

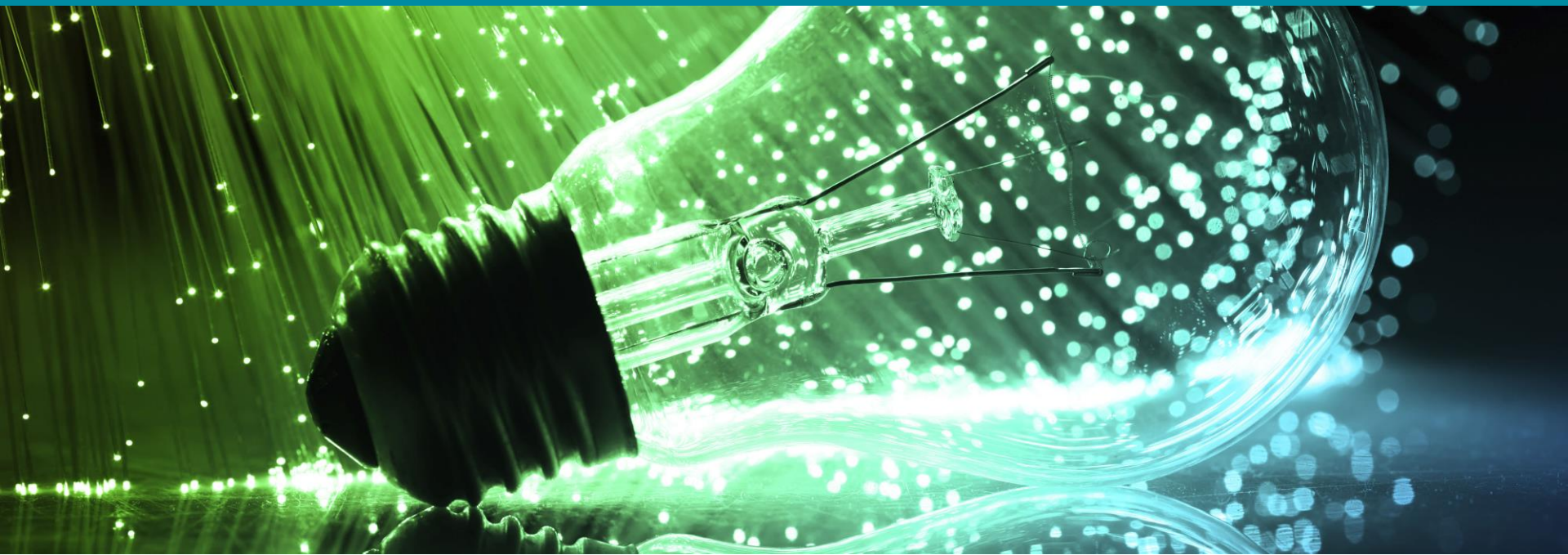
# Parental Decision Making About Enrolling Children in Clinical Trials: An In-depth Interview Study

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## **Disclaimer**

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# Methods

**Quantitative Research  
vs  
Qualitative Research?**

# Sample Question

## Qualitative vs. Quantitative

1. Which do you prefer, Apple pie or Chocolate cake?

a. Apple pie

b. Chocolate cake

# Qualitative Research

## ▣ Focus Groups



# In-depth (one-on-one) Interviews





But you said you  
wanted single  
women between  
30 and 50.



# In-depth Interviews: Parents Approached about Enrolling Their Children in a Clinical Trial

 24 in-depth interviews

- **19** enrolled their children in one or more clinical trials (also turned some down)
- **5** did not enroll their children in any trial
  - **Newborns to teens**
  - **National geographical mix**
  - **Wide variety of health conditions**



# Research Goals

- Understand the factors important to parents' decision about whether to enroll their child in a clinical trial.
- Gain insight into why some parents enrolled their children in clinical trials while others did not.
- Identify barriers to pediatric clinical trial participation and strategies for overcoming those barriers

# Summary of Findings

## The Initial Contact

- The importance of trust, timing and empathy

# Trust is Critical

➤ Who first contacts parents = key to their decision

➤ Prefer to first learn about a study from:

1. Child's pediatrician
2. Doctor or nurse who cared for child in the hospital.

Assumed only agenda is genuine concern about their child's wellbeing

- a. Trusted to have their child's best interests at heart
- b. Especially true for parents of premature newborns, very young children, very ill children & those who have never participated in a trial

# Trust is Critical (cont'd)

*“The doctor at the hospital had been taking care of our baby, and we came to trust him. She was taking an antibiotic for a lung infection and our doctor asked if we would like to participate in a study of a new antibiotic. He wasn’t pushy at all. It was only one dose, and she could have immediate benefits, so we decided to have her take it.”*

# Trust is Critical (cont'd)

3. “Strangers” (Clinical trial personnel who don’t know the parents) assumed to have other agendas (filling trial slots)
4. Being “cold called” by researchers was off-putting, even if they were knowledgeable and friendly.

