

How to improve recruitment and retention in paediatric clinical trials

John Eric Chaplin¹, and the EU RESPECT project² (Relating Expectations and Needs to the Participation and Empowerment of Children in Clinical Trials)

¹ Göteborg Pediatric Growth Research Center, Dept of Pediatrics, Institute of Clinical Sciences, Sahlgrenska Academy at University of Gothenburg

² Partners: University Hospital of Hamburg-Eppendorf, European Patients Forum, University Children's Hospital Ljubljana, Good Clinical Practice Alliance Europe, Azienda Ospedaliera di Padova, Consorzio per le Valutazioni Biologiche e Farmacologiche, Pavia.

Purpose

The project sought to identify the needs of the children and their parents who participated in clinical trials throughout Europe in order to find out their reasons for participation and how trials should be organised in the future.

Method

- Case study interviews with parents and children;
- focus groups with parents and clinical staff;
- online surveys of parents and staff;
- surveys of patient organisations;
- workshops.



Conclusions

We cannot be sure whether parents and children have really understood what they are being asked to do in a clinical trial. This leaves them in a vulnerable position.

Parents and children are more likely to participate if they understand the need for research.

Patients have different needs and we should find out what these are before the trial begins.

Physicians are in a unique position to inform trial sponsors about children's unmet medical needs and to influence which trials are conducted.

The clinical staff must respond to the family's trust by being honest; they should give and take feedback before, during and after the trial.

It is important to ensure that families are acknowledged for their contribution to the trial and have access to the results they have helped to produce.

Gaining motivation through empowerment

Four areas for improvement:

Self-determination: Increase opportunities to find out about ongoing trials and to self-refer to a trial.

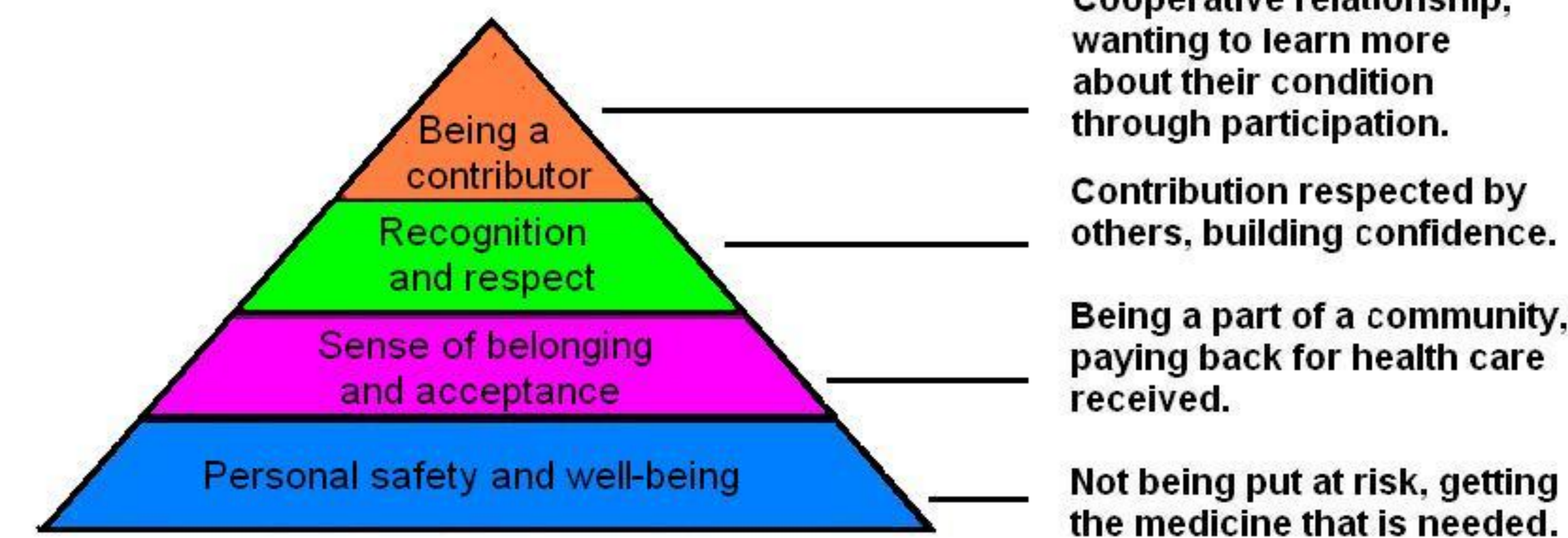
Accountability: Establish patient reported outcomes (PROs) as additional objectives for the study. Establish an independent body to oversee GCP and PROs.

Co-operative relationship: Establish patient panels for advice on patient identified needs (PINs), protocols and informed consent procedures for children.

Knowledge: Develop short education programs for children and parents to go beyond informed consent.

Hierarchy of patients' needs in clinical trials

Participants need to be assured of their safety and belonging but they also need to be recognised for their contribution and ultimately become a contributor to the research and not just a participant.



For additional information, please contact:

John Eric Chaplin, PhD
 respect@patientneeds.eu
www.patientneeds.eu
www.gpgrc.gu.se



UNIVERSITY OF GOTHENBURG