

# Systematic Review of Evidence for Selective Reporting of Analyses

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## BACKGROUND

Selective reporting within clinical trials has, to date, mainly been described with respect to selective outcome reporting. However, there are other selective reporting mechanisms that may affect the validity of findings from clinical trials. Selective reporting of analyses may occur if analyses are selected based on favourable results that may not be observed if the data were analysed as originally planned. It has also been shown that discrepancies in outcomes often occur between protocol and publication; discrepancies can also occur in analyses, if outcome data are analysed and reported differently than planned in the statistical analysis plan.

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## Systematic Review of the Empirical Evidence of Study Publication Bias and Outcome Reporting Bias — An Updated Review

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## OBJECTIVES

1. To review and summarise the evidence from studies that have assessed discrepancies or selective reporting bias of analyses in randomised controlled trials (RCTs).
2. To assess current reporting guidelines to identify where improvement is needed.

## METHODS

We included research that assessed any aspect of the reporting of analyses of RCTs. The Cochrane Methodology Register, Medline (Ovid), PsycInfo (Ovid), PubMed were searched in May 2013. Two authors independently selected studies, performed data extraction and assessed the risk of bias. We refrained from statistically combining results from the different cohorts due to the differences in their design and outcomes. A narrative summary of the included empirical studies is provided.

Guidelines that cover different aspects of the trial process were reviewed to identify where improvement was needed.

## RESULTS

### 21 studies identified in 30 publications (Figure)

#### Cohort studies published 2000-2013

Marketing approval/new drug application (2)  
Protocols (5)  
Abstract/methods/results (9)  
FDA reviews (1)  
Internal company documents (1)  
Grant proposal and protocols (1)  
Trial registry (1)

#### Included RCTs published between 1966-2010

90% (19/21) included only RCTs  
Median 59 (IQR: 40 to 74; min 2, max 776)

#### Funding

Industry, median 64% (IQR: 40 to 100)  
11 not stated

#### Risk of bias

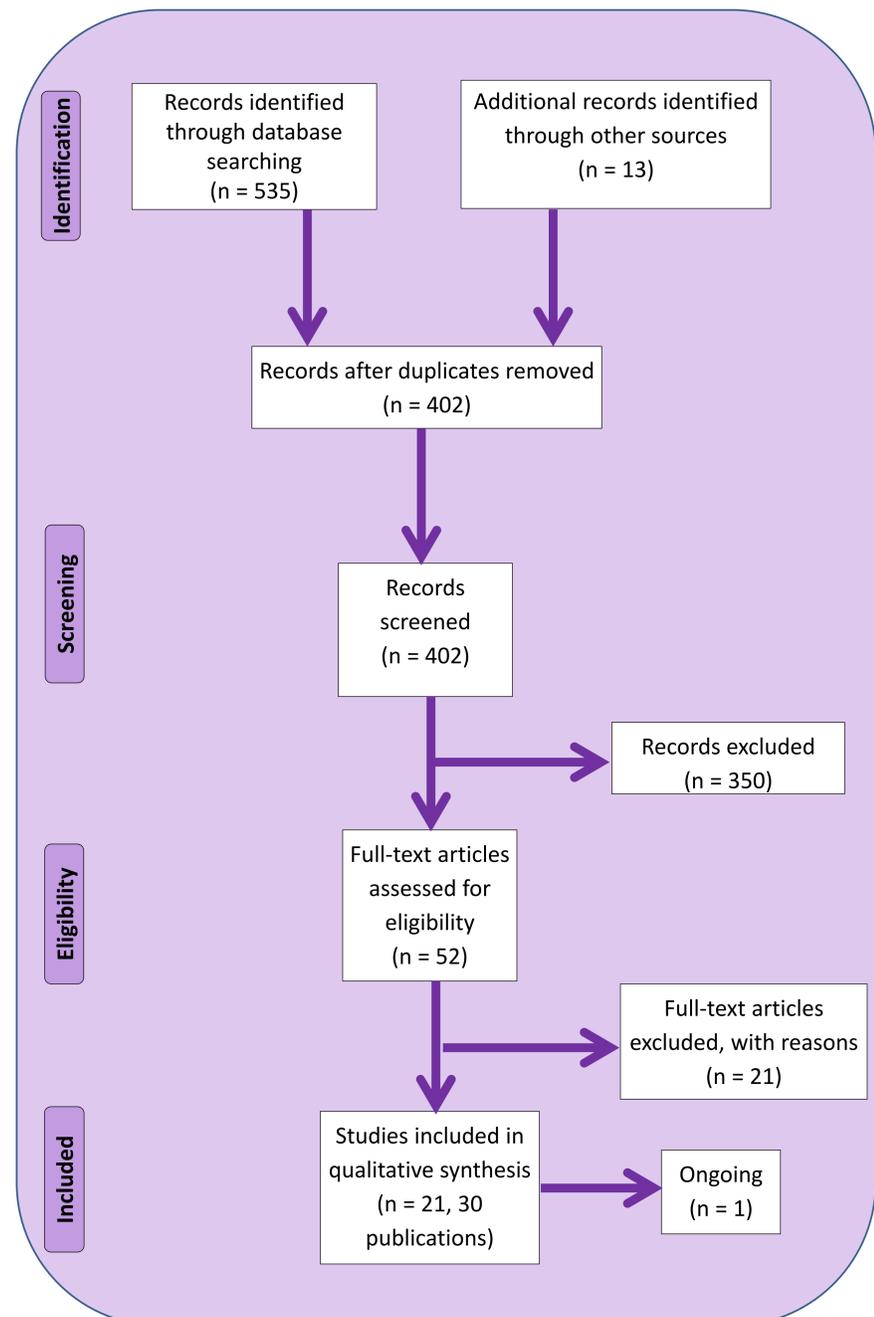
Low risk of bias: 1 study  
Methodological concerns: 16 studies  
Unclear methodology: 4 studies

There are many discrepancies in analyses between documents (Table). Guidelines such as ICH, SPIRIT, CONSORT, Declaration of Helsinki and the OPEN ([www.open-project.eu](http://www.open-project.eu)) guidelines were reviewed. Most aspects of the trial process were covered but guidance needs to be extended to include the reporting of all pre-specified outcomes and analyses. There is no guidance to cover the production of the statistical analysis plan which is not routinely included in a protocol.

Item	Number of studies	Range of discrepancies
Statistical analyses	8	22 - 88%
Unadjusted versus adjusted analyses	3	46 - 82%
Subgroup analyses	12	61 - 100%
Handling missing data	3	8 - 80%
Continuous measure rendered binary	2	9%
Composite outcomes (definition)	1	33%

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## CONCLUSIONS

No empirical studies consider selective reporting bias of analyses. This is possibly due to the difficulty in undertaking such a study due to the need to access documents and the raw data.

Discrepancies in analyses between study documentation were common; although reasons for these were not discussed in the reports. To ensure transparency, statistical analysis plans and protocols need to be published and information in trial registries needs to be improved.

Current guidance needs to be extended to include reporting of all outcomes and analyses. There is also a need for guidance on production of statistical analysis plans (Gamble et al. – an ongoing project).