

Overview of Methods Projects in the Content Strategy



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Methods projects overview

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1.1 Introduction

In April 2018, the Cochrane Governing Board approved the Content Strategy plan and budget. In this paper we describe progress against the 2019 objectives for the six methods priorities detailed in the Content Strategy.

1.2 Purpose

Our **vision** is that Cochrane will be positioned to adapt rapidly, efficiently and consistently to the changing needs of health care decision makers.

Our **mission** is to create an effective and efficient road map that can be used to introduce changes and enhancements that increase Cochrane's capability and capacity to meet the needs of decision makers consistently.

1.3 Governance and accountability

The Editor in Chief (EIC) is the sponsor the programme of works that together comprise the implementation plan. (S)He will be assisted by the Project Team, which includes the following:

- Ella Flemyng, Methods Implementation Coordinator, EMD
- Kerry Dwan, Methods Support Unit Lead, EMD
- Tari Turner, Cochrane Australia, Programme Manager
- TBC, Senior Methods Editor, EMD

1.4 Key target areas

The following methods were previously identified as 2019 priorities. The Project Manager for each is also included:

- Risk of Bias 2 tool (*Planning for implementation*) – Ella Flemyng and Kerry Dwan
- Living Systematic Review (*Planning for implementation*) – Tari Turner
- Network meta-analysis (*Planning for implementation*) – Kerry Dwan
- Rapid Reviews (*Proposal and rationale*) – Ella Flemyng
- Reviews of prognosis studies (*Implementation*) – Ella Flemyng
- Use of Clinical Study Reports as the data source for drug implementation reviews (*Proof of concept*) – Ella Flemyng

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Risk of Bias 2 tool for randomised studies included in intervention reviews

Stage: 4. Planning for implementation

Importance: High

Urgency: High

Core project team: Ella Flemyng, Kerry Dwan, Julian Higgins

Strategy to 2020 target in 2019? Yes

Impact:

This project aims to develop a clear and streamlined process for authors, editors and other users to conduct or assess risk of bias in intervention reviews using the RoB 2 tool. The use of RoB 2 will result in Cochrane Reviews that have more reliable risk of bias assessments, providing more concrete conclusions on the reliability of the evidence, and ultimately contributing to making health decisions more informed.

Success criterion:

Implementation of Risk of Bias 2 (RoB 2) in all new Cochrane Intervention Reviews that include randomized controlled trials initiated from 1 January 2020. Whilst it is highly desirable for updates that are started after this date to adopt the new method, there will be no requirement to apply RoB 2 retrospectively in published reviews.

2019 progress:

- **Guidance** - The new Cochrane Handbook details RoB 2 methods, MECIR guidance has been updated, the RoB 2 paper has been published in the BMJ, and the full guidance document has been posted on riskofbias.info.
- **Tools** - The Cochrane data extraction form has been updated, Word and Excel tools for completing RoB 2 assessments is available, robvis tool supports RoB 2 figures.
- **Training** - Cochrane training (CIL and webinars) have been updated to reflect the new tool, held a three-day in-person training event in July 2019 (Bristol, UK) for CRGs, Network editorial teams and some Trainers (50 attendees).
- **Support** - The Methods Support Unit, Editorial and Methods Department Team and RevMan Team have been on hand to answer users' queries.
- **RevMan/CLIB/Other tech** - Reviews can switch to RoB 2 within RevMan Web, the RevMan Web Practice Platform allows users to practice RoB 2 input, a 'how-to' guide for this has been developed.
- **Community engagement** - A strategic session was run at the mid-year Governance Meetings on RoB 2 to provide attendees with information on the project and get their feedback on priorities going forward (see this [Cochrane Community post](#) and [Cochrane Methods post](#) for more information). Consultation on implementation plans with all CRG Networks held via teleconferences.
- **Pilot** - A Starter Pack for review teams in the pilot has been developed, inc. FAQs. 12 reviews across seven Networks are involved in the pilot; all review teams have either had, or have scheduled, initial kick-off calls; the Methods Support Unit are providing feedback on protocols to review teams; monthly webinar clinics available to all pilot groups.

