by entities, to guide Steering Group initiatives.
- 4. To identify at an early stage any obstacles to achieving the mission of The Cochrane Collaboration.
- 5. To identify areas of Cochrane activity where policy outlined in *The Cochrane Policy Manual* needs to be either formulated or reviewed by the Steering Group.
- 6. To identify areas of best practice which might usefully be shared with other entities within The Cochrane Collaboration.
- 7. To provide feedback to entities on their achievements.

A2.6.2 Principles of monitoring



The monitoring process is conducted according to the following six principles:

- 1. Participation and full engagement with the monitoring process is a mandatory requirement of registered and approved Cochrane entities [20].
- 2. Entities are not in competition with one another; rather, they are encouraged to set their own targets.
- 3. Peers within The Cochrane Collaboration monitor the performance and productivity of entities.
- 4. The Monitoring and Registration Committee strives at all times to be supportive and helpful in its dealings with entities.
- 5. Access to monitoring documents is restricted in order to preserve the confidentiality of the monitoring process.

A2.6.3 Monitoring process

The Monitoring and Registration Committee works to a timetable that is reviewed every year, as follows:

January

Entities [20] are sent their monitoring forms biannually. In odd years, Review Groups are fully monitored, whereas Centres, Fields, and Methods Groups are financially monitored. In even years, Centres, Fields and Methods Groups are fully monitored, whereas Review Groups are financially monitored. As the Collaboration needs basic information each year for planning and reporting purposes, entities not being fully monitored in a particular year will still be required to complete a financial form which should be returned to the Secretariat [1]. It is hoped that the inclusion of this form will provide a 'safety net' to ensure that the Monitoring and Registration Group does not fail to notice a threat to an entity's existence in the two-year interval between full monitoring.

March

Entities are expected to return their monitoring forms to the Secretariat.

April

The Monitoring and Registration Committee support person allocates the monitoring forms to pairs of Monitoring and Registration Group members; one person is the Lead, the other is the Checker. The Lead is responsible for reviewing the response against last year's self-set targets for the entity, and for writing the first draft of the entity's report. Once the Lead has completed the report, she/he sends it to the Checker in time for the review of the current year's entity monitoring form. The Checker is responsible for commenting on the draft report prepared by the Lead. Both the Lead and the Checker read all parts of the form, although it is usual that only comments on parts A and B are included in the report that is sent to the entity.

May

The monitoring teams complete the first drafts of the monitoring reports. The Leads return these draft reports to the Monitoring and Registration Committee support person.

June

The Monitoring and Registration Committee meets face-to-face to review all draft entity reports. Amendments are made, common themes are identified and, where necessary, new policy suggestions are drawn up for presentation to the Steering Group [13] at its next meeting. Each entity about which the Monitoring and Registration Committee is concerned will be assigned a member of the Monitoring and Registration Committee to stay in regular contact with the entity



to offer support, and this member of the Monitoring and Registration Group will provide a verbal report on the entity's progress in the non-monitoring year.

June - July

The Monitoring and Registration Committee support person incorporates the changes made at the face-to-face meeting, and circulates the final draft reports to the Monitoring and Registration Committee. The Leads and Checkers are responsible for ensuring that the comments made at the meeting have been incorporated into the draft final reports. When these drafts have been finalized the reports are e-mailed to the entities concerned, with a letter inviting a

response.

August/September Entities respond to the monitoring reports if there are questions to be

answered, and agreed reports are sent to the relevant Centre

Director(s).

October The Monitoring and Registration Committee meets briefly face-to-face

during the annual Cochrane Colloquium. Also, the Convenor(s) present the Monitoring and Registration Committee's report to the Steering Group at their meeting during the Colloquium. Extracts from the report may be included in the Steering Group's progress report to

The Cochrane Collaboration's Annual General Meeting.

December If necessary, the Monitoring and Registration Group revises the

monitoring forms in response to the comments made by entities

during the annual monitoring process.

In between its twice-yearly meetings the Monitoring and Registration Committee communicates mostly by e-mail and occasionally by teleconference.

A2.6.4 Criteria for monitoring

The criteria and forms used to monitor the progress, performance and productivity of <u>entities</u> [20] varies according to the type of entity (<u>Annex A2.D</u> [240]). However, they are broadly based upon entities' core functions, resources and the achievement of self-set targets. These criteria include:

- Is the entity fulfilling its core functions?
- Are the targets realistic and achievable?
- Are the targets being met?
- Does the entity have sufficient funding for future activity, future targets and satisfactory performance?
- Is the entity meeting the requirements of Cochrane Collaboration policies outlined in *The Cochrane Policy Manual?*
- How productive is the entity?
- Has the entity completed the monitoring report satisfactorily in terms of completeness, <u>quality</u> [5] of response and ability to perform?
- Is the entity progressing satisfactorily given its stage of development, existing resources and stated targets?

A2.6.5 Criteria for identifying entities about which the Monitoring and Registration Committee should be



concerned

Part of the remit of the Monitoring and Registration Committee is to identify <u>entities</u> [20] that seem to be experiencing particular difficulties in meeting their objectives. The criteria for defining such an entity are as follows:

- The entity says that it is experiencing particular difficulties.
- The entity fails to meet its self-set targets in fulfilling its core functions.
- There are internal problems within the entity.
- The entity has not provided sufficient information (e.g. by not completing its monitoring form) for the Monitoring and Registration Committee to assess whether any of the above apply: this might also be an indication that the entity is experiencing particular difficulties.
- The entity does not have secure funding for the next twelve months.
- The entity is facing substantial changes.

