Cochrane Editorial Unit Quality Assurance and Editorial Process Integrated Plan

Cochrane Editorial Unit targets for 2016

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Background

The Cochrane Steering Group (CSG) has identified quality as one of its highest priorities and a critical part of our sustainability. Recent audit work and the Cochrane Editorial Unit (CEU) Screening Programme have demonstrated a year-to-year improvement in certain aspects of methodological quality. However, we are also aware that some aspects of review quality and timeliness continue to need improvement. We have identified a number of CRGs who we consider to be at high risk of signing off reviews that do not meet our Methods Expectations of Cochrane Intervention Reviews (MECIR) standards. Additionally, we continue to see reviews from a much wider subset of groups that include elements such as inconsistent reporting, poor application of the GRADE methodology, unit of analysis errors and inappropriate over-reliance on an arbitrary measure of statistical significance. We are particularly concerned about the quality of updated reviews coming to publication, and the number of protocols that contain issues that then feed through into the final review.

The screening process has provided us with clarity on the issues raised. Many CRG teams have used the CEU feedback to change processes accordingly. However, we believe that there is not yet sufficient evidence of consistent progress across the board. Given the importance of review quality to the sustainability of Cochrane, we must engage in a concerted, collective effort to implement the learning points and build on the best practice examples we have identified. This must include further consideration of solutions aimed at ensuring consistent quality across Cochrane. Such solutions need to be consistent with Cochrane's ethos and principles and we want to ensure that we energise our contributors rather then demotivate them.

Discussions have been taking place in the CEU and amongst some Co-ordinating Editors for some time seeking to explore mechanisms that would allow for separation between *review production* (author support) and *editorial process*es (publication issues), including 'sign-off'. This will not be something that will be appropriate for all CRGs, but we believe that it is worth considering, and we will seek to explore a pilot project of volunteers in the next 12 months.

We will need to co-ordinate activities from different departments and wish to pilot solutions with a selected number of volunteer CRGs. We will use the pilots to gather information and to identify areas that can be implemented across the wider Cochrane community.

The CEU integrated plan will be carried out over the next four to five years. Within this plan, we aim to ensure that CRG teams, review authors, and others have the materials, support and environment necessary to be able to produce reviews that are of consistently high quality. This requires us to focus our attention on a re-evaluation of the editorial process, while continuing to attend to quality assurance. For 2016 we have set ourselves targets that have been approved by the Steering Group.

Finally, the role of the CEU needs to change. We have a responsibility to ensure that we work with CRG teams, the methods community and contributors to set standards, and to measure progress against these standards. We also need to ensure that the environment is optimised to facilitate the production of reviews, in terms of the review production technology, the Handbooks, access to learning, and the availability of standards and policies. We also have a role in support CRG teams and helping them to solve problems. However, an ever expanding CEU that also provides a backstop process for reviews is not sustainable or even desirable. Part of this strategy has to be an adjustment in the role of the CEU.

Our vision

Our vision is that Cochrane Reviews will consistently produce credible, high quality and timely evidence that meets the needs of end-users and informs clinical care and health policy, in line with our *Strategy to 2020*.

We seek to develop processes to ensure that appropriate methods – which reflect best current practice – are used in Cochrane Reviews, and that Cochrane contributors have the necessary tools to deliver our vision.

Quality and Standards Advisory Committee

Action point:

To develop an advisory committee to support the CEU team in implementing the integrated plan.

In support of the integrated quality programme we will convene a Quality and Standards Advisory Committee (QSAC). This committee would comprise a mix of senior Cochrane editors and methodologists. Its main function will be to provide advice to the Editor-in-Chief, alongside existing executive groups such as the Co-ordinating Editors Executive, Managing Editors' (MEs') Executive, Trials Search Co-ordinators' (TSCs') Executive, and the Methods Executive.

The terms of reference will be to:

- oversee the progress of the integrated quality strategy and to provide advice and feedback to the CEU team;
- provide guidance, support and advice in relation to the management of CRGs identified as being at high risk of producing reviews that do not meet agreed standards;
- act as 'quality advocates' within Cochrane in support of the strategy.

We will explore the possibility of providing an approved 'title' (e.g. Honorary Senior Cochrane Fellow) to members of the QSAC. All members of the board would be expected to attend at least 75% of the monthly teleconferences.

Make-up of the QSAC

It is envisaged that the QSAC would consist of:

- three Co-ordinating Editors from high-performing CRGs;
- three other editors from high-performing CRGs who have advanced methodological skills; and
- three experienced methodologists.

