

**Nuffield Council on Bioethics Working Party on Ethical Issues for research
involving children: Report on consultations with community representatives and
secondary school students in Kilifi, Kenya
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A report on a consultation undertaken in Kilifi, Kenya, between January and March 2014 by Irene Jao, Nancy Mwangome, Alun Davies, Sassy Molyneux and Vicki Marsh, Department for Public Health Research, KEMRI Wellcome Trust Research Programme.

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1. Background and aims of consultation

This document describes a consultation activity undertaken in Kilifi County on the coast of Kenya to support the development of a UK Nuffield Council on Bioethics Working Party report on Ethical Issues for Research Involving Children. While the Nuffield report has a primary goal to support ethical practice in clinical research involving children in the UK, the Working Party has aimed to ensure its findings have as much international relevance as possible. The Working Party also recognised that involving stakeholders from varied sociocultural backgrounds internationally would support understanding of multicultural influences within UK society. The consultation reported on here is one measure taken by the Working Party to draw globally diverse experiences and opinions into its deliberations.

The choice of the site in Kenya was pragmatic, based on the inclusion of two individuals (job sharing) in the Working Party who have worked in an international collaborative health research programme in Kenya (Kenya Medical Research Institute/Wellcome Trust research programme, or KWTP) for many years; and who have a particular interest and involvement in community engagement in research in this setting. The approach taken to consultation was built into ongoing community engagement activities in the research programme in Kilifi, including stakeholders from secondary school students and the wider community in the County. Since the report builds on research conducted in the Public Health Research Department at the KWTP since 2005, references to publications from this group relevant to the consultation have been included.

2. THE KEMRI Wellcome Trust research programme and community engagement

The Kenya Medical Research Institute (KEMRI) Wellcome Trust Research programme (KWTP) is an international health research programme set up as a collaboration between KEMRI, the Wellcome Trust and Oxford University in 1989. This multidisciplinary programme has its main base in Kilifi on the coast of Kenya, a second unit in Nairobi and collaborative links to research institutions and universities in many countries in Africa and elsewhere.¹ The research centre is based in Kilifi County Hospital, and has developed a series of community engagement activities to build mutual understanding between researchers in the programme and residents in the geographic area surrounding the hospital, steered and implemented by a community liaison group. Many in this population, approximately 260,000 people, are participants in a Health and Demographic Surveillance System (KHDSS), set up through a collaboration between the research programme and the county government health management team to support health and research policy development and implementation in the county. Kilifi County includes rural and semi-urban populations of around 1 million. Subsistence farming is the primary livelihood and between 55% and 65% households live below the poverty line.² The majority of residents are from the Mijikenda ethnic group; 47% describe Christianity, 13% Islam and 24% traditional beliefs as their faith system. 45% adults reported an inability to read a newspaper or letter during randomised household surveys in 2005.

Of relevance to this report, one component of community engagement in research in Kilifi draws on a network of nearly 200 KEMRI Community representatives (KCRs),^{3, 4} working in smaller

¹ www.kemri-wellcome.org

² Virtual Kenya 2011, www.virtualkenya.org

³ As described in Marsh, V., et al., Beginning community engagement at a busy biomedical research programme: experiences from the KEMRI CGMRC-Wellcome Trust Research Programme, Kilifi, Kenya. *Soc Sci Med*, 2008. 67(5): p. 721-33; Kamuya, D., et al.,

groups from each of 15 locations (administrative areas) in the KHDSS. Throughout the year, KCRs are regularly consulted by community liaison staff and researchers on research activities, including planning and policy.⁵ To support this role, KCRs attend annual participatory workshops on research, including research governance, protocol review processes and research ethics. Individual KCRs are selected every 3 years through community based elections; those involved in this consultation had been elected in 2013.

A second component of community engagement relevant to this report is the Schools Engagement Programme (SEP), an initiative that links researchers and community liaison staff in the programme with an expanding group of secondary schools in the KHDSS area, aiming to support school science, build understanding of research and the research programme and help scientists within the research center have a better understanding of community interests and priorities.

3. Consultation methods

Participants and their selection

The consultation activities involved small group discussions with 4 groups of KCRs and 4 groups of secondary school students from SEP. In total, 33 KCRs and 24 students participated. A detailed list of participants is given in Appendix A.