A2.6.6 Strategies to help those entities experiencing particular difficulties

Cochrane Centres have a responsibility to support the Cochrane entities [20] located in those countries for which they act as a reference Centre. Once an entity that appears to be experiencing particular difficulties has been identified, the Monitoring and Registration Committee alerts the Centre Director(s) of the reference Cochrane Centre to the potential or actual problem. It is then the responsibility of the Centre Director(s) to determine what steps, if any, can be taken to provide additional support to the entity.

If the Monitoring and Registration Committee is concerned about a Cochrane Centre, it informs the Co-Chairs of the <u>Steering Group</u> [13] and the Director(s) of the Centre. It is the responsibility of the Co-Chairs to decide what steps should be taken to provide additional support to the entity.

A2.6.7 Examples of good practice

The Monitoring and Registration Committee asks <u>entities</u> [20] to contact the relevant Cochrane entities or Advisory Groups with examples of good practice (if they have not already done so), to share the information with other entities to facilitate <u>quality</u> [5] improvement.

A2.7 De-registration of an entity

The Monitoring and Registration Group has the responsibility of recommending the de-registration of an entity to the full <u>Steering Group</u> [13]. This is a very rare occurrence and will only happen when all other possible alternative courses of action have been exhausted, and will only be decided upon by the whole Steering Group.

The de-registration process has two objectives:

The Monitoring and Registration Committee has the responsibility of recommending the de-registration of an entity to the full Steering Group. This is a very rare occurrence and will only happen when all other possible alternative courses of action have been exhausted, and will only be decided upon by the whole Steering Group.

The de-registration process has two objectives:



- 1. To provide the opportunity either for a new entity to be formed which might have a better chance of fulfilling a defunct entity's role, or to facilitate the transfer of functions to another entity/other entities [20].
- 2. To safeguard the mission of The Cochrane Collaboration.

A2.7.1 Principles of de-registration

The de-registration process is based on the following principles:

- De-registration of a Cochrane entity is a last resort.
- De-registration does not necessarily reflect upon either the ability or the integrity of the members of an entity.
- The decision to de-register an entity requires discussion and agreement by the full Steering Group [13], based upon a report from the Monitoring and Registration Committee, supported by compelling evidence.

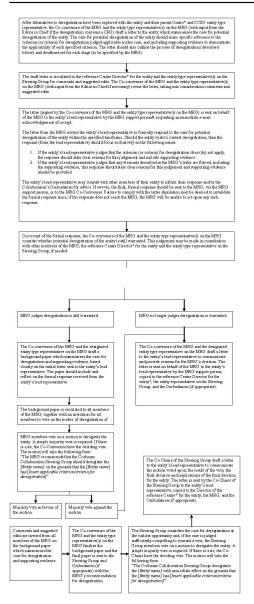
A2.7.2 Criteria for de-registration

The four criteria for de-registration rest upon the core principles of The Cochrane Collaboration, and its objectives as outlined in its mission statement. Any one of the four criteria could lead to deregistration. The four criteria are that:

- 1. Either an entity is no longer able to function (e.g. to fulfil its core functions) or funding ceases leading to an inability to function and the entity has no reasonable likelihood of being able to function in a timeframe specified by the Monitoring and Registration Group'; or
- 2. There is persistent failure to provide evidence of core function activities to the Monitoring and Registration Committee; or
- 3. An entity is in contravention of the principles of The Cochrane Collaboration such that a continued relationship cannot be sustained; or
- 4. An entity is bringing The Cochrane Collaboration into disrepute to the extent that a continued relationship cannot be sustained.

A2.7.3 Process for de-registration

Process by which the Monitoring and Registration Group (MRG) recommends to the <u>Steering Group</u> [13] that an entity be deregistered (as a result of the monitoring process and if one of the criteria for deregistration is met:



*If the entity involved is a Cochrane <u>Centre</u> [34], the Steering Group will take the place of the reference centre in any discussions.

#The MaRC [30] support person is currently the Deputy Administrator of the Secretariat [1], providing administrative support to the MaRC.

Annex A2.A: Requirements for registration by type of entity

Checklist for registering a new Centre

Those proposing the **Centre** [34] should:

I General issues

1. Have demonstrated both an enthusiasm for, and a basic expertise in, performing systematic reviews. It is essential for at least one person from the Centre participate as an author in a registered Cochrane Review [22] Group.



- 2. Suggest which countries/states/geographic regions it is willing to support, after consultation with the Cochrane Centre(s) currently responsible for the area
- 3. Show that there are reasonable numbers of registered authors or editors to be served in the region, or that the proposed Centre is of importance to the Collaboration for other reasons (e.g. because many new trials have been published in a language which is not currently dealt with adequately, or because of geographical distances, or if there is a major source of potential authors).
- 4. Show that it has an advisory board, including at least one consumer representative.
- 5. Ascertained a commitment of funding for the Centre to become self-supporting.
- 6. Reflect the Cochrane spirit of unselfish collaboration and indicate a task of service to the entire Collaboration that the Centre plans to undertake.
- 7. Submit a <u>strategic plan</u> [14] for activities and goals as part of the application. The plan should particularly focus on activities in support of Authors, Editors, Managing Editors, handsearchers and members of Fields and Methods Groups in the region, i.e. training of authors and editors.
- 8. Show the commitment to prepare an annual report which contains a strategic plan for the next twelve months.
- 9. If possible, identify a contact person in each country where there are persons listed in Archie (the Collaboration's Information Management System), who will be responsible for local Cochrane activities as part of a formal or informal Cochrane Network affiliated with the new Centre.
- 10. The combined FTE should be at least 50% to work for the Collaboration, and it is recommended that within 12 months of registration, the Centre should have the equivalent of at least three full-time persons on its staff The time commitment for the staff should be made explicit in the application.
- 11. Include a draft module [102] (according to the specific format that describes the Centre) and a list of targets as part of the application to register with the Collaboration

II Ability to meet core functions

- 1. Be able to provide local training and support for review authors, editors, handsearchers, and other contributors to The Cochrane Collaboration in performing systematic reviews and having demonstrated sufficient training skills.
- 2. Be able to handsearch general healthcare journals in the linguistic area of the Centre and to submit the search results to the Collaboration's trial database.
- 3. Be able to provide help with software and methodological difficulties (in consultation with the IMS team and Methods Groups), and advice on search strategies.
- 4. Show that you are able to raise funding to (a) become self supporting and sustain their progress, and (b) to assist Cochrane entities [20] in their region of responsibility.

