CONSENT IN PEDIATRIC CRITICAL CARE RCTS: A SYSTEMATIC REVIEW
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Introduction: Consent for participation in RCTs in pediatric critical care poses various challenges, many of which are due to the need for a proxy decision maker on behalf of the critically ill child. These challenges include the need to obtain consent in emergency settings where immediate intervention is required, or where parents are unavailable or emotionally unable to consider participation. Alternative approaches to consent (such as deferred or waived) have been used to increase the feasibility of trials in these cases.

Objectives: To describe pediatric critical care RCTs with respect to the consent models, timing and methods used, the completeness of reporting of the consent process and consent rates.

Methods: Searching: We searched the Evidence in Pediatric Intensive Care Database (epicc.mcmaster.ca) from inception to July 4, 2013. This database is part of a scoping review that searches MEDLINE, EMBASE, LILACS and CENTRAL for pediatric critical care RCTs using comprehensive search strategies. Inclusion criteria: RCTs and quasi-randomized trials published in English that administered any intervention to children in a pediatric critical care unit. Exclusion criteria: Trials enrolling exclusively newborns and cross-over trials. Data extraction: Pairs of reviewers screened studies for eligibility and abstracted data independently. Discrepancies were resolved by consensus.

Results: We included 243 RCTs. Trials were published between 1986 and 2013 and were conducted in 32 different countries. 225 (92.6%) of the RCTs reported any information on consent. 7 (2.9%) of trials reported the use of any approach other than written consent from the child or their parent or guardian (2 studies used waived consent, 2 used deferred consent, 2 verbal and one only sought consent from one group) and 13 (5.3%) reported that they sought assent from the child. 20 (8.2%) reported consent was obtained prior to PICU admission. 74 (30.6%) of the RCTs reported a consent rate. The median (interquartile range) consent rate was 89.9% (71.5%, 97.4%) and varied from 23.0% to 100%. 11 (4.5%) of the trials reported a consent rate of 100%. Using linear regression the of year of publication, commercial funding, prophylactic or pharmaceutical interventions, and pre-PICU consent were not independently associated with increased consent rate. Only 4 (1.6%) reported some characteristics of those who did not consent.