

Outcome Reporting Bias in Primary Literature (ORBIP): Insight into the detection and management of outcome reporting bias by biomedical journals

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Background

- Outcome reporting bias (ORB) - selective publication of outcome data that was collected during the study protocol
- Becoming an increasingly recognized source of bias and has been incorporated into the Cochrane risk of bias assessment
- Prevalence - up to 60% reported in multiple clinical trials
- ORB influences primary literature and subsequent systematic reviews and meta-analyses, changing the magnitude and direction of the pooled point estimate
- No literature examines how biomedical journals detect ORB

Objectives

- To describe current practices undertaken by the major biomedical journals to detect and minimize outcome reporting bias
- Propose a practice for biomedical journals which would practically eliminate ORB

Methods

- Prospective, cross-sectional analysis (email and telephone)
 - Inclusion: Top 30 biomedical journals ranked by impact factor
 - Cochrane Database Syst Rev excluded, leaving 29 journals
 - Questions created and refined by team of investigators (See table 1) and administered via e-mail or telephone
 - Post-hoc categorization of responses performed independently by two investigators
 - Discrepancies were resolved via discussion and consensus
 - Descriptive statistics used for results analysis
 - Anonymity promised due to editor concerns

Table 1: Questions

Q	Set of Questions Posed to Biomedical Journals
1	Does your journal have a specific method with which to detect outcome reporting bias? If so, what is this method?
2	Does your journal ALWAYS compare submitted manuscripts to their registered protocols or do you rely on peer reviewers?
3	How often is outcome reporting bias detected from submitted manuscripts?
4	If outcome reporting bias is detected, what is done to address it?
5	Are the discrepancies that your journal identifies reported or made public? Would you be willing to release this information upon request?

