

50. Oxford Vaccine Group 240314

Questions 1-6

In responding to the questions below, you may find it helpful in some cases to distinguish between three broad groups of children:

- *those incapable of any meaningful involvement in a decision (e.g. babies)*
- *those capable of expressing a view, whether verbally or through their behaviour (in varying degrees, from young children to teenagers)*
- *those who would be regarded as competent to consent for themselves if the intervention were for treatment, rather than research (those who are 16 or over, or under-16s meeting 'Gillick' requirements in connection with the particular intervention(s))*

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

- Clinicians may have had little exposure or involvement in research. If better informed they may be willing to partake or encourage families to become involved in research
- Overprotective clinicians: Especially those who have worked with families of children with a chronic or life limiting condition.
 - Long term relationships of trust have been built
 - Clinicians influencing families decisions
- Parents may have had little exposure or involvement in research. If better informed they may be willing to become involved in research.
- Concerns could include: Suspicious, Risky procedures, Unethical
- Logistical Issues- Parents coming to extra clinics for research
- REC's
- Portrayal of research in the media often focuses on the negative. This could be overcome if media portrayal was more positive

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?

- We should apply 'Gillick' approach for under 16's in research decisions as well as in decisions about treatment
- Easy for young children and teenagers, but difficult when child is in a transitional age ie Over 10 years of age
- Hard to generalise-depends on condition of the child
- Family centered care approach, as in medicine, would work towards care that is acceptable to all parties.

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.)

- Complex issue in research and medicine
- As with everything it depends in what context. Each situation has to be looked at in context.
- The focus for professionals should always be to take the child and parents along with them, especially in sensitive situations. Unless life threatening would not want to overrule anyone

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3. How useful is the concept of assent? Is it helpful to distinguish between consent and assent for young people?
 - Assent is not the answer. Nonsensical term
 - No one understands the difference between consent and assent, mainly a term used in research, less so in medical practice
 - Asking a child to sign something (that is not recognised legally), undermines the process
 - Assent is, in effect a process of communication in research: How could this be put in some sort of framework?

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?
 - Emphasis on context of that particular child, condition, family dynamics, child's level of understanding etc
 - Family centered care approach, is essential as in medicine, works towards a decision that is acceptable to all parties.
 - Interesting concept: who is approached first about the study Can affect how the other decision maker feels about the research:
 - Teenagers giving talks and leaflets in schools
 - Letters addressed to the teenager/ child
 - Parent approached first

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?
 - Goes back to making sure the child and the parent are on board, with the emphasis on the child as they get older and begin to develop decision making capabilities with age
 - This can be very difficult in sensitive situations
 - Both parents and child should agree. Need to respect the family context as this is long term
 - Parents do have a stake in their child so there is a role for both individuals
 - *'please check with the person who is paying the bill'* could apply to all ages
 - Should not have a battle unless life threatening

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?
 - Adults are reimbursed so children should be
 - Children may be used by parents wanting the money: one study paid £50 a visit. As a site we felt this was too much but overruled by other sites
 - Secondary school vouchers are ok. Which vouchers though? 'healthy V non healthy vouchers eg book v computer game
 - One school had charity box for money to be put (some did)
 - Child over 16 years should receive the money as they are allowed to consent. What if two siblings, one 15 and one 16 were in a study, would this be fair?

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- Parent signs consent so they should decide if the child has it?
- Travel and time should be reimbursed
- Appropriate to provide a child with a reward
- Participating in research is an extra burden for parents and the child. Some form of compensation is necessary. Probably the type of compensation can be chosen by the family.
- The amount of money is too much for children
- Drug companies will eventually make money so a trust fund could be set up in the child's name
- Book vouchers thought in a study to be appropriate, but is this paternalistic ie books vs sweets
- Depends on who is collecting the reward
- Variation in wealth: One private school said '*£10 would be nothing for our pupils*'
- Timing of when they are told about the compensation may matter. NRES says compensation should be listed in info booklet, not as an incentive but for transparency. Otherwise concealing something from the families
- In developing countries:
- Vulnerable families (even in developed countries these exist)
- Access to healthcare is enough of a reward, but drug companies will still profit so compensation should occur

Questions 7-10

7. How helpful is the notion of the best interests of the child participant? How would you define 'best interests'?
 - Healthy investigative medical product/ intervention that might or might not work
 - Risk v altruistic benefit
 - Always very hard to get something that is of benefit for the participant
 - Cannot say if participating as a control or receiving treatment would be of benefit to either parties
 - As long as no unacceptable risk is there
 - If the child had a negative experience in research, ie traumatic blood test: could make future necessary medical interventions more traumatic. A good research experience may actually be helpful in future medical care
 - Aim to benefit all
 - Often research outcome is unknown, cannot ensure benefit to everyone
 - Is any research ethical v Is not doing research ethical? See question 7
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)?
 - See question 7

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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.
 - See question 7

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?
 - Yes! For clinical purposes
 - Should be up to families. Rec's cannot withdraw research opportunities from participants
 - REC's should be protecting participants from bad science and families from themselves: risks taken when clutching at straws: clinical hopelessness
 - All science must be evaluated adequately. Not up to REC's to decide if science or not
 - Families could attend REC meeting (PPI patient and participant involvement is becoming back practice)

Questions 11-13

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?
 - Some are too prescriptive: RCP guidelines
 - Reference to age should be removed
 - EXTEND FURTHER: The assumption that a child will be taking part in research, unless they actively opt out: In oncology generally what happens and has transformed treatment
 - Opt out of storing of samples

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?
 - Pharmaceutical companies driven by money
 - Health DA
 - Pharmaceutical approach OVG:
 - OVG have an idea, we go and get funding ourselves: public money eg needle size for immunisation

13. What responsibilities do funders, researchers and stakeholder groups have to encourage the coordination of children's clinical research?
 - Publications: non-commercial studies
 - Websites
 - Researchers should know all the research happening in their field
 - Portfolio adoption

Question 14

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

- Results of the study: using lay friendly terminology as well as the actual paper
- Results regarding participant if agreed in advance (eg. Low immunity)
- All studies published, whatever the results
- Researchers have a responsibility to participants to be published and responsibility to get the results into the public domain
- If not published, poster presentations accessible to participant
- Practical issues: sample storage, data storage, document storage, archiving
- Safety follow up: open access to contact team to discuss past studies and worries

Any other comments?

Please highlight any relevant areas you think we have omitted, or any other views you would like to express about the ethical issues arising in clinical research involving children.