III Evidence of support from The Cochrane Collaboration and local key organisations (credibility)

- 1. Provide evidence of support from relevant individuals and entities in the proposed region, especially from Cochrane Review Groups, other people listed in Archie (the Collaboration's contact database), and from the other Cochrane Centre(s) currently responsible for the geographic area.
- 2. Be in a position to advocate for the Centre and The Cochrane Collaboration in the countries for which it is responsible and to include letters of support from key organisations.
- 3. Obtain and attached a letter of endorsement from the Chair of the Centre Directors' Meeting, letters of support from all entities in the countries for which you will be responsible, and a letter of support from the hosting institute.

Checklist for registering a new Cochrane Review Group (CRG)



A CRG [15] applying for registration will have:

1. Scope

1. Defined a scope that is sufficiently broad (e.g. covers prevention, acute <u>treatment</u> [8] and rehabilitation); and considered potential duplication with existing CRGs.

2. Editorial base [103]

- 1. Identified the geographical location for an editorial base.
- 2. A co-ordinating editor who can spend at least 0.1 FTE fulfilling this role.
- 3. Ascertained a commitment of funding to employ a Managing Editor, Trials Search Co-ordinator and secretarial support. These roles may be fulfilled by one or more people, but should amount to at least 1.0 FTE.
- 4. Ascertained a commitment of funding to provide resources at the editorial base (e.g. computers, photocopying, travel, and training).
- 5. Made plans for supporting its members, (authors, consumers, editors, etc), including those who communicate in other languages.

3. Editorial board and contributors

- 1. Editors who are willing to give enough time to fulfil the editorial functions of the CRG.
- 2. A majority of editors who have already prepared or are preparing a Cochrane review [22].
- 3. Identified a statistical adviser and a feedback editor.
- 4. Multidisciplinary and global representation, in the editorial team and among the authors, including plans to involve people from developing countries.
- 5. Members who are willing to participate on a voluntary basis, or not through core funds (e.g. authors).
- 6. Made specific preliminary plans to involve consumers and liaise with the Consumer Network.
- 7. A plan to ensure that its reviews are of high quality [5].

4. Specialised register [58]

- 1. Made specific preliminary plans to develop a <u>search strategy</u> [178] and establish a specialised register of studies, including plans for translation.
- 2. Determine how authors will be informed of the results of searching the entity's Specialized Register.

5. Targets

1. A strategic or business plan that includes appropriate targets (e.g. dates for staff to start work dates first protocols and reviews expected).

6. Process

- 1. Have obtained and attached a letter of endorsement from your reference Cochrane <u>Centre</u> [34] and letters of support from relevant <u>entities</u> [20] with which it is likely to collaborate.
- 2. Held at least one formal exploratory meeting, including a member of the Monitoring and Registration Committee (i.e. a <u>MaRC</u> [30] representative should be invited to attend either in person, by VOIP, or by teleconference, but if they cannot attend, the registration process and a provisional agenda for the meeting(s) should be discussed with the relevant MaRC representative(s) in advance).
- 3. Prepared and attached a draft module [102].

Checklist for registering a new Field

The following checklist (for registering new Fields or <u>Networks</u> [27]) is based upon the current information in Section 3 of *The Cochrane Policy Manual* (updated in February 2004), and the following document represents the amendments thought appropriate to the changes to the core functions for Fields and Networks which were implemented at the Barcelona Colloquium in October 2003.

Those proposing the Field should:



- 1. Ensure that the proposed Field reflects a health care setting, category of consumer or other grouping of interventions that encompasses more than one <u>Cochrane Review</u> [22] Group.
- 2. Explain why it is thought necessary to form the Field within The Cochrane Collaboration.
- 3. Ensure that if the health area is not sufficiently covered by existing Fields, letters of support are provided by those Fields whose scope could potentially overlap with the proposed Field.
- 4. Include plans to address the following core functions that are required of Fields:
 - 1. Ensure effective and efficient communication between Field members and members of other <u>entities</u> [20] within The Cochrane Collaboration.
 - 2. Contribute to maintaining Archie (the Collaboration's Information Management System).
 - 3. Create and maintain a Field module [102] at least on an annual basis.
 - 4. Ensure sustainability and continuity of the Field's programme of work.
 - 5. Identify relevant trials and make them accessible through a <u>specialised register</u> [58].
 - 6. Ensure the proper representation of its specialist area of health care in Cochrane Review Groups.
 - 7. Act as a liaison point between the entities within The Cochrane Collaboration and its specialist area of health care.
 - 8. Promote the accessibility of Cochrane reviews in its specialist area of health care.
 - 9. Help identify appropriate funding opportunities for Cochrane reviews.
- 5. Include a clearly documented action plan as to how the core functions will be addressed over a realistically defined time-period (e.g. one to three years).
- 6. Include details of at least one exploratory meeting of those individuals with an interest in the Field and/or support from the relevant Cochrane Review Groups who have collectively agreed to the concept of registering the Field within the Collaboration. This meeting should include a representative from the Monitoring and Registration Committee (i.e. a MaRC [30] representative should be invited to attend, but if they cannot attend, either in person, by VOIP or by teleconference, the registration process and a provisional agenda for the meeting(s) should be discussed with the relevant MaRC representative(s) in advance).
- 7. Identify an individual (or group of individuals) who are prepared to take responsibility for co-ordinating the broad range of tasks, which may need to be undertaken by Field Co-ordinators.
- 8. Ascertain a commitment of funding and resources required to establish and maintain activities within the Field. Are these resources available (or are strategies in place to secure such resources)?
- 9. Include details of an Advisory Group (or plans for one) comprising individuals who would be acceptable to a broad representation of people within and affected by the Field (including consumers).
- 10. The proposal is in accordance with the principles of The Cochrane Collaboration and any guidelines or other requirements it currently has in place.
- 11. Have obtained and attached a letter of endorsement from its reference Cochrane Centre [34] and letters of support from relevant entities with which you are likely to collaborate.
- 12. Prepared and attached a draft module.