Figure 1: Biomedical journal participants

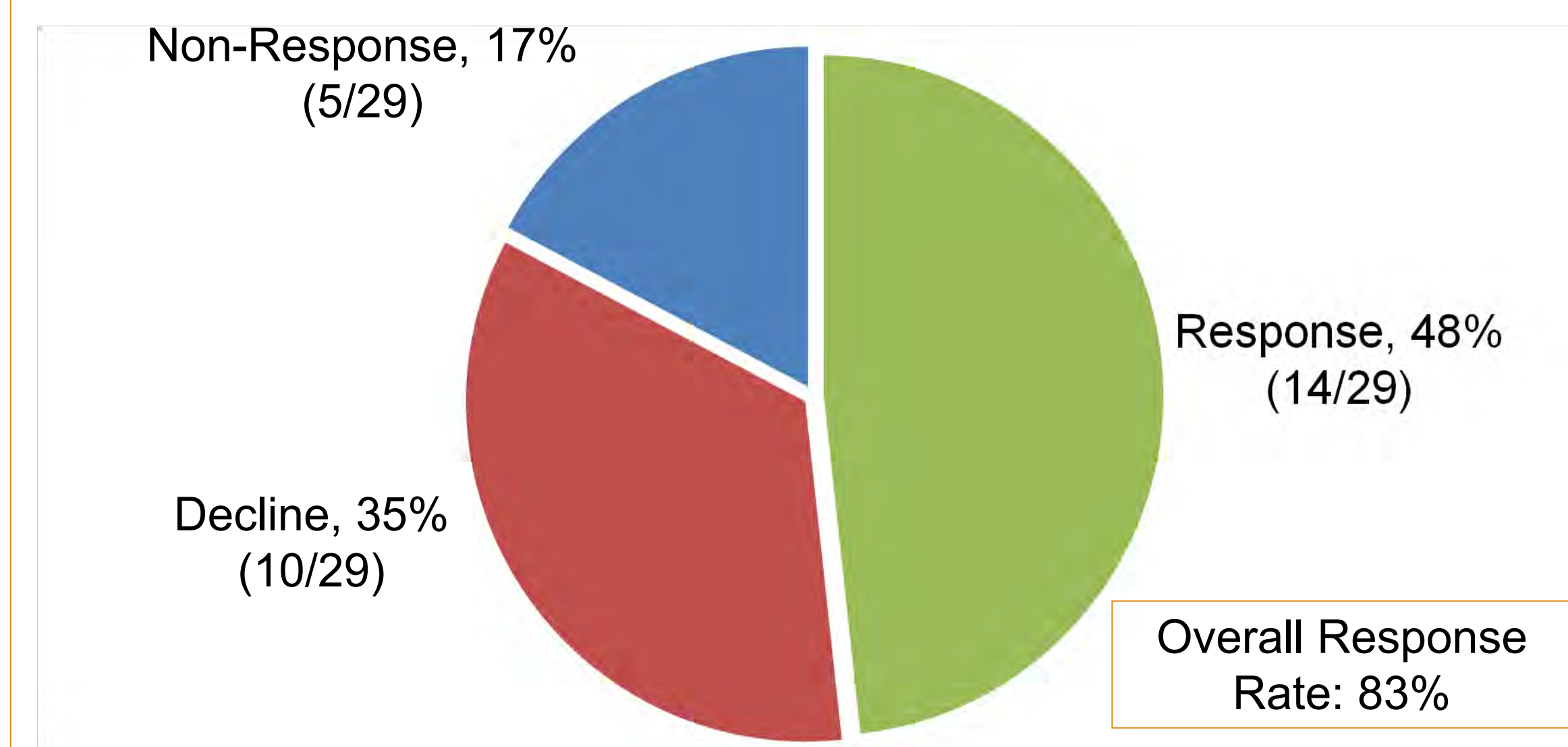


Figure 2: Q1 - Does your journal have a method to detect ORB?