KCRs' discussions were held as part of regular consultation meetings with community liaison staff, that is, acted at natural groups. In order to ensure that group sizes would allow sufficient individual participation, KCR groups with less than 10 members were chosen for this consultation. As Figure 1 in Appendix A shows, groups included roughly similar numbers of men and women (a criteria for KCR group selection), as well as a mix of levels of exposure to formal education, ages and religions.

Within SEP, schools were identified on the basis of diversity; representing a girls' boarding school; a girls' day school; a boys' boarding and day school; and a mixed day school. Within these student groups, representatives were chosen from the final two year groups, forms 3 and 4. The individual students were selected by form teachers, asked to bring together a diverse group including a mix of religions and academic interests, but positively selecting students likely to contribute to a group discussion of this nature. Based on experience in SEP, each focus group included only boys or girls to promote open discussion.

Data collection and analysis methods

All 8 group discussions were held in community-based venues between January and March 2014. KCR groups met at their normal meeting places, often the offices of local administrative leaders; students' discussions were held in a classroom in their schools. Discussions lasted about one hour, and were held in Swahili, a Mijikenda language or a mixture of Swahili and English. Facilitators were social scientists at KWTP with experience of moderating group

Engaging communities to strengthen research ethics in low-income settings: selection and perceptions of members of a network in coastal Kenya. *Developing World Bioethics*, 2013. **3**: p. 10-20.

⁴ By 'representative', we mean *to speak as typical members* of the community, not *to speak on behalf* of wider communities.

⁵ For example, see Marsh, V., et al., Managing misaligned paternity findings in research including sickle cell disease screening in Kenya: 'consulting communities' to inform policy. *Soc Sci Med*, 2013. **96**: 192-9.

discussions. For SEP groups, a note taker accompanied the facilitator, and at KCR groups one or two community facilitators were also present, allowing for discussion and documentation of key points during and after each discussion. The group discussions were voice recorded, transcribed and translated into English. The two main facilitators and other social scientists involved in this project undertook analysis, including discussions of the data, development of analysis charts around broad themes informed by the question guide, and synthesis of findings by group and across groups, cross referenced to provide illustrative quotations included in this report.

Ethical approval for data collection was provided under an existing scientific proposal supporting action research around community engagement activities in the research programme, including community consultation. All participants gave verbal consent for participation and voice recording. The County Education Director, school principals and class teachers also gave permission for students' meetings to be held.

4. Findings

Acceptability of involving children in research

General perceptions of research involving children

Across all groups, including KCRs and students, many participants *acknowledged the importance of health research* as a means of developing new treatments and vaccines and improving understanding of illness, for the benefit of wider communities in future.⁶ Many KCRs in particular had a reasonable understanding of the nature of research, although in both groups health research and health care were often conflated⁷. By extension of their support for research in general, many gave general but conservative support to the involvement of children in research where this was specifically indicated, with universal caveats about understanding, safety and discomfort:

I would want to be explained in detail... so that I understand the amount of sample that will be drawn won't affect her... So if there will be any side effects as a result, then I'll say I do not want... [Moderator: And if there are no side effects?] Ah, the truth is I would feel that to me it could be happiness because we clearly understand that if research will continue and succeed, and perhaps maybe treatment be found, after some time, that treatment would benefit every child or everyone in general. (P8 KCR1, male, 60y)

The main reason research was seen as important by KCRs and students across all groups was that *new understanding and treatments were needed for some diseases and health conditions that occur specifically in children*. This recognition of the need to involve children in research because their age group was primarily affected was either raised spontaneously in groups, or was introduced as a probe by the moderator. In the latter situation, there was general agreement on the principle. On this basis, for example, many students saw an importance of

⁶ A main message of KCR training and other community engagement activities in the programme.