Checklist for registering a new Methods Group

In their registration application, the proposed Methods Group must specify which elective core functions (if any) will be adopted for the first two-year period in addition to the three core functions that apply to all Methods Groups. Only those sections of this checklist that are applicable to the three core functions that apply to all Methods Groups and to specified elective core functions are used to assess the registration application.

Process



- 1. Is the Methods Group dealing with a substantial methodological issue not already under investigation within The Cochrane Collaboration?
- 2. Is the methodological area a core topic relevant to all or a subset of Cochrane Reviews, or an area of new methodological development which may influence the way in which Cochrane Reviews will be undertaken in the future?
- 3. Has the Methods Group contacted the reference Cochrane <u>Centre</u> [34] (to ensure linkage to other interested individuals), and obtained a letter of support?
- 4. Has the Methods Group held at least one exploratory meeting involving relevant members of The Cochrane Collaboration, including a representative from the Monitoring and Registration Committee (i.e. a MaRC [30] representative should be invited to attend, either in person, by VOIP or by teleconference, but if they cannot attend, the registration process and a provisional agenda for the meeting should be discussed with the relevant MaRC representatives in advance)?
- 5. Has the Methods Group provided a draft <u>module</u> [102] and an outline of the proposed focus of its activities and outputs against its proposed core functions for at least the first two years post-registration?
- 6. Has the Methods Group provided letters of indicative support from relevant individuals and entities [20] within The Cochrane Collaboration with related scope and responsibilities?
- 7. Has the Methods Group agreed its elective core functions with the Methods Executive?

Core functions

Providing policy advice

- 8. Will the Methods Group respond to requests from the Handbook [54] Editorial Advisory Panel (HEAP) or Methods Board to produce or update material relevant to their aims and scope for inclusion in the relevant sections of the Cochrane Handbook [55] for Systematic Reviews of Interventions, and/or the Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy within a reasonable time period?
- 9. For methods innovations and developments, will the Methods Group produce interim reports for dissemination and discussion throughout the Collaboration?
- 10. Will the Methods Group respond to requests channelled through the Methods Board or the Methods Executive, or received directly from Cochrane Review Groups (CRGs) to provide methodological advice intended for use to inform Cochrane Collaboration policy (including the policies of individual CRGs)?

Serving as a forum for discussion

- 11. Will the Methods Group hold appropriate forums for discussion and disseminate the outcomes appropriately?
- 12. Will the Methods Group implement an e-mail discussion or distribution [31] list for its members?

Ensuring that the Group functions as part of The Cochrane Collaboration



- 13. Will the Methods Group ensure effective communication between members of the Group and other Cochrane entities?
- 14. Will the Methods Group ensure its module is updated at least annually and the convenors' and co-ordinators' contact details are up to date in Archie (the Collaboration's Information Management System)?
- 15. Will the Methods Group instigate a plan to ensure the sustainability and continuity of the Group as long as there is a programme of work to be completed?

Providing training (if applicable, elective core function)

- 16. Will the Methods Group submit proposals to provide methods training workshops at colloquia?
- 17. Will the Methods Group respond to requests made by the Training Working Group, Cochrane Centres and/or the Methods Board to develop and provide methods training materials for contributors to The Cochrane Collaboration?

Hosting a network of CRG-based methods individuals (if applicable, elective core function)

- 18. Will the Methods Group enlist at least one individual from each CRG to be part of this network?
- 19. Will the Methods Group maintain an up-to-date list of CRG-based methods individuals in Archie?
- 20. Will the Methods Group provide a discussion forum such as an e-mail list/blog?
- 21. Will the Methods Group provide backup for methods questions that are not resolved by CRGs (resolution of unanswered questions)?
- 22. Will the Methods Group ensure that training material and handbook guidance is understood by CRG-based methods individuals?
- 23. Will the Methods Group provide feedback on work undertaken within CRGs if requested (e.g. 'Is this Summary of Findings table acceptable?')?

Providing <u>peer review</u> [131] (if applicable, elective core function)

- 24. Will the Methods Group implement a mechanism to identify members willing to provide peer review of relevant components of Cochrane Protocols and Reviews on behalf of the Methods Group?
- 25. Will the Methods Group implement a process to offer timely peer review of relevant components of Cochrane Protocols and Reviews?
- 26. Will the Methods Group communicate the availability of peer review and the process to be used to access this service to CRGs?
- 27. Will the Methods Group set target response times for provision of peer review of relevant components of Cochrane Protocols and Reviews?
- 28. Will the Methods Group be able to provide peer review within target response times?



