

Background information and aims of the picture cards

During the year 2008, a group of experts formed by Finnish Investigators Network for Pediatric Medicines, FINPEDMED, had a task to create document templates for informed consent and patient information for paediatric clinical trials. This group stated that the use of illustrative material to aid the understanding of patient information has thus far been minimal, and formed a picture card team to create a set of picture cards for the use of investigators to help paediatric trial participants understand the content of patient information.

Paediatric clinical trials enable the creation of new, safe and investigated medicines and drug formulations, which are particularly suited for children, as well as new research information. All children under the age of 18 are the target group of paediatric clinical trials. Before participating in a clinical trial, the child and his/her guardians (under 15-year-olds) are given both written and oral patient information on the trial. The content of this notification must be fully understood so that further questions can be asked and answered. After receiving this information, the child who has been asked to participate in the trial and his/her guardians are able to express their willingness to participate in the trial and sign the informed consent forms required by law (in certain cases over 15-year-old adolescents may sign the informed consent independently).

Some children participating in the trials may have difficulties understanding the content of the written patient information because of their developmental level. These difficulties are encountered in trials with young children, children who are not yet fully literate, or who have some neurological or psychiatric disorder. Furthermore, it may be challenging for guardians to understand completely new concepts e.g. due to lack of experience. Giving the patient information and understanding it is often easier if there is illustrative material available, such as drawn pictures, photographs, video film or other equipment.

Design and implementation of the picture cards

The manuscript of the picture cards was written by the FINPEDMED picture card team, and the planning of the illustrations was carried out in collaboration with a student of graphic design as a diploma work completed under a contract between Clinical Research Institute HUCH Ltd. and Helsinki Metropolia University of Applied Sciences. The manuscript included a set of 31 pictures of both objects and situations. In the set there are 12 pictures of different drug formulation and administration methods, 12 pictures of the basic medical examination situations, different additional

examinations and procedures, and 7 pictures depicting time, visits to the hospital, the hospital environment and trial documents. There is also a transparent No-card with a red cross.

Knowledge of both developmental- and educational psychology, as well as neuropsychology was used in the planning of the cards. The cards were implemented as digitally drawn pictures, with a smiling gender-neutral child as the main character. The figure of a guardian appears on some of the cards. The trial physician, who is identical on all cards, is depicted as a gender-neutral, positive figure. The colourings on all the cards are clear, and the cards are simplified and include very few details to emphasize certain aspects and clarify understanding. The FINPEDMED mascot, a small blue lion, appears on some of the cards. The content for the pictures has been collected from literary, photographing at the hospital's (HUCH) paediatric clinic, and by consulting experts and investigators specialised in paediatric clinical trials. Children, ages 1 to 6, attending a day nursery in Espoo commented the coloured picture cards. The children were shown the cards in nearly all groups of all ages during their free time, and they were told that the cards have to do with visits to the doctor. The children could freely express what came to their minds, and day nursery staff recorded the anonymous comments on the pictures. Based on these comments the pictures were modified to better suit the objects and situations in question.

All the cards are labelled in Finnish, Swedish and English. They are designed in pdf-format and sample pictures (containing a *sample* text) in pdf-format are also available for presentations. The picture cards are under copyright law © 2009 and are marked with a HYKS-instituutti Oy / FINPEDMED text and the designer's autograph. The finalized versions of the texts have been approved by the picture card team. The picture cards, sized A6, have been printed on cardboard and come in a labelled plastic folder sized A5. The folder includes 31 picture cards in their individual pockets, abstracts and a removable transparent No-card.

Various possibilities for the further use of the picture cards

Many of the topics of the picture cards are not solely restricted to the use of clinical trials. The general pictures can easily be used very broadly in health care, education and, for example, in speech instruction. The digital pictures are also easily adaptable to suit different purposes. For example, by changing skin tone or the surrounding environment on the pictures, they are suitable for international use. On a global scale, illiteracy is one of the most common ethical research problems in paediatric clinical trials. With the aid of these pictures, it is significantly easier and more reliable to ensure the understanding the patient information in the informed consent process in paediatric clinical trials.