

# RoB 2 implementation

**Matthew Page**  
25 November 2019

Trusted evidence.  
Informed decisions.  
Better health.



# Key messages

- New tool needed to address issues in application of previous version
- Rollout will be slower than RoB 1, focus on reviews at an early stage
- Supported, gradual rollout in 2020
- Pilot underway to support review teams who want to use RoB 2 now (author use, software, editorial process and presentation in published reviews)
- Will be optional for reviews in progress and updates to switch
- RveMan Web needed at data entry but not before



# Rationale for new tool

- Confusion over application of domains in RoB 1 (Savovic 2014)
- Use of Other bias
- Open label trials
- Focus on ‘studies at risk of bias’ rather than impact of bias on results



## RoB 2: When?

Possible for titles **registered** from now to plan use of RoB 2

- Individually randomised parallel group trials covered by current tool in RevMan Web
- Extensions for variations on this design (cluster/crossovers) being finalised and not yet in RevMan Web

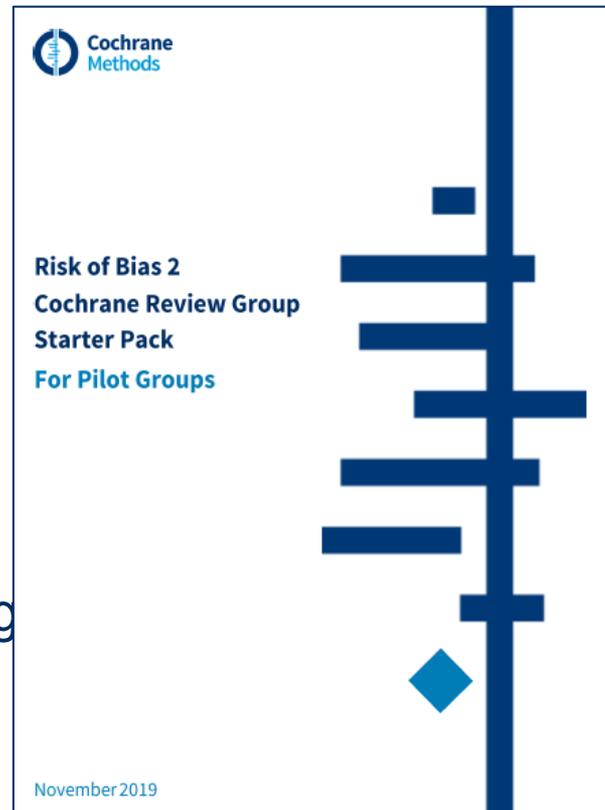
No formal requirement to adopt until dependencies worked through

Associate Editors to be informed if CRGs have a team of authors keen to adopt now



# RoB 2 pilot

- Cohort of eight early adopters (to-date)
- Reviews already at protocol stage or later
- Methods & tech support from central team
- Gathering evidence on how people find using tool, what editors need to look for, impact on technology/publishing/presentation



# Methods support

- Hands on support for early adopters by Methods Support Unit
- Clinics – drop ins to help people over methods & technical hurdles
- Scale up likely from pilot as new author teams join



# Tools

- Updated data collection form
- RoB 2 Excel tool
- Potential plans for an online tool



# Training

- Cochrane Interactive Learning is RoB 2 compliant
- Held a three-day, in-person training course in July 2019
- Initiated updates for the SATMs
- Looking into the feasibility of virtual workshops, a webinar series, creating learning profiles within Cochrane Account to track completed training of Cochrane members, and more.

# Guidance

- *New Cochrane Handbook for Systematic Reviews of Interventions*
- MECIR Conduct Standards updated
- RoB 2 cribsheet that summarises and explains the tool, fields, signalling questions and key considerations for reaching risk of bias judgements (for each domain and overall)
- Development of RoB 2 FAQs
- How-to guide for RoB 2 data input in RMWeb and the RMWeb Practice Platform

# RoB 2

## Why focus on reviews at registration?

Protocols in pilot indicate stress points beyond subheading in methods section:

- Effect of interest (assignment/adherence)
- N and prioritisation of outcomes - link with SoF table needs emphasis
- Dealing with missing data (ITT, best case-worst case)
- Subgroup/sensitivity analysis – can focus on overall RoB and not domain specific approach



# Reviews in progress and updates?

- Possible, but needs careful thought
- Working changes in to review post-protocol can be difficult
- For updates consider bias assessment in last version and effort for N included studies
  - Was RoB 1 implemented fully (RM5 allowed you to deselect any domain)?
  - Was it implemented reliably?
  - N studies contributing information to SoF table outcomes?

# RevMan

RoB 2 can be used outside of RMWeb, but:

- RM5 table structure tied to study; care needed in making right outcome level selection
- Not all studies need assessment
- Unclear ≠ some concerns
- Additional table hard to construct

Currently RoB 2 can only be switched on in RMWeb by ITS team (this breaks backwards compatibility)

RoB 1 OR RoB 2.0 not both in same review



# RevMan Web

- Switch over to RMWeb not needed immediately
- Can stay in RM5 until data entry (T > P > R)
- Authors and editors get used to new features before completing RoB 2



# What we don't know (yet)

- Time (SWAR)
- Changes to MECIR reporting standards & results subheading **!**
- Proposals for presentation on CLIB

