# Cochrane Scientific Committee

## Recommendation statement/report

**Date:** July 2017

**Relates to agenda item and meeting reference:** 6i 18th May 2017

**Priority:** Medium

**Open access/restricted:** Open

## Review of the updated 'Risk of bias' tool RoB 2.0

**Lead developers/investigators:** Jonathan Sterne and Julian Higgins

**Summary of development:** Developers initiated revisions to the current tool based on work developing the ROBINS I tool. Development involved expert working groups (for different domains of bias and different trial designs) and consensus, with piloting of draft versions with Cochrane collaborators and revisions made. Higgins and colleagues (2016) describe 10 key changes to the original tool (2008, 2011). Please see extract from *Cochrane Methods* for summary and qualification of these changes. There is also a table that shows changes to the domain terminology between the current and new tools. Some of the key changes are (i) the assessment is at the level of a specific result (i.e. a specific comparison at a specific time point and using a specific statistical analysis); (ii) the assessment is specific to whether interest focusses on the effect of assignment to intervention or the effect of starting and adhering to intervention; (iii) the domain of selective outcome reporting has been re-focussed. As with the ROBINS I tool, signalling questions are introduced. The new tool also provides a procedure to reach an overall risk of bias. Finally, there are different templates for different trial designs.

There remain some outstanding issues. These are:

- How many results should be assessed for each study?
- How best can the assessment be integrated into the data extraction process, given that some relevant information is study-level, some is outcome-level and some is result-specific?

Developers have introduced the tool to Cochrane members at both the Seoul and Geneva meetings. They have yet to publish this development and thus undergo peer review.

**Caveats:** There is increased complexity and changes that impact on updating of reviews particularly with many included studies. Balancing the implementation demands might compromise methodological integrity when applying the RoB 2.0. Consideration therefore is given to allow both tools operate but not in the same review, including updates.

**Impact:** We expect the transition between tools may pose both practical and technical issues.

**Resources needed:** Software development is required and is important to facilitate easier transition. This includes the ecosystem of authoring tools e.g. Covidence and RevMan. Developers have developed algorithms to map responses to signalling questions to judgements about risk of bias. Training and methods support for implementation are needed, along with consideration of implementation issues.

Higgins JPT, Sterne JAC, Savović J, Page MJ, Hróbjartsson A, Boutron I, Reeves B, Eldridge S. A revised tool for assessing risk of bias in randomized trials In: Chandler J, McKenzie J, Boutron I, Welch V (editors). Cochrane Methods. Cochrane Database of Systematic Reviews 2016, Issue 10 (Suppl 1). dx.doi.org/10.1002/14651858.CD201601.

The following table lists the tools and guidance for the different versions, please visit www.riskofbias.info.

| | |
|---|---|
| **Individually randomized, parallel group trials** | 1. Guidance for using the RoB 2.0 tool for individually randomized trials<br>2. The tool<br>3. Blank templates with two variants:<br>a. RoB 2.0 when interest is in the effect of assignment to intervention<br>b. RoB 2.0 when the interest is in the effect of starting and adhering to intervention |
| **Cluster randomized, parallel group trials** | 1. Guidance for using the RoB 2.0 tool for cluster-randomized trials.<br>2. The tool (cluster-randomized trials)<br>3. Blank template with one variant<br>a. RoB 2.0 for cluster randomized r trials when the interest is in the effect of starting and adhering to intervention. |
| **Individually randomized, cross-over trials** | 1. Guidance for using the RoB 2.0 tool for cross-over trials<br>2. The tool (cross-over trials).<br>3. Blank templates with two variants: |

| | |
|---|---|
| | a. RoB 2.0 for cross-over trials when interest is in the effect of assignment to intervention<br>b. RoB 2.0 for cross-over trials when the interest is in the effect of starting and adhering to intervention. |

## CSC RECOMMENDATION

[x] *Highly recommended*
The is mandatory for new reviews when officially launched. For updates, it is not reasonable to re do previously included studies and a strategy is required to handle these situations.

[ ] *Recommended with provisions*

[ ] *Optional/advisory (one among several options)*

[ ] *Not recommended*

## CSC STATEMENT

### Summary statement

Members agreed the tool should be implemented. Although, one member raised the definitional difficulty in shifting from 'unclear' to 'some concerns'. Further explanation was that, unclear covered two distinct points: (i) you cannot ascertain what happened to assess bias, or (ii) you know what happened but it is inadequate (unclear) to assess risk of bias. The new signalling questions will highlight where there is no information and the overall assessment allows a judgement to be made to inform the reader (e.g. serious concerns). The signalling questions are mapped to the risk of bias judgements. Another member of the CSC had applied the tool to fifty different kinds of studies successfully and welcomed the new version of the tool. Recent meetings presenting the tool to the Co-ordinating editors had not raised any issues of concern.

### Credibility & validity

This tool has high credibility in its RoB 1.0 version and this version involves developments (signalling questions used in other validated tools (QUADAS 2))

### Limitations/caveats

Implementation awaits some final adjustments to the tool and integration into RevMan requires further consideration. Also, implementation of the tool may reveal other issues.

### Areas of concern/uncertainty

None specified

### Impact on Cochrane

Minor as one tool replaces another for new reviews. There are issues for CRGs and the editorial unit to ensure its implementation when fully released.

### Cochrane resources needed

Training, distribution of guidance and software development are key factors for implementation once the developers have produced a final version.

### Implementation

CSC members are not responsible for managing implementation of these recommendations which will require an implementation plan to ensure co-ordination for a smooth introduction. This will include launch, timescales and roll out strategy. Therefore, this statement does not signify immediate implementation.