PE 16P

Beyond Informed Consent: Educating parents to empower them in the clinical trial process

Part of the EU project: RESPECT

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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.
A literature search revealed no systematic processes for educating patients related to clinical trials.

Aim

The needs and motivations of paediatric patients and their parents were used as a foundation for developing new educational materials.

Method

1. Interviews with parents

Special materials were developed on the basis of qualitative data gathering.

Interviews with children and their parents, during clinic visits, to identify their needs and motivations for participating in clinical trials

Focus groups with clinical trial staff to identify background material.

2. Intervention:

Group education with specially constructed materials for clinical trial participants

3. Evaluation of training material

Evaluation was carried out with patients and clinicians.

Two focus groups with 16-17 year old natural sciences students. None with previous experience from clinical trials

Interviews with experienced clinicians and nurses working in different clinical trial.

Results -Interviews with parents

Questions parents considered before participation:
-The informed consent process
-The practical details of the clinical trial process
-The benefits their child would have from participation
-The meaning of technical terms such as 'standard treatment' and 'randomization'.

The main reasons for agreeing to participation were:
- Belief that they would receive better medical treatment
- Receive closer medical supervision
- Belief that safety risks would be minor

Results –Evaluation of training material

- The teenagers 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.
- Physicians and nurses felt the education material covered the main issues but were concerned that this might be discouraging to participation and that trained health educators were needed.

Conclusions

The pilot study indicates that the education material is an empowering tool that could positively increase willingness to participate in clinical trials.

As with health education, education for potential clinical trial participants should be undertaken with specially constructed materials.

A health educator would be a valuable addition to the clincial trials team.

Clinical implications

Time spent in educating the parent and child is paid back through increased willingness to participate.

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