BACKGROUND

Systematic reviews of clinical trials aim to include all relevant studies conducted on a particular topic and to provide an unbiased summary of their results, producing the best evidence on the benefits and harms of medical treatments. Recommendations made by the National Institute for Health and Clinical Excellence (NICE), who issue guidance on the use of treatments and procedures within the NHS, are based largely on systematic reviews. To be considered a reliable source of evidence about healthcare practice, systematic reviewers should explicitly address the issue of missing outcome data at the study level. Systematic reviewers should be encouraged to obtain any missing outcome data from trialists, failing this it is recommended that reviewers present missing outcome data from their reviews in a transparent way. Outcome reporting bias (ORB) as a result of missing outcome data is one of the many problems that has been shown to affect the validity of a review meta-analysis [1].

OUTCOME MATRIX GENERATOR

The outcome matrix generator application has been set up as a tool for identifying missing outcome data at the study level in a review. Using the outcome matrix generator, we propose a five step approach for investigating missing outcome data in a review and subsequently using the matrix as a tool to assess for ORB.

GO TO MATRIX GENERATOR APPLICATION:
http://mcrctu.org.uk/orbit/

A FIVE STEP APPROACH FOR ADDRESSING MISSING OUTCOME DATA IN REVIEWS

Step 1 - Exclusion Criteria
The first step is to ensure that no potentially eligible studies are excluded from the review for the sole reason of not reporting on any review outcomes of interest. If a study report does not give results for, or mention, certain outcomes this does not necessarily mean that they were not measured or analysed. For this reason, studies MUST NOT be excluded if they do not report on any of the relevant review outcomes.

Step 2 - Constructing the Outcome Matrix from study reports
The outcome matrix is constructed by listing all the eligible studies as rows and all the review outcomes of interest as columns in the matrix. Outcomes can be distinguished in terms of review primary and secondary outcomes. Outcomes that are not of interest in the review but are reported in the reports for eligible trials are also listed. Our Matrix Generator will automatically create your blank matrix.

Step 3 - Completing the Outcome Matrix
Once the outcome matrix has been constructed, the outcome matrix can be filled in using the Matrix Generator. For each study, a reviewer should indicate which outcomes were reported and differentiate between ‘full reporting’, ‘partial reporting’, ‘not reported – not clear whether measured or not’ and ‘not measured’. Guidelines for filling in the matrix can be found on our website (http://www.liv.ac.uk/nwhtmr/orbit/outcome_matrix.htm).

Step 4 - Contacting Trialists
After the outcome matrix has been completed, reviewers should make an attempt to contact the trialists from the studies included in the review that partially reported the review outcomes of interest or where it was not clear whether the outcome was measured or not. The purpose of this contact is to try and obtain missing outcome data to include in the review analysis or to confirm that the outcomes of interest were not measured. The matrix should be updated accordingly.

Step 5 - Assessment of ORB
Once the outcome matrix is complete and trialists have been contacted for missing data, a reviewer may then want to assess the potential risk of outcome reporting bias as a result of outcomes being partially reported or measured but not reported. A tutorial for assessing the potential for outcome reporting bias in a review, using the ORB classification system (Kirkham et al, 2010) [1] is provided in Dwan et al (2010)[2].

CONCLUSIONS

Our outcome matrix generator has thus far received positive feedback from Cochrane reviewers and the Cochrane handbook editors. We encourage all review authors to use the outcome matrix generator as a tool to transparently report missing study data from their reviews. The matrix generator has a built-in facility to easily copy and paste the matrix into their reviews. We also encourage reviewers to assess the potential risk of outcome reporting bias as a result of missing outcome data. Collaborations are ongoing with regards to including the outcome matrix as a standard tool for reporting missing study data in all Cochrane reviews.

REFERENCES