

9. Children and Young People Oral Health Research Group, School of Dentistry, University of Sheffield 231013

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

In the field of child oral health research the main obstacles to recruiting children to research are finding participants who meet the eligibility criteria and gaining their participation. To overcome obstacles about eligibility we have recruited from both primary and secondary dental care settings and used multiple sites. Obstacles to gaining participation can be overcome by considering how best to tell children and young people about the research and producing appropriate information leaflets by involving children in their development.

In the past we have had difficulties recruiting children from black and minority ethnic groups although this obstacle has been overcome by involving researchers from black and minority ethnic groups, making participation more convenient, worthwhile for families and offering a range of participatory data collection activities. We have overcome obstacles to involving children with learning disabilities by working with researchers who have had experience of working with people with learning disabilities.

**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.)**

We feel it is important that, where possible, children who are capable of expressing a view and those who are competent to consent themselves have the right to decide about their participation in research. When parent and child disagree the role of the health professional or researcher should be to 1) facilitate the decision-making process by providing appropriate information without influencing it one way or the other and 2) to reduce the traditional authority relations between adults and children so that children's consent can be given freely.

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

The concept of assent is not particularly useful as we feel children should, wherever possible, have the right to decide about their participation in research.

**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?**

Yes, this approach is helpful, just as a shared decision-making model is helpful for decisions about healthcare generally. Problems may arise in communicating to children what the research entails in a balanced way, lessons can be learnt from the science of shared decision-making.

**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?**

As a researcher, we need to reassure ourselves that children participating in research are doing so freely, but are equally not being excluded. A shared decision-making model developed in the UK may facilitate this but needs to be culturally sensitive.

**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?**

We think vouchers are an acceptable way of thanking children for giving up their valuable time to participate and acknowledging their contribution. As the pecuniary value of the vouchers is usually small (£5-10) they could not be considered exploitative in gaining participation. Where children are required to do drawings or writing diaries etc it is nice to give them a good selection of pens/pencils/stationary to use and keep as a thank you.

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

The terminology 'best interests' is not particularly useful in the context of children and parents' understanding – we should look for a more participant-friendly and modern phrasing. It could be defined as what psychosocial or health benefits may be gained directly by child as a result of participating in the research.

**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)?**

The rights and dignity of children involved in research should be upheld and children should not be treated as research 'objects'. Autonomy of children needs to be respected, and anonymity should be viewed as a way of protecting children as research facilitators. Children should not be exposed to risks that are any greater than they would encounter in their everyday lives. However, some research with higher levels of risk may be considered legitimate if the longer-term gains outweigh the short-term immediate risks to participants (provided that these risks are minimal and neither have lasting effects nor induce prolonged personal discomfort).

**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, in situations where child participants experience minimal discomfort and or risk we feel it is acceptable to invite a child to participants to obtain knowledge for future children as long as the child consents freely.

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 really difficult question to respond to and it relies entirely on autonomy, the context, and should be perhaps decided on a case by case basis? Level of review should equal level of risk, and there should be some sort of mediation which involves the parent and young people in the reviewing process as well.

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, for the research we do the current regulations strike the right balance. It would help our research if there was less variation between research ethics committees in their views on involving children in research, for example the content and format of participant information sheets. We spend a lot of time with children developing these information sheets to meet their needs then we have had ethics committees who prefer to see them presented in their own way.

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?**

We believe children and their families should have an input into setting the research priorities and agenda for health. There should be greater collaboration between research teams from small specialties to ensure that these groups are represented. There is a tendency for high profile conditions such as cancer to have disproportionately high funding, but it is important that conditions which are common to all children, and may cause distress such as tooth decay, are not overlooked.

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

Funders, researchers and stakeholder groups have the responsibility to listen to the priorities of children and families when commissioning children's clinical research.

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

Researchers should disseminate the results of the research to the children who have been involved and to other children and young people more generally. Parents should also be included with a separate report. The most appropriate approach for dissemination will vary between projects.

**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.**

A variety of methods, both qualitative and quantitative, should be used to engage children in clinical research. Examples include 1) interviews and focus groups with or without participatory activities such as drawing and creative writing can be incorporated, acting as ice-breakers or to enrich the data 2) written or video diaries to explore day-to-day activities or specific events in a child's life 3) questionnaires developed using child-centred methods. From our experience of using these methods children have provided insights which could not have been anticipated and which were extremely valuable in addressing research questions to improve the oral health and oral healthcare of children.