

# Clinical trials: the viewpoint of children

J Cherrill, H Hudson, C Cocking, V Unsworth, L Franck, J McIntyre, I Choonara

*Arch Dis Child* 2007;**92**:712–713. doi: 10.1136/adc.2006.114207

The views of 30 children (8–16 years old) attending paediatric medical clinics on paediatric clinical trials were determined by semi-structured interviews. Nineteen children recognised that there were risks involved with taking part in clinical trials. Risks concerned with being paid were recognised by all children.

There is growing recognition of the need for clinical trials in children.<sup>1</sup> However, the views of children on this subject have not been extensively explored. Children are capable of understanding medicine-related topics<sup>2</sup> and children who have participated in clinical trials have been asked their views on the research process.<sup>3,4</sup> The aim of this study was to ascertain the viewpoints of children on aspects of clinical trials.

## METHODS

The study was approved by the Derbyshire Research Ethics Committee and involved a semi-structured interview with children attending the medical outpatients' department at Derbyshire Children's Hospital. Children were approached by their consultant paediatrician in the clinic at the end of their consultation. Children and parents who agreed to participate were introduced to the research nurse who explained the study in more detail.

Written informed consent was obtained from the parents together with verbal and/or written assent from the child. Subsequently the parent was asked to leave the interview room and the interview took place between the research nurse and the child. A few parents stayed in the room but did not participate in the interview.

The themes included in the semi-structured interview were as follows:

- use of regular medicines by the child,
- knowledge of where medicines come from,
- knowledge of clinical trials,
- participation in clinical trials,
- payment for clinical trials,
- problems with payments,
- understanding of what a placebo is,
- opinions on which illnesses we should study,
- whether clinical trials should be restricted to ill children only.

All the interviews were conducted by one of two research nurses (HH, JC) using the same schedule of questions. All the interviews were tape recorded and subsequently transcribed by a secretary and checked by the research nurses. The children's answers were assessed by the research nurses independently to determine their understanding of questions asked and a consensus agreement was then reached.

## RESULTS

Interviews were conducted with 30 children aged 8–16 years (median 12 years) who had a variety of medical conditions

(table 1). Nineteen of the children were receiving regular medication. Many children had an understanding of where medicines came from (table 2). Only three children, all aged 16 years, had a full understanding of the nature of clinical trials. Only one child was able to explain what a placebo was. Nineteen children (aged 8 to 16 years) recognised that there were risks involved with taking part in clinical trials.

## Payment

Most children did not expect to be paid to participate in a clinical trial as they felt it was in the interests of other children if they took part in a study. However, 17 children said that they would take money if it was offered. Nine stated that they would not want money (several felt it was like taking a bribe) and four were uncertain. However, there was recognition even amongst children who felt payment for participating in clinical trials was appropriate, that there were risks with regard to being paid for clinical trials.

One 16-year-old who stated that he would like to be paid also commented, "If you get paid too much, someone might keep coming and coming and coming. Might get drugged up or something". A 13-year-old girl said, "It's like a bribe that is. It's like trying to get children to test things for money. It's like they are getting pushed into doing something". A 14-year-old girl said the following: "If you had asked them without the money they probably would have said no. So it is trying to bribe them into doing something that they might not want to do". A 9-year-old girl said, "It's very good if you get paid. I can go and spend it on some clothes".

## Benefits and risks

In relation to the understanding of why clinical trials are needed, a 13-year-old boy stated, "To get the dosage right with children so other children can benefit". A 15-year-old boy commented, "You could improve the medicine that is used, give better advice on what to do and what not to do when people are taking the medicine".

