



Parents' perceived obstacles to pediatric clinical trial participation: Findings from the clinical trials transformation initiative

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ABSTRACT

Enrollment of children into pediatric clinical trials remains challenging. More effective strategies to improve recruitment of children into trials are needed. This study used in-depth qualitative interviews with parents who were approached to enroll their children in a clinical trial in order to gain an understanding of the barriers to pediatric clinical trial participation.

Twenty-four parents whose children had been offered the opportunity to participate in a clinical trial were interviewed: 19 whose children had participated in at least 1 clinical trial and 5 who had declined participation in any trial. Each study aspect, from the initial explanation of the study to the end of the study, can affect the willingness of parents to consent to the proposed study and future studies. Establishing trust, appropriate timing, a transparent discussion of risks and benefits oriented to the layperson, and providing motivation for children to participate were key factors that impacted parents' decisions.

In order for clinical trial accrual to be successful, parents' priorities and considerations must be a central focus, beginning with initial trial design. The recommendations from the parents who participated in this study can be used to support budget allocations that ensure adequate training of study staff and improved staffing on nights and weekends. Studies of parent responses in outpatient settings and additional inpatient settings will provide valuable information on the consent process from the child's and parent's perspectives. Further studies are needed to explore whether implementation of such strategies will result in improved recruitment for pediatric clinical trials.

1. Introduction

Since 1997, multiple federal policies have attempted to stimulate pediatric drug development through encouragement of pediatric-specific studies [1–5]. Despite these efforts, relatively few pediatric drug trials have been performed, and many trials have enrolled < 100 participants [6,7]. In general, enrollment of children into clinical trials is

challenging because of the relatively small number of available participants, ethical concerns regarding participation of children in trials, and technical challenges such as blood volume collection limitations and monitoring required for certain trials. These factors are further complicated by the challenges of obtaining parental consent for the child to participate [8–10]. Previous studies have shown that parental willingness to allow their children to participate in clinical trials is

Abbreviations: ABDD, antibacterial drug development; ADHD, attention-deficit/hyperactivity disorder; FDA, Food and Drug Administration; HPV, human papillomavirus; IRB, Institutional Review Board; MRI, magnetic resonance imaging; NICHD, National Institute for Child Health and Human Development; NIH, National Institutes of Health; ABDD Peds Trials, Clinical Trials Transformation Initiative ABDD Pediatric Trials

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variable based on numerous factors, including: recruitment strategies used [11,12], age of the child [11,13], race [14], socioeconomic status [15], type of study or the perceived risk [15,16], and health status of the child [13]. Fewer data exist that describe specific operational tactics and interventions that have the most impact on parents' perceptions of clinical trials.

Clinical Trials Transformation Initiative (CTTI) is a public-private partnership co-founded by Duke University and the U.S. Food and Drug Administration that seeks to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials [17]. In 2014, CTTI implemented a multifaceted project to characterize the scientific and operational challenges in the design and conduct of antibacterial drug clinical trials in children [18]. In this article, we describe the findings from one of those studies. The objective of this CTTI study was to use in-depth telephone interviews with parents whose children had been approached to participate in clinical trials in order to gain a better understanding of parents' decision-making, with particular attention to the barriers to enrollment and ways to overcome them when possible.

2. Methods

2.1. Participants

Participants in this study were parents whose children were offered an opportunity to participate in a clinical trial, regardless of whether they had agreed to participate. The initial goal of the study was to recruit only parents approached for antibacterial drug development (ABDD) pediatric trials. Because only a limited number of parents exposed to ABDD trial recruitment were identified, additional parents who had been approached for other types of pediatric trials were interviewed as well. Potential parent participants were identified through two approaches: 1) partnership with patient advocates from the neonatal intensive care unit follow-up clinic at Duke University (Durham, NC, USA), who were approached face-to-face regarding participation; and 2) participant recruitment through Schlesinger Associates, a healthcare marketing research firm (Atlanta, GA USA). Through its national database, Schlesinger identified parents with children, aged newborn to 17 years old. Schlesinger then emailed the identified parents to ask if any had been approached about an opportunity to enroll their children in clinical trials during the last five years. Those who responded positively were contacted by the study team and screened for eligibility. Eligible participants gave verbal consent to participate in the study. The study was approved by the Duke University Health System Institutional Review Board (IRB). Schlesinger was paid for its recruitment services, and parents were given a small honorarium as a token of appreciation for taking the time to share their experiences and insights.

