

Outcome Reporting Bias in Systematic Reviews A Sample of Published Literature

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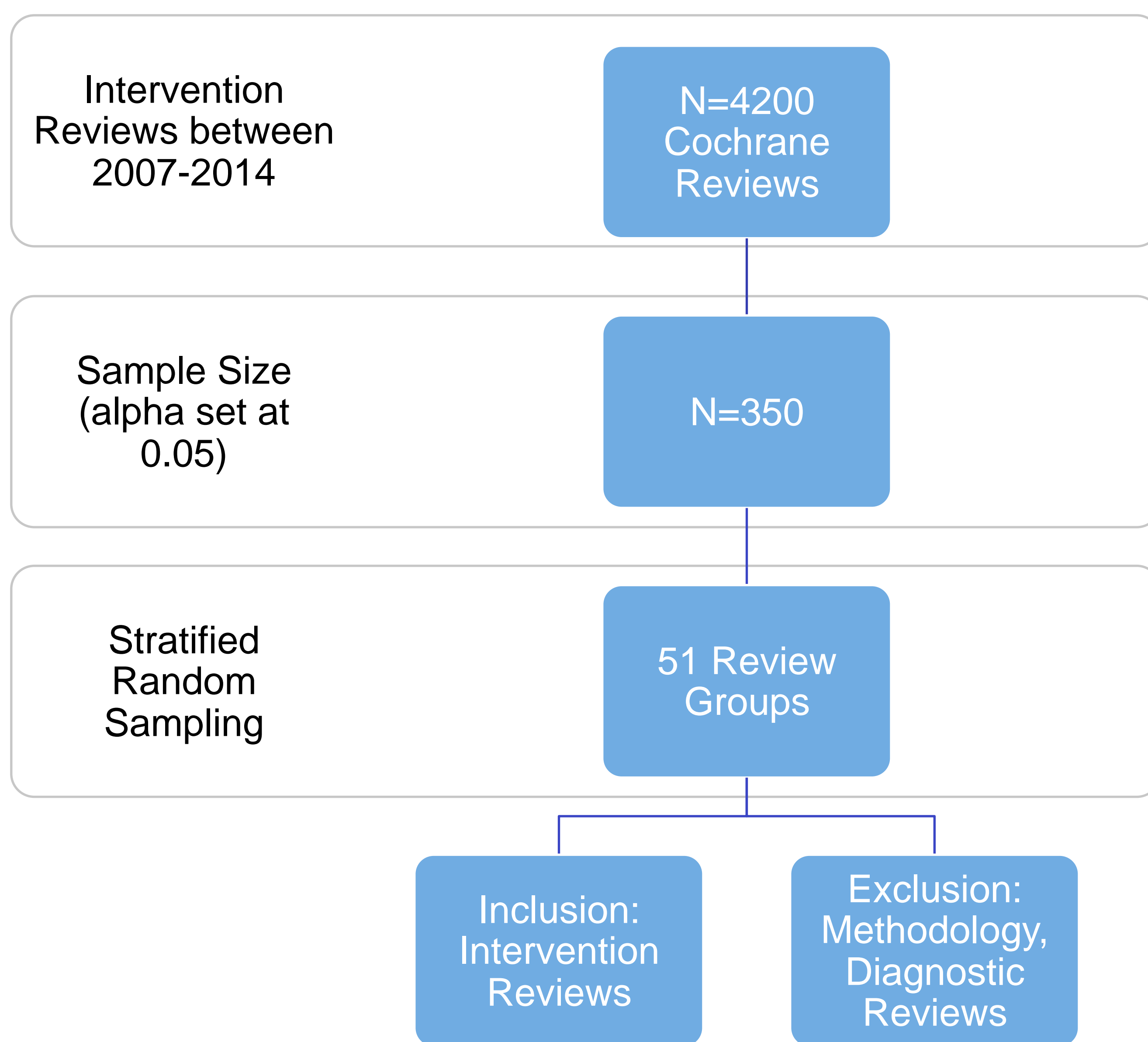
Background

- Outcome Reporting Bias (ORB):** selection (on the basis of results) of a subset of original outcomes recorded for inclusion in a study publication
- Impacts up to 60% of randomized controlled trials (RCTs), affecting systematic reviews & meta-analyses
 - Potential to overestimate treatment effects and underestimate harms, thereby influencing clinical decisions
 - Systematic Reviews: outcome discrepancies presented in 38% of Cochrane reviews published prior to 2007
 - No data on outcome discrepancies and ORB after several strategies proposed to mitigate this (Cochrane Handbook, PRISMA etc.)

Objectives

- To estimate the prevalence of discrepant outcome reporting between Cochrane protocols and published reviews and assess their risk for ORB.
- To estimate the prevalence and categorize the types of discrepancies presented and to describe any patterns we identify.