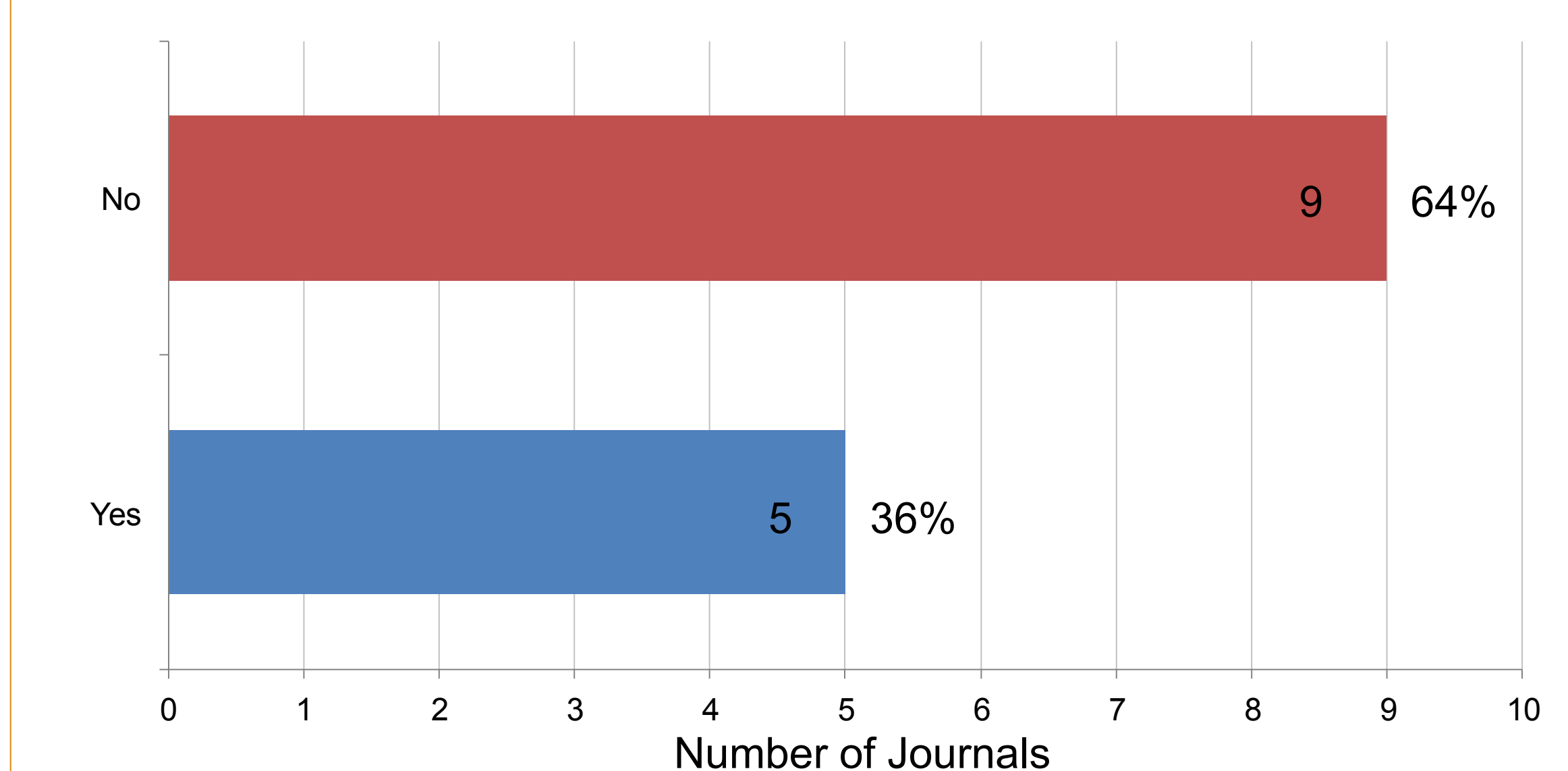


Figure 3: Q3 - How often is ORB detected?

