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

The main obstacles to recruiting children to research are the limited capacity within the child health services to recruit children to studies and ultimately run those studies. It is currently not an expectation amongst the paediatric work force that children will routinely be offered the opportunity to participate in research, despite this being the situation that the RCPCH and the DoH would promote. Research in children is somehow still seen as remarkable, that only a small number of doctors and professionals will engage with, and that limited numbers of children will want to take place. A child's participation in research is too often seen as "exceptional", and to have overcome significant difficulties with ethics/R&D etc to have achieved that registration. This is erroneous. The additional burden of running research in children is over stated, and it should be an expectation of parents/carers/children coming to health care professionals that they have the opportunity to participate in research, and it should be an expectation amongst the work force that this be the case.

Research must be embedded in the curriculum and training of health care professionals involved in the care of children, with evidence of active participation in research necessary for career progression. The environment must exist to facilitate this activity to, with investment in research infrastructure, and time within consultant and other professional's job plans to allow this work to be carried out.

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.)

Involvement in research should be the decision of the child where ever possible, with similar criteria applied to competence to make decision around clinical care. Where children are not competent to make these decisions then parental responsibility must be used. A not uncommon situation is the child who can assent but not consent. In these circumstances I think assent should be a requisite of involvement in research. A child may not have the maturity to fully consent, but can indicate a clear opinion to involvement in research.

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

Assent is a very useful concept, as detailed above. Children and young people will often have the capacity to assent but not consent, and in these circumstances assent should be required.

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?

Shared or collaborative decision making is a potentially useful model, but it is important in these models that a clear, unbiased advocate for the child is identified. The “weighting” of the opinions of the parties in these partnerships is essential though, and this must be determined in each individual cases. It is also important to determine if decision making is through a unanimous consensus of the group, or if the group is to inform the decision of a smaller number of people.

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?

Comparable to the situation around clinical care, the opinions of families must be respected to a large degree, and differences (culturally and personally) in parenting style acknowledged. I do not believe that this should over rule the importance of gaining assent from a child. Even when parents do not believe this is necessary, I believe it should be sought and respected.

Clinically situations are acknowledged where parental wishes may be over ruled for the benefit of the child, e.g. blood transfusion etc, often requiring judicial review. It is difficult to directly transfer this situation to research, as the benefits of an intervention are, by definition, unproven. Situations exist where an “experimental” treatment may be the only treatment option, which makes these decisions more complicated. Children should have the right to participate in research activities if capable of consenting, and should be able to overrule parental decisions in the same circumstances as with clinical treatments. Given the uncertainty of research though, some third party assessment of the potential risk/benefits of the research treatment may be necessary.

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 have no problem with the concept of rewards, but they should not be sufficient to incentivise a child to participate in research they would otherwise avoid. It is difficult to draw the line at a monetary or over value for these rewards, and I would suggest children and young people should dictate to us what they think would be an appropriate level. This could be judged on a case by case basis for trials planning to offer rewards.

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

The notion of best interests of the child is paramount. The difficulty is in actually determining this, balancing the needs and views of the child, the family, clinicians and researchers. In paediatric practice, particularly around rare conditions, “best” clinical care may often be experimental. Mechanisms should exist for third party reviews of situations regarding a child’s involvement in a given trial to ensure that best interests are in mind. This depends upon the nature of the trial, the risks and potential benefits. For some studies a case by case review of each child’s involvement may be necessary given the potential for risks, informed at all times by most prevalently by the wishes of the child in view of their capacity to consent/assent to treatment/trial involvement.

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)?

As suggested above, third party review of involvement of children on a case by case basis may be necessary. Sweeping blanket judgements/decisions are not easy to make.

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.

Yes – frequently when participation could benefit others. The risk or discomfort to the child must be minimal though, and it should be clear that they will not personally benefit and that care will not be affected by the decision not to participate. An example would be obtaining an additional sample of blood when blood is already being taken for a child with a known condition to act as a positive control for a new diagnostic test.

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?

This is a difficult topic, and one in which case by case review is necessary. Circumstances all too frequently exist when only high risk treatments offer any potential benefit. It is clear that the research team must be able to demonstrate the limited benefits of other available options and that parents/cares/children are fully aware of the risks. It could be seen that at a certain level of risk third party review would be advisable prior to inclusion in a study.

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?

I do not see the regulations as the key issue. Barriers around regulation are, to my mind, more perceived than real. The real barrier is the competency and mindset of the

workforce and the empowerment of CAYP to feel the right to demand to be involved in research.

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?

A very good question! A coordinated approach to funding can help to ensure key problems are addressed, encourage collaborative working, and to avoid duplication. The difficulties I see are twofold- how to set the priorities (who would this reside with?), and how to prevent a situation where only research on the list was funded.

A consultation on a 5 yearly basis could help establish some consensus priorities, which perhaps could have ring fenced funding, with money left for other elements of research. The additional difficulty is that too long a cycle of review and the system is unresponsive to emerging problems and breakthroughs enabling new avenues to be explored. To short and it is expensive and becomes too short a time period other which to evaluate research. It is also difficult to say absolutely who the stake holders should be for setting the consensus.

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

Best outcomes can be achieved by coordinate studies, with participants from many centres. There should be encouragement for the establishment of such networks, with centres looking to perform complementary and not competitive work. In many conditions in child hood limited numbers of potential participants are available. This resource should not be squandered by spreading across many studies in different centres.

Funds should be made available to develop networks, with training and support available to researchers working in many centres. Academics should not be encouraged to "go it alone", unless it can be clearly demonstrated that the research question they wish to answer can definitively be answered by a single centre. Incentives should exist for centres to ensure that a proportion of studies they perform are collaborative, which if achieved allows access to additional research support.

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

Children differ from adults in that an intervention may potential alter a child's development. This is not the case for all interventions, but when this possibility does exist, some responsibility must exist to try to follow up. An example would be research into interventions in the neonatal period. The short term follow up may suggest beneficial effects, but what about outcome at 6 years, or 12 years etc? Clearly this must be dependent upon funding being made available to perform this kind of work. Researchers should indicate how they would plan to do this kind of follow up when

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applying for initial ethics, but demonstrating the capacity to perform this work cannot be a pre-requisite for the study.