

**By Group** 

<b>Cochrane Methods</b> Adverse Effects

- Daniela Junqueira, with support from other members of the Group and experts in the field, has continued updating the CONSORT Harms Extension.
- NIHR fellowship project entitled: <u>Using unpublished data</u>, text mining and social media to maximise the efficiency and <u>effectiveness of the retrieval of adverse effects data</u>. This study will assess the usefulness of social media (e.g. Facebook, Twitter) and unpublished material (e.g. reports, manufacturer data) and will create database searches to find information on the side effects of healthcare interventions.
- Developing the methodology of searching for adverse effects of non-drug interventions particularly surgical and medical devices
- Feasibility study of using social media as a data source for information on adverse effects using a case study of Humira and drugs in pregnancy.
- Joey Kwong returned to Cochrane Hong Kong, after working at Cochrane China and Cochrane Taiwan. She will actively promote Cochrane activities with the existing HK team. She is leading the development of an Asia-Pacific clinical practice guideline focussing on the adverse effects of non-steroidal anti-inflammatory analgesics (NSAIDs) in patients with arthritis.



- Working relationships with individuals working in the NIHR, WHO EU office and NICE. The Group benefits from such links and is actively seeking to recruit individuals from other relevant research organisations.
- Two workshops at the Edinburgh Colloquium 2018.
- Updated Group website to provide more accessible resources including categorisation of resources and quick guidance documents; examples of priority setting both for prioritisation of reviews and prioritisation of methods research; and using systematic reviews to inform prioritisation of primary research.
- The Cochrane Consumer and Communication Review Group provided an excellent example of how to adapt the methods group guidance for a review group.
- Regular calls that are open to any individual with interest to engage in research priority setting. Contact us



- The <u>Group</u> would like to pay tribute to its senior co-convenor Doug Altman who sadly passed away in June 2018. Doug leaves behind an incredible legacy to medical research and statistics.
- Collaborated with Julian Higgins and Jonathan Sterne at the University of Bristol on finishing and implementing the ROBINS-I (previously ACROBAT-NRSI) tool and on revising the Cochrane Risk of Bias tool for randomised trials (Risk of Bias Tool 2.0).
- Collaborated with Julian Higgins and Jonathan Sterne from University of Bristol and the Editors of the *Cochrane Handbook* on updating core chapters of the *Handbook*.
- Evaluated and redefined its ways of working and communicating with members. Producing a Bias Methods Group Strategy which has been published on the Cochrane Methods <u>website</u>. Implementation and adjustment of the strategy is ongoing.

Over the next year the Group plans to:

• Continue the work on updating bias relevant chapters of the *Cochrane Handbook*.



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	<ul> <li>Participate in the development of a tool for assessing the severity of conflicts of interest in medical research (the TACIT project).</li> <li>Lead the work on developing a tool for assessing risk of bias due to missing results (the ROB-ME tool).</li> <li>Organise the Methods Symposium at the 2018 Cochrane Colloquium in Edinburgh in honour of David Moher.</li> <li>Evaluate and adjust the Group Strategy.</li> <li>Update and revise the Group website and continue to distribute newsletters to members and people interested in the work of the group.</li> </ul>
Cochrane Methods Comparing Multiple Interventions	<ul> <li>The <u>CINeMA tool</u> has been refined to allow assessment of confidence in a network meta-analysis.</li> <li>Network meta-analysis (NMA) implementation work to address the new Cochrane Content Strategy continues, including:         <ul> <li>(i) identifying individuals to work with each CRG Network;</li> <li>(ii) completion of the NMA Handbook chapter and decision to put it in the core methods section of the Handbook;</li> <li>(iii) planning for an online leaning module on NMA;</li> <li>(iv) initiation of a process to develop MECIR standards for NMA.</li> </ul> </li> </ul>
Cochrane Methods Economics	<ul> <li>National Institute for Health Research funding awarded to provide methods support for a series of Cochrane intervention, prognostic and diagnostic reviews conducted by the Cochrane Gynaecological, Neuro-oncology and Orphan Cancer Group. The economic components vary from the inclusion of Brief Economic Commentaries, to Integrated full reviews of economic evidence and some include decision analytic models as a further level of evidence synthesis. The first of these reviews are now in the editorial process, with one fast tracked to support UK NICE guidelines.</li> <li>Conducted an integrated full review of economic evidence and sophisticated economic model directly incorporating the meta-analysis of effects for the Cochrane Eyes and Vision and the Effective Practice and Organisation of Care Groups on increasing uptake of screening for diabetic retinopathy. This work has been published. Cochrane Library link.</li> <li>A series of brief economic commentaries within the suite of reviews looking at surgical approaches to treat women with stress urinary incontinence have been published. This topic is high profile with concerns over the safety of some techniques. The brief economic commentaries summarised the economic evidence to highlight some of the trade-offs in outcomes.</li> <li>A new chapter outlining economic methods has been submitted for inclusion into the editorial process for the Cochrane Handbook. This will be supported by supplementary material hosted on the Group Website.</li> <li>Revised methods guidance for the Campbell Collaboration will be developed.</li> </ul>
Cochrane Methods Equity	<ul> <li>Vivian Welch, co-convenor of the Equity Methods Group was appointed Editor-in-Chief of the Campbell Library in September 2017.</li> </ul>



