Consent in pediatric critical care RCTs: A systematic review

Background

Randomized controlled trials (RCTs) are difficult to conduct in critically ill children. The process of obtaining informed consent contributes to these difficulties. The consent rate in a trial is a critical factor in determining its feasibility. The effect of trial features on consent rates has not been well characterized.

Alternative approaches to written parental consent have been used to increase the feasibility of trials, particularly in emergency settings where immediate intervention is required, or where parents are unavailable or emotionally unable to consider participation.

Reporting the characteristics of those children who do not participate is required to assess the representativeness of the children enrolled.

Methods

**Searching:** We searched the Evidence in Pediatric Intensive Care Database¹ (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.

**Inclusion trials**

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.

**Mode of consent:** 120 (49%) of the RCTs reported that written consent was obtained and 21 (8%) reported that consent was obtained verbally.

**Assent:** 13 (5%) of the RCTs reported that they sought assent from the child.

**Timing of consent:** 20 (8%) reported consent was obtained prior to PICU admission. The children in these trials were enrolled pre-operatively and admitted to the PICU post-operatively.

**Alternative approaches to consent:** 73 (30%) of trials reported the use of any approach other than written consent from the child or their parent or guardian.

Results

**Consent Models Used in 243 Pediatric Critical Care RCTs**

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Consent Model</th>
<th>Country</th>
<th>Intervention</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Klein (1989)²</td>
<td>Deferred</td>
<td>USA</td>
<td>Protective isolation or usual care</td>
<td>Parents provided written consent within 24 hours of enrollment. Consent rate 99%.</td>
</tr>
<tr>
<td>Hutchison (2008)²</td>
<td>Deferred</td>
<td>Canada, UK and France</td>
<td>Hypothetica for traumatic brain injury</td>
<td>Deferred consent if parents not available within 8 h. Frequency of use not reported.</td>
</tr>
<tr>
<td>Beattie (2004)²</td>
<td>Waived</td>
<td>Brazil</td>
<td>Two doses of epinephrine in cardiac arrest</td>
<td>Consent obtained for continued data collection and follow-up after discharge.</td>
</tr>
<tr>
<td>Scoble (2001)²</td>
<td>Waived</td>
<td>Australia</td>
<td>Two methods of enteral nutrition</td>
<td>Waived because both nutritional techniques were routinely used.</td>
</tr>
<tr>
<td>Yildizdas (2008)²</td>
<td>Consent in 1 group</td>
<td>Turkey</td>
<td>Terlipression in septic shock</td>
<td>Consent sought for children randomized to terlipression only.</td>
</tr>
<tr>
<td>Schultz (2001)²</td>
<td>Verbal consent</td>
<td>USA</td>
<td>Two methods of weaning ventilation</td>
<td>Verbal consent obtained from parents or guardians.</td>
</tr>
<tr>
<td>Chi (2013)²</td>
<td>Verbal consent</td>
<td>Vietnam</td>
<td>Milrinone for brainstem encephalitis</td>
<td>Written or verbal informed consent was obtained from parents or representatives.</td>
</tr>
</tbody>
</table>

**Consent Rate:** 73 (30%) of the RCTs reported a consent rate. The median (interquartile range) consent rate was 90% (71%, 97%) and varied from 23% to 100%. 11 (5%) of the trials reported a consent rate of 100%.

Using linear regression none of the following were significant: RCTs included, consent rate, or any of the trial features.

**Representativeness:** 4 (2%) of trials reported some characteristics of those who did not consent.

**References:**


Conclusions

The majority of the pediatric critical care RCTs reported the use of parent/guardian consent. Alternative approaches such as deferred and waived consent were used in a small proportion of studies.

There are important opportunities to improve the quality and transparency of reporting; very few trials reported the information necessary to determine the representativeness of those that consented to participate.

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