Future plans (next 12 months):

- **Guidance** - A series of papers will soon be submitted for publication (one paper per domain), updates to the MECIR Protocol Standards need to be made. Guidance for cluster-randomized trials and crossover trials extensions will be finalised.
- **Tools** - An online tool for completing RoB 2 assessments is planned that we hope will streamline data input into RevMan Web.
- **Training** - Plans for virtual workshops, a webinar series and screencasts are under discussion, Standard Author Training Materials (SATMs) being updated.

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- **Rev Man/CLIB/Other tech** – Improving data entry for RevMan Web under discussion. Cochrane Library interactive tables in development. Developments for the cluster-randomized and crossover trial extensions of RoB 2 will need to be added.
- **Pilot** – The first review in the pilot to publish is expected in Q2 2020.

Issues and Challenges:

- Concerns and hesitations from CRG editorial teams have been raised in using RoB 2 because RevMan Web is not ready for general use by editors.
- Data formats and migration between systems requires updates from the different platforms (Covidence, EPPI-Reviewer, GRADEPro).
- Creating a streamlined process between systems and for authors is heavily reliant on the new study centric data structure project in RevMan Web.

Living Systematic Reviews

Stage: 4. Planning for implementation

Importance: High

Urgency: High / moderate

Core project team: Tari Turner, Julian Elliot, Joanne Brooker

Strategy to 2020 target in 2019? Yes

Impact:

The impact of this project would be that Editors and authors have a clear and streamlined process for conducting a Living Systematic Review if their Review meets all of the following predetermined criteria:

- the review question or topic is a priority for decision-making
- there is an important level of uncertainty in the existing evidence
- there is likely to be emerging evidence that will impact on the conclusions of the LSR

Success criterion:

Living Systematic Reviews identified and initiated across all Networks by end 2019.

2019 progress:

- Five LSRs and 3 LSR protocols on the Cochrane Library, including 4 living network meta-analysis.
- **Guidance** – Released new guidance for Cochrane LSRs (for authors and editorial teams). Four webinars have been held in 2019: publication issues; living network meta-analysis; and tech enablers (2 webinars). Section on LSRs in Chapter 22 of new Cochrane Handbook. Qualitative study to understand facilitators and barriers associated with linking LSRs to guidelines underway.
- **Tools** – No update.
- **Training** – *Introduction to LSRs* for the Brain, Nerves and Mind Network web clinic.
- **Support** – Ongoing support to CRGs submitting funding protocols, peer review of protocols for new LSRs, and checking methods for reviews that are being transitioned from existing standard Cochrane Reviews to LSRs.
- **RevMan/CLIB/Other tech** – No update.
- **Community engagement** – LEN has over 280 members.
- **Pilot** – LSR pilot finalised and evaluation report released on Cochrane LSR webpage. Paper on LSR pilot evaluation has been published.

Future plans (next 12 months):

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- **Guidance** – paper on key elements of LSR methods and guidance to be published; and another paper on defining living evidence is underway. Complete the qualitative study on facilitators and barriers associated with linking LSRs to guidelines. Consider LSR workload implications for KT and language translation. Determine which aspects of the LSR guidance could be migrated to the Editorial Publishing and Policy Resource.
- **Tools** – No plans.
- **Training** – Continue with LEN webinar program.
- **RevMan/CLIB/Other tech** – One member of the LSR team (Kahale, Akl, et al.) is participating in the pilot of study-centric data in RevMan Web.
- **Pilot** – N/A.