Individuals with the relevant skills will be invited to apply for the QSAC, and membership will be confirmed by the Editor-in-Chief. Members of the QSAC will be required to demonstrate a record of exceptional performance and credibility in relation to understanding and applying methodological standards within reviews for which they have had responsibility, including the use of GRADE. They will also need to demonstrate a willingness and capacity to take on the role,

and an appreciation of the commitment required. There will be a need for diversity in geographical location, native language, and sex amongst those appointed.

Quality management

Action points:

To develop and follow a management plan for each of the high-risk groups that successfully addresses the problems identified.

To work with CRGs to identify a range of metrics that reflect performance appropriately and fairly, and to ask them to provide transparent and regular feedback on these metrics.

Managing the challenge of variable quality reviews (Target 1.1.)

As described in the Background section of this paper, the CEU has identified a small number of CRGs at risk of signing-off reviews as ready for publication that fall short of our standards. However, it is overly simplistic to regard the challenges of ensuring quality to be limited to a few CRGs. The CEU screening programme has also identified reviews that do not sufficiently meet the MECIR standards from a wider group of CRGs outside this subset. Among the causes that we have identified are the overly inclusive approach to title registration, leading to over-production of protocols and reviews relative to the available resources; editorial "exhaustion" with problematic reviews, and a lack of methodological expertise, particularly in respect of more recently developed methods such as GRADE within the editorial boards.

Our goal is to create an individualised plan for each of the "high risk" CRGs, which consists of the following components:

- regular teleconferences between the CRG team and members of the CEU team to discuss details of protocols and reviews, including common errors;
- early intervention in the review process, after the authors have performed GRADE and submitted the review, but before sign-off;
- for high priority topics, assessment of the protocol and reviews with a methodologist external to the CRG;
- development of a transparent mechanism that describes the support to be provided and potential sanctions if milestones are not reached.

The Editor-in-Chief will seek to identify a bank of methodologists and other relevant professionals who will appraise Cochrane Reviews from high-risk groups on a consultancy basis. These professionals will receive payment in recognition of any service provided, and if possible, may also receive a title such as 'Honorary Cochrane Fellow'.

However, we also need a wider discussion within the CRG and methods communities to consider appropriate solutions to the challenge of ensuring that Cochrane reviews are consistently of high quality. In our view, whilst we now have a greater understanding of the issues, we have not yet sufficiently identified the successful solutions we need to address this. Solutions that we need to consider include the following:

- Centralised sign off for some groups

- Peer to peer sign off

- Appraisal of Co-Eds based on the quality of the group's reviews and other measures of performance

- "Supergroups" i.e. high performing CRGs receiving financial support to mentor others

We will introduce a broad discussion of this issue at the mid year meeting in London. We actively encourage CRG teams to identify solutions, and want to work collaboratively to address the challenge of inconsistent quality.

Audit and metrics (Target 1.1.)

Many steps have been taken to deal with issues of review quality. Clearly, some of these steps are more acceptable than others, and we intend to discuss further developments with CRGs based on what we have learned from the projects that are underway.

For example, the *Screening Programme* has identified some common errors that can now be used for specific training and support for CRGs. Once measures have been implemented to build capacity in those areas identified as common errors, cyclical audits might prove helpful in the assessment of improvements in reporting quality.

CRG review metrics

The *CRG Review Metrics* project has now been completed. Its main goal was to recognise and reward CRGs that produce high quality, relevant, and timely reviews, while taking into consideration other parameters, such as the production of more complex reviews. We believe that it is important for us to identify mechanisms for measuring quality performance that are transparent, fair, and that reward CRGs for seeking improve the quality of their reviews and their utility to end-users. The current pilot delivered on some of these goals, and has also highlighted areas for improvement that we will consider as we determine which activities need to be incorporated into the metrics for the future. There were no means to address quality directly within the pilot; we will further examine this issue in the next iteration.

Quality improvement

Action points:

- **CEU team to continue screening reviews that are high priority and those that have been identified by CRGs as problematic.**

- **To initiate screening of review updates by assessing potential issues with the published review (before update) and to provide feedback to authors.**

- **To explore mechanisms for screening of protocols in conjunction with the Methods community.**

- **To develop a screening guide for CRG teams, and to deliver targeted training to CRGs in conjunction with Learning and Support Department (L&SD).**

- **To provide consultation to the training programme being designed by the L&SD.**

- **To explore and pilot initial changes to the editorial process, including title registration, empty reviews, and centralised peer review process for reviews involving CRG team members as authors.**

Changes to the Screening Programme (Target 1.1.)

The *Screening Programme* was set up in 2013; it uses a considerable amount of the editorial resources available to the CEU Quality Team. Currently, minimum standards are used to check compliance at the final stage of review production; this leaves limited opportunity to act on the identified problems. It is clear that we must place greater emphasis on good practice throughout the life-cycle of reviews.