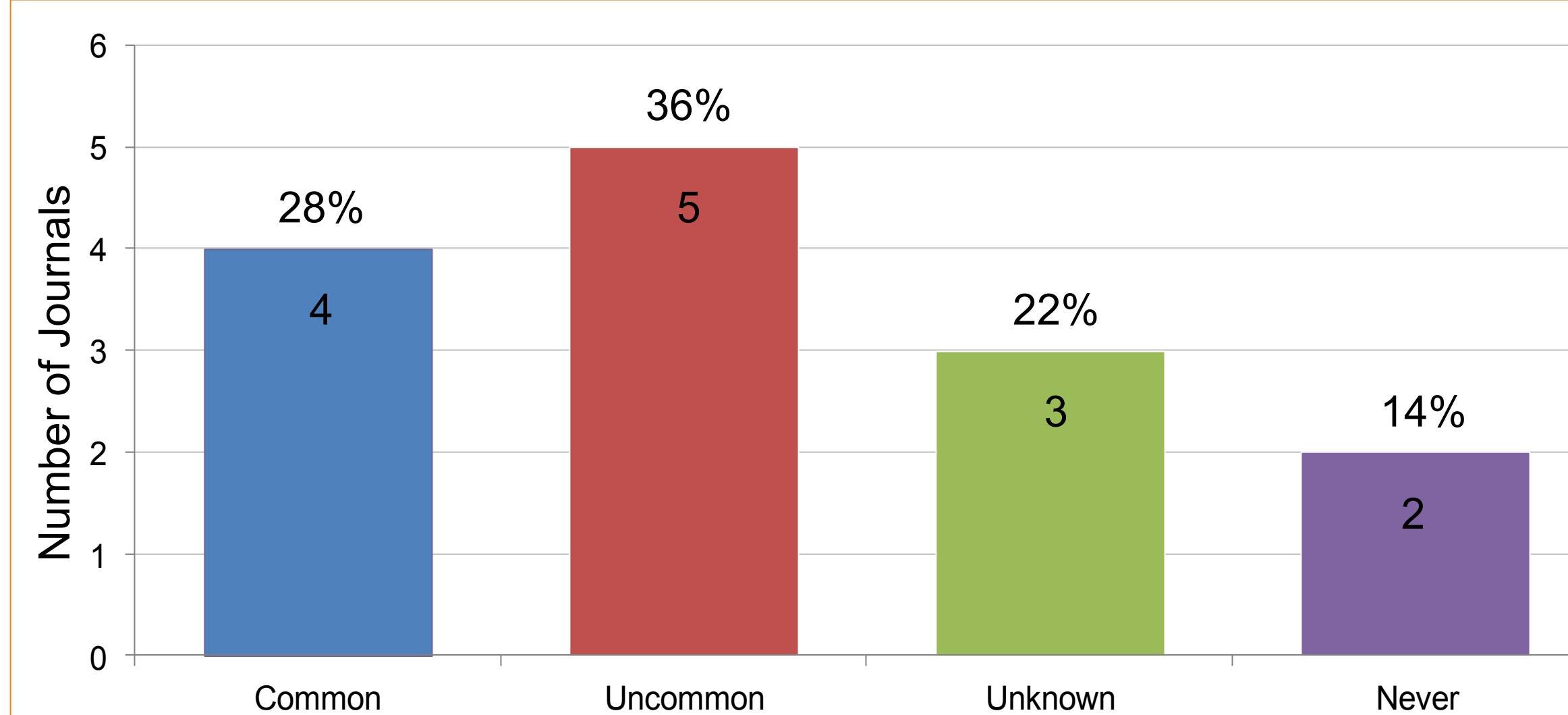
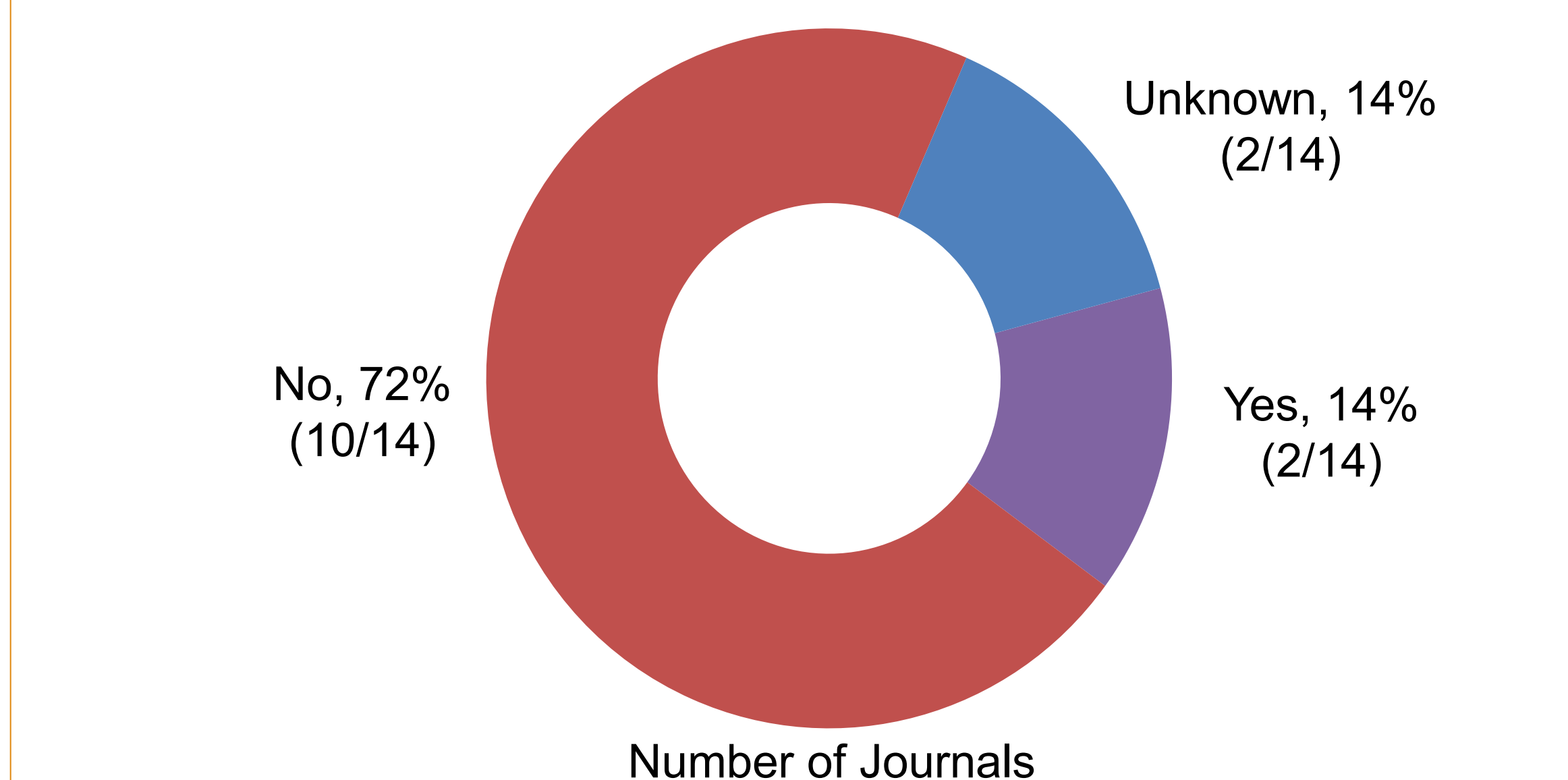