*“Rather than just talking to random parents of kids in the waiting room, it would have been more effective for the researchers to approach the kids’ doctors and tell them about the study, and get those doctors on board with informing parents that this was available. They probably would have had many more patients enroll if they had done it that way. Not only would more patients know about the study, they would learn about it from someone they trusted rather than from a stranger who was hanging out in the waiting room.”*

# Trust is Critical (cont'd)

➤ **Exception:** Parents more amenable to discussing clinical trial participation with a “stranger”

- If child participated in previous trials
- If child has only minor medical issues
- If trial tasks not risky, (taking photos of premature newborns' eyes or weighing their diapers)

# Timing is Everything

- Some parents of very premature newborns said they were approached too soon and too often by too many researchers about enrolling their baby in clinical trials (including antibacterial trials).
  - First few days after the birth = not a good time to approach parents
    - Babies fragile
    - Survival uncertain
    - Parents overwhelmed



# Waiting Longer = More Sensitive

*“The first several days in the hospital were very traumatic and difficult. Our child was critically ill, and we didn’t even know if she would live. During those first few days we were asked about our daughter participating at least five studies. The timing for these researchers coming in and asking for study consents was not good and caused us additional feelings of pressure and stress.”*

*“I would have preferred not to be approached during the first few days after the baby’s birth. My husband and I were overwhelmed with worry and fear at that point, and investigators coming in during that time only added to our anxiety. If there was some reason why a decision had to be made immediately after the delivery, I would have wanted one of our care providers to come talk to us about it first, rather than a researcher who knew nothing about us or our daughter’s condition.”*





# Empathy is Essential

- Some parents of premature newborns perceived investigators who approached them about clinical trials as too focused on filling study slots and not focused enough on expressing concern and empathy for the baby and the family
  - Didn't know the baby's name
  - Hadn't taken time to brief themselves on baby's medical condition
  - Didn't show sensitivity/compassion for the child's misfortune
  - Were "a little too excited" about their baby's problems



# Empathy is Essential (cont'd)

*“Researchers who approached us talked about our daughter as ‘Baby Girl \_\_\_\_ [last name],’ and that made us feel like she was a research subject rather than the fragile human being that she was. It would have been much better if they took the time to learn about us and our child before approaching us about a study. They should be sincere and convey to parents that they genuinely care about the well-being of their child. No parent wants their child to be just a guinea pig for the sake of science.”*

*“I just felt like [the investigators] really got a little too excited about kids having problems and it made us feel like we were in a science lab — like Frankenstein. We had to tell them to go away.”*



# Conveying the Right Messages

## Message #1 - Direct benefits of participation to the child's health or quality of life

- Improvement in health parameters
- Greater ability to engage in childhood activities with peers
- Access to state-of-the-art medical monitoring
- Access to medications that would otherwise be unaffordable or unavailable
- Post-study access to the study drug to participating patients – including placebo group

# Conveying the Right Messages (cont'd)

*“We always asked the investigators how this study would benefit our child. We only participated if we were assured that participating would be either beneficial or neutral.”*

*“One study we were approached about required an endoscopic evaluation of our baby. We didn't consent because the investigators couldn't give us any reason why this would help our baby. They just wanted to know how many premature babies have paralyzed vocal cords secondary to patent ductus arteriosus.”*

# Conveying the Right Messages (cont'd)

## ➤ Message #2 - Their child's safety and well-being are of paramount importance to study team

- Parents understood trial participation presents some level of risk, but wanted to know that if their child experiences an adverse event, they will have access to a study team member 24/7.

# Presenting Risks and Side Effects: Full Disclosure, Transparency and Plain English are Essential

▀ Parents wanted to be made aware of *all* possible risks and side effects their child could experience as a result of participating in a particular trial and whether each was probable, possible or extremely rare.

- Helps weigh the risks and benefits of enrollment
- Lets them know what to look for and do should side effects arise

# Presenting Risks and Side Effects: Full Disclosure, Transparency and Plain English are Essential (cont'd)

*“We definitely wanted to know any and all risks and side effects, even those which were scary. Because we were forewarned, we were better prepared to handle the two episodes [adverse events] when they did happen. I think we would have been more scared if we hadn't been warned about what could happen and how to respond if it did.”*

# Presenting Risks and Side Effects: Full Disclosure, Transparency and Plain English are Essential (cont'd)

*“My son has CF. We wanted to know all of the possible side effects, so I could spot complications if certain symptoms presented themselves. Even the ‘it only happens in very rare cases’ were things I wanted to know, just in case they did occur, so I would know it was study drug related and I need to report it to the study coordinator and get direction on handling it. One potential risk is that the child could develop flu-like symptoms from the drug. I would know that such symptoms had to be immediately reported to the coordinator rather than just treating it like an ordinary childhood illness.”*



# When Deciding Whether to Enroll Child in a Trial, Some Parents Sought Input from Their Child's Pediatrician

- ▶ If the child's own doctor was not in favor of the child participating, all said they would not enroll their child

