

Examining pediatric clinical studies' underfunding risk

May 11 2023



Credit: Pixabay/CC0 Public Domain

A clinical study with children as participants entails extra costs often omitted in the initial budget. Clinical studies involving children are thus at risk of being undercompensated, new research shows.

Kids will be kids when they take part in [clinical studies](#), as at other times. Sometimes they need a break to do something else for a while before the next study session can start. With children as study participants, researchers also need to involve more people—frequently two legal guardians—and this, too, boosts the time a study requires.

Jenny Kindblom, associate professor (docent) at the Institute of Medicine, Sahlgrenska Academy, University of Gothenburg, and senior consultant clinical pharmacologist at Sahlgrenska University Hospital, and her colleagues at the Hospital's clinical trials unit for children and adolescents had long noticed that, in [budget](#) proposals from the [pharmaceutical companies](#) to cover study activities performed at the hospital, activities in pediatric clinical studies were often undercompensated. This pattern emerged clearly when the researchers embarked on a more structured type of work, supported by a team member with expertise in budget and contract issues.

Their article in *Acta Paediatrica* is based on 10 clinical studies with children as participants, and their true costs proved to be 59% higher, on average, than the total initial budget in the proposal from the pharmaceutical company sponsoring the trial. The problem was that the studies were based on adults and had not been adapted to the pediatric setting.

Child studies require extensive planning and coordination with various people, including some around the child. In addition, child studies often comprise a great many investigations, with staff and resources from various units.

"In implementing the study, you need to have the child on your side. Forcing kids to participate in study activities never works. You need to adjust to what the child can cope with—and sometimes have a break and a bit of rest and recreation," Kindblom says.

Younger children, unlike adults, may also need to be sedated during, for instance, a magnetic resonance imaging (MRI) scan or bowel examination. Anesthesia comes with a wide range of input requirements from different units, which makes the activity more time-consuming.

Budget processing important

The study's first author is Stavros Koulizakos, the team expert in charge of budget and contractual matters for the pediatric clinical studies underway at Sahlgrenska University Hospital. He describes the major gaps between budgeted and actual costs as follows.

"The budget items that generate the biggest discrepancies are, first, the expenses involved in clinical trials; second, the estimated time required for the study activities; and third, the costs of examinations."

The researchers emphasize that [drug companies](#) are enormously important for driving development in the direction of new and improved medicines, for [children](#) and adolescents as well as adults. Nevertheless, the compensation for study activities must be as much as possible representative of the study costs for the Hospital and the respective companies alike.

Kindblom states, "There's a definite risk of fewer studies being conducted because of underfunding. An increased risk of pediatric studies not reaching completion has been observed. To an extreme extent, undercompensation can contribute to this outcome. But an even more clearcut consequence is for the [health care services](#) to engage in pediatric trials sponsored by drug companies, without getting compensation. It's not a reasonable state of affairs."

More information: Stavros Koulizakos et al, Paediatric clinical trials need paediatric clinical trial budgets, *Acta Paediatrica* (2023). [DOI](#):

[10.1111/apa.16808](#)

Provided by University of Gothenburg

Citation: Examining pediatric clinical studies' underfunding risk (2023, May 11) retrieved 11 May 2024 from <https://medicalxpress.com/news/2023-05-pediatric-clinical-underfunding.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.