Beyond Informed Consent: Educating parents to empower them in the clinical trial process
Part of the EU project: Respect

Andrea Sandberg, student *
John Eric Chaplin, Chartered Psychologist, PhD **
Catriona Chaplin, Psychologist, PhD **

* Dept. of Medical Cell Biology, Uppsala University
** Göteborg Pediatric Growth Research Center, Sahlgrenska Academy at University of Gothenburg

Background
Strict ethical concerns have heavily restricted clinical trials in children. The number of off-label drugs prescribed to children in Europe estimated to be ~50% of the total drug usage. In 2007, EMA introduced a new regulation that medicinal products intended for children must be tested in paediatric clinical trials. In this study, the needs and motivations of paediatric patients and their parents identified in the European RESPECT project were used as a foundation for developing educational material to empower families in the future.

Method
Focus groups with professionals and an extensive literature search were carried out to identify background material. Interviews with participants in clinical trials were carried out to identify motivations. Based on this evaluation an education package was developed and piloted with staff and teenagers who also completed a questionnaire on their attitudes to clinical trials before and after the presentation of the educational material. The educational material was presented to secondary school pupils in two groups.

Results
Questions parents considered before participation concerned: the informed consent process; the details of the clinical trial process; the benefits their child would have from participation; and what was meant by certain technical terms such as 'standard treatment' and 'randomization'. The main reasons for agreeing to participation were: receiving better treatment, additional medical oversight and access to medical staff. Safety risks were assumed to be minor. The teenagers in the educational session had no previous knowledge of clinical trials and their attitude was mostly neutral when given the first questionnaire. They were highly engaged by the material and discussed openly the ethical dilemma surrounding the consenting process. Several of the teenagers expressed a dislike of copious texts and felt that an education session would reduce this stress factor. In the follow-up questionnaire, the teenagers expressed increased positive attitudes towards paediatric research.

Summary
The educational material would make it easier to decide about potential participation in a clinical trial. This pilot study indicates that the education material is an empowering tool that might decrease the frequency of withdrawal, increase compliance and develop a positive attitude toward future trial participation.