⁷ It was sometimes difficult to separate perceptions that the primary goal of research was to provide medical care for the child, as a 'therapeutic misconception' of research, discussed further in section 4.3. This confusion dominated discussions in one KCR group and one student group, and were present to some extent in all groups.

involving children in trials to develop malaria vaccines, recognising that children are the group primarily affected by serious forms of malaria on the Coast:

I think it makes a difference because if it's a vaccine [malaria] for these children. If you check children's medication and those of adults they have a difference; because if you compare an adult's dosage and that of a child, they are very different. If an adult's dosage is given to a child, it can affect the child because it's strong. So if they are working on something for the adults, let them specify ages, and that will be good. (P1, SEP3, female, 17 years)

Similarly, many KCRs saw a need for more research on health issues in pregnancy, including for mothers and babies in the perinatal period, drawing directly on friends' and relatives' experiences of losing babies at this time. This included perceptions of high risk for babies born prematurely:⁸

Sometimes it brings problems if she [a mother] carries a pregnancy, but before getting to term she gives birth prematurely at seven months and then maybe even the baby dies. So, I think research is not bad both on adults and children too. (P7 KCR4, male, 65 years)

Overall, positive support for research, particularly for KCRs, was much stronger and reflected in all contributions when the research involved sick children seen as *likely to benefit directly* through medical care or tests included in the research:

You know with research, a child can be involved in research when he is sick, perhaps then you will be asked to be involved in research. Now there as the parent, you accept immediately because you want the treatment for your child to get well. So there's no way you will feel bad about research... [Later] Yes, she gets treatment so there when the parent is asked for permission to be involved, she will immediately accept. (P5 KCR2, female, 37 years)

In the absence of direct benefits, participants were more cautious about involving children in research. In this case, decisions were pegged on the perceived safety and inconvenience or discomfort of participation. Many students particularly expressed a view that it would be acceptable for children to be involved in research without direct individual benefits if there were no risks of harm:

[Discussing participation without individual benefits] As for me I will participate because I would like to help the community, I might be having our family in this area so I will have to participate because, as a girl for example, I will want to be married and get

⁸ In a separate study-specific consultation on this proposed research, involving two FGDs with 12 KCRs, views expressed were very supportive of the study, similarly seeing the issue of high mortality in newborn babies as an important problem locally. The study was a trial of an arginine food supplement and did not involve extra sampling. The nature of the intervention as a 'food supplement' and perceptions of the already high risks that such babies face seem to have underpinned support for this study in this separate consultation activity.

children, so it will help my children and therefore I will participate.
(P4 SEP3, female, 16 years)

Other students, talking about their own feelings about participation, felt they should be given some compensation or incentives for participating in research with no direct benefits, for example, pointing to the sodas and biscuits that were provided during these group discussions. In some groups, many students were particularly enthusiastic in their support for research in general, seeing this as a way of contributing to learning about diseases affecting children in the community (which some saw as exciting), learning about their own health, learning about research and meeting different types of people:

I will be excited because if the research, okay it comes to a good conclusion like you get the vaccines and I will be like "Yeah, my blood sample was taken in the research!" so I will be excited.
(P5 SEP1, female, 16 years)

Ok with me you see I will enjoy because I will be able to interact with the different people from different back grounds also ...you will enjoy that. (P1, SEP4, male, 19 years)

I'll also be happy, I'll know much about issues of health and research and I'll learn much out of that. (P2, SEP4, male 18 years)

However, while KCRs and students generally saw research in children as important, *there were major caveats to their involvement based on the child's age and the type of research*, specifically the extent to which research was seen as safe enough for children at different ages. These views are described below.

Concerns about involving children in research

There were common and strong concerns across all groups about research in children that involved perceived risks to safety, particularly in young children. KCRs were often also concerned about risks of unreasonable pain or distress to children involved in research, even if these were temporary. In this way, *the age of the child* and the *type of research* were central and interrelated issues across all discussions about the acceptability of research involving children. The only exception was for research seen as therapeutic in sick children, where - as has already been suggested - it was thought important for children of any age to be involved.

