



Project dissemination meeting

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RESPECT

Young patients' and their parents' experiences of clinical trials

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Information sources

- Case study interviews with children and parents
 - Diabetes
 - Epilepsy
 - Mitochondrial disorders
 - HIV
 - Growth hormone
- Focus groups with clinical trial doctors & nurses
 - their experience of families' motivations



Case study interviews

- What do children and parents say?



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Information needs



Including the child

Most often, the child does not have much say in the decision to participate.

He/she trusts that the parents have understood what the trial will involve, but it is not clear for the parents either.

“I wish doctors would give more information in layman’s terms.”



Trust

Parents often assume there are no risks involved in a trial.

“It’s ok to participate as long as there are no side-effects.”

The doctor-patient rapport is very important. If they trust the doctors, they rarely refuse to participate.

“I would trust my regular doctor”



Understanding what is involved

Parents were not always sure what was expected of them or what the study was about.

“It's easy to agree to something if you don't know what it actually involves.”

It often comes as a surprise that it is time-consuming or painful or that there may be side-effects.



Interest in the research

Some parents researched the disorder on the internet.

“It is an opportunity to learn something new.”

“We checked out the references and saw that it was a serious study.”

They want all information available.

In small disease groups, families have seen enormous progress in treatment and have good knowledge of how things work.



Receiving results of the study

Parents repeatedly express an interest in receiving feedback on the study findings but rarely get any.

“We want to know what this study found. Some report would be good.”



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**Altruism or
personal benefit?**



Altruism through group commitment

They felt a duty towards all children with their child's condition to find out more about the illness and to participate in the development of new approaches.

"I hope that my son's condition will be treatable one day."

Families in a small 'disease community' were all willing to participate in clinical trials and were not concerned about time lost (off school, work, etc).

"It is for the good of all and not the individual"



Altruism or personal benefit?

Parents say it is worth the time and trouble as long as somebody's child stands to benefit.

But in practice, they hope for direct benefit to their own child. They don't want their child to get the placebo or miss out on the latest treatment.

“We only participated because there was a 60% chance of getting the vaccine.”



Benefits of extra health care

Some parents felt it was a chance to get a more precise diagnosis or more specialist health care for their child.

“We participated because of the opportunity to get an MRI scan for her.”

Some saw little difference from any other visit to the doctor.



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Barriers to participation



Child's pain & distress

Needles are particularly distressing.

The child often wants to stop at first but is persuaded to continue.

Some teenagers said they have now adjusted to the discomfort; others say they would refuse if asked again.

“I would participate in a continuation but not in another trial.”



Parent's distress

No-one wants their child to suffer.

“It was difficult watching my child going through it.”

General anaesthesia and giving blood samples were unpleasant for the child.

“We would not participate again if it included general anaesthesia.”

Parents do not want their child to participate in future if it could cause harm to the child.



Inconvenience

Younger children don't mind time off school but it can cause problems for older children and for parents

"I had to get permission from my employer to take a day off work."

"I missed double maths every time I came to the clinic. Now I will fall behind."



Being used as a research object

Parents want to know that the physician will not abuse their trust.

“Most important that it does no harm ”

“I wouldn't let my son be used as a 'guinea pig' in an experiment that could harm him.”



Focus groups with CT staff

- what do families tell them?



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Motivations for participation



Improving their child's health

Parents want to contribute to better medical care.
They wish to do everything possible to help the child.

Families consider their participation to have no real disadvantages while having the advantages of potential benefit to their child's health and that of other children.

At some clinics, it is extremely rare for patients to refuse to participate.



Partners in the research

Parents of children with a serious diagnosis search for information themselves about the condition.

Sometimes the children are so well-informed that even a 5-year-old can say if he/she wants to participate or not.

Families consider themselves active participants in the research (not just passive patients) and feel entitled to know the findings at the end of the study.



Barriers to participation



Pain and distress

Most parents worry that their child might be treated as a 'guinea pig' but it depends strongly on the diagnosis.

Pain and distress to the child are mentioned frequently, both by parents and by children (blood tests and injections - pain and fear of needles).

Several parents do not want their child to participate in future trials if it involves more needles.

In some paediatric conditions, families show 'trial fatigue'.



Being excluded

Parents are more likely to refuse to participate if the study has a placebo arm.

The families get info about the child's health status during or after the trial, but the sponsor does not disclose the research results.



Main conclusions

- Participation is an opportunity to obtain medicine or other treatment which would otherwise not be available to them, but also to help others.
- Neither the children or parents fully understand what is involved. They trust the clinical staff to do them no harm, so the pain and distress come as a surprise.
- Appreciation of their sacrifices and their contribution to research is important. Distribution of results and progress made through trials, to the family and to the relevant patient organisations, might encourage participation.



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Thank you!

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