CONSORT-C: a shared responsibility for truth and quality

Much uncertainty remains in the evidence base for child and adolescent health. Not only is the quality of clinical trials involving neonates, children, and adolescents inconsistent; in numbers, they lag behind adult trials. The unique needs of paediatric populations are often inadequately considered and described, partly because no specific reporting guidelines exist. Published in *The Lancet Child & Adolescent Health*, the CONSORT-Children and Adolescents (CONSORT-C) extension guideline for trial reporting—alongside its companion SPIRIT-C guideline for trial protocols—marks a new era for child and adolescent health research.

SPIRIT-C and CONSORT-C aim to improve the quality and completeness of clinical trial protocols and reports involving participants aged 0–19 years. Each provides reporting items that are necessary for all research with and for children and adolescents, such as developmentally appropriate outcome selection and nuances of consent and assent. Importantly, these new guidelines reflect real priorities of the young people and family caregivers directly involved throughout their development. The youth impact is clear: each checklist includes six youth-endorsed items and additional youth-generated items, all warranting attention. For example, trial protocols should describe "the anticipated impact of trial participation on the child/adolescent's daily life" and how participants "will be given recognition". Young people want to know whether trial interventions will be "delivered with help from a support person" or induce fear, pain, or distress, along with efforts to reduce risks. Together, these reporting requirements underscore the importance of treating young people and families with dignity and respect, empowering them to make informed decisions about study participation and treatment effects.

The Lancet Child & Adolescent Health now requires all submissions reporting on clinical trials to include the CONSORT-C 2026 checklist (alongside CONSORT 2025 and relevant extension checklists), which will be assessed for completeness and accuracy in line with the journal's research integrity policies. As editors, we recognise the burden of many checklists on authors and reviewers, but CONSORT-C will only achieve its aim if fully embraced by the child and adolescent health community and beyond.

Suboptimal reporting poses a threat to the validity and reliability of trial results, creates research waste, and delays therapeutic advances—its effect carries through to systematic reviews, meta-analyses, and clinical guidelines, potentially compromising patient care. Poor reporting is common; more than one quarter of 206 paediatric trials included in a systematic review reported no primary outcomes; where outcomes were reported, measurement details were often missing. Suboptimal reporting hampers critical appraisal of trial data and might obscure their appropriate application to real-world settings. Faced with a weak evidence base, clinical practice and guidelines might be driven instead by clinician bias and beliefs, which risks perpetuating treatments that are ineffective at best and dangerous at worst.

Paediatric trials are rare—only 10% of trials registered on the International Clinical Trial Registry Platform in 2000–23 included children. Yet they are in demand, not least to close the gap in regulatory approval time between drugs for adults and children. Given limited funding and small patient pools, researchers owe it to participating young people and families to maximise scarce resources and answer meaningful clinical questions. Paediatric studies are also challenging to do because they require exceptional breadth of expertise. From care providers and youth advisory groups to researchers, multidisciplinary teams operate through a children's rights lens, use accessible language, and apply developmentally appropriate outcome measures to meet young people's needs. In this respect, SPIRIT-C and CONSORT-C offer a useful resource to ensure studies with young participants—including trials with mixed populations (eg, adolescents and adults, parent–child dyads) and non-randomised studies—are thoughtfully designed, transparently reported, and meaningful for young people.

Implemented widely, SPIRIT-C and CONSORT-C will have a profound impact on child and adolescent health and equity. Yet challenges remain. Embedding SPIRIT-C and CONSORT-C guidelines into clinical and research training will be important to develop expertise and reinforce integrity and transparency as core principles of responsible research practice. Dismantling barriers to implementation will require commitment across the entire research ecosystem. Such commitment derives from a culture of shared responsibility for truth and quality and for protecting and improving the health of young people. ■ *The Lancet Child & Adolescent Health*

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For the **CONSORT-C extension statement** see **Online/Statement**
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For the **SPIRIT-C extension statement** see **Online/Statement**
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For more on **young people's involvement in guideline development** see **Online/Reflections**
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For more on **reporting in paediatric randomised controlled trials** see *J Clin Epidemiol* 2017; **81:** 33–41

For more on the **paediatric clinical trial ecosystem** see **Series** *Lancet Glob Health* 2025; **13:** e732–39

For more on the **importance of the extensions in child health and equity** see **Online/Comment**
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