

Few studies consider the appropriate measurements for assessing clinical trials in children

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Very few studies have asked what the appropriate measurements are for assessing treatments in clinical trials in children, according to a systematic review of paediatric clinical research conducted since 1950. The review by Ian Sinha and colleagues from the University of Liverpool, published in this week's PLoS Medicine, also shows that few studies have involved parents and none have involved children in the process to select which measurements to use to assess clinical trials.

Before conducting a clinical trial of a new drug, researchers choose several "outcomes." These are measurements chosen in advance of the trial to ensure that as much information as possible is provided about the drug's safety, effectiveness and its impact on the patients' health and daily life. Children's bodies handle certain drugs very differently to adults – it can't just be assumed that drugs effective in adults simply need to be scaled down to work for children – and so paediatric clinical trials need to be designed with these differences in mind.

By using a search strategy and consulting experts in paediatric clinical research, the researchers identified all the studies since 1950 that have examined the selection of outcomes in clinical trials conducted in children. Their initial search was very wide to minimize bias, leading to the retrieval of 9,000 abstracts. Only twenty-five articles met the criteria established by the review and examined the selection of outcomes in clinical research in children. These studies came from thirteen groups

researching different conditions – including asthma, Crohn’s disease and cystic fibrosis – but for many paediatric areas there has been no work done into the selection of appropriate outcomes for clinical trials in children.

Reaching agreement on standard outcomes for clinical trials in children is important because it enables researchers and clinicians to compare and combine the results of clinical trials. Standardization also helps avoid selectivity and bias in the conduct of research. Several of the studies reviewed by Ian Sinha and colleagues used methods that had previously been used to select outcomes in clinical trials in adults. These include a technique in which individual opinions are sought and fed back into a group discussion before a final consensus agreement is reached, as well as a technique that involves face-to-face discussion followed by a vote. But although the groups selecting the appropriate outcomes in these studies included clinical experts and specialists in a particular paediatric condition, only three groups asked parents about the outcomes that should be included to assess the clinical trials and none of them asked children directly.

In an accompanying perspective, Mike Clarke of the UK Cochrane Centre and Trinity College, Dublin - not involved in the systematic review - suggests the approaches identified should “make it easier to plan, appraise and use initiatives that have already attempted to standardize outcomes.” But as Ian Sinha and colleagues conclude, further research is urgently required to make this process easier and more uniform and to involve children and their parents in assessing which outcomes should be used in clinical trials.

Citation: Sinha I, Jones L, Smyth RL, Williamson PR (2008) A systematic review of studies that aim to determine which outcomes to measure in clinical trials in children. PLoS Med 5(4): e96.

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