HOW DO RESEARCERS WEIGH ETHICAL PRINCIPLES IN PEDIATRIC CLINICAL TRIALS?

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1. INTRODUCTION & AIM

Pediatric drug researchers are confronted with several ethical problems because they have to balance the rights and interests of the participating children and parents with societal interests and scientific demands. Much has been written about the ethics of designing pediatric studies, but little is known about the experiences and ethical decision making of researchers when a trial is already running.

The goal of this local survey was to gain more insight in the way researchers experience the practical and ethical challenges of pediatric clinical trials. We aim to describe some of the tensions and difficulties that researchers have to deal with and to make some practical suggestions about how to handle these issues.

Informed consent has been a core issue in the ethics of pediatric clinical trials. Additionally, we focused on the start-up and actual conducting phases of trials to be able to paint a picture of the context within which pediatric clinical trials are being performed.

2. METHODS

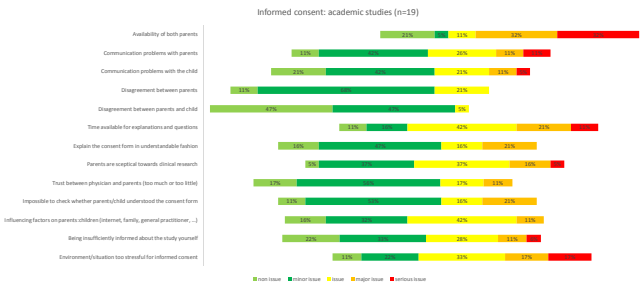
A questionnaire was sent out to 67 researchers from every sub specialty within the Princess Elisabeth Children's Hospital, Ghent University Hospital (Belgium). We received 27 questionnaires, a response rate of 40%. The questionnaire was completed by 19 physicians, 6 study nurses, one pharmacist and one clinical trial coordinator. The participants spent an average of 49 hours per month (range 1-140) on research.

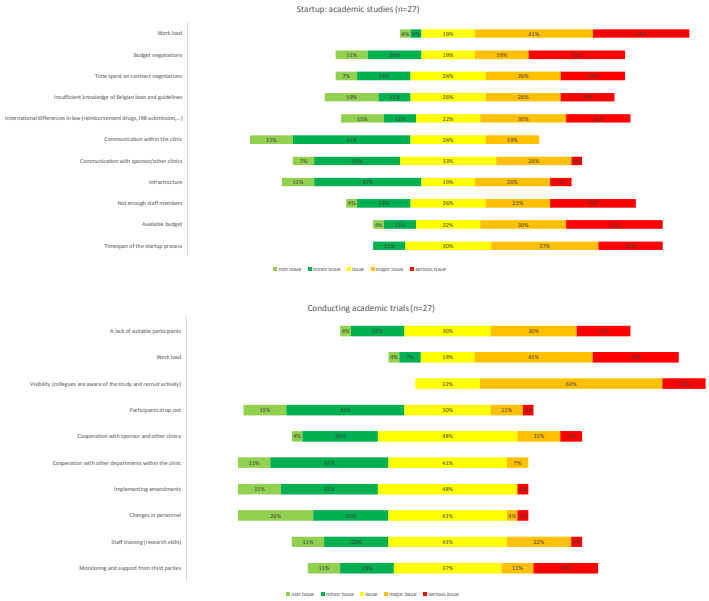
Participants were asked to rate a series of issues regarding pediatric clinical trials on a scale from 1 to 5 where 1 meant 'not problematic' and 5 meant 'highly problematic'. At the end of each series, participants were given the opportunity to write down extra comments. The results can be interpreted very negatively, because every category from 2-5 implies that there is some kind of problem. However, small problems will always occur in practice, but they should be easily manageable. Therefore, we analyzed the data similarly to Likert scale data to distinguish between minor issues and structural problems.

3. RESULTS

The participants were confident in their ability to obtain informed consent. The problems they reported all pertain to external factors like availability of both parents, time and stressful environment. Several study nurses remarked that they should be allowed to be more actively involved in the informed consent process.

The participants experienced many problems during the start-up of pediatric clinical trials. The two biggest issues are work load and the time it takes to start up a trial, but a lot of participants experience serious issues with every aspect we questioned except for communication.





With regard to conducting a trial, the most problems were reported concerning visibility, work load and a lack of suitable participants. Especially concerning visibility, defined as the awareness about trials run by colleagues and actively recruiting for these trials, it is worth noting that every participant indicated that there is a problem.

Some people used the extra comments section to remark that clinical trials have a bad name on the work floor. They are seen as unnecessary extra work, especially among nursing staff with no direct affiliation to research.

4. CONCLUSIONS & DISCUSSION

- A general theme in the survey was time management. Most researchers combine research with clinical care and other duties, which means that at critical times like the start-up, performing clinical trials can be very burdensome.
- Physicians reported to be very confident about their communication skills and their ability to manage the trust relationship with patients and to explain the informed consent form.
- Pediatric studies will often run parallel without much interaction because of the fragmented nature of a pediatric clinic where very different subspecialties are represented. This explains why visibility and awareness of studies was experienced as highly problematic.

➢ Pediatric research is best conducted in a general center of excellence instead of on independent islands. This will diminish some of the most serious issues that were identified in the data: more visibility, better management of workloads, stronger positions in budget negotiations, dedicated research staff and creating a better environment for informed consent. A research center can also provide support with fundraising, help with IRB submission, coordinate service departments within the hospital and manage multicenter studies better.

5. ACKNOWLEDGMENTS

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