After two years of screening every new review and providing feedback to CRGs, the CEU Quality Team will begin to adapt the screening programme to assess those reviews that have been **referred** by CRGs, either because the CRG has methodological concerns or because the review has been identified as being of high priority. The CEU team will create a transparent policy of accepting and rejecting referred reviews, and will provide support in the dissemination of high-priority reviews.

In addition to this, the CEU team will pilot strategies for screening of updates, protocols, and very large reviews (≥ 50 included studies), as follows.

- We propose to use a similar model to the one currently used for Targeted Updates for a number of reviews before a full update is underway. This will include a full assessment of the methodological challenges of the current review, a clear set of recommendations to be given to the author team, and support to implement changes.
- For Cochrane protocols, the CEU team will liaise with the Methods Co-ordinator and seek to support the creation of a Methods Support Unit that will work on a number of protocols per CRG, focusing on design and implementation issues.
- We will screen high-priority reviews that are likely to have particular impact, or some media effort, but will aim to appraise them at an earlier stage, perhaps even at the protocol or first submission.

Editorial development (Target 1.1.)

In addition to the changes to the screening programme, we need to ensure that CRGs have the skills to screen their own reviews effectively prior to publication. The Cochrane Learning and Support Department (L&SD) is designing an active training programme to support editorial teams, and we will work closely with L&SD to ensure that the lessons learned from the CEU Screening Project are incorporated into the strategy.

Within the CEU integrated plan we intend to pilot the following activities:

- creation of a series of webinars in critical areas identified by the Screening Programme that can be used for training or as self-learning material;
- creation of a screening guide for CRG teams to use prior to publication;
- regular teleconferences to discuss reviews and protocols to cover common errors that have been identified in individual CRGs.

The CEU team will provide support for implementation of these innovations.

Piloting changes in the editorial process with a limited number of CRGs (Target 1.2.)

Within Cochrane, CRGs are the main groups that are engaged in developing and applying innovations for conducting Cochrane Reviews. However, there are often delays in communicating innovations across CRGs and this limits the diffusion of good practices. In this project we want to capture and communicate experiences, in order to overcome these structural barriers to development. Examples of innovative solutions that CRGs are trying within their own groups and that might be of interest to the wider Cochrane community include:

- combining title and protocol registration to increase the efficiency of the initial part of the review process;
- creating an abridged version of the 'Characteristics of included studies' table;
- creating clear standards for editorial process for Editors and peer reviewers.

We are also interested in exploring further how the development/support roles can be separated from the 'editorial'/publishing process, and we will initiate this process by organising a meeting with a number of Co-ordinating Editors who have expressed their intention of working closely with the CEU in piloting changes in the editorial process before wider implementation. For 2016 we intend to work on the following initiatives.

- Exploration of ways to increase transparency of title registration, including possibly, the use of an automated system for registering title requests for priority reviews.
- Creation of transparent criteria for rejecting titles, protocols, and reviews using a traffic light system.
- Discussion of the possibility of simplifying the end-deliverable for empty reviews with Groups. We believe that empty reviews are important in identifying important uncertainties and guiding future research, but they need to be completed within a much shorter time frame than the current 24 to 36 months.
- Creation of alternative processes for peer review when one or more members of the editorial team are active authors for a review. Our goal is to ensure that editorial process mechanisms are in place in these circumstances which ensure a clear firewall is constructed between the review authors and editors.

Expand and amend the Cochrane Review prioritisation list (Target 1.3.)

We will amend the existing processes for identifying new priority reviews and updates, seeking to make the rationale for inclusion of each title more transparent and to increase the focus on externally derived priorities that explicitly address the needs of global decision makers.

In early 2016, we will develop new guidelines for the priority list and disseminate the information to CRGs. The goal is to have a clear rationale for inclusion of new titles and the evidence to underpin this. For example, a title may be judged as a priority if it is known to have been identified by a major regional or international guideline group or is based on the global burden of disease data. We will also seek particularly to include titles that are important in low- and middle-income settings. To that end we will explore how we can utilise the knowledge and skills of our colleagues inside and outside Cochrane to ensure that the healthcare needs of these countries are fairly reflected in Cochrane's priority review list. Where appropriate we will to

encourage groups to engage new review author teams or individuals from both high and low income settings.

The size of the list overall will be reduced, which will mean that for some groups there will need to be a reduction in the number of titles on their individual lists that are included in the Cochrane-wide list. We will especially look at current lists on which very few or no reviews have been published and discuss with these groups how they might reduce their lists to a more realistic size relative to the resources available to them. An upper limit of 6-8 reviews per group will be set. A new title(s) can be added once a review(s) has been published.

Updating strategy for Cochrane content (Target 1.4.)

We propose to develop a comprehensive updating strategy with work commencing in 2017 and developing over the following year.

