

Final Report N61: Refinement of and extension to the Cochrane Risk of Bias tool for Randomised trials

Summary/list of the original objectives

- (i) To revise the Cochrane Risk of Bias assessment tool through the development and incorporation of signalling questions that will guide the assessor to reach domain-level and outcome-level risk of bias judgements, extending its remit to cover RCTs with non-standard designs (e.g. crossover trials, cluster-randomised trials).
- (ii) To pilot the revised tool.
- (iii) To collate an openly-available pool of worked examples for review authors, to accompany the tool as a learning aid.

What was achieved:

(i) Tool development:

- We conducted two reviews to inform the development of the revised tool before the first development meeting. The first was an up-to-date review of empirical evidence of bias in RCTs, which included all meta-epidemiological studies addressing biases relevant to the tool development.[1] The second review collated critiques of the existing Cochrane risk of bias tool and assessed how the tool was used in practice.[2]
- First development meeting was held in Bristol on 18-19 August 2015 and was attended by 24 contributors, with representation from all Hubs. An initial proposal of the revised tool was presented together with the empirical evidence and by the end of the meeting the first draft of the tool emerged. Bias-domain specific working groups were formed and tasked with further developing the signalling questions and related guidance.
- Work continued within working groups, spearheaded by the core team, to prepare the material ready for the first round of piloting and post-pilot refinements before the second development meeting.
- Second development meeting was held in Bristol on 21-22 April 2016, attended by 24 contributors. Issues identified in the pilot were addressed and the structure of the tool firmed up. Working groups were tasked with developing default algorithms for reaching a domain-level judgement and producing worked examples. Another round of piloting was agreed to test the refined version of the tool.
- Working groups continued development of the algorithm and guidance after the meeting.

(ii) There were two rounds of piloting:

- The main 3-day piloting event was held in Bristol (9-11 February 2016) with 17 participants taking part in house and further 10 participants contributing to the piloting remotely.
- Second round of piloting took place in Summer 2016, with 10 reviewers testing the mature version of the tool.

(iii) Launch and dissemination of the tool:

- The tool and the full guidance with examples was posted on www.riskofbias.info in October 2016 (beta version for public use)
- We held a formal launch event at the Cochrane Colloquium in Seoul, South Korea in October, consisting of a special lunchtime session (~100 delegates) to announce the tool and a half-day training workshop (~60 delegates).
- We held talks with Cochrane representatives in Seoul about implementation of the tool within Cochrane and building the tool into the new version of Cochrane review software.
- We held 2 training webinars for the tool.

Next steps over coming 12 months:

- A decision was made to delay the main journal publication of the tool until the tool has been extensively used in the 'real world' to provide sufficient user feedback and testing. We expect to submit for publication in 2017.
- We have set up a collaboration with several review groups who will use the tool in their reviews and contribute to a validity study
- Formal talks with Cochrane about implementation will take place at Cochrane Mid-year Meeting in March 2017 in Geneva.