2.2. Data collection and analysis

In 2015, a series of one-on-one in-depth semi-structured telephone interviews were completed with parents whose children had been offered an opportunity to participate in a clinical trial. Each interview lasted from 30 min to an hour and was conducted by a single professional interviewer using an open-ended topic guide of questions (Appendix). This methodology was chosen because its open-ended nature allowed for a rich exploration of the topics under investigation. The interviewer was an independent social scientist with no prior relationship to the participants. Interviews were audio-recorded in order to facilitate a systematic analysis.

Interview questions related to the factors most salient to parental decision-making about whether to enroll their child in a pediatric clinical trial. The interview focused on how parents were approached about their child's participation, what information was provided at that time and why they decided whether or not to enroll their child. Parents who had enrolled their child in any clinical trial were asked to describe

and critique their child's experience during the trial. Data from the interviews were analyzed using a standard, systematic, qualitative approach in order to identify themes that emerged from the interviews, to assess the strength of those themes, and to identify illustrative verbatim quotations from participants.

3. Results

3.1. Study population

Participants in the study were parents whose children had been offered an opportunity to participate in a clinical trial ($n = 24$), including 19 parents whose children participated in at least one clinical trial and 5 parents who declined an opportunity for their children to participate in any trial. Five participants were recruited from the Duke patient advocacy group, and 19 were recruited through the marketing research firm. Three parents were approached when their children were inpatients in the neonatal intensive care unit, while 21 parents were approached in the outpatient setting. The parents interviewed represented a wide geographic mix encompassing 13 states. Their children ranged from newborns to 14 years of age at the time of approach for trial participation and had a variety of conditions and illnesses, including lung infections, asthma, allergies, chronic pain syndromes, cystic fibrosis, clotting disorders, epilepsy, attention-deficit/hyperactivity disorder (ADHD), Hashimoto's thyroiditis, and other autoimmune diseases (Table 1). There was wide variation in the types of trials represented, from non-interventional studies (e.g., weighing of infants' diapers) to more interventional studies (e.g., new medications, new dosages for already approved medications, new devices or delivery mechanisms).

3.2. Themes identified from participant interviews

3.2.1. The initial contact: trust, timing and empathy

3.2.1.1. Trust is critical. All of the parents interviewed said they would strongly prefer to first hear about a clinical trial participation opportunity from either their child's own pediatrician or from a doctor or other health-care provider caring for them in the hospital, rather than being approached by a stranger. Being "cold called" by a

Table 1
Clinical trial participation by indication.

Trial type (indication)	Participated ^a (n)	Declined participation (n)
ADHD	2	1
Allergy	2	–
Antibiotic dosage for premature infants	1 ^b	1
Asthma	4	1
Bipolar disorder	1	–
Breathing problems	1	–
Childhood obesity	–	1
Chronic pain	1	–
Clotting disorder	1	–
Cystic fibrosis	3	–
HPV	–	1
Insulin	1 ^c	–
Mental illness	2 ^d	–

Abbreviations: ADHD, attention deficit/hyperactivity disorder; HPV, human papillomavirus.

^a A participant was counted in the "Participated" group if his/her child participated in at least one clinical trial.

^b The participant was approached for approximately eight clinical trials (to the best of the participant's recollection) and participated in one.

^c The participant was approached for approximately three clinical trials (to the best of the participant's recollection) and participated in one. Participation was declined in antibiotic studies.

^d The two participants were twins.

researcher about participating in a clinical trial was off-putting to many, even if the researcher was knowledgeable and friendly.

“I would have preferred that the researcher contact my doctor to tell me about the study and that my doctor would contact me and discuss it. It was somewhat uncomfortable being called by someone who didn't know our child.”

However, if the child had participated in a previous trial, had only a minor medical condition, or was subject to trial tasks that were not perceived as risky, parents were more amenable to discussing clinical trial participation with a stranger.

