Parents' perspectives on pediatric clinical research: A focus group study with laypeople

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Parents' perspectives on decisions to participate in pediatric clinical research: Results from a focus group study with laypeople

[submitted]

ABSTRACT

Knowing why parents decide to consent or dissent to participation of their child in pediatric clinical research is essential to further the ethical debate concerning pediatric research. We performed this qualitative focus group study with 16 parents from the Dutch general public to explore their perspectives on decisions to participate in pediatric clinical research.

Group discussion revealed: Parents conflate clinical research and clinical care; they do not grasp the trajectory of pediatric drug development; their protectiveness matches current research guidelines; and benefit for their child is the most important factor in their decision.

Research professionals should be aware of the knowledge gap of parents, the pitfalls of jargon, and unintended false expectations.

INTRODUCTION

'Are you allowed to do that, test drugs on children?' That's the response we quite often received from friends and family at social gatherings when we tell them about our research on how to test new drugs on children in an ethically responsible way. Funnily, we hardly encountered such reactions during our research into the decision-making of parents and children concerning their participation in clinical research. Could it be that a lot of the children and parents questioned in previous studies were actually *'proto-professionalized',* leading to a skewed view, and that we do not have a good idea of how laypeople view the dilemmas concerning participation of children in clinical research?

The views from parents not recruited through hospitals, but from the general public are very much underrepresented in the literature. Most research in motivations and decision-making in pediatric research is done with (parents of) hospitalized sick children.[1] The perspectives of parents from the general public might differ from parents of hospitalized sick children due to not being familiar with clinical research and not having to cope with a sick child. Our hypothesis is that this selection created a bias in the literature.

Knowing why parents decide to consent or dissent to participation of their child in pediatric clinical research is essential to further the ethical debate but especially the practices concerning pediatric research. The goal of informed consent for clinical research should be for potential research participants to make an informed decision, not simply for them to opt in to research participation.[2] In practice the informed consent process often fails to achieve that objective, e.g. because people misunderstand information or receive irrelevant information.[3-7] More insight in the decision-making of parents enables us to tailor pediatric clinical research and the accompanying recruitment and informed-consent processes to their needs and perspectives. This includes the needs and perspectives of 'first timers' in a hospital, who have little experience in research and hospitalization but can be confronted with offers for participation of their child in clinical research. It is therefore important to add their 'laypeople' perspectives to the body of evidence.

Of course these perspectives cannot be taken at face value but should be used to inform normative deliberation on this topic.[8] As a first step they should be incorporated in a reflective equilibrium.[9 10] Reflected upon they may further the ethical debate concerning pediatric research. A valuable method to gain access to these perspectives is a focus-group study. A focus group does not only create the opportunity to collect perspectives, but also to deepen them.[11] Parents will not only interact with us as researchers, but also with each other. This makes them question others' ánd their own intuitions, creating

a dynamic development of their perspectives. Surprisingly, even though these advantages have been acknowledged in the literature, focus group research into parents' perspectives on pediatric clinical research is scarce. A systematic review about motivations of minors and their children to participate in clinical research identified only two focus group studies [1]. Lebensburger and colleagues identified with their focus groups common barriers and facilitators in pediatric Sickle Cell Disease trials.[12] And Caldwell and colleagues showed with their focus groups that educating parents about trials, improving communication, increasing incentives while decreasing inconveniences, and providing decision aids for parents may increase parents' willingness to let their child participate in trials.[13]

We designed and performed this qualitative focus group study with parents from the Dutch general public to explore their perspectives on decisions to participate in pediatric clinical research. We assessed their intuitions concerning pediatric research, their motivations to endorse or refuse their child's participation in clinical research and which factors would influence their decision.

METHOD

This study is reported in accordance with the consolidated criteria for reporting qualitative research (COREQ).[14]

This qualitative focus group study was deemed exempt from ethics approval by the research ethics committee of Erasmus Medical Center (protocol number: MEC-2016-060). Written informed consent was obtained from all participants before start of the focus groups. All in accordance to Dutch legislation for medical research with humans.

POPULATION

The study population consisted of 16 parents from the Dutch general public. Participants needed to have at least one child below the age of 12 years old and speak Dutch. To ensure a wide range of perspectives, purposive sampling was used by including a variety of parents concerning family composition, educational level and age of their children. Participants were recruited from the general public with assistance from 'CG Selecties' a bureau specialized in recruitment of participants for marketing research. This approach enabled us to recruit laypeople from the general public with minimal foreknowledge and experience in hospitals and medical research.