I will accept...when we go back to a child who is sick and I take him to the hospital for example, and the way we understand that research is voluntary, so you will be asked those questions. So I have already said I will accept since he is already sick. ... The outcome of the research might teach us which medicine has cured the disease and won't that help us in the future? So I will agree because when the child gets well as the research continues, the drugs will help another person who will be suffering from a similar disease. (P6 KCR3, male 57 years)

Concerns about safety

In relation to types of research, concerns about safety were particularly associated with *drug and vaccine trials* (as opposed to the other examples of studies given, that is, interviews or sampling/observations only). Given that participating in drugs trials was often perceived as being in a sick child's own interests, particularly in KCR groups, these concerns were pronounced for any trials involving *healthy children* and in discussions where it was less clear that the individual child would directly benefit. The most serious concerns were about irreversible damage that might be caused to the child through 'side effects' of an experimental product. On this basis, across all groups most participants expressed very conservative attitudes towards allowing children to participate in trials, and were particularly uncomfortable with involving very young children (less than one year, for example). One KCR group (FGD1) were more evenly divided in their views for and against involving children in trials, but even here involvement of very young children was seen as unacceptable.

what will make me refuse is if the child is taken when he is probably not sick... researching on someone who woke up well, took a good breakfast and then that child has a drug administered to do research on the drug, despite being well, no! I don't think it is okay.
(P8 KCR3, male, 30 years)

Concerns about involving young children in research (for some, under a year, for others up about 3 years) centred on perceptions of this group's relative *fragility* or *lack of resilience* to physical harms related to their immaturity, and their inability to express or defend themselves in any way. In general, the younger the child, the greater was the aversion to involving them in research:

Aah, looking at the age, I think a person's feelings, I think a baby of perhaps a month or even less, now, the amount of that blood, and the syringe she will be injected with, you know, their hearts, I don't know whether to say it is weak, or what? Because, they [parents] think that when the syringe is put there, that needle and the age of that child, aah, she is being hurt more, you see? (P5 KCR2, female 37 years)

This was most marked for trials, but was an important argument in views about all types of research. The lack of ability to communicate in a young child would leave parents unable to understand the nature or extent of any 'side effects' experienced, upsetting as a safety risk as well as in watching their child suffer:

She is a small child, under five years, she cannot tell you where she hurts. She can tell you the hand is hurting only to find that it's hurting inside there, so expressing herself becomes a problem.
(P8 KCR4, female, 26 years)

Amongst students and KCRs, some participants across different groups felt that any research – not just trials - was unreasonable in very young children, given their relative frailty, seeing risks in even taking blood samples from very small babies. In these groups, a young child's lack of resilience was often talked about in relation to levels of immunity children were perceived to have at different ages, with very young children described as having little immunity because of low exposure to different types of illness:

[Talking about children under one year]They're very...their immune system is very sensitive so anything that is negative in their body they will first notice it, their immune system will notice it so it will be kind of not good for their immune system. (P3 SEP1 female 17 years)

At the same time, as mentioned earlier, some KCRs and students perceived the same importance for involving young children in some types of research as older children, that is, *where their involvement was needed to address health problems specific to their age.*

The earlier examples of recognised high mortality in preterm babies and the need for a malaria vaccine in children under 5 years are also illustrative. In addition to perceptions of relative fragility, a few individuals saw an importance in taking particular care of safety issues for children in research because of *their future potential*, sometimes linking this to the future of the nation:

it is like we are experimenting, so if you see benefits, well and good, but if you encounter problems? So it's trial and error of some sort. [Later] Because that's the life of a child. It's like the nation, that is like the future nation...' (P8, KCR3, male, 30 years)

[While safety was a common and important concern, some views (particularly amongst students) reflected fears about research risks that seemed unrealistic, including a high possibility of dying or getting serious illnesses, and this affecting many people involved in research:

Maybe let's say from a few months up to around four to five years, you know if you conduct research maybe at that age, if a vaccine is harmful, you will end up losing millions of young people who will be coming up in the next generation. (P1 SEP4, male 19 years)

While KCRs were more often aware of research review processes through training workshops and regular interactions with research staff, others – particularly students – seemed to have little awareness of research review processes that provide checks on safety and levels of risk, or trial stages. For these reasons, in many groups, students made strong points about drug trials only being done in labs, or animals, or human tissues first. In one group, it was suggested that researchers should first experiment on themselves and other research staff to demonstrate to the wider community that drugs under trial were safe:

Let them [researchers] start testing the drug on themselves first... perhaps when he [researcher] himself arrives there, he should demonstrate, even if it won't be when he goes to every homestead, but he should test that drug [on himself] at least to motivate the others. (P1 SEP2 male, 20 years)

In addition to risks in trials, some sampling procedures were seen as risky. For example, nasopharyngeal swabbing, a procedure to test for respiratory pathogens in the upper respiratory tract, was seen by many as risky and unreasonably painful. Participants were commonly worried about safety for blood taking where repeated sampling occurred (potentially affecting the child's strength), although single sampling was seen as a fairly routine. In discussing risks, a few KCRs

voiced fatalistic attitudes towards risk, seeing risks as part of normal life or unavoidable events in life.

Concerns about discomfort

In relation to *discomfort*, many types of observational and intervention research could be implicated. As above, the taking of repeated nasopharyngeal swabs in a particular study was particularly commented on as an example of high discomfort and provided a good example for these discussions since samples were taken from all members of a household – adults and children – over a period of months:

We have those who say ‘She was well and [then] she started walking around with a handkerchief all the time until two to three months before the mucus dried up’. So, there you must think first, because she won’t be sick. So accepting quickly, if it’s about a sample for malaria or any other disease, you can just accept, but issues of being taken nasal swabs, being scraped until mucus comes out, that’s when there can be difficulty...[my] concern is [the child] having a runny nose for nearly three months before it dries up. (P1 KCR2, male, 32 years)

Discomfort could also be psychological: a KCR described being asked to bring his child to the research centre for an assessment involving observing of play (study on neurological disabilities). This father strongly resisted bring his child to a place that was unfamiliar and likely to be frightening to the child:

It is that I find hard. How will he play there, and those children don’t know each other at all? She doesn’t know even the place where he is going [Laughter]... Even if you tell her “play, play, play this way, play this way”, now how will she play? ... She will be afraid to play there! (P1 KCR3 male, 55 years)

Decision-making for research involving children

The influence of age and capacity

Across all groups – KCRs and students – ideas about age strongly influenced perceptions of the extent to which children and young people should be involved in making decisions about their participation in research. In general terms, there was wide agreement that very young children should not be involved at all in decision-making; that there was an intermediate age when children should be involved to some extent, at least to ensure their cooperation; and that older children or young people should have more or complete control over the decision taken. Views expressed by KCRs and students were largely similar, although students’ assertion of their independence in making these decisions was more commonly and strongly made.

At the same time, the age limits for children seen as having different levels of independence in decision-making were described variably. Much of this variation was explained by the widely held view that children mature in different ways and at different rates, such that independence in decision-making could not be pegged entirely on age. The capacities that seemed most important in ascribing independence in research decision-making were the ability to understand and reason (e.g. illustrated by asking good questions) and understanding of self (e.g. not being

easily swayed by others) and the wider situation, including what was being proposed. These capacities were linked to age, to the types of activities that particular children commonly undertook, their experience of formal education and individual variation. Students particularly described experience of formal schooling as an important influence on the extent to which children and young people should be involved in decision making related to its effect on their understanding of KEMRI, research and aspects of human biology thought to be important to making decisions.

I can say involving the child [in decision making] is okay, but it depends on the type of research and also the age of the child. For example, my younger brother [aged 13 years] was involved in a pneumonia study and was given a diary to fill in for three days. Now when they came home they found me and him, I'm not his parent, the parents are not there, but the boy is big... he can explain everything. Now they involved me, if I can agree and I told them even he himself can agree because there's nothing there, it's just talking and filling. He himself said "I will do it". You see? He is a child, but can express himself. And if perhaps the research involves drawing blood and then maybe the child is not sick, she has been involved yet she is not sick... [or] If perhaps the child is sick, she has gone to the hospital ... the parent can immediately agree because she has considered the child's situation ... So I'm saying it depends on the sickness, and the situation of that child and the type of research being done. (P8 KCR4, female, 26 years)

I don't think it's 18 and above or less than 18, if you are going to participate in the research right now you have to use your intelligence, if you consider the advantages and think it is going to help, it's you who will make the decision you don't have to quote the age or something. (P6, SEP4, male, 17 years)