3.2.1.2. Timing is everything. A few parents of very premature newborns with long stays in the neonatal intensive care unit said that they were approached too soon and too often by multiple researchers asking them to enroll their child in a wide array of clinical trials (including antibacterial drug trials). They said that the first few days after the birth was not a good time to approach traumatized parents whose infants were fragile and their survival uncertain. They suggested that waiting longer would be more sensitive and likely be met with greater acceptance:

“The person who approached me was very kind, but there's no great time to approach a person about [enrolling our baby in a clinical trial]. It's kinda like the taxman coming to you — there's no good time. ... My son at this point in time still looked lethargic, and he was barely two pounds ... Once he started gaining weight and filling in and the bruising started going away — then we thought he was doing a lot better, and we weren't on such tenterhooks. It's better to approach a parent when the child is doing somewhat better from a visual perspective.”

3.2.1.3. Empathy is essential. Parents emphasized the importance of empathy from the study team in both the outpatient and inpatient settings. Several parents of premature newborns thought that the investigators who approached them about clinical trial participation were primarily focused on filling study slots and not focused enough on showing empathy for the parents or concern for the infants. In fact, many of those who first approached the parents didn't even know the name of the baby. Some parents felt their infants were being viewed purely as “study subjects in a science lab” or “guinea pigs” rather than as “fragile human beings.”

“I couldn't stand some of the people who asked us about clinical trials. I just felt like they really got a little too excited about kids having problems. ... Every day they would come by and say, ‘We think this is wrong or that is wrong, so we're going to stick her for this and stick her for that.’ They got a little too excited, and it made us feel like we were in a science lab — like Frankenstein. We had to tell them to go away.”

3.2.2. Conveying the right message: benefits, risks, and side effects

3.2.2.1. Discussion of benefits. When receiving information about a study, parents felt that the most important pieces of information they wanted to hear were: 1) that their child's safety and well-being would be of primary importance to those conducting the study; and 2) how their child would “directly benefit” from participating in a particular study. Parents said they felt reassured when told that someone from the study team would be available to them by cell phone 24/7 should any problem occur. The direct benefits of clinical trial participation most obvious to parents could be the improved health of their child or tangible improvements in their quality of life. Other benefits that motivated some parents to consider enrolling their children in a trial included:

- State-of-the-art medical assessments of the child's condition: some

parents were enthusiastic about enrolling their children with cystic fibrosis in a clinical study because they would receive regular magnetic resonance imaging (MRI) monitoring of their lung condition rather than the standard chest x-rays (i.e., more extensive data with less risk).

- Medications that would otherwise be unaffordable or unavailable: a parent of a child with cystic fibrosis said that the same medication provided free in the context of the clinical trial would have cost \$4000 a month outside of the study.
- Post-study access to a study drug that was not Food and Drug Administration (FDA)-approved for all patients who participated in the trial, including the placebo group.

On the other hand, if parents were not convinced by the study team that their children could benefit from being in the study, they reported being unlikely to consent.

“Some of the consent forms made the drugs seem a little too experimental. The ones we thought were beneficial to [our baby] in the moment were the ones we said yes to, as long as there were no bad side effects, because we couldn't play around with her since she started out so sick. But otherwise, if we could see immediate benefits, we chose it.”

3.2.2.2. Discussion of risks. The vast majority of participants considered complete disclosure and full transparency to be essential when the study team explained potential risks and side effects of a clinical trial intervention. Almost all of the parents interviewed said they would want to be made aware of whether the possible risks and side effects their child could experience as a result of participating in a particular trial were probable, possible, or extremely rare. Very remote risks that are very unlikely to happen should be identified as such. Percentages are helpful, e.g., “The risk of [adverse effect on study drug] is less than 0.2%.” Reminding parents that “everyone knows there is some risk with every medication” is helpful for putting the potential side-effects into perspective. They said that this information would not only help them weigh the risks and benefits when deciding whether to enroll their child, but also would give them an idea of what to look for and what to do should side effects arise.

“He used a lot of technical terms about side effects, and I couldn't even tell you what he said because I didn't understand it. I would tell him to stop with the medical jargon. They need to talk to me like I'm a 5 year-old. They need to tell me more about the medication in a way that I could understand.”

Choice of wording also may play a role in parents' willingness to participate in a clinical trial. Some respondents suggested that the term “study” is less off-putting than “clinical trial.” Another parent said that using the more common name of medications is less intimidating than using their “chemical” names.