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• In February 2018, the Lancet published a <u>Series on Canada's Global Leadership on Health</u> including a paper entitled 'Canada's global health role: supporting equity and global citizenship as a middle power' of which Peter Tugwell was a co-author.
<ul> <li>Active participation in the ongoing debate around data sharing and how this might best be achieved from the perspective of the systematic reviewer by:         <ul> <li>Contributing to a consensus-building process. Results have led to the publication of principles and recommendations for the sharing and re-use of IPD.</li> <li>Participating in a series of academic round table discussions with the developers of Vivli. Launched in July 2018 Vivli aims to become a global clinical research data sharing platform.</li> <li>Contributing to the European Medicines Agency Technical Anonymisation Group regarding the appropriate methodology for anonymising IPD while maintaining data utility for data sharing</li> </ul> </li> <li>Richard Riley, Jayne Tierney and Lesley Stewart are writing/editing a book on meta-analysis using IPD (Wiley), which aims to be a highly practical guide to the concepts and methods.</li> <li>Update of the IPD reviews chapter of the Cochrane Handbook.</li> <li>NextGen project: Lesley Stewart chaired a Cochrane Strategy Group to consider the future role of IPD synthesis within Cochrane (diverse data component development of the Cochrane Content Strategy). This international group included several Group members and its consensus opinion was that Cochrane should engage more with IPD synthesis. Not only because the direction of travel in the wider community is towards more sophisticated methods of synthesis, but also because increasing numbers of Cochrane Reviews are revealing that synthesis of published aggregate data is often insufficient. A report which is intended as a starting point for wider discussion is available on request. Led by Jayne Tierney, the Group intends to develop a decision tool to help reviewers decide when IPD are needed.</li> </ul>
<ul> <li>Carol Lefebvre and Julie Glanville have worked with other Group members to undertake a major revision of the <i>Cochrane Handbook</i> chapter on "Searching for and Selecting Studies". Feedback from the Group membership and the Cochrane Information Specialist community was incorporated.</li> <li>Julie Glanville and Carol Lefebvre will present a workshop at the 26<sup>th</sup> Cochrane Colloquium in Edinburgh entitled 'Searching for studies for inclusion in Cochrane reviews: an introduction for Cochrane review authors and others.'</li> <li>Alison Weightman together with other Group members &amp; the Cochrane Rapid Reviews group are preparing a funding bid to investigate the effect on review findings from the use of abbreviated search and text mining methods for study identification across the spectrum from clinical to public health/social science review topics.</li> </ul>
<ul> <li>Development of the ROBINS-I risk of bias tool alongside revisions to the risk of bias tool for RCTs. The concept of using algorithms to reach bias judgements based on signalling questions has emerged, initially for the risk of bias tool for RCTs, where the permutations of answers to signalling questions are simpler; this is now being adopted for ROBINS-I.</li> </ul>