FOCUS GROUPS

The two focus groups were held at Erasmus Medical Center in July 2016 and lasted up to 120 minutes. One researcher (SvdV) moderated the discussions; One researcher (KT) took notes and aided in the discussions when required. Interaction and discussion between the participants was allowed and encouraged. But the researchers interfered when the debate strayed away from the purpose of the focus group or saturation was reached.

Informed consent was obtained from the participants before start of the focus group. This included permission to audio-record the focus groups to be transcribed later. To ensure confidentiality only participants and the two researchers were in the room, and confidentiality of the discussions was discussed and agreed upon by all participants.

The two focus groups were divided in three parts:

PART 1: INTRODUCTORY ROUND

In part 1 participants were asked to introduce themselves by use of several key questions. 1) Who are you? Who are your children? Do you or your children have hospital experience? Do you or your children have experience with clinical research experience?. Answers to these questions were also collected at the end of the focus groups by use of a written questionnaire (supplementary file 1)

PART 2: INTUITIONS

Part 2 consisted of a facilitated group discussion to explore intuitions concerning medical research. Discussion centered around three key themes: 1) clinical research; 2) pediatric clinical research; 3) specific knowledge. Table 1 lists the key questions used in the discussion.

Table 1: key questions – part 2

Key questions – part 2
1. Clinical research with humans:
a. What do you think about then?
b. What kind of research?
c. Would you participate?
2. Clinical research with children:
a. What do you think about then?
b. What kind of research?
c. Would you let your child participate?
3. Specific knowledge:
a. Off label use of pediatric drugs
b. Sick vs. healthy children
c. Research vs. care

PART 3: VIGNETTE DISCUSSION

To identify relevant factors influencing parents' decisions we used a vignette method in part 3. Two vignettes presented two hypothetical research protocols. Participants were asked which factors would influence their decision to participate in these two studies. With post-its they identified motivating and discouraging factors, followed by a group discussion about these factors. Table 2 and table 3 present the discussed vignettes.

Table 2: Vignette A

Clinical drug trial (phase 1/2)
The goal is to investigate the safety and efficacy of a cancer drug. The product has already been tested on animals, it was found safe in that study. Subsequently it was tested in adults, and for them it was found to be safe and working. Now the researchers want to investigate the drug in children.
- The study lasts a total of 8 weeks. - Your child needs to take the medicine twice a day (by mouth) after a meal. - Your child may not drink carbonated drinks during the study period. - At 0, 4 and 8 weeks your child must come to the hospital for monitoring. - During these visits, your child will have: - a physical examination - a blood sample taken - At these moments, you and your child will also be asked to complete a questionnaire.

Table 3: Vignette B

Observational cohort study
By collecting data in different ways, research is carried out into the development and growth of children, into the development of diseases and behavioral problems. The research thus makes an important contribution to health and care for all children in the Netherlands.
- The study lasts a total of 5 years. - You and your child must visit the hospital every year for examination. This visit takes about 4 hours each time. - During these visits, the following examinations are carried out on your child: - Physical examination (blood pressure, hearing, vision) - Lung function test - Electrocardiogram (ECG) - X-rays of the teeth - Urine sample - Blood sample (1 tube of blood) - Bike test (exercise test) - Echo of the abdomen - MRI scan to look at the brain and the heart - IQ test - Questionnaire (about health, feelings and school) - We also ask you as parents to fill in two questionnaires (health, lifestyle, important events). We also take your blood sample (1 tube of blood).

CODING AND ANALYSIS

The focus groups were audio taped and consequently transcribed verbatim by an independent person. Focus groups were analyzed using thematic analysis. Through systematic objective coding, we identified and labelled themes, in order to elucidate relevant concepts. KT initially coded the focus groups. SvdV coded the focus groups as a second researcher. Disagreements were settled by consensus. Initial coding tree was based on the focus group guide and included: 1) Intuitions clinical research; 2) Intuitions clinical research with children; 3) Knowledge clinical research with children; 4) Motivating factors vignette A; 5) Discouraging factors vignette A; 6) Motivating factors vignette B; 7) Discouraging factors vignette B. During the process of coding and analysis this initial tree was adapted and elaborated based on the data generated from the focus groups. Interview coding and analysis continued until no new codes, concepts, or patterns emerged. We coded and analyzed the qualitative data using QSR International's NVivo 11 qualitative data analysis software.

