Objective reporting bias (ORB) has been defined as the selection for publication of a subset of the original recorded outcome variables based on the results [1]. Empirical research provides strong evidence of an association between significant results and publication in randomised controlled trials (RCTs); studies that report positive or significant results (P<0.05) are more likely to be published and outcomes that are statistically significant have higher odds of being reported [2]. The prevalence and impact of the problem in Cochrane reviews is unknown. Some of the reasons provided by trialists for the non-reporting of non-significant outcomes help demonstrate the existence of ORB.

"It was just unintentional and we thought it confusing so we left it out. It didn’t change [i.e. was non-significant] so it was a result that was not particularly informative let’s say and was to us distracting and unintentioning."

"In the end there was nothing really in it, I mean there were no differences. If the result was statistically significant - I guess we would have had to put it in."

"Yes because what happened is, I am left with a study where everything is [non-significant], even though we walked in believing that we would see a difference, and even though we had some preliminary information you know anecdotal that there should be a difference, there was no difference. So, it really turned out to be a very negative study. So we did collect that information, and again it’s a non-result, but there are only so many negative results you can put into a paper."


table

Other outcomes help demonstrate the existence of ORB.

\[
\begin{array}{ccc}
\text{Classification} & \text{Total} & \text{n (%)} \\
\hline
\text{Clear that the outcome was measured and analyzed} & 30 (4) & 8 (1) \\
\text{Analysed but insufficient for MA (Low Risk)} & 117 (16) & 0 (0) \\
\text{Measured but not necessarily analysed (High Risk)} & 122 (17) & 33 (5) \\
\text{Measured but not necessarily analysed (Low Risk)} & 207 (29) & 176 (25) \\
\text{Not measured - UNLIKELY measured (Low Risk)} & 19 (3) & 712 \\
\hline
\end{array}
\]

CONCLUSIONS

ORB is an under-recognised problem in systematic reviews. To be considered a reliable source of evidence, systematic reviewers need to address explicitly the issue of missing outcome data. Extra care is required during data extraction, reviewers should identify when a trial reports that an outcome was measured but not reported. Trials were classified according to whether:

- Clearly the outcome was measured and analysed
- Clearly the outcome was measured and not necessarily analysed
- Unclear whether the outcome was measured
- Clear the outcome was not measured

For each category assignment an assessment of the risk of outcome reporting bias, in terms of high, low or no risk, was made. Lead reviewers assisted with all assessments because of the specialist clinical areas involved.

\[\text{Classification} \rightarrow \text{Total} \rightarrow \text{n (%)}\]

**RESULTS**

Over half (157/283, 55%) the reviews did not include data for the review primary outcome from all eligible trials (Figure 1). The median amount of review primary outcome data missing for any reason was 10%, Whilst 50% or more of the potential data was missing in 70 (25%) of reviews.

For 788/2562 (31%) trials, the review primary outcome was either partially reported or not reported in the review. Seventy-six trial reports could not be assessed as the articles were non-English language, leaving 2486 assessable trials and a total of 712 trial reports requiring a classification (545 included in reviews and 167 excluded from reviews due to no relevant outcome data).

In 155 (6%) of 2486 assessable trials, it was clear from the trial report that the review primary outcome was measured and analysed but results were not reported or only partially reported (Figure 1). The specificity for predicting that the outcome had been measured was 92% (23/25, 95% CI 81%, 100%) while the specificity for predicting that the outcome had not been measured was 77% (23/30, 95% CI 62%, 92%). For trials with no mention of the outcome in the report, judging the presence of bias was shown to have a sensitivity of 88% (95% CI 65%, 100%) and specificity of 80% (95% CI 69%, 93%). A third of Cochrane reviews (96/283, 34%) contained at least one trial with high ORB suspicion for the review primary outcome.

\[\text{Impact} \rightarrow \text{Effect estimate by 20% or more.} \]

**CONCLUSIONS**

ORB is an under-recognised problem in systematic reviews. To be considered a reliable source of evidence, systematic reviewers need to address explicitly the issue of missing outcome data. Extra care is required during data extraction, reviewers should identify when a trial reports that an outcome was measured or observed no events, and contact with trialists should be encouraged. Many reviewers will need to use judgment regarding the potential for outcome reporting bias and we have shown that accurate assessment is possible.