

## Documents

Webbe, J.<sup>a</sup>, Baba, A.<sup>b</sup>, Butcher, N.J.<sup>b c</sup>, Rodrigues, C.<sup>b</sup>, Stallwood, E.<sup>b</sup>, Goren, K.<sup>b</sup>, Monsour, A.<sup>b</sup>, Chang, A.S.M.<sup>d e</sup>, Trivedi, A.<sup>f</sup>, Manley, B.J.<sup>g</sup>, McCall, E.<sup>h</sup>, Bogossian, F.<sup>i</sup>, Namba, F.<sup>j</sup>, Schmölder, G.M.<sup>k</sup>, Popat, H.<sup>f</sup>, Nguyen, K.A.<sup>l</sup>, Doyle, L.W.<sup>m</sup>, Jardine, L.<sup>n o</sup>, Rysavy, M.A.<sup>p</sup>, Konstantinidis, M.<sup>q r</sup>, Muhd Helmi, M.A.<sup>s</sup>, Lai, N.M.<sup>t</sup>, Hay, S.<sup>u v</sup>, Onland, W.<sup>w x</sup>, Choo, Y.M.<sup>a</sup>, Gale, C.<sup>a</sup>, Soll, R.F.<sup>b c</sup>, Offringa, M.<sup>b r y</sup>, CORE OUTCOME REPORTING IN NEONATAL TRIALS (CORINT) STUDY GROUP<sup>z</sup>

**Strengthening Reporting of Neonatal Trials**

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<sup>a</sup> Neonatal Medicine, School of Public Health, Imperial College London, United Kingdom

<sup>b</sup> Child Health Evaluative Sciences, Hospital for Sick Children Research Institute, Toronto, ON, Canada

<sup>c</sup> Department of Psychiatry, University of Toronto, Toronto, ON, Canada

<sup>d</sup> Quality, Safety and Risk Management (QSRM) and Department of Neonatology, KK Women's and Children's Hospital, Singapore

<sup>e</sup> DUKE-NUS Medical School, Singapore

<sup>f</sup> Children's Hospital at WestmeadNSW, Australia

<sup>g</sup> The Royal Women's Hospital, Melbourne, Australia

<sup>h</sup> School of Nursing and Midwifery, Queen's University BelfastNorthern Ireland, United Kingdom

<sup>i</sup> University of the Sunshine Coast, Sunshine Coast, Australia

<sup>j</sup> Department of Pediatrics, Saitama Medical Center, Saitama Medical UniversitySaitama, Japan

<sup>k</sup> Department of Pediatrics, University of Alberta, Edmonton, Canada

<sup>l</sup> Claude Bernard University Lyon, Lyon, France

<sup>m</sup> Department of Obstetrics and Gynaecology, University of Melbourne, The Royal Women's Hospital, Parkville, VIC, Australia

<sup>n</sup> Department of Neonatology, Mater Mothers' Hospital, South BrisbaneQLD, Australia

<sup>o</sup> University of Queensland, Brisbane, Australia

<sup>p</sup> University of Texas Health Science Centre at Houston, Houston, TX, United States

<sup>q</sup> Li Ka Shing Knowledge Institute, St Michael's Hospital, Unity Health Toronto, Toronto, ON, Canada

<sup>r</sup> Institute of Health Policy, Management and Evaluation, University of Toronto, Toronto, ON, Canada

<sup>s</sup> Department of Paediatrics, International Islamic UniversityKuala Lumpur, Malaysia

<sup>t</sup> School of Medicine, Faculty of Health and Medical Sciences, Taylor's UniversitySelangor, Malaysia

<sup>u</sup> Department of Neonatology, Beth Israel Deaconess Medical Center, Boston, MA, United States

<sup>v</sup> Harvard Medical School, Boston, MA, United States

<sup>w</sup> Department of Neonatology, Emma Children's Hospital, University of Amsterdam, Amsterdam, Netherlands

<sup>x</sup> Amsterdam Reproduction and Development Research Institute, Amsterdam, Netherlands

<sup>y</sup> Division of Neonatology, Hospital for Sick Children, University of Toronto, Toronto, ON, Canada

**Abstract**

**BACKGROUND AND OBJECTIVES:** There is variability in the selection and reporting of outcomes in neonatal trials with key information frequently omitted. This can impact applicability of trial findings to clinicians, families, and caregivers, and impair evidence synthesis. The Neonatal Core Outcomes Set describes outcomes agreed as clinically important that should be assessed in all neonatal trials, and Consolidated Standards of Reporting Trials (CONSORT)-Outcomes 2022 is a new, harmonized, evidence-based reporting guideline for trial outcomes. We reviewed published trials using CONSORT-Outcomes 2022 guidance to identify exemplars of neonatal core outcome reporting to strengthen description of outcomes in future trial publications. **METHODS:** Neonatal trials including >100 participants per arm published between 2015 to 2020 with a primary outcome included in the Neonatal Core Outcome Set were identified. Primary outcome reporting was reviewed using CONSORT 2010 and CONSORT-Outcomes 2022 guidelines by assessors recruited from Cochrane Neonatal. Examples of clear and complete outcome reporting were identified with verbatim text extracted from trial reports. **RESULTS:** Thirty-six trials were reviewed by 39 assessors. Examples of good reporting for CONSORT 2010 and CONSORT-Outcomes 2022 criteria were identified and subdivided into 3 outcome categories: "survival," "short-term neonatal complications," and "long-term developmental outcomes" depending on the core outcomes to which they relate. These examples are presented to strengthen future research reporting. **CONCLUSIONS:** We have identified examples of good trial outcome reporting. These illustrate how important neonatal outcomes should be reported to meet the CONSORT 2010 and CONSORT-Outcomes 2022 guidelines. Emulating these examples will improve the transmission of information relating to outcomes and reduce associated research waste. Copyright © 2023 by the American Academy of Pediatrics.

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