Issues and Challenges:

- We aren't always aware of new LSRs early in the planning and protocol development process, so can't support teams as effectively as we would like. Aiming to address this by building connections with MEs to ensure they know how to get early support, and will notify all CRGs about revised LSR Guidance.
- Resource limitations for some author teams and editorial teams is a barrier to initiating an LSR.
- Issues with versioning and publication - generation of new DOIs for updates to LSRs can discourage review teams from publishing an update to an existing LSR or initiating a new LSR.
- Increasing visibility of LSRs in *CDSR*; e.g. with a searchable field that tags LSRs.
- The Updating Classification System has been difficult to utilised as general roll-out has been pulled back.
- Some LEN feedback indicates that monthly searches are too onerous and a disincentive to undertaking LSRs. We plan to work with the LEN to revisit the question: "How frequent do searches need to be for a review to be considered living?", taking into account the review topic, clinical area and other factors.
- The LSR guidance has been developed with a standard Cochrane intervention review in mind. Although the LSR concept is relevant to other review types (e.g. DTA), work needs to be undertaken to explore any nuances in how the LSR approach is applied to different review types.
- Authors have requested a policy on managing authorship for updates to an LSR. Feedback has been provided by EMD publishing policy Senior Editor on the conflict between proposed guidance and existing editorial policies.

Network meta-analysis (NMA)

Stage: 4. Planning for Implementation

Importance: High

Urgency: High / moderate

Core project team: Julian Higgins, Tianjing Li, Deborah Caldwell, Georgia Salanti, Kerry Dwan, Ella Flemyng

Strategy to 2020 target in 2019? Yes

Impact:

The impact of this project would be for Cochrane to be able to scale-up its inclusion of network meta-analyses in order to provide comparisons across multiple interventions within Cochrane Reviews that are methodologically coherent, as well as being more applicable and intuitive to the end users.

Success criterion:

Network meta-analysis being conducted efficiently and consistently according to new guidance across all Networks by the end of 2019.

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2019 progress:

- **Guidance** – New Handbook includes a chapter dedicated to NMA.
- **Tools** – Work commissioned from University of Bern to improve the CiNEMA tool.
- **Training** – New CIL module on NMA launched. NMA webinar series underway (on question formulation, MetaInsight tool, GRADE/SoF, and clear reporting and what editors should be looking for).
- **Support** – Methods Support Unit now first point for support on Cochrane NMA. Methods Groups Convenors are escalated more complicated queries.
- **RevMan/CLIB/Other tech** – No update.
- **Community engagement** – No update.
- **Pilot** – N/A.

Future plans (next 12 months):

- **Guidance** – MECIR extension for NMA underway, protocol template for NMA under development by Network Support Fellow.
- **Tools** – CiNeMa development to be completed, CRSU developing a user guide for their NMA tool (MetaInsight, Shiny app).
- **Training** – SATM updates underway.
- **Support** – Capacity building and the need to develop a network of NMA experts to support CRGs in NMA (to potentially be authors, peer reviewers or advisors). The Methods Support Unit assessing common issues | NMA protocol to design training.
- **RevMan/CLIB/Other tech** – Developments required to RevMan Web to support NMAs. Confirming how NMA output will be presented in the Cochrane Library will need to be considered. Data formats and migration between systems requires updates from the different platforms (Covidence, EPPI-Reviewer, GRADEPro) will need to be considered.
- **Community engagement** – No plans.
- **Pilot** – N/A.

Issues and Challenges:

- Creating a streamlined process between systems and for authors is heavily reliant on the new study centric data structure project in RevMan Web.
- Current problems with table structures due to the number of results that need to be tabulated, and size of some NMA reviews (>200 included studies) mean that producing large NMAs requires a different approach to standard intervention review formats.
- There is disagreement over appropriate Summary of Findings table formats, and this is creating uncertainty over which tables to implement.

Rapid Reviews

Stage: 1. Proposal and rationale

Importance: Moderate

Urgency: Moderate

Core project team: Chantelle Garrity, Barbara Nussbaumer-Streit, Ella Flemyng

Strategy to 2020 target in 2019? Yes

Impact:

The impact of this project will be to determine the desirability and feasibility of producing rapid reviews in Cochrane, and make a decision on whether or not to proceed further towards implementation. Rapid reviews could have potential impacts to reputation, sustainability, and perceived value to decision makers, which would all need to be considered.