3.2.3. Properties of the trial itself affecting decision to participate

If the risks were minimal or unlikely to occur, parents reported that they were more likely to allow their child to participate in a clinical trial, even if the study protocol was disruptive to their daily routine. This was especially true if they thought their child could derive a direct health benefit or improvement in quality of life. Parents were also more comfortable having their child participate if the drug had been approved by the FDA, even for another condition or age group (e.g., adults). Several parents whose children participated in trials to determine dosages for children said that having FDA approval gave them more confidence in the safety of the medication. In addition, knowing that the trial consisted of “only one dose” of medication was seen as low risk. A few parents also seemed to gravitate more toward studies where their child would get what seemed like a “natural” substance that their body makes.

Many of the parents interviewed were mystified by placebo studies. Some didn't understand why they couldn't know whether their child was receiving the study drug or placebo as the trial was underway. Some were upset because they were not given this information, even after the study ended. In the particular case of children with ADHD, parents did not want to take their children off a medication that was working well enough, only to then be put on a placebo.

3.2.4. Motivating the children

Many of the parents interviewed said that they discussed the trial with their children if they were old enough to communicate their wishes. Typically, a study team member also talked with the children and even had them sign a consent form indicating that they knew what was involved in the study and that they were in agreement about participating. The majority of the parents said they would be unlikely to try to coax their child to participate in a study if the child objected. According to the parents interviewed, the most common reason for children to reject participation was the need to go through procedures that were “scary” or painful like MRIs, injections or blood draws. In other cases, the required time commitment for traveling to the study site for evaluations interfered with other activities the children preferred. Some said that to overcome these barriers, it is important for the study designers to incorporate “motivators” into the study for the child to participate.

For young children (ages 3 to 7), friendly people, fun activities, a kid-friendly environment and other children to play with are important motivators. Access to toys, games, and videos at the study site encourages them to want to go back for future appointments. Repeated expression of praise and enthusiasm from the study staff for their participation is also important. Small tangible rewards (e.g., prizes, toys, tablet games) are also good. The less “medical” their experience and the less austere the environment (e.g., brightly colored, video games, toys, kid-sized furniture), the more likely they are to enjoy their participation in the study and even enroll in future studies.

Older children often are more reluctant to participate in studies because they prefer to spend their free time with friends or in sports or school activities, and the incentives they need are different from younger children. The most successful incentive is money or money substitute (gift cards or online credits) that provide them the opportunity to buy things they would like to have. Token compensation is typically inadequate to keep them involved in the study. According to parents, the compensation should be commensurate with what the child is being asked to give up in time or undergo in medical evaluation. An initial “signing bonus” followed by compensation for each of the subsequent appointments is a more attractive model than the promise of a payoff at the end.

3.2.5. Impact of clinical trial participation

Parents who had decided not to participate in a clinical trial were asked about barriers to their participation (Table 2). Parents who had enrolled their children in clinical trials reported that many of the children had participated in several clinical trials, often with the same investigators. If their child's first experience was positive, they were typically open to participating in subsequent studies exploring different facets of their condition or illness.

The majority of the parents said that their children's experiences in clinical trials were very positive. Overall, once their children were actually enrolled in the study, they found the study personnel and physicians kid-friendly, caring, and responsive. Most parents noted that staff members were extremely appreciative of the children's participation, and often praised the children for the important contribution they were making. Almost all said that their children liked interacting with the study staff and, in some cases, other children at the study site, and that they felt that it was “cool to be a part of a medical study.”

Other aspects of study participation that parents appreciated included receiving information about their child and the study results.

Parents who had some experience with previous clinical trials also recognized that being involved in these studies can provide positive “teachable moments” for their children, such as personal discipline, finishing what you start, developing planning skills, communicating effectively with adults, and learning the importance of “giving back or paying it forward” so others benefit.

4. Discussion

In this study of 24 in-depth interviews with parents who were approached to enroll their children in a clinical trial, themes that emerged across a majority of participants were identified. These findings were discussed at a multi-stakeholder expert meeting focused on pediatric trials in antibacterial drug development, which contributed to the development of recommendations to improve the design, conduct, and feasibility of pediatric trials for those drugs [19]. We found that each aspect of the study, from the initial explanation of the study to the end of the study, can affect the willingness of parents to consent to the proposed study and future studies as well. The need for trust in the study team was a consistent theme throughout the parent interviews. Trust could be established in multiple ways, including using layman's terminology, appropriate sensitivity training by study staff, and keeping the child's personal provider informed and involved. Parents stressed the importance of the initial contact person and almost universally preferred that their child's own trusted provider present the study. Contact from a “stranger” was much less preferred, and if this type of approach was necessary it was important that “strangers” be aware of details about the child (such as the child's name) and the child's medical condition. These findings are consistent with previous studies in which parents have reported valuing the involvement of their pediatrician or own specialist in deciding whether to participate in clinical trials. In one study of parents of children with cancer, parents reported that having the treating pediatric oncologist explain a study allowed the oncologist to present the most amount of information in the most appropriate manner to allow for understanding [20].