RESULTS

STUDY POPULATION

A total of 16 parents participated in in two focus groups. 9 participants in one focus group and 7 participants in the other. Age, gender, educational level, and number and age of their children were very diverse in the population. Some parents had experience as a research participant in clinical research themselves, but the majority had no experience with clinical research, neither personally nor with one of their children. Some parents had a chronically ill child (e.g. eczema, asthma) and some had experience with hospitalization of their children. Table 4 presents an overview of participant characteristics.

Table 4: Participant characteristics

	Characteristic	No. of participants
Gender	Father	9
	Mother	7
Educational level	Secondary school	2
	Intermediate vocational education	5
	Higher vocational education	7
	University	2
Median age [range]	Median age [range]	39.5 [32-53] years of age
Number of children	Median number [range]	2 [1-5] children
Age of children	Median age [range]	7 [0-18] years of age

Table 4: Participant characteristics (*continued*)

	Characteristic	No. of participants
Approached for clinical research	Yes	5
	No	11
Clinical research participant themselves	Yes	5
	No	11
Child approached for clinical research	Yes	3
	No	13
Child clinical research participant	Yes	3
	No	13
Child hospitalized	Yes	6
	No	10
Child with chronic illness	Yes	3
	No	13

INTUITIONS: RESEARCH IN GENERAL

Parents' intuitions about research with humans included reference to the importance of doing research:

> *"I think it's really important that it happens, because you have to know the effect on people; you can keep testing on mice for a very long time, but in the end you can only know when you actually check things, check on people."*

> *"So yes, it never stops, healthcare, there will always have to be research."*

Feelings of distrust, associations with animal research and 'guinea pigs' and financial incentives for participation were also common first reactions:

> *"No, personally I think it does, a lot happens that we do not know of."*

> *"Do you know how far reaching the power of the pharmaceutical industry is? They buy entire countries; they cause the collapse of economies."*

> *"I see it right in front of me, these mice and those swollen heads, that's a picture I get right in front of me, so I would be careful"*

> *"At first I think of studies that you can earn a lot of money with, then I think: the more money, the more danger."*

Parents in the focus groups associated 'research' with a broad range of activities. They started talking not only about clinical drug trials, but also about clinical testing (e.g. an MRI scan, CT scan), new operating techniques, screening programs, IQ tests, behavioral tests and vaccinations:

> *"Yes, or cancer research, that can also be preventive, like the research on cervical cancer, that is also in your own interest to see if you have something."*

> *"A few years ago vaccination was announced, that everyone had to vaccinate against ..."*

INTUITIONS: RESEARCH WITH CHILDREN

Their first reactions concerning research specifically with children revealed that their knowledge about this topic was limited and that it was hard for them to grasp the trajectory of clinical research and drug development. As some parents stated:

> *"... I would not know how a company, a hospital or an agency, a medicine magnate will approach my daughters like 'You want to participate in research?'. Never heard about it too."*

> *"I think that no medication is given to children ... I think it will be tested on adults and if it is in an advanced stage ... I do not think that drugs will be tested on children just like that."*

Another parent grasped and expressed the dilemma of drug development and off-label drug use in children very well:

> *"Yes, I think it's ambivalent, because on the one hand, if my child gets a medicine that has never been tested, I think that's bad. But on the other hand, I also find it very bad when my child ... that he will test that medicine."*

The consensus in the group was that parents are more protective of their child than of themselves. As one father explained:

> *"That was also the reason why I just said: the children ... I would more easily participate myself than allow them to participate in research. I myself am responsible for my own situation; I can judge for myself what is happening. And I do not want to place that responsibility with my daughter who cannot defend herself. I think that's really a point. Imagine that I make a wrong deci-*

sion and I destroy her life, then I am responsible for it. And I just do not want that on my conscience. So that would be an important reason for me to say no, I'm not going to do that fuss with my daughter, only when she wants to herself, then she is allowed to decide herself, but I will not start it."

Parents were reluctant to let their child participate in clinical research, and expressed a lack of trust, and fear of risk and burden:

"My first impression is that my children are not allowed to participate in medical research. It may be important, but I do not want to expose my children to it. But my first thought goes to a kind of drug research. But perhaps that can be broader, if it is only weighing and measuring, then I may judge differently. But the first impression is: No."