Methods – Figure 1: Project Design



Methods - Figure 2: Data Collection

- Outcomes compared between review and protocol pairings
 - Discrepancy type collected
 - Reasons for discrepancies collected
 - Independent and group analysis risk of ORB*
- | Risk Level | Description |
|------------------|---|
| High Risk ORB | Outcome changed after collecting results |
| Low Risk ORB | Outcome changed independent of results |
| Unclear Risk ORB | No reason provided/reason unclear – authors contacted for further clarification (see table 1) |

Table 1: Authors' Responses for Discrepancies

Reasons	Risk of ORB*
New outcomes included because studies included it	High
Outcomes omitted because no studies included it or because of partial reporting in studies	High
Author not aware of change	High
Outcomes redefined standard of practice/guideline updates efficacy and safety monitoring measures	Low
Editorial/Peer Review feedback	Low
Changes as per Cochrane Handbook update	Low
Discrepancies between authors who created protocol and those who wrote the final review	Low

*Risk of ORB determined as per group consensus (Independent and group analysis performed for each reason)

Figure 3: Discrepancies and Risk of ORB

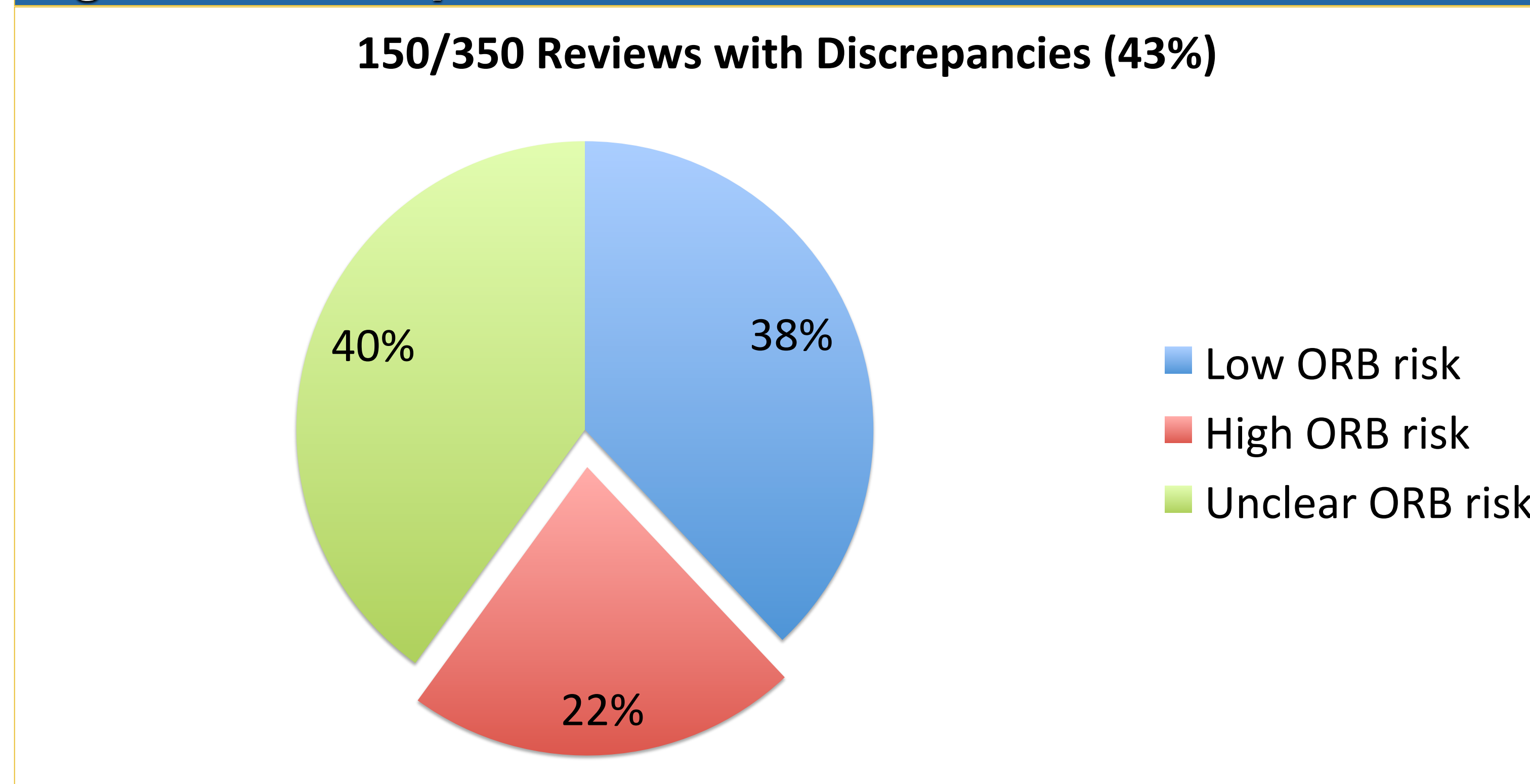
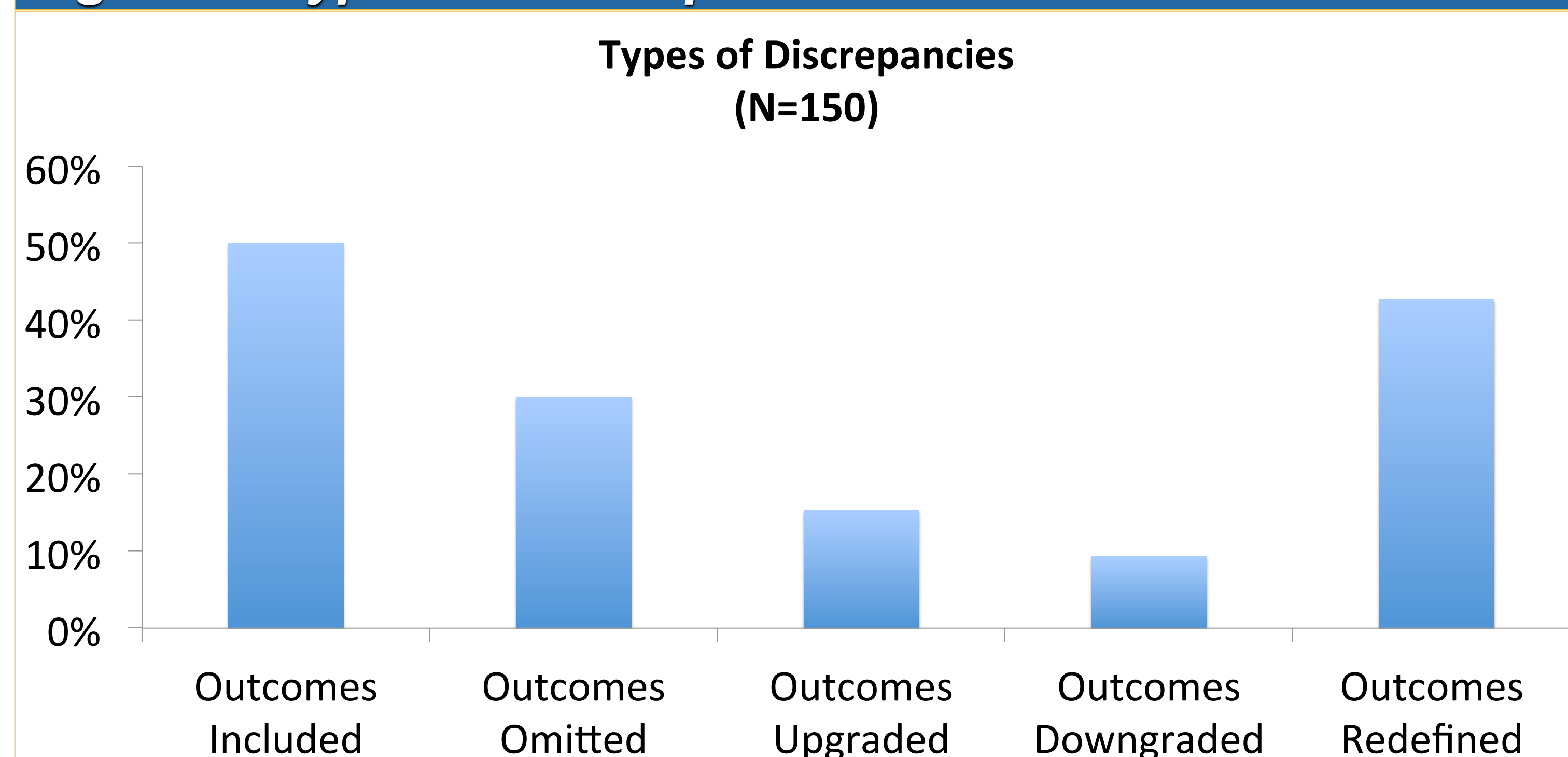


