



Selective outcome reporting: risk of bias

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Definitions

- Selective reporting bias:

The selection, on the basis of the results, of a subset of analyses to be reported

- Usually linked to statistical significance

Types of selective reporting

- **outcomes**
- subgroups
- adjusted vs unadjusted results
- first period results in crossover trials
- per protocol vs ITT
- complete case vs LOCF vs other methods

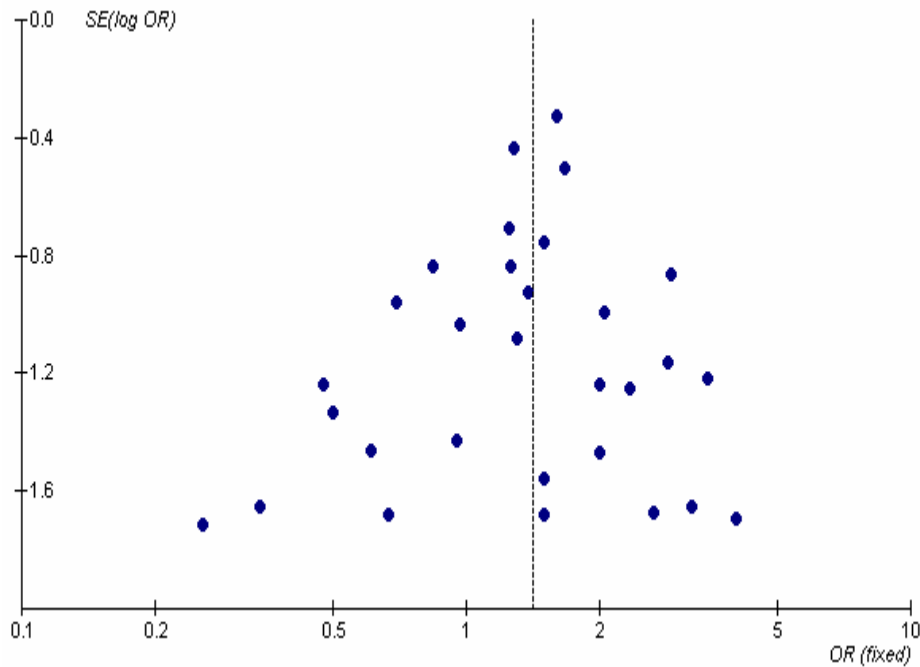
Types of selective outcome reporting

- Selective reporting of the **set** of study outcomes
 - Not all analysed outcomes are reported
- Selective reporting of a **specific** outcome
 - Selection from multiple time points
 - Selection from multiple subscales
 - Endpoint score versus change from baseline
 - Continuous versus binary (choice of cut-offs)
 - Different measures of same outcome, e.g. pain
- **Incomplete** reporting of a specific outcome
 - e.g. "Not significant" or " $p > 0.05$ "

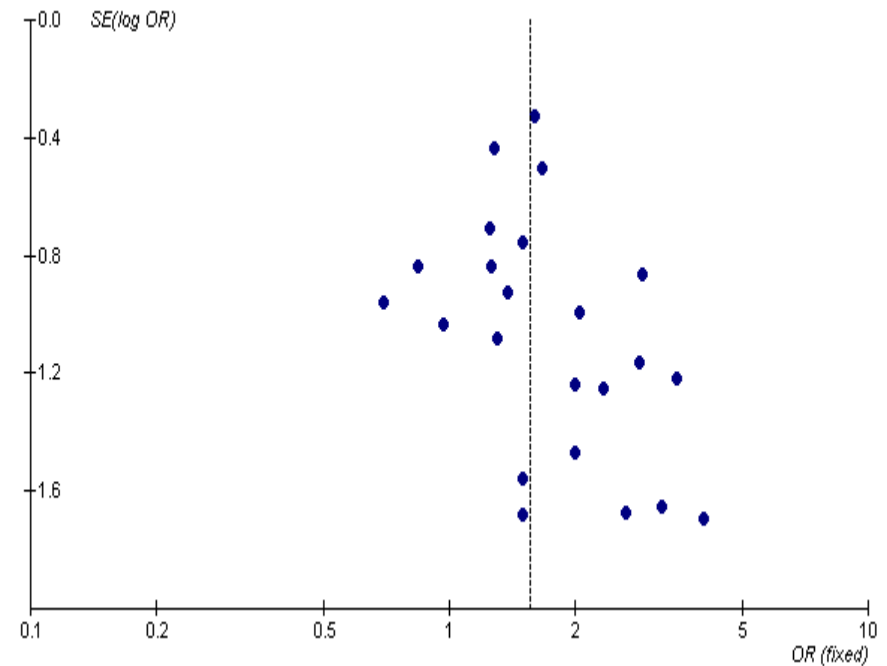
Selective reporting of the set of study outcomes

- Some trials in your review do not report the review outcome of interest
- Was this not measured or not reported?
- A missing data problem – potentially a similar impact to publication bias (i.e. non-publication of whole studies)

Impact of ORB



OR 1.41 (1.04,1.91)



OR 1.55 (1.13,2.14)

Empirical evidence

- Three studies have found that statistically significant outcomes were more likely to be fully reported compared to nonsignificant outcomes
- Studies comparing trial publications to protocols have found that 40–62% of reports of RCTs had at least one primary outcome that was changed, introduced, or omitted.

[Dwan et al, *PLoS ONE* 2008]



Options for investigating missing outcomes

- Protocol
- Methods section vs results section
- Examine reporting across the set of studies
- Clinical knowledge

Example: trial protocol available

Diabetes trial
Drug intervention

Protocol

Primary outcome:
% change in Hgb_{A1C}

$P \geq 0.05$

Publication

Primary outcome:
Withdrawal rate

$P < 0.05$

Matrix: Ultrasound versus 'clinical touch' for catheter guidance during embryo transfer in women

Trial ID (author, date of publication)	Review primary outcome Live birth	Other Review Outcomes			Other trial outcomes	
		Clinical pregnancies	Multiple pregnancies	Adverse Events	Implantat -ion rate	Abortion Rate
Bar Harva 2003	x	✓	x	x	✓	x
Coroleu 2000	✓	✓	x	✓	✓	x
Coroleu 2002	x	✓	✓	✓	✓	x
Garcia- Velasco 2002	x	✓	✓	✓	✓	x
Kosmas 2006	✓	✓	x	✓	✓	x
Li 2005	x	✓	x	x	✓	x

Cochrane Handbook: guidelines for assessment of selective reporting bias in each trial

- **Authors' judgment:** Are reports of the study free of suggestion of selective outcome reporting?
- **Yes (low risk of bias):** Clear that published report includes all pre-specified outcomes and all expected outcomes.

Basis for judgment: available protocol, protocol unavailable but clear from report that it follows pre-specified plan (uncommon)

Guidelines continued

- **No (high risk of bias):** Any one of the following:
 - Not all specified outcomes (e.g. in protocol or methods section) have been reported
 - One or more reported outcomes were not pre-specified (e.g. in protocol or methods section)
 - One or more outcomes are reported incompletely in a way related to the actual results (e.g. “not significant”)
 - One or more outcomes that would be expected to have been reported for such a trial have not been reported (even if not mentioned in methods section)
- **Unclear**