

18. Paediatric Oncology Reference Team (PORT) 291013

1. **What do you consider to be the main obstacles to recruiting children to research? How might these be overcome?**

There is still a lot of ignorance about the importance of research and clinical trials. People think their children are being guinea pigs and there is an element of danger involved. We really have to educate parents (and society) about how important research is and how it has improved healthcare. One idea was posters around hospitals and GP surgeries. Patient information sheets also play an important part.

2. **Who should make the final decision as to whether a child participates, or continues to participate, in clinical research when parent and child disagree? What responsibilities do health professionals or researchers have in such cases? (You may wish to distinguish between children at different stages of development and/or the different ways in which disagreement may arise or be expressed.)**

The parent.

3. **How useful is the concept of assent? Is it helpful to distinguish between consent and assent for young people?**

I don't think assent is helpful.

4. **A 'shared' or 'collaborative' decision-making model is often advocated for decisions about a child's research involvement, involving the child, relevant family members and professionals. Is this a helpful approach? How might any problems arising in this model be overcome?**
5. **Parents' views on whether (and how) children should be involved in decisions vary enormously both within and beyond the UK. How should the law and professionals take account of such different parenting approaches?**
6. **Rewards (such as vouchers) for children participating in research may be welcomed as an appropriate way of saying 'thank you', or criticised as a form of undue incentive (to either child or parent). What forms of compensation/reward/expression of gratitude for research involvement do you think acceptable, and why?**

I think it should be made clear the safest and best place for a child to be treated is on a clinical trial. They will be closely monitored, if anything unusual happens the CI will be informed, and the treatment cannot be arbitrarily changed by the doctor. For life threatening illnesses this is far more important than any compensation or financial reward.

7. **How helpful is the notion of the best interests of the child participant? How would you define 'best interests'?**

The child's best interests must be paramount at all times. This must override all other concerns at all times. The child's welfare is more important than participation or otherwise in research.

8. **How can the rights and interests of individual children (potential participants in research) be balanced against the rights and interests of all children (potential beneficiaries of the knowledge gained by the research)?**

9. **Are there any situations in which you think it would be acceptable for a child to be invited to participate in clinical research when there will not be any personal benefit to them? If so, please give examples.**

Absolutely definitely. For example many paediatric oncology trials may not be of any personal benefit. There are benefits of being on a clinical trial, but this is a slightly separate issue. The way the treatment for leukaemia has improved over the years is by clinical trials. We need to educate families how important it is for society as a whole for more people to go on clinical trials.

10. **Are there any circumstances where it would be right for a research ethics committee to approve research involving risks they would usually regard as too high, if parents and young people had clearly expressed their willingness to accept these?**
11. **Do you think the current regulations strike the right balance between promoting clinical research in children, protecting child participants, and involving children in decisions about their own participation? What (if anything) would you like to change?**

The trend seems to be asking younger and younger children for consent. We are against this trend.

12. **With limited resources, how would you decide which childhood conditions should be the priorities for research? Who should be involved in making these decisions?**
13. **What responsibilities do funders, researchers and stakeholder groups have to encourage the coordination of children's clinical research?**
14. **What responsibilities do researchers have towards child participants and parents when the study is over?**

There should be a formal mechanism whereby trial results are published. CRCTU in Birmingham are planning to have a webpage for each paediatric oncology clinical trial. This would contain patient information sheets, consent forms, and when available the trial results. At the moment trial results are not reported consistently and even when they are, all the parents are not informed.

Other comments

Clinical trials and research covers many different types of illness. There is a big difference asking a young child to join an observational trial for a vaccination compared with a clinical trial for life threatening or life changing disease such as leukaemia. This means the patient information sheets need to be different and the whole issue of consent and assent has to be considered. At the moment there are blanket guidelines for all children entering any clinical trial. The current guidelines even talks about patient information sheets for under 5s. This is absolutely ridiculous regardless of the illness. A clear difference needs to be made between the types of illness.

For example, an 8 year old with leukaemia might be seriously unwell when diagnosed. Children often act even younger when they are unwell. So the decision of whether the child joins the trial should be made by the parents. The children does not need to be consulted, assent or consent is an unneeded complication. For example, as a parent I choose what

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school they go to, possibly even which college they go to, which holidays they go on, so I want to be the one that decides if they go on the clinical trial.