

## Introduction

1. The Academy of Medical Sciences welcomes the opportunity to contribute to the Nuffield Council on Bioethics' consultation on 'Children and clinical research: ethical issues'. The Academy promotes advances in medical science and campaigns to ensure these are translated into healthcare benefits for society. Our elected Fellowship includes the UK's foremost experts drawn from a broad and diverse range of research areas.
2. Approaches to clinical research involving children have shifted over the last fifteen years or so. In the past, the community had a much more paternalistic approach. There was little idea that children could engage meaningfully about their involvement in research and many guidelines emphasised the protection of children. Recently, however, there have been increasing moves to proactively involve children and parents in the research process. For instance the Medicines for Children Research Network has an active children and young people's panel.

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

3. One of the main barriers to recruitment can be the clinicians who are looking after the children. They may have general concerns about children participating in research or the potential burden on families<sup>1</sup>. Another barrier is the heavy workload of healthcare professionals, which may prevent them from talking to families about the aims and details of research, and from undertaking research.
4. Encouraging understanding of the importance and relevance of research among healthcare professionals at all levels will be essential to address these barriers. This should be part of a wider effort to instil a culture change amongst all professionals in contact with children - including in child health and mental health organisations and schools - so that research is accepted as an essential part of care. Distinguishing research on the basis of risk may help towards achieving this culture change. Risks to do with taking a new medication, for example, are very different to those involved in cognitive or play assessment.
5. There are also opportunities to capitalise on recent moves to conduct more clinical research involving children to fill the current evidence gap. The EU Regulation on Medicines for Paediatric Use (2007), for instance, requires that a Paediatric Investigation Plan is in place for all new medicines. These underscore the importance of clinical research involving children and could act as additional drivers to bring about the culture change amongst professionals involved in children's care.
6. Another area to consider is ways of communicating the research. Families may be asked to provide consent to participate when they are under psychological

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<sup>1</sup> Shilling V, et al. (2011) *Processes in recruitment to randomised controlled trials of medicines for children (RECRUIT): a qualitative study*. Health Technology Assessment **15(15)**

distress, for instance during the time of diagnosis or when a relapse is identified. Consent procedures should be orientated towards the needs and realities of the parents and children, to allow accurate assessment of the child's chances of benefiting from research. It would also be helpful to improve public awareness of clinical research involving children in general. Parents and children may feel more comfortable about making decisions when they are placed in a position to consider research participation.

**(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.)**

7. Collaboration with families is critical for research. There are psychological and social consequences of going ahead with research where there is parent-child disagreement. On a practical level, parental agreement can be integral – even for adolescents – for instance in providing ratings and helping or enabling access to health care during research. Efforts should be made at all times to try and reach a position that all parties are comfortable with. Appropriate clinical input may be required to reach this position.

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

8. It probably isn't very helpful to distinguish between consent and assent for young people: assent is consent, in so far as the child is able to understand the full implications, even if they are under the age of 16.

**(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?**

9. This is a helpful approach. As highlighted in our response to question 2, it is important to try and get to a position that everybody is comfortable with. Children should be told the full implications of participating in research and where relevant, the full diagnosis of their condition. Whilst as much autonomy as possible should be given to the child, up to the age of 16 it is the parents or guardians who can decide.
10. Problems in achieving agreement may arise when children are in care or when the child's parents are separated. It is important for researchers to know which adults to approach when making decisions.

**(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?**

11. The approaches between countries are perhaps not as different as the question suggests. Variation should be respected but collaboration where parents and children are actively involved is important, with the children given a reasonable degree of autonomy.

**(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?**

12. If handled correctly, certain rewards are appropriate. Children give their time and effort, and in the case of young people they may have to forgo weekend or part-time jobs, so recognition of this is suitable and important. Furthermore, a very strict guidance for a more neutral 'thank you' without any rewards may impact the recruitment of certain groups of children who are already difficult to include into studies: for instance adolescents with mental health problems or in very deprived circumstances.
13. The reward, however, should never reach the level of monetary incentive and it is acknowledged that judging the boundaries so that they do not become an inducement can be difficult. Payment for travel expenses and wherewithal to enable participation in research is also important and appropriate.

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

14. This should not become a paternalistic concept. Children – as far as possible and especially if old enough – should be brought into the discussions about what is in their best interest. This may include exploration of best interest now or in the longer term regarding the potential benefits to themselves or a society they will belong to. The healthcare professional involved in the care of the children can help to bring them into these discussions. Parents are also good at judging what level of discomfort, if relevant, is reasonable for the child to experience.

**(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)?**

15. Each family – child and parent – should make a decision based on the nature of the project. A qualitative study of families' and practitioners' perspectives on recruitment to medicines studies (RECRUIT<sup>2</sup>), however, shows that children are generally very altruistic and willing to participate in research. Parents, whilst being more cautious about the risks involved and wanting to ensure the safety of the child, are generally also very supportive of research without direct benefit to the child.

**(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.**

16. There are many areas of research where there may not be any personal benefit to the participant, for instance observational and cohort studies, where children already take part willingly.

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<sup>2</sup> Shilling V, et al. (2011) *Processes in recruitment to randomised controlled trials of medicines for children (RECRUIT): a qualitative study*. Health Technology Assessment **15(15)**

**(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?**

17. Yes. If the committee is uncertain, asking the children and parents may be helpful, where this is possible. Care must be taken, however, that the decision is not solely based on the family's willingness as other factors may influence this, such as the family's desire to get access at all costs to a new treatment for the child.

**(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?**

18. There should be more widespread inclusion of children's perspectives by the various organisations that regulate this area, for instance the research ethics committees, Medicines and Healthcare Products Regulatory Agency, and the European Medicines Agency. As noted before, the Medicines for Children Research Network has a very active children and young people's panel that provides strong input into its work, which may serve as a useful model.

**(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?**

19. Factors that could be taken into account include high prevalence, high burden (including global burden), poor outcomes including survival, and limited treatments.

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

20. Funders, researchers and stakeholder groups could all take on board the perspectives of children, young people and parents more often. In terms of co-ordination, it is acknowledged that the wide variety and types of research involving children make this a difficult task. All parties should contribute to support co-ordination where this is appropriate.

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

21. Researchers have the responsibility to make sure that the results of research are communicated in a way that can be understood by the participants and their parents. Ongoing provision of information and feedback is desirable. For most studies no additional resource will be available once the grant finishes, so the activity is likely to be confined to website updates, sending e-mail alerts and provisions of newsletters.

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