

**The CORE-KIDS Core Outcome Set for Childhood Limb Fractures**

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**Purpose:** There is considerable variability in the measurement and reporting of outcomes during trials relating to childhood fractures. This is limiting synthesis of results and pooling of studies into effective meta-analyses that influence practice around the world. This could be addressed with a core outcome set, an agreed set of outcomes to be measured in all trials of childhood fractures. The aim of this study is to develop a core set of outcome domains that should be measured and reported in all future trials of childhood limb fractures.

**Methods:** The study was reviewed by the North London–Hampstead research ethics committee (HRA/REC IRAS number 262503). A four-phase study was conducted to agree a core set of outcome domains. Outcomes relevant to professionals were identified through systematic review of trials, and outcomes relevant to families were identified through semi-structured interviews with 20 families (parent-child dyads). Outcome domains were prioritized using an international three-round Delphi survey with 205 panelists and then condensed into a core outcome set through a consensus workshop with 31 stakeholders including surgeons, therapists, nurses, and patients.

**Results:** The systematic review and interviews identified 85 outcome domains as relevant to professionals or families. The Delphi survey prioritized 30 upper and 29 lower limb outcomes at first round, an additional 17 upper and 18 lower limb outcomes at second round, and 4 additional outcomes for upper and lower limb at the third round as important outcomes. At the consensus workshop, the core outcome domains was agreed as: (1) pain and discomfort, (2) return to physical and recreational activities, (3) emotional and psychosocial well-being, (4) complications from the injury and treatment, (5) return to baseline activities daily living, (6) participation in learning, (7) appearance and deformity, and (8) time to union. (9a) Recovery of mobility and (9b) recovery of manual dexterity were recommended as core outcomes for lower and upper limb fractures, respectively.

**Conclusion:** This set of core outcome domains are recommended as a minimum set of outcomes to be reported in all trials. It is not an exhaustive set and further work is required to identify what outcome tools should be used to measure each of these outcomes. Adoption of this outcome set will improve the consistency of research for these children that can be combined for more meaningful meta-analyses and policy development. Further work is required to identify and validate outcome instruments (including patient-reported outcomes) that can be used to measure these domains. This core outcome set has been endorsed by the British Society of Children's Orthopaedic Surgeons, the Orthopaedic Trauma Society, and the Nederlandse Orthopaedische Vereniging as the reporting standard for clinical studies of childhood limb fractures.

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.