Providing specialist advice (if applicable, elective core function)

- 29. Will the Methods Group implement a mechanism to identify members willing to provide specialist advice on behalf of the Methods Group to support production of relevant components of Cochrane Protocols and Reviews?
- 30. Will the Methods Group implement a process for members to offer timely specialist advice to support production of relevant components of Cochrane Protocols and Reviews?
- 31. Will the Methods Group communicate the availability of specialist advice and the process to be used to access this service to CRGs and/or individual authors?
- 32. Will the Methods Group set target response times for provision of specialist advice on a case-by-case basis?
- 33. Will the Methods Group be able to provide specialist advice within target response times?

Contributing to new products or lines of activity (if applicable, elective core function)

- 34. Will the Methods Group identify specific new products or lines of activity to which a contribution will be made in consultation with the Methods Board, the Methods Executive and other stakeholder groups within the Collaboration (e.g. Cochrane Collaboration Steering Group [13], the Cochrane Editorial Unit [49]), as appropriate?
- 35. Will the Methods Group set targets and deadlines for deliverables (outputs) on a case-by-case basis?
- 36. Will the Methods Group be able to meet targets and deadlines for deliverables (outputs)?

Contributing to software development (if applicable, elective core function)

- 37. Will the Methods Group identify specific software to which a contribution will be made?
- 38. Will the Methods Group set targets and deadlines for deliverables (outputs) on a case-by-case basis?
- 39. Will the Methods Group be able to meet targets and deadlines for deliverables (outputs)?

Conducting Cochrane methodology reviews (if applicable, elective core function)

- 40. Will the Methods Group set targets for registration of titles for new Cochrane methodology reviews with the Cochrane Methodology Review Group (CMRG)?
- 41. Will the Methods Group set targets for publication of new CMRG protocols in the Cochrane Database of Systematic Reviews (CDSR [128])?
- 42. Will the Methods Group set targets for publication of new or update Cochrane methodology reviews in the CDSR?
- 43. Will the Methods Group be able to meet targets for registration of titles with the CMRG and publication of CMRG protocols and new or update CMRG reviews in the CDSR?



Contributing to the Cochrane Methodology Register (CMR) (if applicable, elective core function)

- 44. Will the Methods Group implement a mechanism (in consultation with the CMR) to identify studies relevant to the methods of systematic reviews of healthcare and social interventions that fall within the aims and scope of the Group?
- 45. Will the Methods Group contribute details of methodology studies relevant to the aims and scope of the Group to the CMR on at least a quarterly basis (deadlines to be agreed with the CMR)?
- 46. Will the Methods Group implement a process (in consultation with the CMR) to tag CMR records of articles by Group members?

Helping to monitor and improve the <u>quality</u> [5] of Cochrane Reviews (if applicable, elective core function)

47. Will the Methods Group respond to requests channelled via the Methods Board or Methods Executive for specialist input to active monitoring of aspects of the quality of Cochrane Reviews or initiatives aiming to improve the quality of Cochrane Reviews?

Conducting methodological research (if applicable, elective core function)

- 48. Will the Methods Group maintain (publicly or privately) an agenda for research relevant to their aims and scope that reflects the kinds of policy advice, training materials, peer review and specialist advice etc. they provide within the Collaboration?
- 49. Will the Methods Group seek funds for <u>empirical</u> [32] or theoretical methodological research studies to be conducted (wholly or partly) under the auspices of the Methods Group?

Communicating Cochrane methodology to external organizations (if applicable, elective core function)

- 50. Will the Methods Group respond to requests from external organizations and <u>networks</u> [27] to provide advice on and/or explain methodology (relevant to the aims and scope of the Group) that is used in the preparation and maintenance of Cochrane Reviews (within available resources)?
- 51. Will the Methods Group maintain a private register of external organizations and networks whose members would benefit most from advice on and/or explanation of methodology (relevant to the aims and scope of the Group) that is used in the preparation and maintenance of Cochrane Reviews?
- 52. Will the Methods Group offer advice or explanations of methodology (relevant to the aims and scope of the Group) that is used in the preparation and maintenance of Cochrane Reviews to external organizations and networks whose members would benefit most from this (within available resources)?"



Annex A2.B: Registration process for new entities

The following is the registration process for <u>entities</u> [20] wishing to register with The Cochrane Collaboration:

- 1. The Applicant of a proposed entity prepares an application using the registration criteria and in consultation with the reference <u>Centre</u> [34] Director.
- 2. The Applicant sends the application to the <u>Secretariat</u> [1] Deputy Administrator (the support person for the Monitoring and Registration Committee [MaRC [30]]), who informs the <u>Steering Group</u> [13]. The application is forwarded to the appropriate entity representative on the MaRC with a request for a <u>review</u> [29] and comments.
- 3. The MaRC entity representative ensures that the application is complete, and any overlap and/or duplication of scope with an existing entity or entities is discussed and managed appropriately, within a two week timeframe. Within this same timeframe, the MaRC entity representative consults with the relevant entity Executive, should one exist, to elicit the Executive's consensus view as to whether or not the proposed entity should be registered. The Executive's consensus view is used to inform the recommendation of the MaRC Co-convenors to The Cochrane Collaboration Steering Group (CCSG [23]) (see '5' below). If the consensus view of the relevant Executive is that the proposed entity should not be registered, the Executive must provide clear reasons for this view to the MaRC entity representative. The MaRC entity representative communicates the consensus view of the relevant Executive (via the Secretariat Deputy Administrator) to the MaRC Co-Convenors and members alongside their comments on the application. Comments are categorized as (a) relevant (major) comments regarding approval of the application, and (b) additional (minor) comments. The MaRC representative may consult with other MaRC members as necessary to inform their comments, which may also incorporate comments received from members of the relevant Executive.
- 4. The MaRC representative sends his/her comments to the Secretariat Deputy Administrator who then forwards it to the full MaRC for review and comment within three weeks. The Secretariat Deputy Administrator collates the feedback and sends all comments to the MaRC for further comment within two weeks.
- 5. Based on the comments of all the MaRC members, the MaRC Co-Convenors prepare a recommendation to the CCSG with a draft letter to the applicant. The Secretariat Deputy Administrator forwards this recommendation to the CCSG for review and comment within three weeks, with a copy to the non-CCSG members of the MaRC. The recommendation to the CCSG should include a statement of the consensus view of the relevant entity Executive (if applicable). The MaRC Co-Convenors' recommendation to the CCSG may differ from the consensus view of the Executive. The CCSG makes the final decision on whether registration of the proposed entity is approved.
- a) If the CCSG approves the application:
 - i. the Secretariat Deputy Administrator forwards the MaRC's letter of acceptance to the applicant with a copy to the reference Centre Director and the relevant Executive (if there is one). All entities are informed of the successful application, the draft announcement having first