As described below, some common approximate age groupings emerged from these discussions, related to capacities, with consistency between KCRs and students. There was least clarity for the middle categories. In addition, family decision-making processes might be complicated by traditional gendered dynamics within families and by the fact that many secondary school students attend boarding schools some distance from their homes, discussed later.

i. Age groups where children should not be involved in process of decision-making

For very young babies, infants and children up to the age of one year, and - for some - up to about 3 years, there was wide agreement that children could not express themselves, understand themselves or what was happening around them, but were completely dependent on their parents for all their needs. At this stage, it was not seen as important or even possible to involve the infant or child in decision-making, which should only involve their parents:

You as the parent knows the importance of that research... you will know whether to let the child be involved in this research. (P1, KCR2, male 32 years)

ii. *Age groups where children should have some non-central involvement in decision-making*

For children a little older, from around the age of 4/6 to 8/10 years, many participants thought children should be involved to some degree in the process of decision-making although not in making the final decision. Where the parents had already taken a decision that the child should participate, the type of involvement described was trying to explain the research to children in a way that did not make them unduly frightened and convinced them to participate:

When she is five, six years onwards, a bit, that's when we have to take the child and say "you know... these people have come and want us to do something, so that they can do something." You have to soothe the child a bit so that she can be involved in that research. (P1, KCR2, male, 32 years)

There were some voices – in KCR and student groups - describing parents' responsibilities to help children to understand the importance of research, as part of their approach to 'convincing':

The 9, 10 years olds there they just understand, somehow they do understand themselves, so they should also, if the parents have agreed they should go for that research, they also should be asked if they want to, and then they should be told the benefits of having this kind of research, they should be educated somehow. Somehow they will end up understanding and making a decision also. (P3, SEP1, female, 17 years)

As earlier quotations illustrated, participants' reasoning about the importance of involving children in this way included that: the child is old enough to have some understanding of what's being suggested, that their active cooperation would be needed to make participation possible or that they already have some independence e.g. walking to school alone, so clearly have some capacity for decision-making (although limited).

Many KCRs recognised the challenges of trying to convince children at this stage of life to participate in research, particularly studies involving sampling. Some described being very unsure about the best way to do this. They were mixed in their views on how far a parent should pursue this course of action for particular studies. For younger children, it was commonly seen as reasonable to restrain a child while, for example, blood samples were taken – particularly if this was a minor and/or familiar procedure (such as taking a finger prick blood sample), the research seen as important, or the child would directly benefit from the testing proposed. For older children, or less individually beneficial procedures, the majority saw it as neither desirable nor feasible to force children to participate in this way:

From that year to about three years there or three, four there, I will decide for her. But when the child is a bit older, I can decide for her and then she says "No, I don't want. If it's being injected, perhaps it will be painful." And I see that it's not a must because she is not even sick. "Okay, then go and play with your friends", because there's not that push because the child is well and she is complaining about it, she might even run away. Should I run after her because of research? [Some Ps laugh]. (P8 KCR3, male, 30 years)

This attitude suggests recognition of some children in this groups' right to refuse to participate, more directly described for the group below.

iii. Age groups where children and young people should be centrally involved in decision-making or make decisions independently

Views about the independent decision-making capacity of children in this group spanned two types of perceived independence, but with much overlap in ages. The broad groups are presented below for children around the ages of 10-13/14 years; and those 14 years and over.

- Children around the ages of 10-14 years

Most KCRs and students felt children of this age⁹ had enough understanding that they should be centrally involved in making decisions about participating in research, and particularly to *have a right to refuse* to participate:

When it comes to deciding? From twelve to seventeen years they can decide for themselves because when they tell you they don't want, they don't want. (P4 KCR4, female, 49 years)

Quite commonly, students and KCRs felt that children in this age group could take decisions alone about participation in some types of research, such as questionnaire-based studies, but only where this did not involve risks of harm. In the case of KCRs, several described some children of this age as already very independent, such that parents 'may not see the child from one end of the day to the other'.

