

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

I think that one of the main obstacles to recruiting babies and younger children to research is concerns from the parent/guardian either that the risk is too high, or that it is an unnecessary unpleasant experience for them. For older children or young adults, I feel the greatest obstacle to recruitment is the lack of general information available to the public regarding clinical research. It is something rarely talked about in the public sphere.

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.)

I have split my answer to this question in three:

- a) For babies: the parent should have the final say, as they have the capacity to rationalise the decision making, especially regarding any benefits the child may gain such as 'unscheduled' vaccinations.
- b) For young children: where a young child clearly does not want to have blood drawn or other form of procedure, I feel it is the health professional's responsibility to ensure that the child is not put under any unnecessary stress or trauma. Ultimately, however, it is the parent's decision; the parent best knows that child's temperament and personality, thus they are able to discern better how genuinely distressed the child is compared to usual reluctant behaviour. However, if the health professional has any doubts regarding the resistance of the child, they should decide to withdraw or reschedule. This is especially important if the safety of the participant/parent/health professional is jeopardised by the situation (e.g. having to restrain the child to administer an injection).
- c) For children more involved in decision making: When the child is able to communicate clearly, one would hope that both parent and child can come to an agreement before the health professional seeks consent and/or assent. I feel that it must be a clear 'yes' from both child and parent before enrolling onto a trial.

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

Assent is a useful concept. It is good to distinguish between the responsibilities of a parent and the responsibilities a young person has for making their own decisions. The participant has an element of responsibility for themselves and their own decisions, therefore should be able to choose not to take part even if a parent wanted them to. However, if a parent did not wish for their child to take part, they should also have a right to opt out. This is especially true if the parent will be

required to be present at or available to transport the child to/from visits. If a parent cannot make that commitment, they should be able to opt out even if the child wanted to take part.

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?

A 'shared' or 'collaborative' model is good. It is important to ensure that everybody is informed and happy with what will be taking place. One issue that I have come across in work that I am unsure how to resolve, but is important to consider, is the scenario where one parent gives consent, but the other parent is clearly not happy with this decision.

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?

Unsure.

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 feel that rewards should be appropriate to the participant's age and stage. For example, vouchers or money would only be an incentive to parents and may see parents enrolling their children for inappropriate reasons. Rewards such as stickers, certificates, small toys, books would be seen more as a token of gratitude that the child would appreciate and understand.

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

The concept of 'best interests' is perhaps not too helpful as it is entirely subjective. You could say that it is 'best' not to put a child through any risk. You could also be of the opinion that it is a positive thing for a child to learn from such experiences, e.g. overcoming fear of needles. There is also the idea, if you value the social collective, that it is good for children to participate in something that is for the 'greater good' so to speak. The concept of 'best interests' is subjective and will depend on your personal value system.

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)?

Answering the question of balancing the rights of individual children against the rights and interests of all children is difficult because, as with the concept of 'best interests', where the balance should lie is subject to opinion.

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.

Studies that involve a placebo will not be of any personal benefit to the child directly if they happen to be placed (randomly) into the group that receives the placebo. The same may be said if the trial involves a control group where sick children would remain on the expected treatment schedule. Such groups are vital to research; you can invite but it is up to the parent/participant whether they wish to take part where potentially there may be no personal benefit.

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?

The decision to approve research that a committee would usually regard as too great a risk would have to be weighed against the actual risk projected by the professionals who have considered all the factors. In the case where (parents of) sick children express their willingness to take these risks, especially where there is no viable alternative treatment, or quality of life/life expectancy is so poor, then perhaps a higher risk is acceptable in the hope of finding treatment for current and/or future patients. In such a situation, additional participants would need to be fully informed of this higher risk factor.

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?

From my personal experience, I feel that much more could be done to involve young children in decisions about their participation. Once they are able to communicate verbally, I feel it is important to ensure that they are willing to participate. I have been in situations where children have had to be restrained in order to conduct the trial procedures. The child was clearly communicating that they did not wish to undergo the medical examination, sit for a blood draw or receive a vaccination. The participant however was still enrolled but I did not feel that it was the right decision.

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?

People who are on the front line (e.g. paediatric doctors and nurses) should be involved in making decisions about which conditions should take priority in research. It is important that the research creates the greatest impact across the greatest number. If the condition is too specialised/rare then not enough people benefit from

the research. However, it should be severe/serious enough across the population otherwise it doesn't make enough of a difference and some really sick children would not benefit. It is a difficult balance to strike, which is why the doctors and nurses who are working both with sick children, and in the community, have the best idea of what would make the greatest difference to the greatest number of people.

13. What responsibilities do funders, researchers and stakeholder groups have to encourage the coordination of children's clinical research?

Funders, stakeholder groups and researchers have a responsibility to promote the safety, legitimacy and achievable goals of the research. It should not be all about money.

14. What responsibilities do researchers have towards child participants and parents when the study is over?

Researchers have a responsibility to maintain accurate records that should be available to participants/GPs (e.g. where a new vaccination has been administered). They also need to ensure the long-term safety of the participants with respect to any problems that later arise from the study. They should also be considerate about providing publications of results. If research leads to changes in nation-wide treatment, e.g. a new vaccine schedule, I feel that there should be a public acknowledgement of gratitude to all who took part in a list of contributing studies (no names given of course). Such public acknowledgement may also serve to raise awareness of the role of clinical trials and clinical research across society.