

## Documents

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### Heterogeneity and Gaps in Reporting Primary Outcomes From Neonatal Trials

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### Abstract

**OBJECTIVES:** Clear outcome reporting in clinical trials facilitates accurate interpretation and application of findings and improves evidence-informed decision-making. Standardized core outcomes for reporting neonatal trials have been developed, but little is known about how primary outcomes are reported in neonatal trials. Our aim was to identify strengths and weaknesses of primary outcome reporting in recent neonatal trials. **METHODS:** Neonatal trials including  $\geq 100$  participants/arm published between 2015 and 2020 with at least 1 primary outcome from a neonatal core outcome set were eligible. Raters recruited from Cochrane Neonatal were trained to evaluate the trials' primary outcome reporting completeness using relevant items from Consolidated Standards of Reporting Trials 2010 and Consolidated Standards of Reporting Trials-Outcomes 2022 pertaining to the reporting of the definition, selection, measurement, analysis, and

interpretation of primary trial outcomes. All trial reports were assessed by 3 raters. Assessments and discrepancies between raters were analyzed. **RESULTS:** Outcome-reporting evaluations were completed for 36 included neonatal trials by 39 raters. Levels of outcome reporting completeness were highly variable. All trials fully reported the primary outcome measurement domain, statistical methods used to compare treatment groups, and participant flow. Yet, only 28% of trials fully reported on minimal important difference, 24% on outcome data missingness, 66% on blinding of the outcome assessor, and 42% on handling of outcome multiplicity. **CONCLUSIONS:** Primary outcome reporting in neonatal trials often lacks key information needed for interpretability of results, knowledge synthesis, and evidence-informed decision-making in neonatology. Use of existing outcome-reporting guidelines by trialists, journals, and peer reviewers will enhance transparent reporting of neonatal trials. Copyright © 2023 by the American Academy of Pediatrics.

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