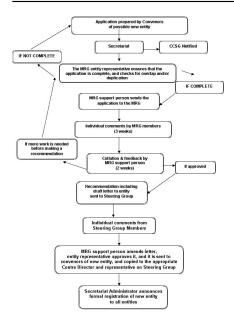


been approved with the applicant. Assistance with entering the <u>module</u> [102] into Archie (the Collaboration's Information Management System) will be provided by the Information Management System team, based at the Nordic Cochrane Centre.

- ii. The CCSG may have requested additional information or modification of the entity's application that is still outstanding at the time that registration is approved. In this case, the MaRC Co-Convenors will ask that the response to this request be sent in writing to them via the Secretariat, and to the reference Centre Director, within one month of registration if possible.
- iii. Registered entities can access the entity website module of the Collaboration's content management system (CMS), available from the Web Team based at the German Cochrane Centre (see http://www.cochrane.org/about-site [241]).
- b) If the application is NOT approved by the CCSG or requires clarification before it can be accepted for registration:
 - i. The MaRC Co-Convenors inform the applicant and the reference Centre Director, copying the letter to the other members of the MaRC, the relevant Executive (if there is one), and the Secretariat Deputy Administrator for information.
 - ii. The applicant, assisted by the reference Centre Director, may clarify and submit a revised application to the Secretariat Deputy Administrator, who circulates it to the MaRC Co-Convenors and the appropriate MaRC entity representative. The MaRC entity representative consults with other members of the MaRC and the relevant Executive as appropriate.
 - iii. If the changes are satisfactory, the Secretariat Deputy Administrator is notified and the acceptance letter is sent to the applicant and the reference Centre Director. The Secretariat Deputy Administrator notifies all entities in The Cochrane Collaboration by e-mail of this new registration, having first approved the draft announcement with the applicant.

If the application requires further clarification, steps 5(b) (i) to (iii) are repeated.

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Annex A2.C: Major and minor changes to entities

RECOMMENDATION FROM THE MONITORING AND REGISTRATION COMMITTEE

MAJOR AND MINOR CHANGES TO ENTITIES [20]:

[Last updated: 1 November 2010.]

APPROVAL: Changes requiring approval.

(Please send details of proposed change to the Secretariat [1] Deputy Administrator (callen@cochrane.org [242]).)

NOTIFICATION REQUIRED: Changes where immediate notification is required.

(Please send notification to the Secretariat Deputy Administrator (callen@cochrane.org [242]).)

NOTIFICATION REQUESTED: Changes where notification is requested through the annual monitoring process.

| CHANGES AFFECTING ALL ENTITIES | STATUS |
|---|---------------------------------------|
| Relocation of entity from one country to another | Approval (letter of support required) |
| Relocation of entity within a country | Notification required |
| Relocation of entity staff | Notification required |
| Change of primary funders | Notification required |
| Change of registered name | Approval |
| Significant reduction in resources available (e.g. drop of more than 20%) | Notification required |



| | Notification requested via monitoring form |
|---|--|
| Closure of entity | Approval |
| Change of legal status or governance (e.g. registering as a company or charity) | Approval |
| Change of status to a Cochrane-Campbell entity | Approval |
| Closure of a sub-group, satellite or branch: Parent entity must give reasons explaining why they require deregistration. The Centre [34] Director (for a CRG [15] satellite, Field sub-group, or Methods Group sub-group) or the Ombudsman [44] (for a Centre Branch) will, if required, facilitate negotiation and communication between the parent entity and the sub-group, satellite, or branch. The sub-group, satellite or branch always has the right to go to the Ombudsmen if they disagree with the final decision. | |
| Change of elective core function | Approval |

| CHANGES AFFECTING CRGs ONLY | STATUS |
|---|--|
| Change of Co-ordinating Editor or addition of a joint or deputy Co-ordinating Editor (please also notify the Co-ordinating Editors' Executive) | Notification required |
| Change of Managing Editor | Notification required |
| Change of editors or other members of staff (for staff with the role 'super user' in Archie, please see above) | Notification requested via monitoring form |
| Change of scope of CRG | Approval |
| Merger with another CRG | Approval |
| Significant changes in editorial practice | Notification requested via monitoring form |
| Establishment of satellites (letter of support required from the reference Cochrane Centre of the country where the satellite will be located, and the country where the <u>editorial base</u> [103] is located. Also, a structure, workplan, and communications strategy are required) | Approval |

| CHANGES AFFECTING CENTRES ONLY | STATUS |
|---|--|
| Change of Centre Director or addition of a deputy or joint Director (please send a CV) | Notification required |
| Change of other members of staff (for staff with the role 'super user' in Archie, please see above) | Notification requested via monitoring form |
| Change of special function | Approval |
| Change of a Centre Branch Director | Notification required |



