



RESPECT
patient needs



CLINICAL TRIALS FROM THE CLINICIAN'S PERSPECTIVE

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BEST PRACTICE RECOMMENDATIONS

- **Gain family's respect and trust**
- **Explain randomisation**
- **Be honest - as for your own child**
- **Listen to their concerns**
- **Reduce distress**
- **Reduce inconvenience**
- **Give and take feedback during trial**
- **Show appreciation - the child is a 'medical hero'**



GAIN FAMILY'S RESPECT AND TRUST

- Try to establish respect, trust and partnership
- Listen to parents and children
- Try to arrange environment in friendly manner
- Protect participants
- Doctor known to family if possible



GAIN FAMILY'S RESPECT AND TRUST

- Give reassurance that their child is being taken care of before asking for participation
- Explain about the condition and possibilities about procedures/treatment
- Let them know you understand that a trial is always frightening
- Be informed to inspire confidence
- Give information regarding safety, efficacy, benefits or problems for the patients within the trial, potential risks and actions needed if some problems occur etc.



EXPLAIN RANDOMISATION

- Be prepared- Translate it into common language, maybe use some examples for illustration
- Randomisation - parents have problems accepting that they will be randomised to different treatment arms (esp. studies with placebo wing)
- Double-blind randomisation - participants find it hard to accept that the doctor is not in charge of the treatment decision



BE HONEST - AS FOR YOUR OWN CHILD

- Explain risks and benefits honestly, as you would like somebody to illustrate things if it were your child
- Clinical trial may not be fully understood by very young patients. Parents should fully understand the process
- Adapt the information for the children
- Participants should have a clear idea of what will happen
- Expectations



LISTEN TO THEIR CONCERNS

- The fear of the unknown - in the case of studies with drugs
- Obligations in the future – parents concern
- Parents and children worry about the side-effects, invasive procedures
- Reassure parents that their child is not a “guinea pig”
- Reassure parents or patients that they will get full and appropriate health care even if they do not participate



REDUCE DISTRESS

- Ask for participation when they have time to consider it and the energy to decide - end of clinical consultation or better still separate occasion
- Discuss the trial with the child and parents together, taking the developmental stage of the child into consideration when explaining
- The study should be presented by the researcher, but an independent person should make the invitation so they have the chance to refuse - it is easier for the patient to say no to the nurse



REDUCE DISTRESS

- Parents and child might have different opinions, for example, the child does not want to have blood tests or refuses all of the procedures
- Risks should be minimal and similar to other routine procedures at the department
- Time constraints – less invasive methods and fewer appointments than adult patients



REDUCE INCONVENIENCE

- Limits to participation: time constraints, travel
- Adapt schedule to parents
- Logistic support
- Reimburse them for time and travel costs
- Schedule visits for CT at the same time as routine check-ups
- Help with transportation to hospital, comfortable room, food & drinks
- Offer supervision of siblings



GIVE AND TAKE FEEDBACK DURING TRIAL

- Talk to participants before, during and **after** the trial
- Clear channels of communication from patient to researchers
- Parents want to be well informed about child's involvement
- Parents are usually interested in the results of the study, especially in the results of their child
- Usually they want more details on the study procedure and practical aspects (number of visits, time, number of days lost)
- Write a report about the results of the CT understandable to general public and give to parents



SHOW APPRECIATION - THE CHILD IS A “MEDICAL HERO”



- Show appreciation
- Offer some snacks, “fancy” meal (for schoolchildren and adolescents)
- A small present after finishing the study, not money
- Tell children that they are ‘brave and strong’ during difficult procedures
- Patients are happy to get attention from medical staff



MOTIVATE PARTICIPATION

- It is hard to motivate the children, they participate because the physician or parent asks them to
- Explain that research can lead to new improved treatment
- With older children, it helps to say that the results will benefit the entire patient group - altruism
- Create a newsletter about ongoing clinical trials, information at patient meetings, flyers & posters
- Increase public awareness about needs and purpose of clinical trials



MOTIVATE PARTICIPATION

- Offer other benefits, such as meeting different specialists that are included in the treatment of the child and getting new information
- Offer counseling on learning difficulties and offer information on the cognitive abilities



ADDITIONAL RECOMMENDATIONS



- Be nice and polite
- Explain anonymity
- Ask participants if they want to discuss anything with someone else
- Emphasize the opportunity to learn more about the child's condition in the recruitment discussion - commit to helping them learn
- Try to discover what could be the benefit for the child and the family
- Be sure that the aim of the study is clear and understandable (discuss with colleagues and check all the possible questions that parents & children could have)
- Consider participants level of knowledge – it differs according to their experience (if they already participated in clinical trials)



ADDITIONAL RECOMMENDATIONS



- Learn about basic guidelines legally prescribed by Medical institutions and Ethics Committees, available to any clinical researcher
- Standardize process and consent documents
- Take special care when there is a patient who could not participate as a fully conscious person, has a learning disability or dying from chronic illness; or when parents and children have lost hope for the illness to be cured



TEACHING MEDICAL STUDENTS

- Include lecture about clinical trials into the study program
- Let students observe how you discuss clinical trials with patients
- Organize role playing workshops
- Include students in clinical trial process with supervision and discuss any arising issues