

**EMBARGOED UNTIL
00.00 2nd February 2012**

Testing medication for children and young adults

Participants and parents speak honestly about clinical trials in children

Insight into the experience of being a child taking part in a clinical trial designed to test new medication or vaccines – as well as the experience of deciding whether to allow your son or daughter to participate in such a study – is provided in two online resources launched today.

Two new sections* of the experiential health websites, www.healthtalkonline.org and www.youthhealthtalk.org, carry interviews with parents and children talking about how they found out about trials, why they decided to take part or, in some cases, decline an invitation to participate, as well as what information they needed and were given and how they felt about the experience.

Welcoming the new sites, Professor Dame Sally Davies, Chief Medical Officer and Chief Scientific Adviser at the Department of Health, said:

“Well designed trials are a vital contribution to advancing medical knowledge in order to improve treatment, care and quality of life for patients. Children have their own specific needs and we need more trials in children to be sure that we are getting the best treatments that work for them and aren’t just relying on evidence from adult trials.”

These two new sections will be a valuable resource to help other families thinking about taking part in a trial to make a more informed choice, and to learn more about trial methods and what they can expect if they take part. The project will also provide a valuable teaching aid for professionals by offering insights in what really matters to parents and young people when they are invited to participate in a trial.”

The project has been produced with the support of the National Institute for Health Research (NIHR). Research was carried out by the Health Experiences Research Group, University of Oxford with carefully designed interviews of 29 parents as well as 32 children aged from ten upwards who have been on, or have been invited to participate in, a trial.

The DIPEX Charity, PO Box 428, Witney, Oxfordshire, OX28 9EU
Tel: 01865 201330 Fax: 01865 289287 email: info@dipex.org.uk

On the site, Dr William van't Hoff, Co-Director of the NIHR Medicines for Children Research Network, acknowledges public anxiety about involving children in clinical research.

“There are real concerns about undertaking research on children, a feeling that they shouldn't be experimented upon. Clinical research has also been slow to recognise that children are not small adults in the way their bodies respond to medication, how they absorb and metabolise it as well as the long-term effects.

As a result, however, half the medicines that we use in children haven't been properly tested for this purpose and we rely on data from adult experience. That cannot be in the interests of children.”

The Network, set up in 2005 by the NIHR to promote properly designed and coordinated studies in the field, has already seen 30,000 UK children recruited to participate in clinical trials. With EC legislation requiring new medicines to be tested on children, many thousands more are set to be invited to take part in trials in future to ensure that newly developed medicines are safe and effective for children.

Dr van't Hoff underlines the importance of children being supported in giving informed consent in order for trials to be ethical and successful.

“It's absolutely vital that the children and their parents receive and understand the information about the trial - with an on-going process of agreement to participation that continues through the study. Every child must be given the opportunity to withdraw at any stage and that is something that every researcher must understand and respect.”

Contributors to the two sites spell out what that means. Joe, 15, says he was ‘overwhelmed’ when he was invited to take part in a trial after being newly diagnosed with juvenile diabetes aged 14. In the end, however, he had no regrets: having to stay in hospital as part of the trial enabled him to be better informed about managing the condition.

Mohini, 12, describes her annoyance when her parents were the first to hear about a clinical trial to test new medication for acute lymphoblastic leukaemia after she was diagnosed with the disease aged nine. But she was pleased that her parents gave her the final decision, realising ‘that I was mature enough and it was my life I was playing with’. She now has ‘no regrets’ about her decision to decline the invitation on the grounds that she preferred to know what treatment she was receiving and therefore did not want to be randomised.

The DIPEX Charity, PO Box 428, Witney, Oxfordshire, OX28 9EU
Tel: 01865 201330 Fax: 01865 289287 email: info@dipex.org.uk

This process of gradually handing over responsibility to the child in a long-running trial is also described. Alison made decisions on behalf of her son who has cystic fibrosis when he was entered into a trial for gene therapy at the age of eight. By the age of 12, she was *'withdrawing from the room if the doctor was in there, if (my son) wanted me to (go)'. When he was 16, she signed a form giving him full consent: 'the hardest thing to learn is that it's actually his life. And if I'm not happy with it, I can't change that.'*

Louise Locock, Deputy Research Director of the Health Experiences Research Group, said parents enter their children for trials for the same mixture of reasons as adults. *"They hope the child will benefit as well as strongly wanting to help to advance clinical research for the sake of others. However, it's important that people understand that trials are carried out precisely because we do not yet know which treatment is best and the new sites will help explain this."*

Overall, most parents and children describe the experience as positive. Rachel describes how her three children decided to take part in a vaccine trial despite an initial aversion to needles. *'It's important to make sure that (the child) really wants to do it and I think I would probably warn them that they would be taking blood a couple of times. We actually found it really interesting and the older two really enjoyed taking part and were very proud of what they had done.'* she said.

*Clinical trials: Parents' experiences

http://www.healthtalkonline.org/medical_research/clinical_trials_parents

*Clinical trials in children and young people

http://www.youthhealthtalk.org/Clinical_trials_in_children_and_young_people/

The DIPEX Charity, PO Box 428, Witney, Oxfordshire, OX28 9EU
Tel: 01865 201330 Fax: 01865 289287 email: info@dipex.org.uk

Note for editors:

www.healthtalkonline.org and www.youthhealthtalk.org are experiential websites based on qualitative research led by experts at the University of Oxford and published by the DIPEX charity. It is funded by a wide range of statutory bodies and charitable trusts and is recognised by the Department of Health and many other professional organisations.

The websites, which recently celebrated their tenth anniversary, have more than a million hits a week and two million unique visitors every year. People log on to watch video and audio clips from interviews with over 2,000 people about their experience of more than 70 health conditions.

About the NIHR

The National Institute for Health Research provides the framework through which the research staff and research infrastructure of the NHS in England is positioned, maintained and managed as a national research facility. The NIHR provides the NHS with the support and infrastructure it needs to conduct first-class research funded by the Government and its partners alongside high-quality patient care, education and training. Its aim is to support outstanding individuals (both leaders and collaborators), working in world class facilities (both NHS and university), conducting leading edge research focused on the needs of patients. <http://www.nihr.ac.uk/>

About the Medicines for Children Research Network

The Medicines for Children Research Network is part of the National Institute for Health Research. We provide researchers with the practical support they need to make clinical studies happen in the NHS, so that more research takes place across England, and more patients can take part.

To interview a parent or child who has taken part in the research, or for further information, please contact Graham Shaw at graham.shaw@dipex.org.uk or mobile 07799664371.