Establishment of Branches (letter of support required from the reference Cochrane Centre of the country where the Branch will be located, and from entities based in the country where the Branch will be located. Also, a structure, workplan, communications strategy, and CV for the person leading the Branch are required)

| CHANGES AFFECTING FIELDS AND THE CONSUMER NETWORK ONLY | STATUS |
|--|--|
| Change of Co-ordinator/Convenor or addition of a deputy or joint Co-ordinator/Convenor (please also notify the Fields' Executive and send a CV to the MaRC [30]) | Notification required |
| Change of other members of staff (for staff with the role 'super user' in Archie, please see above) | Notification requested via monitoring form |
| Change of registered scope | Approval |
| Merger with another Field | Approval |
| Establishment or change to new or ongoing bursary schemes | Notification required |
| Establishment of sub-groups (letter of support required from the Field concerned, the reference Cochrane Centre of the Field concerned, and the reference Cochrane Centre of the country where the sub-group will be located. Also, a structure, workplan, and communications strategy are required) | Approval |

| CHANGES AFFECTING METHODS GROUPS ONLY | STATUS |
|--|--|
| Change of Convenor or addition of a deputy or joint Convenor (please also notify the Methods' Executive) | Notification required |
| Change of other members of staff (for staff with the role 'super user' in Archie, please see above) | Notification requested via monitoring form |
| Change of registered scope | Approval |
| Merger with another Methods Group | Approval |
| Establishment of sub-groups (letter of support required from the Methods Group concerned, the reference Cochrane Centre of the Methods Group, and the reference Cochrane Centre of the country where the sub-group will be located. Also, a structure, workplan, and communications strategy are required) | Approval |



Annex A2.D: Monitoring forms

All Cochrane Entities, Part B: Cash flow forecast

Please complete one of these forms for the entity base, and any satellites, sub-groups, or branches.

(Please see 'Notes for completion', to which row numbers refer.)

1. Currency used

Financial Year

2. 1 April to 31 March

2004-05 2005-06 2006-07 2007-08 2008-09

Income

3. [Main funder, e.g. Government funding, Department of Health]

[Supplementary income, e.g. other state funding]

[Supplementary income, e.g. charitable trust]

[Supplementary income, e.g. publisher]

4. Funding from commercial sources

[Company name]

[Company name]

Total income

- 5. Expenditure
- 6. Staffing (current and assumed pay rates)



| 7. | Institutional overhead (at rate [nn]%) |
|------|---|
| | Travel, conferences and meetings |
| | Other expenditure (total) |
| Tota | al Expenditure |
| 8. | Surplus (Deficit) |
| | Do you anticipate any (non-financial) threats to your entity over the next 12 months? |

Notes for completion

Any other comments:

General points

This cash flow forecast gives you the opportunity to describe your financial planning over a five-year period (if, for later years in this period, your financial status is unknown, please write 'unknown' in the table). Having this information is likely to be of benefit to you for financial planning, fundraising, and for internal governance. It will help the Monitoring and Registration Committee (MaRC) and the Secretariat [1] by providing an accurate picture of each entity's financial stability, and helping to identify current and potential future problems. It will enable the Collaboration to report (in aggregated/anonymised form) an accurate picture of the Collaboration's financial status.

Individual entity figures will remain confidential between the entity, MaRC, Secretariat and <u>Steering</u> <u>Group</u> [13], although aggregated/anonymised data will be used more widely in fundraising, publicity, and related material.

Both 'income' and 'expenditure' refer to funds allocated and used specifically for Cochrane activities. If it is difficult to divide your overall funding into 'Cochrane' and 'other' activities, please make a common-sense judgement – there is no need to make extensive investigations.

Specific points

- 1. For simplicity, use your usual currency (please state what this is).
- 2. The Collaboration works to a financial year that runs from 1 April to 31 March each year, and it would help us if you could also use the same period. However, if this proves difficult, please use your normal financial reporting period, and change the description of the financial year in Row 2 as appropriate.



- 3. The table enables you to record your actual or planned annual income and expenditure for years 2004-05 to 2008-09. Please list income by source rather than by function. If you have obtained funding for a specific purpose, list the name of the funder and not the purpose. For example, if you had obtained funding for translating articles from the Spanish Government, this would be listed under 'Spanish Government', not 'Translation'.
- 4. Please detail any commercial funding (as defined by the Collaboration's policy on commercial sponsorship) as a separate item.
- 5. Expenditure has been categorised by specific functions. Please use the categories listed, but add others if you need to.
- 6. For future cost of staffing use a sensible estimate, such as the average percentage increase over the last three years. Please note that this makes no assumption of actual pay increases, which will no doubt be different from those estimated. The figure is used solely so that you have an estimate of future costs that you can use for planning purposes.
- 7. 'Institutional overhead' is the amount paid by you to your 'parent' or 'host' institution, and it would be helpful if you could provide the percentage figure at '[nn]'. Please use an explanatory note in 'Any other comments' if you feel that this would be helpful.
- 8. This is the total income minus the total expenditure.

Finally, if you need help to complete this table, Nick Royle is very happy to discuss this with you (+44 (0)1865 310138, nroyle@cochrane.org [122]).

Monitoring forms

For copies of monitoring and feedback forms, please contact the Monitoring and Registration Committee (callen@cochrane.org [242]).

APPENDIX 3: Contact people at John Wiley & Sons Limited (Wiley-Blackwell)

Updated by the Secretariat [1] Administrator on 25 February 2011.

Postal address of Chichester, UK, office: The Atrium, Southern Gate, Chichester, West Sussex, PO19 8SQ, UK. Fax +44 (0)1243 770 460.