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Success criteria:

Define a Cochrane Rapid Review, conduct methods research on vital points concerning the validity of rapid reviews, and determine the utility of rapid reviews in Cochrane for consideration by the Governing Board.

2019 progress:

- **Guidance** – Identified existing definitions and abbreviated methods employed to better understand the landscape of rapid reviews to inform discussions. Catalogued rapid reviews methods research and prioritizing future areas for development. Two research projects identified as gaps in knowledge that are completed (English-only and abstract only screening).
- **Tools** – N/A.
- **Training** – N/A.
- **Support** – N/A.
- **RevMan/CLIB/Other tech** – N/A.
- **Community engagement** – Survey completed with key Cochrane stakeholders to gauge feedback on the potential definition of a Cochrane RR.
- **Pilot** – N/A.

Future plans (next 12 months):

- **Guidance** – TBC.
- **Tools** – TBC.
- **Training** – TBC.
- **Support** – TBC.
- **RevMan/CLIB/Other tech** – TBC.
- **Community engagement** – TBC.
- **Pilot** – Proposal for the Editorial Board to consider rapid reviews in development for the 2020 mid-year governing meetings (April 2020) and if the decision is favourable, plans for a pilot would need to be developed.

Issues and Challenges:

- Yet to be identified from the pilot, should this progress.

Prognosis Reviews

Stage: 4. Implementation

Importance: Moderate

Urgency: Moderate

Core project team: Carl Moons, Lotty Hooft, Anneke Damen, Ella Flemyng, Toby Lasserson

Strategy to 2020 target in 2019? No

Impact:

The impact of this project will be the ability to scale-up the capacity and capability of Cochrane Review Groups and Networks to conduct prognosis reviews, and that authors and editors have a clear understanding of what's involved, how to assess or use the methods, and where to go for help and guidance.

Success criteria:

The start of at least 15 Prognosis Reviews across the CRGs, development of a streamlined process for CRGs to engage with the Prognosis Methods Group during the conduct of a prognosis review for help and support, and publication of 5 or 6 Prognosis Reviews by the end of 2020.

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2019 progress:

- **Guidance** – Templates for registering a title, writing a protocol and for writing the full review are finalized, competency list for review author team, peer reviewer and trainer has been developed, paper on systematic reviews and MA of prognostic factor and prognostic model studies have been published
- **Tools** – A variety of tools and guidance has been developed and are available via the PMG website: For example, guidance for searching, for review question, PICOTS definition and data extraction (CHARMS), RoB (QUIPS and PROBAST), for meta-analysis various papers and R scripts have been made available, and for grading is underway.
- **Training** – Three face-to-face training courses have been run through 2019 (including in total approx. 30 CRG members). Online Teaching material is being developed with Cochrane Training.
- **Support** – Ongoing support for reviews from the PMG.
- **RevMan/CLIB/Other tech** – None.
- **Community engagement** – Developed a network of prognosis review experts to support CRGs in prognosis reviews (who help as authors, peer reviewers and advisors). Survey of Cochrane editors completed to assess user and training needs.
- **Pilot** – Four published prognosis reviews and 22 ongoing.

Future plans (next 12 months):

- **Guidance** – Interest in a Cochrane Handbook for Prognosis Reviews. Further development of statistical guidance tools for prognosis reviews. Guidance for grading the quality of underlying evidence of systematic reviews of prognosis studies, including overall prognosis (defined), prognostic factor studies (underway), and prognostic models (underway).
- **Tools** – R scripts for meta-analysis of prognosis reviews.
- **Training** – New comprehensive courses for Cochrane authors, reviewers are being planned (on request). Other online webinars and teaching tools being developed with Cochrane Training.
- **Support** – Ongoing support for reviews from the PMG.
- **RevMan/CLIB/Other tech** – Initial discussions with the RevMan Web team held and need to develop templates in RevMan Web in 2020. Need to confirm how Prognosis Reviews will be supported in RevMan Web and confirm how data will efficiently feed between the necessary systems involved in the whole process (request involvement in the new study centric data discussions).
- **Community engagement** – PMG members are actively participating in developing methods/guidance/surveys/teaching material, as well as to help reviewers in the process of their Cochrane Review (where needed).
- **Pilot** – Need to scale-up rapidly as the request from CRGs/networks to embark on prognosis reviews increases and thus the request for guidance from more experienced prognosis reviewers is needed.