"No, but I think with people it [red: research] is important, and in children as well, but to a certain level because children themselves cannot say what they want or not, because they cannot see and judge what the consequences are."

"Look, if they take a little blood, I think it's fine… if you are fully pumped with a new drug: Yeah, that's different."

During the group discussion parents mentioned a variety of reasons for letting their child participate in clinical research. Expected benefit from participation for their child was mentioned by almost all parents as the main reason for having their child participate in clinical research. A lot of the discussion in the group about reasons for participation circled around the concepts of familiarity, knowing the disease first hand, and proximity, having a relative/neighbor with a disease. Both concepts played an important role in their future decisions:

"I can imagine if my niece gets seriously ill, that I would also like to let my children participate in a study."

"Yes, but also in general, you are a little bit more supportive of the research when there is something of a link with a child you know."

VIGNETTE DISCUSSION

The vignette discussion centered around the questions: 'Would you let your child participate?' and 'What factors would influence your decision?'. Table 5 and 6 present an overview of the mentioned motivating and discouraging factors for both vignettes,

illustrated with quotes from the group discussion. In response to both vignettes the parents most frequently mentioned factors related to expected benefit and burden for their child. Their notion of benefit did not only entail direct health benefit (e.g. finding a cure), but also entailed getting a check-up for their child. In the context of vignette B parents in both focus groups referred to a periodic MOT-test for cars. Interestingly, the mentioning of a periodic check-up as an important reason for participating created a discussion in both focus groups about the return of individual research results. Most parents assumed that they would learn the results of all the tests during participation, while this was not mentioned in the vignette.

> *"... so only if you get results right away, otherwise I would never do it."*

The discussion also revealed factors that parents mentioned would be relevant for their decision but were unknown in the proposed vignettes. These included for vignette A: age of their child (referring to their ability to execute research procedures and to their decisional capacity), health status of their child and alternative treatment options, and for vignette B: consent of their child, financial compensation, logistical aspects, and privacy-guarantees.

Table 5: Would you let your child participate and what factors would influence your decision? (Responses to vignettes: Motivating factors)

Motivating Factor	Quote Vignette A: clinical drug trial	Quote Vignette B: observational cohort study
Altruism		
Helping other children	*"I would like to participate because you can help other children, I wrote that down."*	*"But when I look at my son again, he would really like to do this, so he can help other people. That is his responsibility."*
Helping science	*"Yes, to actually mean something to science that is good."*	*"Well, if science benefits from this, then that is always a reason."*
Benefit for child		
Treatment / last resort	*"Then you come back to the point where we just were. Look if you hear that, I think you would seize everything to save your child."*	[not mentioned]
Checkup of child	*"I like that there is, for example, a periodic check-up, I think that's a nice thing. And I like it that it is a factual check."*	*"At first what [participant x] said, like a regular MOT test actually , that you can see closely how the development of your child goes ... Then you know right away if they are completely healthy, you have had everything."*
Educational / interesting for child	[not mentioned]	*"…my daughter would really like this…she would find that very interesting, I'm sure."*

Table 5: Would you let your child participate and what factors would influence your decision? (Responses to vignettes: Motivating factors) (*continued*)

Motivating Factor	Quote Vignette A: clinical drug trial	Quote Vignette B: observational cohort study
Minimal risks		
Is safe (tested on animals/ adults	*"Because it is a test and it is safe on adults and cancer is of course bad enough, so I almost think how bad can it be."*	[not mentioned]
No adverse events	Not mentioned	*"And it does not affect [his] health. While with those other pills or whatever, medical research, or medication, then of course that could be the case."*
Minimal burden		
Burden is low	[not mentioned]	*"Okay, they have to spend a few hours once a year. But yeah they are just a little bothered by it."*
Short study period	*"Well I found eight weeks a short period of time... Would it be you have to do something for six months, I would find that too much."*	[not mentioned]
Curiosity		
Self-interest of parents	[not mentioned]	*"I like to participate because I find it interesting to follow the developments in this way."*

Table 6: Would you let your child participate and what factors would influence your decision? (Responses to vignettes: Discouraging factors)