	<ul> <li>Separate versions of the ROBINS-I tool are also being developed for different key non-randomized study designs for evaluating interventions (NRSI). The underlying structure of the bias domains is maintained across the different versions of the tool, but the signalling questions are adapted to reflect the ways in which the biases arise in different kinds of studies.</li> </ul>
Cochrane Methods Patient Reported Outcomes	<ul> <li>An inventory of published anchor-based minimally important differences (MIDs) associated with patient reported outcome measures (PROMs) has been created by searching MEDLINE, EMBASE, PsycINFO, and CINAHL to identify studies estimating anchor-based MIDs of PROMs. This inventory of available MIDs in the medical literature and their associated credibility will be of great use for anyone using PROMs to inform healthcare decisions, including clinical trialists, systematic review authors, patients, and clinicians. The use of credible anchor-based MID estimates will be promoted by the Group.</li> <li>A comprehensive systematic survey of published RCTs to determine the extent to which trialists use MIDs when evaluating the impact of interventions on PROs is almost complete. The survey determines         <ul> <li>The frequency of MID use.</li> <li>The credibility of these estimates among studies that use an MID.</li> <li>Investigator's reasons for using MIDs i.e. interpretability or trial design (E.g. sample size).</li> <li>How are effect estimates presented in relation to the MID.</li> <li>The inferences investigators' make about the PROM result in relation to the MID.</li> </ul> </li> </ul>
Cochrane Methods Prognosis	<ul> <li>The implementation of reviews of prognosis studies within Cochrane has started with material developed to support this e.g. a title registration form, protocol template, review templates (underway).</li> <li>The exemplar program now includes 16 registered titles and 9 registered protocols. The first full reviews will be published in the last quarter of 2018.</li> <li>By Autumn 2018 all editors of Networks and CRGs will be surveyed to gather feedback on the implementation, necessary training, and sustainability of systematic reviews of prognosis studies.</li> <li>Updates to the Group website to make information about current processes better accessible.</li> <li>Development of further training material for both distance and face-to-face learning for Cochrane authors and editors.</li> <li>Development of guidance for conducting and reporting prognosis reviews, similar to MECIR for intervention reviews. A draft MECIR-type document for consultation is expected by late 2018.</li> </ul>
Cochrane Methods Qualitative and Implementation	<ul> <li>A series of 5 papers have been published in the Journal of Clinical Epidemiology outlining new Cochrane methodological guidance on the conduct of qualitative evidence synthesis         <ul> <li>Paper 1: introduction</li> <li>Paper 2: methods for question formulation, searching, and protocol development for qualitative evidence synthesis</li> <li>Paper 3: methods for assessing methodological limitations, data extraction and synthesis, and confidence in synthesized qualitative findings</li> </ul> </li> </ul>



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	<ul> <li>Paper 4: methods for assessing evidence on intervention implementation</li> <li>Paper 5: methods for integrating qualitative and implementation evidence within intervention effectiveness reviews</li> <li>A series on CERQual that further elaborates GRADE CERQual has been published in <i>Implementation Science</i>.</li> <li>Updated chapter for the <i>Cochrane Handbook</i>.</li> <li>Contributed to the WHO working group on complex interventions and complex health systems and produced 4 papers for the series to be published in <u>BMJ Global Health</u>.</li> </ul>
Cochrane Methods Rapid Reviews	<ul> <li>Increased social media profiles solidifying the Group's presence on Facebook and Twitter with the aim to reach a broader audience of interested stakeholders.</li> <li>The Group newsletter now has over 260 subscribers and highlights the activities of the group, upcoming events including training opportunities, new publications in the field, and other relevant items.</li> <li>Results of a membership survey conducted in May 2018:         <ul> <li>72% respondents conduct systematic reviews or 68% rapid reviews</li> <li>45% regularly read rapid reviews</li> <li>47% do research on systematic reviews and/or 36% do research on rapid reviews</li> <li>13% reported to have no experience with rapid reviews</li> <li>81% expressed interest in helping to conduct ongoing research projects; providing expert opinion/consultation; or developing joint research projects.</li> </ul> </li> <li>Methods projects that evaluate the current reporting of rapid reviews are nearly completed         <ul> <li>We will be taking a closer look at the report structures of rapid review reports (both journal and non-journal published).</li> <li>We will be completing our study that assesses rapid reviews as an information product.</li> <li>We continue work on developing reporting guidelines for rapid reviews planned to coincide with revision of PRISMA-SR. The team is developing protocols to assess certain abbreviated methods in the conduct of rapid reviews.</li> </ul> </li> <li>Rapid reviews have been identified as one of the key areas of focus of Cochrane's content strategy. A work plan has been created outlining considerations for the development of a Cochrane Rapid Review as an official product. This plan will:             <ul></ul></li></ul>



	<ul> <li>When approved the Group will implement the work plan over the next 12-18 months. This will lead to the eventual development of a chapter in the Cochrane Handbook with accompanying education and training materials.</li> </ul>
Cochrane Methods Statistics	<ul> <li>The Group's scientific meeting will take place on Monday September 17, 2018, from 07:30-08:45. The following presentations will take place:         <ul> <li>Methods for evidence synthesis in the case of very few studies. Guido Skipka (Institute for Quality and Efficiency in Health Care)</li> <li>A comparison of seven random-effects models for meta-analyses that estimate the summary odds ratio. Ian White (MRC Clinical Trials Unit)</li> <li>Methods to calculate the uncertainty in the estimated overall effect size under the random-effects model. Areti Angeliki Veroniki (University of Ioannina).</li> </ul> </li> </ul>