In support of this, we aim to complete the implementation of the updating classification changes in Archie and provide support for CRGs willing to start piloting the classification of their own reviews.

In addition, the *Targeted Updates* project should be completed by June 2016. After completion, we will seek feedback from participating CRGs and the greater Cochrane community regarding the lessons learned from the process. The results of this assessment should be communicated by December 2016 and should inform our strategy for 2017.

We will also initiate implementation of the Methodological Expectations of Cochrane Intervention Reviews (MECIR) standards for updates.

Editorial and publishing policy development

Action points:

- **To sign a memorandum of understanding with CRG leaders and host institutions.**

- **To develop agreed-upon policies for peer review and fraud management.**

- **Periodically to update the Cochrane Editorial and Publishing Policy Resource.**

Memorandum of Understanding (MOU)

During 2015 substantial progress was made in drafting a MOU for CRGs. We have consulted amongst the Co-ordinating Editors' Executive, and also within the Senior Management Team and with Cochrane's legal advisor. In addition, we have taken account of the ongoing governance process across Cochrane. We are now working to ensure that this MOU for CRGs is consistent with other, similar MOUs being prepared between Cochrane and other Cochrane group types and their leaders, and plan to start consultation and implementation early in 2016.

Developing policy on peer review and fraud management

Over the past few years, the CEU team led by Harriet MacLehose has been constructing the Editorial and Publishing Policies Resource (EPPR). The team has developed a successful model for the process of developing policies. This includes assembling a small team of editors with an interest in the subject, and incorporates wider consultation on the proposed content, leading to its formal ratification and implementation. There remain policy areas that are either incomplete or in need of updating, so the work of populating and refreshing the EPPR will remain a continuous process.

The CEU is currently working with Cochrane colleagues to develop a peer review policy and supporting guidance, aiming to clarify for Cochrane authors, CRGs, and readers/users of Cochrane Reviews, how and when Cochrane Reviews are peer reviewed, what processes we use for peer review, and who does peer review. The policy will be supported by guidance to help CRGs manage peer review and implement the policy. The policy and guidance will include topics such as: open versus anonymous peer review; number and expertise of peer reviewers; declarations of interest for peer reviewers; acknowledgement and credit for peer reviewers; communications and feedback for authors and peer reviewers; deciding when to peer review updates; and assessment of turnaround times. We will aim to use evidence to support the policy, and make use of existing standards, guidance and best practice. We have developed a draft policy, informed by a workshop at the Colloquium, and have contacted the Executives (and other groups) for a small number of volunteers to join an advisory panel in 2016 to support the development of the policy.

The team has a list of other policy areas that it intends to pursue over the next 12 months, including the management of suspected or known scientific fraud and 'authorship and credit'. The latter is particularly important within Cochrane because of our commitment to updating high priority reviews. For a variety of reasons, it may be necessary to change the author team between different issues, and this can lead to confusion about how previous authors can be credited. In the future this will become even more important as Cochrane incorporates 'crowd-sourcing' into its processes.

Methods

Action point:

To set up a revised structure, based on a 'Scientific Committee' model, to facilitate decisions regarding potential new or additional methods, or changes to current methods Cochrane should consider.

To identify key uncertainties in the conduct and reporting of reviews and to investigate the impact of different approaches.

Over the next 12 months, the key priority for the CEU's methods portfolio will be to complete and implement the agreed recommendations of the Methods Structure and Function Review.

We aim to use the recommendations to identify better ways to determine how methodological developments are identified, evaluated and agreed.

One important area, highlighted in a number of ways over the past 12 months, is the process for determining which methods are appropriate for inclusion within Cochrane Reviews and in what circumstances. We recognise that changes in methods can achieve a range of desirable objectives, including:

- improving the quality or efficiency of traditional reviews;
- increasing the range of evidence sources e.g. regulatory agency submissions, non randomised studies;
- introducing novel methods into traditional reviews e.g. network meta-analysis;
- improving the utility and impact of traditional reviews;
- addressing questions that are not related to effectiveness or diagnostic test accuracy such as prognosis, or complex reviews that incorporate mixed methods and include qualitative or economic evidence.

We will develop a 'Scientific Committee' that will include senior methodologists and editors, with the ability to co-opt others as appropriate, to consider methodological changes and determine whether – and under what circumstances – they should be used.

In addition, we will be exploring ways to ensure that there are drivers (whether financial or otherwise) to recruit, retain and nurture methodologists within Cochrane, and that the people who form this resource are able to contribute to the development of reviews, and rewarded appropriately. This work will be co-ordinated with other initiatives identified by the Methods Structure and Function Review, the wider and more far-reaching Cochrane Groups' Structure Review and the extension of the Methods Innovation Fund to support these activities.