Discouraging factor	Quote Vignette A: clinical drug trial	Quote Vignette B: observational cohort study
Burden		
Burden for child too high	*"Swallowing by mouth is difficult for my child …I think a hospital admission is a bit much."*	*"X-rays of the teeth, well we go to the dentist twice a year, that could just as easily be requested from the dentist. And blood sample and an ultrasound and that MRI scan... yes that's a bit scary, that makes me think about it. If that is not the case. If, for example, it had been just one of those tests, only a blood sample, I would say well okay, that is still limited. But all those tests together I find it drastic."*
Too many restrictions	*"Well anyway, those drinks they aren't allowed. And I miss the explanation why carbonated drinks aren't allowed to be drunk, I would absolutely want to know."*	[not mentioned]
Study period too long	[not mentioned]	*"I think it's too much to state it like that. And I just think it takes a long time. It's five years, the research lasts four hours."*

Table 6: Would you let your child participate and what factors would influence your decision? (Responses to vignettes: Discouraging factors) (*continued*)

Discouraging factor	Quote Vignette A: clinical drug trial	Quote Vignette B: observational cohort study
Risks		
Fear of risks / adverse events	*"I drop out with the word cancer, the fact that it's drugs against cancer. For me, that means a heavy drug. And I do not want a heavy drug in my children... Or if there is too much risk, I think that's more precise."*	*"Those x-rays, they are equal to so much radiation. And if your child is healthy ... you just said it yourself: if you have a child that maybe is not healthy then you might do it, but now: No."*
Consequences unknown	*"It does not say anything about the consequences."*	[not mentioned]
Not enough check ups	*"In this case, I found that there were few control moments, because quite a lot can happen in four weeks. And especially when it comes to oral medication, I think I would feel safer if the child would drop by every week to see how things are going and what the effects are."*	[not mentioned]
Study design		
Questionable study reliability	*"And last, answering a questionnaire with the child… I have my thoughts about that: I think what will that be?"*	*"What I had written as negative: The purpose of research. It only concerns research on disease causes and behavioral problems. But the link between behavioral problems and an MRI scan, I do not see that. …We live in a very prosperous country, and these diseases in children are they very common? Is that why you want to do research? Isn't there a goal behind it, shall I say?"*

DISCUSSION

PARENTS CONFLATE CLINICAL RESEARCH AND CLINICAL CARE

Our focus group study revealed that parents have various interpretations of the term 'research' and not everyone understands the difference between research and care. This difference however does matter to them and influences their decision. Responsible research professionals should focus on this difference during the recruitment and informed consent process for pediatric clinical research.

In medical practice the word 'research' is used in very different contexts. Especially in Dutch, the native language of the participants in the focus groups, 'research' (in Dutch: 'onderzoek') has multiple homonyms. Dutch people do not only use this word to address clinical research, but also use the word for specific clinical tests (e.g. MRI/CT/blood tests) and for screening purposes. Therefore, it is not surprising that parents have very diverse

associations with the term 'research' and that they conflate these different contexts. This conflation can create a therapeutic misconception.[15 16] This becomes problematic when unjustified therapeutic optimism influences parents' decisions to have their child participate in clinical research. A recent study by Janssen and colleagues showed that decliners of study participation had significantly fewer therapeutic misconceptions than consenters.[17] Discussion in our focus groups showed that the difference between research and care, when understood correctly, does matter to parents and that they make different decisions concerning research and clinical care. Although some authors argue we do not have to focus on the fundamental difference between research and care or even try to avoid the therapeutic misconception,[18] our findings emphasize the importance of disentangling research and clinical care to potential research participants and their parents. Therefore, it is crucial that health care and research professionals explain this difference to parents (and their children) during the recruitment and informed consent process, and start this discussion with explaining what 'research' actually means and avoid the pitfalls of jargon.

PARENTS DO NOT GRASP THE TRAJECTORY OF PEDIATRIC DRUG DEVELOPMENT

The discussion in the focus groups revealed that most parents do not grasp the trajectory of pediatric drug development. For parents to be able to make an informed decision about their child's participation in clinical research, they must understand to what they consent or dissent. Our study indicates there is a knowledge gap between starting level of the information in informed consent documents and the basic knowledge of parents about what clinical research and drug development entails.

