

46. Professor Faith Gibson 051113

Kate I have addressed the questions asked for my response, responding within the context of my personal experience as a mainly narrative researcher working with children and young people who have cancer, but in addition with my role on an NHS ethics committee. I have written them as reflections on our work with a particular population so bear that in mind, rather than in the main evidenced based views which you know already exists:

1. How should children be recruited to clinical research?

I would like to reflect on children and young people/young adults separately. But one challenge shared by both groups, particularly relevant to social science research, is the priority placed by professionals regarding this kind of study. Recruiting children, relies on children knowing that the study actually exists. This is a difficult one, families are faced with many challenges, and may be suitable to enter a number of studies, I believe here there is a role to have a portfolio of studies, making it clear to families which ones are open to them, so that they can see the range of studies available to them: so that we as professionals are open about the range of studies open and work with families in making their decision. So of course engagement with stakeholders is an important place to start, whether this be in health, schools etc, it takes time so should be factored into every study. Mapping out in the first instance stakeholders, participants, and any roles that could support your study at a site is important for success.

Children: Children like all other populations can make a choice. The key for me is knowing the population of children so that the initial research conversation starts off well. Children in particular need time, they need to know that we value their opinion and that you (as an adult) are wanting them to understand about your study and what it will mean for them. In all our studies permission is sought first from parents to talk with children, children need to know who we are and trust us, trust only comes I believe if you have already connected with their parents/people they know and trust already. Engagement is about talking, reading, showing children what it means to participate to say yes or no. Many of our studies involve children 'doing things' so showing them pictures, using fuzzy felts, board games to help them see this and ask questions about it is important. There are now a few examples of creative techniques to help children; these can be used in addition to a well-written age/developmentally appropriate information leaflet. With time, and some extra cash the possibilities are endless, but I do believe that in all research, if children are well enough at the time they should be included in knowing what the study is about and what their participation means to them. Children's capacity to make decisions and choose is well documented so I am not going to say anything about that here, being recruited is about access to studies and this initial approach, should be part of every study where it is possible, seen as a first important step, not just a token gesture. Of course special considerations will need to be taken for children who are very young, or cognitively impaired, or too poorly to know when it is in a treatment related clinical study. But there are some core principles that we can build. I always like the notion of engaging in a research conversation, that is what it should start.

Young people/young adults: The main challenge here, as I see it, is for some studies that young people get the chance to participate. Professionals can play the gatekeeper role, and only share with young people some studies. I am not suggesting here that there is a priority exercise going on, but maybe with some populations clinical studies/pharma studies, might be offered more easily than a study about quality of life/experiences of care. Then for young people in particular we need to be really creative in our approaches to recruitment, using all the formats/places young people visit to recruit. I know that twitter/face book challenges some RECs, my view is we now need to build the processes and safety nets around these creative approaches, not just taking a blanket view of 'not possible yet'. But we as researchers need to test some of these approaches out, and use a range in one study to really see what works. But I guess we will always need a range to account for individuals in research. I cannot stress enough how important PPI is in getting this right at the outset of any study, it is so important to find out from that particular population, of that age, cultural background etc. what will work, rather than apply a blanket 'in approach' to a study. There is still a role for face-to-face, but we need to be prepared to take some risks, with support structures around them, to use different mediums.

All of the above I believe could be useful to clinical and social science research.

2. What research proposals should be regarded as ethically acceptable?

Of course the four core ethical principles need to be addressed and debated in all studies. Overall it will be important to assess any study and ensure the researchers are acting in an ethical way to prevent research participants from coming to any harm. Open dialogue on the pages of a protocol are important to show how researchers have questioned the ethics of their research. The nature of a child's vulnerability is such that all research and its possible impacts must be considered, again PPI can help here, there is really no such thing as a study that has no ethical implications, even asking children a few focused questions can leave them worried about their participation. For me then I would be looking in a study for this dialogue, where intellectual and informed debate justifies each element of the research design, where there is a very clear understanding and use of the relevant ethical guidelines. And of course PPI is essential, even in a small way this can help researchers ensure their protocols are as child friendly as possible.

3. How should research in children be encouraged?

All organizations that care for children, funding bodies, and policy makers need to celebrate the range of research that can help us either treat or care for children. The first step in encouraging research in children, particularly in social sciences research and non-clinical research, is to share the view that children have a view, a view that we are prepared to take seriously: I think this step has already been taken and in contemporary research it is accepted that children have the ability to make decisions. What this means is that there has developed a cohort of researchers that have developed the skills and

research methods to work with children. This is a particular set of skills, but we can now be confident that involving children in this kind of research is safe, will produce robust data, and hence should be encouraged and made possible to answer particular questions about their experiences of care, for example. So to continue this we need to ensure there is training for researchers who want to work with children, and we have some way to capture this skill set on for example research passports that provide reassurance about a research team who might be new to an environment. The skills they have developed can then be shared with researchers not as skilled in the field of 'child-centred studies', providing opportunities for shared learning is important here. Equity of access is also key here, and of course recent work around access to clinical trials/pharma studies has had an important role, but this feels like work incomplete with ages for some clinical trials not clear. There is an important role here for hospitals in particular to have information available to families about research, what it is, what happens in that hospital/setting that families can get involved in, and to ask about research that is happening in relation to their care. We know that there is a different perception from the general public and patients'; we need to learn more from this and put in place strategies that help with that understanding. Strong PPI structures can help here.

My final comment here is about the various levels of approval and where expertise that relates to children lies. This is a particular challenge for researchers that attend an NHS Ethics review where they feel their views as 'experts' with this population are not being taken into consideration, so changing odd words to suit a committee even where it is known children do not understand that word is less than helpful. We might want to consider going back to named REC's that have this expertise, or have expertise on each REC, offering enhanced advice to what is there on the NRES web site. I am concerned that if this does not improve, we will see less research with children rather than more, researchers will avoid REC's, and in particular those working with children at end of life. Contemporary research positions children as having agency, this will not be enabled if researchers avoid research with children because they worry about not getting approval even before they have submitted their application.

4. What should happen when the research is over?

Dissemination to those who have participated is just so important. So often I hear, from young people in particular, that they often participate in research but they never hear back about what happened. Depending on the length and nature of a study I would suggest that there is often a role for newsletters (paper/and E version), throughout a study, just letting children (and family members) know what is happening is beneficial. But certainly at the end, a brief study report, written for a range of formats, that is age appropriate, with input through PPI to whatever is produced to make sure 'it does the right job' would be essential. In our qualitative studies we would be disseminating information about the whole study, not an individual's own contribution, and that feels right. In fact I think for most dissemination of research, a combined response feels right. I might suggest for some studies to have a workshop at the end might be useful, particularly where researchers might be thinking

about say service design, where a contribution to shaping the findings might be required. I know how long it can take to complete a final report, so a 1 page that the study has ended would be a useful first step, and shows we as researchers have valued the input of those families. More recently for young children we have included certificates, signed by the researcher the child had most contact with, we can also offer this to young people too, we might be surprised that this would equally be acceptable for their portfolio. We can use this opportunity to ask children if they want to be involved in future studies where they/or their parents can contact us: this leaves the door open for future involvement based on a families decision to participate. Dissemination does become tricky, in end of life studies, where a child may have since died. Again we might be surprised here that families may still want feedback. In these cases that 1 pager is particularly useful (sent knowing the child has died, so relies on contact between researcher and clinical team), providing the families an opportunity to say if they want to receive a final report. Use of web sites, parent newsletters are all useful places to disseminate. Even laminated posters in clinical areas/out patients would be welcome by families.