Further information on Wiley offices can be found at www.wiley.com [243]

Main contact person

Responsible for the day-to-day management of <u>The Cochrane Library</u> [18], and the relationship with The Cochrane Collaboration:

Deborah Pentesco-Gilbert, Publisher, The Cochrane Library

Tel. +44 (0)1243 770 693; dpentesc@wiley.com [138]

Deborah Dixon, Vice President and Publishing Director Tel. +44 (0)1243 770 521; ddixon@wiley.com [244]

Charles Young, Global Clinical Solutions Publishing Director Tel. [insert]; cyoung@wiley.com [245]

Development and management of derivative products

Tracey Curtis (tcurtis@wiley.com [246]) providing maternity cover from March 2011



for Bryony Urquhart, Editor, The Cochrane Library

Tel. +44 (0)1243 770384; burguhart@wiley.com [152]

Editorials, podcasts, Copy Edit Support

[Vacancy], Associate Editor, The Cochrane Library (formerly Laura Simmonds)

Tel. +44 (0)1243 770 562; [name]@wiley.com [247]

Marketing and promotion

Liaison with Cochrane <u>entities</u> [20] regarding marketing and fulfilment issues, including complimentary access and trial access:

Sarah Wilkins, Associate Divisional Marketing Manager, *The Cochrane Library* Tel. +44 (0)1865 476372; swilkins@wiley.com [248]

Jeni Coates, Journals Fulfilment +44 (0)1243 779777; <u>icoates@wiley.com</u> [249]

Web publishing

Philippa Scoones, Director for Web Publishing, *The Cochrane Library* Tel. +44 (0)1865 476261; psecoones@wiley.com [250]

Public relations

Liaison with Cochrane entities and media regarding publicity: Jennifer Beal, Global Publicity Manager Tel. +44 (0)1243 770 633; ibeal@wilev.com [251]

More information at:

www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/pressroom.html [252]

Production of The Cochrane Library

David Hives, Project Manager and Production Controller, *The Cochrane Library* Tel. +44 (0)1243 770 297; dhives@wiley.com [253]

Permission requests

Duncan James: Tel. +44 (0)1243 843356; permissionsuk@wiley.com [144]

Production Technology

Colleen Finley, Project Manager and User Acceptance Technology Test Manager +1 (201) 748 6983; cfinley@wiley.com [254] (Hoboken, New Jersey, USA)

Peter McFayden, Cochrane Technology Project Manager Tel. [insert]; pmcfayden@wiley.com [255]

For online and CD-ROM orders:

www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/AccessCochraneLibrary.html [256]

For customer services:

www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HELP_Cochrane.html [257]



For online customer support:

www3.interscience.wiley.com/cgi-bin/rightnow [258]

APPENDIX 4: The Cochrane Collaboration supports prospective registration of clinical trials

The Cochrane Collaboration is committed to providing the most reliable evidence of the effectiveness [101] of health care through systematic reviews of randomised controlled trials (RCTs), and recognises the importance of prospectively registering trials to ensure that the evidence assessed is complete and unbiased.

The Cochrane Collaboration recommends that:

- all randomised controlled trials are registered at their inception (at the time of ethical approval and/or funding approval);
- registered information should be potentially accessible to all interested parties;
- registration should be with a register that complies with an appropriate minimum standard of practice;
- prospective registration of trials should be part of ethical guidelines for clinical trials;
- government agencies should ensure that adequate mechanisms and infrastructure are provided so that all randomised controlled trials can be registered prospectively;
- government agencies should explore legislative and other strategies to mandate prospective registration as a condition of, for example, funding, ethics or regulatory approval.

In addition, The Cochrane Collaboration supports:

- the principle of a global trials register;
- a unique international numbering system such as the ISRCTN (International Standard Randomised Controlled Trial Number) currently available through the organization Current Controlled Trials (www.controlled-trials.com [259]);
- activities that facilitate the widespread adoption of this unique numbering system:
- If a fee is charged to obtain this unique number, and this fee is a significant barrier to obtaining a number, The Cochrane Collaboration encourages endeavours that would result in a reduction or removal of this fee;
- the comprehensiveness of the global trials register through the incorporation of the <u>Cochrane Central Register of Controlled Trials</u> [19] (CENTRAL).

The Cochrane Collaboration recognises that the registration of trials at their inception will:

- Help identify health care strategies that require research, and set priorities for research in the light of concurrent studies in progress.
- Avoid unintentional duplication of clinical trials or allow replication of trials when appropriate.
- Foster collaboration between investigators considering similar trials.
- Assist recruitment to trials in progress.
- Allow patients and patient support groups to be kept informed.
- Ensure that all trial results do eventually become publicly available (through publication) and are subsequently used in systematic reviews of the evidence.
- Ensure that more ethical and worthwhile trials are undertaken by better defining the unanswered questions (through systematic reviews of completed trials) and through knowledge of similar trials in progress.

Many clinical trials, especially those with negative or inconclusive results, may fail to be published



in medical journals. This risks the unethical use of healthcare resources and participants in trials. To prevent this, ethics committees should promote prospective registration of clinical trials and thus ensure that trial results can subsequently become publicly available.

References

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Dickersin K, Rennie D. Registering clinical trials. JAMA 2003; 290: 516-523.

Horton R, Smith R. Time to register randomised trials. The Lancet 1999; 354: 1138-1139.

Simes RJ. <u>Publication bias</u> [260]: the case for an international registry of clinical trials. Journal of Clinical Oncology 1986; 4: 1529-1541.

26 July 2004

Source URL: http://www.cochrane.org/policy-manual/welcome

Links:

- [1] http://www.cochrane.org/glossary/5#term401
- [2] mailto:secretariat@cochrane.org
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