Context is crucial; for detailed information on a specific trial (e.g. goal, burden, risk) to stick, knowledge about the whole research enterprise is essential. However, empirical research in this field of comprehension mainly been focused on the understanding of specific elements of informed consent documents and improvement of these documents.[19 20] This could explain why single interventions to improve informed consent documents are not consistently effective.[21 22] Initiatives to improve parents' understanding should therefore not only focus on interventions for the informed consent documents for specific trials but also on interventions to improve this knowledge gap. For example, before giving information about a specific trial, give short, but comprehensible information about clinical research and drug development in general.

PARENTS PROTECTIVENESS MATCHES CURRENT RESEARCH GUIDELINES

Parents in our focus group were more protective of their children than of themselves, and stated it is better to test drugs on adults than on children. They value their child's opinion in the decision to participate. Current guidelines concerning informed consent/assent and burden and risk thresholds in pediatric research are in line with these parental intuitions.

In important legal and ethical guidelines (e.g. CIOMS guideline, Declaration of Helsinki, EU Clinical Trials Regulation) additional measures are taken for the protection of minors.[23-25] For example, all three documents: 1) State that research with children cannot be carried out if it can be carried out with less vulnerable subjects. This matches parents' statements that it is better to test drugs on adults than on children; 2) Set limits to acceptable risk for pediatric research without a direct benefit, matching the greater protectiveness that parents have for their children than for themselves; and 3) Value the opinion of the child by requiring assent of the child for participation, matching the importance parents attach to their child's choice.[23-25]

BENEFIT FOR THEIR CHILD IS THE MOST IMPORTANT FACTOR IN THEIR DECISION

Discussion in the focus groups revealed benefit for their child to be the main motivator of parents to endorse participation of their child in clinical research. Interestingly, parents use a much broader definition of benefit than direct health benefit, e.g. being regularly checked up also constitutes a benefit for them. However this can only be a benefit when they are informed about the results of the check-up, so a proper return of results policy is necessary in these cases. The discussion in our focus groups showed that people expect the individual test results to be returned back to them and see no return of result as a good result (my child is healthy). Such a return of results policy is not always at hand. To the contrary, in practice, tests with a research objective are done and evaluated most of the time without a clinical look, and are sometimes not even evaluated during the trial but afterwards.

As expected benefit plays an important factor in the decision-making of parents to participate in research, we should ask what counts as benefit. Research can only be acceptable when the risk-benefit ratio is positive. A lot has been written and discussed about the risk and burden in that equation for pediatric research,[26 27] but much less research focused on the other side of that equation, benefit.[28] The parents in this focus group study, next to a direct health benefit for their child, also considered being checked up regularly and, for example, an educational benefit for their child, as benefits for their children. Staphorst and colleagues found similar results concerning benefit in their interview study with children.[29] These children also had a much broader notion of benefit than direct health benefit. Staphorst and colleagues argued, based on these results, that next to direct health benefit other specific forms of benefit (learning, altruism and fun) could also be justifiably qualified benefits of research participation. But they also argued that 'getting extra attention from healthcare staff' isn't one of those justifiable benefits that could be used in the risk-benefit analysis.[29 30] We completely agree. Patients (including parents and children) should not be dependent on research to get the attention they wish for in clinical practice.[1] It can be considered an undue inducement for

research participation. That parents do state it as an important reason for participation is therefore problematic and deserves attention.

STUDY LIMITATIONS

This study has some limitations that deserve mentioning. Unfortunately, the study consisted of just 2 focus groups with a total of 16 participants. Ideally, more participants should have been included to make the results more robust. On the other hand, data saturation was reached within both focus groups. The focus group sample was diverse in many aspects (e.g. age, gender, educational level) and people with different ethnic backgrounds participated, but ethnicity of the participants was not registered. Therefore, this aspect could not be taken into consideration, while it can be a relevant aspect in empirical research into research participation.[31]

CONCLUSION

Despite its limitations this focus group study makes two important contributions to the tailoring of pediatric research to the perspective of parents. First, it makes clear that parents have various interpretations of the term 'research' and do not always understand the difference between research and care. But this difference does matter to them and does influence their decision. During recruitment and informed consent for pediatric clinical research this difference should therefore be explicitly discussed. Secondly, the main motivator for parents to endorse participation of their child in research is expected benefit for their child. Their definition of benefit however is much broader than direct health benefit as commonly discussed in research ethics committees. For parents being regularly checked up is a benefit as well. This implies research professionals need to present a proper return of results policy.

On the whole, research professionals should be aware of the knowledge gap of parents concerning drug development and clinical research, the pitfalls of jargon, and unintended false expectations.

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