# Parents like it when study investigators keep the child's pediatrician in the loop.

*"Our son had asthma and couldn't participate in sports. We asked his pediatrician if he could find a study for him. We relied heavily on our pediatrician to advise and guide us through the process. The fact that our pediatrician was going to be actively involved throughout the study gave us peace of mind. He was the one who was going to be monitoring our son and collecting the data that would be sent to the study."*

*"It would be best for the researchers to involve the child's own doctors in the study — both in talking to the parents about it in the first place, and then telling the doctor the results of the study so they could incorporate the results in the treatment of the child."*

# Parents' Decision-making Roles: Approach the Mothers!

- Fathers tended to lean away from study enrollment initially and were more irritated when approached at a highly stressful time
- Mothers were more pro-active in conducting research online to check information provided by study investigators
- If mothers strongly favored enrollment, fathers typically went along with that decision, even if they disagreed initially

# Parents expressed a strong interest in communicating with other similarly situated parents who had enrolled their children in a particular trial.

*“Talking with doctors, nurses and study coordinators is important, but talking to another parent who has already gone down the road you are looking down is extremely valuable.. It’s hard to duplicate the value of a one-on-one relationship with another parent.”*

*“We would have liked to have had the opportunity to talk to other parents who had children in the NICU about their experiences with clinical trials — which ones they chose to do and why.”*

# Parents discussed participation with their children who were old enough to communicate their wishes.

- ▶ A study team member typically also talked with the children and had them sign a “consent form” indicating they knew what was involved in the study and were in agreement about participating.

# Parents discussed participation with their children who were old enough to communicate their wishes. (cont'd)

- ▶ Most common reason children didn't want to participate:
  - Scary or painful procedures (MRIs, injections, blood draws)
  - Older children didn't want to give up time with friends and activities they liked
- ▶ Parents usually respected their child's decision unless they had a very serious illness that had the promise of being improved through the trial.

# Parents suggested study designers incorporate age-appropriate “motivators” for participation and retention.

## For young children

- Fun activities (toys, games, videos)
- Kid-friendly environment (not “medical”)
- Other children to play with
- Small tangible rewards
- Repeated expression of praise and enthusiasm from the study staff for their participation

# Parents suggested study designers incorporate age-appropriate “motivators” for participation and retention. (cont’d)

## ► For older children

- Best incentives: money, gift cards or online credits
- Initial “signing bonus” followed by compensation for each visit is more attractive than the promise of a payoff at the end
- The older children typically received \$75 to \$125 per appointment
- Several said their children considered dropping out, but completed the study because of the money



# Why Parents Enrolled Their Children in a Clinical Trial

- ▶ **Primary motivation**: Potential health benefits or improvement in QOL for their child
- ▶ **Secondary motivation**: Sense of social responsibility (their child's participation could further the common good/ help bring new meds to children in the future)

*"The biggest reason to participate was a benefit for our baby. I also wanted my daughter's involvement to help other babies and families in the future, so long as it did not come at a negative cost to her."*

# Why Parents Enrolled Their Children in a Clinical Trial (cont'd)

- ▶ **Other motivations: “Teachable moments” for their children**
  - Personal discipline
  - Finishing what you start
  - Developing planning skills
  - Communicating effectively with adults
  - Learning the importance of “giving back” or “paying it forward”

# Parents More Likely to Consider Enrolling Their Children if:

- Participation was requested by their child's own doctors or by doctors who took care of the child in the hospital.
- The person who approached them for participation wasn't "pushy," knew their situation and showed compassion and concern for the child and the family.
- Their child had a positive experience in a previous clinical trial, especially with the same investigator or study team.
- The trial had minimal risks.
- The trial didn't involve introducing or changing medications.

# If the Trial Involved a New Medication

- **Parent's would be more likely to enroll their children if:**
  - Side effects were thought to be minimal or very unlikely
  - It was something the child needed anyway, e.g., antibiotics.
  - The drug being tested had FDA approval for another condition or age group
  - It is a trial to establish pediatric dosages and consists of only one dose of medication
  - The child has a serious medical condition
- **The more serious their child's condition, or the more limited the child's life, the more willing the parents were to try promising new treatments in spite of inherent risks**

# Why Parents Declined Participation

- Initial contact by investigator did not engender interest or trust
- Parents saw no direct benefit to their child
- The study had worrisome potential risks /side effects
- Study logistics, e.g., distance from the study site and inflexibility of appointment scheduling would make participation arduous
- The child didn't want to participate.
- The parents didn't want to take the child off of a medicine that was working if there was a chance they would be randomized to the placebo arm and have no medication.

# Why Parents Declined Participation (cont'd)

*“I wouldn’t have wanted to take my kid off the [ADHD] med she needs and that I know works for her and then not have her on anything. Then all of the sudden she’s acting out and not doing well in school. I don’t want to do that to her.”*

# Conclusion

➤ Several key themes have emerged from these interviews including the importance of:

- Trust
- Timing
- Sensitivity, empathy and concern
- Full disclosure, transparency and plain language
- Age appropriate motivators

➤ We'll explore these issues further this afternoon and in the breakout sessions

# Thank you.



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