In relation to the risks associated with clinical trials, an 8-year-old boy stated, "It could kill you. It could really make you poorly or paralyse you". An 11-year-old girl stated, "It could cause side effects and it might not work". A 13-year-old boy commented, "There is always a possible chance that some people might be allergic to it or that they could come out in a rash". A 13-year-old boy who stated that he would like to receive the money also recognised the risk: "If you take a

**Table 1** Diagnoses of children

| Diagnoses                   |   |
|-----------------------------|---|
| Endocrine                   | 8 |
| Epilepsy                    | 6 |
| Abdominal pain/constipation | 5 |
| Headaches                   | 4 |
| Ulcerative colitis          | 2 |
| Miscellaneous               | 5 |

**Table 2** Source of medicines

| Where do medicines come from? |   |
|-------------------------------|---|
| Pharmacy                      | 8 |
| Chemicals/minerals            | 3 |
| Laboratories                  | 3 |
| Plants                        | 3 |
| Animals                       | 2 |
| Rainforests                   | 1 |
| Diseases/dead cells           | 1 |
| Do not know                   | 9 |

medicine that harms you and could kill you money is no use is it?".

### Illnesses

Most children had opinions as to which diseases required clinical trials involving medicines. Only three children said they did not know. Cancer was suggested by seven children and the remainder suggested a wide variety of diseases. Eleven children mentioned two separate diseases and two children suggested studying three different diseases. Very few children suggested studying medicines for their own illness. Almost two thirds of the children (19) felt that it was appropriate for healthy children to be involved in clinical trials. Six children felt that only ill children should participate in clinical trials. The remainder were uncertain.

### DISCUSSION

Almost half the children had a good understanding of where medicines came from. Most children recognised that there were risks involved with participating in clinical trials and there were differing views on whether children should receive payment. However, it was significant that even children who felt it was appropriate to receive payment recognised that there were risks. Within Europe it is illegal to pay children for participating in research. However, within the United States it is common practice.

Our findings were consistent with a previous Danish study suggesting that children are altruistic.<sup>5</sup> Several American studies have interviewed children who have already participated in clinical research. These studies in children with ADHD or diabetes mellitus suggested that as well as altruistic reasons, other important factors included financial incentives, access to

once daily medication and access to free supplies of equipment.<sup>3,4</sup>

It was interesting that most children felt it was appropriate to consider recruiting healthy children to a clinical trial. This is more likely to happen in North America where it is accepted practice. In Europe it has so far been considered inappropriate, for example, to recruit healthy children for pharmacokinetic studies.

The children who participated in the interviews had all agreed to do so and they were therefore a self-selected group. However, they all however had strong opinions about clinical trials in children. Children's viewpoints were not considered at all during the extensive consultation process regarding the European legislation promoting paediatric clinical trials. Children should be engaged more in the discussion about research in this area and should also be given more information about medicines, their side effects and the need for clinical trials.

### Authors' affiliations

**J Cherrill, H Hudson, C Cocking, V Unsworth, J McIntyre, I Choonara,** Academic Division of Child Health, University of Nottingham, Derbyshire Children's Hospital, Derby, UK

**L Franck,** Institute of Child Health, Great Ormond Street Hospital for Children, London, UK

Competing interests: None.

Correspondence to: Professor Imti Choonara, Academic Division of Child Health, The University of Nottingham, Derbyshire Children's Hospital, Uttoxeter Road, Derby DE22 3NE, UK; imti.choonara@nottingham.ac.uk

Accepted 22 March 2007

Published Online First 3 April 2007

### REFERENCES

- 1 **Saint-Raymond A,** Seigneuret N. Medicines for children: time for Europe to act. *Paediatr Perinat Drug Ther* 2005;**6**:142–6.
- 2 **Hameen-Anttila K,** Juvonen M, Ahonen R, et al. How well can children understand medicine related topics? *Patient Educ Couns* 2006;**60**:171–8.
- 3 **Fogas BS,** Oesterheld JR, Shader RI. A retrospective study of children's perceptions of participation as clinical research subjects in a minimal risk study. *J Dev Behav Pediatr* 2001;**22**:211–16.
- 4 **Broome ME,** Richards DJ, Hall JM. Children in research: the experience of ill children and adolescents. *J Fam Nurs* 2001;**7**:32–49.
- 5 **Wolthers OD.** A questionnaire on factors influencing children's assent and dissent to non-therapeutic research. *J Med Ethics* 2006;**32**:292–7.