It was not seen as either reasonable or possible to force children of this age to participate against their will, unless there was some reason to believe the child would gain important health benefits from participation, that is, for ill children. At the same time, children of this age were not generally seen as mature enough to understand all that was being proposed, and to still be prone to changing their minds as a result of peer influence or other forms of persuasion. For this reason, as for the younger age group, parents had an increased responsibility to try to explain the research to their children, including trying to convince them if they thought the child should participate:

That one from ten years onwards, those ones should come and we sit together, but any decision should be from them. Truly, those we have control over are under 10... The smaller ones have no problem but those from eleven onward, aah, those should make their own decision... Ours as parents is to try to help them... [by explaining] participate because this is assistance which will help even your own children in future, a drug might be developed from research you participated in... (P3 KCR1, male, 45 years)

The reasons for this central involvement of children included:

⁹ Illustrating the variability in ages associated with this level of independence, in one group (FGD4) nearly half the participants thought that 6 year old children should have a main role in making decisions about participation, while others strongly disagreed.

- the levels of understanding and reasoning ability children were likely to have, including having enough understanding to be able to undertake procedures reliably (e.g. keeping research diaries as requested);
- drawing lessons from the recently revised (2010) Children's Act in Kenya¹⁰ on children's rights to protection from physical and emotional abuse;
- recognition that 'modern' children were more independent and likely had more exposure to formal education than their parents at the same age.

If he can answer question, let him just answer. Sometimes they do things which the parents themselves get surprised, because they know how to do things [P8: Nowadays!]. Now if at thirteen years he goes to Mombasa, Malindi, and back, by himself, if you ask him silly questions, won't he surprise you with his answers? (P2, KCR4, male 55 years)

I see, per my perception, according to these children of nowadays, they call themselves 'digital', they are too difficult! You can decide for that small child, let's say from 0 to 10 years, but from 11 onwards, heh! There's difficulty (P6, KCR1, male, 46 years)

In addition to highlighting the increased access to information that 'digital children' might have, parents and student recognised that children of this age may often now have more formal education than their parents.

- For children over 14 years

As they progressively neared the age of adulthood, young people were seen as increasingly capable of making their own decisions about participating in research. These views were based on the same reasons as for those aged 10-13 years but with greater confidence in their ability to understand what research would involve and to be stable in their decisions, recognition of their greater exposure to formal education and science and reflecting the increasing independence of their lives overall. For example, if at secondary school, many children in this age group would be attending state or private boarding schools often hundreds of kilometers from home. In general, KCRs and students felt that young people at around 16 years and above were capable of making their own decisions about research participation, but many still recognised that parents had a role to 'sit and help' young people understand what was being proposed, and some might still need their parents support in making this decision.

Students' discussions of decision-making for this age group were detailed and particularly informative, noting that this group included young people between 14 and 17 years, although some students were in fact already legally 'adult', at 18 and 19 years old. Students' views encompassed seeing a central role for their parents or themselves and – commonly – the importance of a joint decision, as described in the following paragraphs.

Seeing that parents should be centrally involved in making decisions about their children's participation in research was often linked to concerns about 'things going wrong'. This view generally related to specific types of research seen as more risky, particularly drug trials, and often reflected quite exaggerated concerns about risks of harm, such as serious and irreversible

¹⁰ The Children's Act, Revised Edition 2010 (2007), published by the National Council for Law Reporting with the Authority of the Attorney General (www.kenyalaw.org).

adverse events. These perceptions led some to feel that their own positive views on participation should be checked and approved by their parents. At an extreme, a few students - both boys and girls – described accepting their parents' positive decision on participation *even if they themselves were against this*. This acceptance of parental authority was based on respect for their parents, recognition that parents have more experience of life and trust that parents would only act in the interests of their child:

I'll agree because the way I know myself since they started bringing me up, my parents can never want any bad thing to happen to me. My parents love me! I'll go because a parent can never allow bad things to happen to their child. I'll respect my parents and go. (P5 SEP3, female, 17 years)

I can add on his point that the parent has seen the sun earlier so she has...I mean she knows a lot...she has experienced a lot and she has seen a lot... whatever she tells you, you can also think well about it, that parents loves you unconditionally, she can never have bad intentions for you. (P2, SEP4, male 18 years)

