

5. Elmer 030913

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

I feel one of the main obstacles is that of ignorance to the field of paediatric clinical research within the general population. I am dual trained nurse who worked on an acute paediatric ward for over 20 years and have moved to research in only the last 3 years. In my 20 years on an acute ward I haven't seen any research being undertaken or parents being approached. Even now I attended a Paediatric resus update within my hospital and was discussing with a colleague how I loved my job and the response was 'whats it like working with "guinea pigs!"

Education and teaching of the public is the most obvious way to encourage children's participation however you need to convince parents first. I have found that parents of children suffering from cancer are more receptive to research as it is seen as working alongside a proven treatment.

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 feel it depends on the clinical research involved, is it for patient benefit, treatment or to increase knowledge. Ultimately if it is in the child's best interest as deemed by the clinician I feel it should rest with the parents however if it is purely to increase knowledge then if the child refuses then I feel that should be respected. The fundamental issue with children's nursing is to respect the child's wishes and treat them as an active participant in their care.

As a children's nurse you are torn between being an advocate for the child and being aware of how this research may improve their health. I personally would not be happy to give a medication, treatment against a child's wishes unless I could be sure it was based on sound advice.

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

Having used assent forms with children on a research ward I found them invaluable. The children were engaged, found a sense of empowerment and were fully aware of what was involved with the study. Having appropriate assent forms for the variety of ages involved is paramount however you occasionally see studies involving children without any assent forms which I feel is a poor reflection on the PI and his understanding of children. There is a need to distinguish between the two types of consent due to the legal nature of consent.

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?

I feel all research carried out with children should be a shared decision as the norm. If research is being carried out with children who are not fully behind the study then compliance issues come into play. Family problems could also be played out using research as an excuse to raise personal grievances between families.

Any model of shared decision making also requires a great deal of time spent explaining all the issues and this may hinder some research which is time sensitive.

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?

I feel you should approach a child/parents using your clinical judgment as a guide. Some children like to know all the pit falls and problems and some just like to know the basics. However all the issues must be explained to all parties concerned to be fully informed, I would not feel comfortable administering a treatment to a child that could potentially cause them harm without them being aware. All these conversations would have to be handled by the appropriately qualified practitioner who was used to dealing with children on a regular basis.

Parents differing wishes may be an issue and I feel that there would need to be some agreement before the child was enrolled in the research.

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 been involved with studies that gave rewards and some that didn't. To be honest I feel a small thank you in the way of a voucher is perfectly acceptable approximately £10-30. I do not agree (which I have seen) a sliding scale of reward depending what activities the child was involved with. Some parents have to take time off work and this is sometimes calculated into the cost of the reward and this I feel could be seen as a coercion as you can be looking at £600 which is a large amount.

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

I have written best interest earlier in a response to a question 2. I feel best interest is seen as in their clinical health.

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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)?

This is a difficult question to answer as the rights of the individual are paramount however society has a duty to all. I believe that ultimately the individual rights will take precedence as they have the final say whether they wish to be involved with the project.

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.

Definitely, that would be wonderful. We are currently looking at healthy children and using dEXA, Bod Pod and calorimetry with them and they receive no personal benefit but are excited about the potential to help others. I feel children could be involved in a variety of projects, trying new equipment, types of dressings.

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?

Defiantly not! The purpose of the ethics committee is to look at all aspects of a trial and to protect patients and participants even if it means protecting themselves from themselves!

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?

Yes, I do

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?

I feel that the diseases/ conditions that begin in childhood should be a priority such as Duchennes, and obesity.

Obesity is a huge problem for our country and should be seen as a priority as the incidence of type 2 diabetes is growing at an alarming rate which in turn will lead to other health issues further down the line.

I feel there should be a committee comprising of experts from the leading paediatric hospitals and large teaching hospitals to look at a priority list for the whole country.

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

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I feel everyone has a responsibility to actively encourage parents and their children to participate in research as it is at the very core of the NHS constitution and children deserve treatment tailored to their own needs

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

I feel that once the study has finished there should be a time set where the parents are able to contact the research team but it should always be documented in their medical notes and with their GP that they have undertaken a trial incase it has any bearing on future treatments or health worries.