Issues and Challenges:

- Biggest challenge is to keep pace with the rapidly increasing interest of prognosis reviews and thus with the required guidance in their review process. The number of ‘independent’ reviewers need to be higher, and also the number of engaged experienced prognosis researchers (with knowledge of both primary and meta prognosis studies) need to increase. This means more advanced and comprehensive training (by the current experienced prognosis researchers) for enthusiastic reviewers in the CRGs is needed. Capacity building has been the main focus of last two years and with great success, but with increasing prognosis reviews this needs to be continued. This is one of the reasons the PMG decided to embark quickly on writing a Cochrane Handbook within the time period of max 2.5-3 years.
- One of the reviews supported by the PMG team published via the EMD fast track attracted substantial criticism during the peer review process, which was partially addressed by the authors but indicates that in some areas of prognosis review methods there remain areas of contention that will need to be developed/defined for Cochrane prognosis reviews.

Clinical Study Reports as one of the main data sources for drug intervention reviews

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Stage: 2. Proof of concept

Importance: High

Urgency: High / moderate

Core project team: Ella Flemyng

Strategy to 2020 target in 2019? Yes

Impact:

The impact of this project will be the development of consensus on when and how to use clinical study reports (CSRs) in Cochrane Reviews, which will be particularly important for reviews of drug therapies where there is a high risk of reporting bias. In such cases the use of these CSRs will result in Cochrane Reviews that are more transparent, of higher-quality and more likely to provide reliable information to guide health decisions.

Success:

Hold a consultation meeting to discuss the feasibility of using Clinical Study Report as the main source of data in Cochrane drug intervention reviews. If agreed, three pilot reviews should be initiated before the end of 2019.

2019 progress:

- **Guidance** – Developed a first draft of a CRG Starter Pack for using (via the CSR Working Group).
- **Tools** – No update.
- **Training** – No update.
- **Support** – No update.
- **RevMan/CLIB/Other tech** – No update.
- **Community engagement** – Held an in-person consultation meeting on using CSRs in Cochrane Reviews in May 2019 (see [here](#)). Cochrane CSR Working Group has 30 members. Cochrane submitted an open response to the CSR sharing pilot from the FDA (see [here](#)) and posted a public statement of support for the EMA CSR sharing policy (see [here](#)). CSRs included in the Advocacy Strategy approved by the Governing Board in Oct 2019. Held initial discussions with Clinical Study Data Request and vivli about sharing possibilities.
- **Pilot** – Five reviews highlighted an interest in using CSRs (some initiated).

Future plans (next 12 months):

- **Guidance** – Develop guidance for authors and editors on how to use CSRs in Cochrane Reviews.
- **Tools** – Need to consider tools as part of a pilot.
- **Training** – Need to consider tools as part of a pilot.
- **Support** – Develop a process for gaining access to CSRs for use in Cochrane Reviews, including appropriate data sharing agreements. Confirm how Cochrane could store and manage information on trials with CSRs.
- **RevMan/CLIB/Other tech** – Need to consider tools as part of a pilot.
- **Community engagement** – Need to proactively recruit relevant stakeholders to the CSR Working Group.
- **Pilot** – To be initiated.
- **Other** - Review and revise the 2013 Access to Data Statement in light of the outcome of this meeting and the project generally

Issues and Challenges:

- Project put on hold after the in-person consultation meeting in May 2019 so the Editorial Board can confirm methods priorities during the Colloquium for Cochrane in 2020.

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