Timing of the initial approach was important as well, and represents a dilemma for research teams who study critically ill children. For very premature newborn infants, the parents in this study recommended that study teams refrain from asking for consent in the immediate period following birth due to the uncertainty of the child's clinical condition and the stress of adjustment to birth and illness. Study teams often choose to approach parents of newborn infants during this initial time period for two major reasons: 1) this period represents a guaranteed time of access to the mother, when she is still hospitalized; and 2) some studies require enrollment very early in the newborn's life.

Engagement and motivation of their child was critical for parental agreement to clinical trial participation. Financial compensation has previously been shown to influence willingness of adolescents to assent to clinical trials [21]. The issue of financial compensation is complex due to ethical concerns, and there is substantial variation among trials regarding the type of compensation offered. One study examined 69 IRB-approved protocols and found that 48/69 (70%) offered at least one form of compensation or reimbursement: 33/69 (48%) for travel/parking, 22/69 (32%) for inconvenience, 13/69 (19%) for time, and 6/69 (9%) for food [22]. Given the logistical barriers reported by parents, it is possible that improved compensation or other motivations may be necessary to improve pediatric trial recruitment in the future [23–25].

Parents who did not consent for their children to participate in clinical trials reported barriers that are consistent with those reported in prior studies. In addition to issues regarding the study risks/benefits and aspects of discussion with the study team, parents cited logistical issues that prevented them from consenting for their child to participate in clinical trials, suggesting that flexible scheduling, including evenings and weekends, are a plus for parents considering enrolling their child in a trial. In an Australian study of recruitment for an obesity trial, approximately 80% of non-consenting parents gave time as a reason for

Table 2
Reported barriers to clinical trial participation among parents who declined, and suggestions to mitigate these barriers.

Barrier	Suggestions from parents to mitigate barrier
Insufficient benefits and/or concern over worrisome risks or management of risks	<ul style="list-style-type: none"> ● Reassurance that there is a “safety net” should the child experience an adverse effect ● Reassurance that there is access to a responsible person 24/7 ● Reassurance that signing a consent form does not mean signing away legal rights if the child is harmed ● Familiarity of study team with child’s medical condition
Initial contact by the study team was not effective	<ul style="list-style-type: none"> ● Initial contact should be made by the child’s doctor or by someone involved in caring for the child ● Use of sensitivity training for study personnel with role playing ● Use of less intimidating terminology such as “study” instead of “clinical trial” ● Framing the study in a positive light, such as: “We would like to offer your child the opportunity to participate in a study to see whether a new medication is an improvement on what is already available”
Study logistics were too complicated or difficult	<ul style="list-style-type: none"> ● Allow child’s pediatrician to monitor vital signs or blood draws to cut down on travel ● Provide for home visits using a study nurse instead of requiring a clinic visit ● Have flexible hours for visits, including evenings and weekends
The child did not want to participate	<ul style="list-style-type: none"> ● Include the child in the discussion of the trial and explain to them at their level ● Have a “kid friendly” place to explain and conduct the study (brightly colored, video games, toys, kid-sized furniture)
The child’s own doctor did not recommend participation	<ul style="list-style-type: none"> ● Monetary or gift card compensations for older children ● Child’s own doctor should present the study to the parents ● Study team should engage community and hospital-based providers to explain the study and gain their acceptance before approaching patients

not participating [26]. Family commitments and transportation problems were also major concerns in this study. Similar results were also found among parents of infants with sickle cell anemia who were approached for a clinical trial of hydroxyurea [27]. Among parents who did not verbally agree to have their children participate in the study, the most common reason cited was “too many lab visits/lab draws” and specifically “transportation problems.” These findings highlight the importance of logistical considerations when planning pediatric clinical trials, particularly outpatient trials. Moving forward, as new pediatric trials are designed for antibacterial drugs, it will be important to consider the suggestions of the participants in this study by budgeting for time and staff for patient visits on nights and weekends.