Figure 4: Q5 - Are the discrepancies reported or made public?



Results and Discussion

- 24/29 (83%) journals responded to our questions (See figure 1)
- Q1: 9/14 (64%) journals did not have a method to detect ORB (See figure 2)
 - Review journals feel checking for ORB is the responsibility of primary research journals. Examples:
 - "The bias issues to which you refer are not relevant to review articles but to the underlying primary research articles."
 - "...as a journal that publishes only review articles, I don't really think this germane to us in the same way that it [does] to primary research journals."
 - One journal suggests time constraints is a major limiting factor
 - "We do not have the resources to [always compare submitted manuscripts to their registered protocols]. Nor do we expect peer-reviewers to go to the registered protocol and compare it with the submitted paper as we do not presume that they have the time to do this either."
- Q2: For comparing submitted manuscripts to protocols, responsibility fell onto peer reviewers (6/14, 43%), peer reviewers and editors (4/14, 28.5%) or neither (4/14, 28.5%)
- Q3: 7/14 (50%) indicated ORB was found uncommonly (<10%) or never found by their journal (See figure 3)
 - Only 4 journals suggested ORB was a common finding, with the highest estimated prevalence at 10-20%
 - Prevalence found in literature ranges from 10% to as high as 60%
- Q4: 11/14 (79%) would reject the manuscript or require transparent revisions
- Q5: 10/14 (72%) were unwilling to make discrepancies public (See figure 4)
 - Previous literature suggests 50% of rejected manuscripts eventually get published within 3 years
 - One study has found 18% of these resubmitted manuscripts will contain no changes suggested by the previous reviewer

Limitations

- Open-ended questions leaves room for subjective interpretation
- Post-hoc categorization and analysis of data for patterns and trends
- Top 30 journals vary widely (ie primary research vs primarily review articles)

Conclusions

- Of the top 30 journals that responded to our survey:
 - The majority did not have a method in place to detect ORB
 - Prevalence of ORB identified by journals was lower than reported in literature
 - If discrepancies have been detected, the majority of journals are unwilling to publicize this information
- We propose:
 - Inclusion of the original trial protocol be mandatory for all primary research submissions
 - Editor(s) should cross-reference the submission to the protocol or ensure a higher standard of quality control is in place for peer reviewers
 - Reviewer concerns related to ORB of submitted manuscripts should be made public by linking their comments to the registered trial protocol