Figure 4: Types of Discrepancies



Results and Discussion

- 43% (95% CI; 43±5%) of Cochrane reviews contained discrepancies in outcomes between their published review and respective protocol and a fifth of these (22%) were suspected of ORB (Figure 3)
 - This is similar to the 38% of discrepant outcome reporting in reviews prior to 2007; therefore we did not see a decrease in discrepancies despite interventions (Cochrane Handbook and PRISMA guidelines)
 - Unfortunately, there was a large portion (40%) of reviews with unclear reasons for discrepancies; we may be underestimating the risk of ORB.
- The most common type of discrepancies were new outcomes included (50%), outcomes redefined (43%), and omission of outcomes (30%). Upgrade (15%) or downgrade (9%) presented less frequently
- Common themes from authors' responses where reasons for discrepancies were unclear in the review are reported in Table 1
- What does this all mean? This bias can affect the magnitude of effect size and statistical significance in Cochrane reviews. As a result, it is inherently carried forward in our medical decision making, and policies and guidelines development.

Conclusions

- The prevalence of discrepant outcome in Cochrane reviews reporting remains relatively the same despite interventions to mitigate it, and a fifth of reviews with discrepancies contain suspected ORB
- We encourage authors to be transparent where outcomes change, and to describe the legitimacy of changing outcomes in order to prevent suspicion of bias as well as adhering to current Cochrane guidelines
- Future directions should focus on solutions in addition to current interventions to further mitigate ORB