The present study was strengthened by the quality of the in-depth one-on-one interviews, which allowed for deep exploration of complex issues. Parents also were given the opportunity to provide suggestions to overcome common barriers to participation. It is, however, important to acknowledge limitations to this study. Originally, it was intended to explore pediatric antibacterial trials specifically, but given the small pool of participants, it was not possible to limit the sample to parents who had been approached for their children’s participation in antibacterial trials. However, the themes generated by this study regarding the factors important to successful pediatric trial accrual can be widely applied to other types of clinical trials. Data were not prospectively collected and represented different research settings, and it should be noted that the factors involved in participation by parents and children in clinical trials vary between a clinic-based study with a relatively low risk intervention and time for consideration, and an intensive-care unit-based study with relatively higher risk interventions, higher levels of psychological stress, and shorter times available between presentation of the study and the need for consent. Finally, participant sociodemographic data were not collected. In previous studies, sociodemographic factors were associated with willingness to consent for clinical research and attitudes regarding clinical research [15,28,29].

5. Conclusions

Parents have ultimate decision-making responsibility for their children’s participation in clinical trials for antibacterial drugs and other drugs. In order for clinical trials to be successful in enrolling children, parents’ priorities and considerations must be a central focus, beginning with initial trial design. The recommendations from the parents in this study can be used to justify budget allocations that ensure adequate training of study staff including sensitivity/empathy

training, improved staffing on nights and weekends, and appropriate compensation for adolescent participants. Further studies are needed to explore whether implementation of such strategies will result in improved recruitment for pediatric clinical trials.

Conflicts of interest

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Appendix

Questions used in qualitative interviews:

I. Introduction

A. Could you begin by telling me a little about yourself and your family?

B. Can you tell me about any recent serious illnesses or hospitalizations that your child/ward has had? What was that like?

II. Questions about experiences and decision-making about taking part in the pediatric clinical trial

A. Can you tell me a little about how you were approached about the possibility of enrolling the child in the trial? What was that process like? (open-ended)

B. Who approached you about the trial? What did that person tell you about the trial?

C. Were you given a consent form to read and sign? Tell me about that. What was the consent form like? What did it say about possible side-effects or risks? What did the (study coordinator) say about the possible risks and side-effects of the drug under investigation?

D. Think back to when you were first approached for consent to have the child take part in the trial. Think aloud for a moment and tell me all your thoughts, good, bad and indifferent. What questions did you have?

E. What did you see as reasons to enroll the child in the clinical trial?

F. What did you see as reasons not to enroll the child in the clinical trial?

G. Was there anyone who you looked to guide you through the decision about whether to participate?

H. What kinds of information did you want to see when you were presented with the possibility of enrolling the child in a pediatric clinical trial? What information was helpful? What kinds of information that you didn't receive would you have wanted to have?

I. At that time, did you want to hear *all* of the possible side-effects or risks, even those which would be extremely rare, or did you only want to hear the risks and side-effects that would be most likely to occur?

J. How, if at all, could the process of approaching you about a clinical trial for the child have been different or better as far as you are concerned?

III. For those who did choose to enroll the child

A. What was your experience and that of the child like in the clinical trial?

B. In what ways could your experience and the child's experiences have been different or better as far as you are concerned?

C. Looking back, how do you feel about having enrolled your/the child in the trial? (open-ended) Would you make the same decision again? Why or why not?

D. If you were on the committee charged with deciding the best ways to approach parents about enrolling their children in pediatric clinical trials what kind of approach would you recommend?

IV. For those who did not choose to enroll the child

A. Can you walk me through your thinking as you made the decision not to enroll the child in the pediatric clinical trial?

B. What was the child's (father's/mother's) thinking about participation in the trial? Were you both on the same page or did you have different opinions about it?

C. Looking back, how do you feel about the decision not to have the child participate? Would you make the same decision again? Why or why not?

D. What, if anything, might have been different that would have led you to have enrolled the child in the trial?

E. What other suggestions would you make to improve the parent or caregiver/child experience of the clinical trial itself?

F. What would you advise a friend who is considering having her child take part in a clinical trial for antibiotics?

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