More often, students felt they *would not be strongly influenced* by parents' views, but see their own assessment as most important. The young person would then try to persuade their parents to agree before taking a decision to participate. Underlying this attitude was a perception that students may often have a better understanding of research than their parents, given their increased exposure to formal education and science. Given this view, the extent to which students would be influenced by their parents' views depended on perceptions of the relevance of parents' knowledge and experiences:

Let's take an example of me, I'm 17 years, I understand, I can give my personal opinion without involving my parents. I'll accept if I see that it will be important to me and if for instance my parents know too but now they are denying me, yet I want, I'll try to educate them because maybe it will be due to lack of knowledge, they don't have education about that issue. I'll have to educate my parents so that when we leave there, we'll be in agreement. I cannot leave without their permission, they are my parents, I must inform them and agree with them. I'll put effort so that they allow me. I'll try to educate them. (P5 SEP3, female, 17 years)

In this situation, students stressed the need for researchers to provide good information to young people to enable them to make decisions on their own. Additional reasons students used to justify taking decisions independently were based on comparisons with other areas of life in which they take decisions alone, listening to but not necessarily taking account of their parents' advice.

A few students *rejected the possibility of parental influence* at all. In this group, students would either inform their parents after agreeing to participate or conceal the fact of participation from their parents if this were possible e.g. if the research did not involve home visits. The group where many students felt most strongly they should be able to make decisions independently included pupils attending a girls' boarding school.

It depends, if your mother is a lawyer or something, obviously... if you refuse, she won't tell you to participate. But if you take a parent with no education, who has lived a life of 'old times', when she's just told something she can say 'let him go'. So you will have use your brain there ... if you have refused, you have refused. (P6, SEP4, male, 17 years)

Most commonly, during these discussions students and many KCRs ended up talking about *the value of parents and young people talking together* to make a decision about research participation. The young person was seen to have the central role in decision-making but parents might be able to support them to think through the advantages and disadvantages of participation. Some saw this as young people educating their parents and others of young people drawing on their parents' knowledge and experience.

If you think your parents are going to have a different decision from yours, you ought to sit down and if your parent is understanding he will involve you in decision making, he cannot leave you and make the decision alone. You will sit and share your views and at last come up with a solution that is going to be binding (P2, SEP4, male, male 18 years)

Challenges where parents don't agree with each other about participation

When parents were thought to have primary responsibility for making decisions about their child's research participation, KCRs and students agreed that ideally the parents should discuss and come to an agreement together. Mothers were seen as having particularly important views in making decisions about research participation in younger children, based on the traditional roles they have in bringing up children, including responsibility for their health. But, in this traditionally patrilineal community, fathers often have primary control over family resources, giving them the role of primary decision makers for issues affecting use of these resources, like research participation.

Given this situation, there were many practical challenges seen for joint decision-making processes for parents. Children may be recruited into studies when they attend health facilities with their mothers during the course of an illness, in which situation fathers may not be present or easy to contact, particularly where mothers have travelled long distances to reach the facility. In addition, in this community, fathers often work away from home for periods of time, and would not be easily reached. In any case, any agreement reached between parents would be likely to primarily reflect the father's views. Although there is much diversity in these dynamics within different family, the expectation that a father should consent to their child's participation in research is still common. This was often described as a form of insurance; that the repercussions for the mother of deciding on her own that children should participate in research would be very serious if anything subsequently 'went wrong', as she would be blamed.

In both KCR and student groups, particularly the latter, participants saw an importance of parental disagreements being settled by including the views of older children and young people. In this case, the view of the parent also supported by the young person would hold sway:

Maybe to add on that, if the parents are different, maybe dad may want, mum may not want, or mum wants, dad doesn't want... I think the best thing is to sit with your parents and explain to them

then, the parent who is on your side can also explain to the one refusing, after he has explained to her you then you can... maybe from there you will have made your decision and tell them everything, isn't it? (P1 SEP3, male 20 years)

For older children, KCRs in one group suggested that the young person themselves should have a role in deciding where the parents do not agree on whether their child should participate in research, suggesting that the parents then listen to the young person and be influenced by their position. In addition, students saw researchers as having a key role to help parents to make a decision when there was disagreement, being more expert than either the parents or the young person in relation to the research proposed.

Role of other adults

Within these discussions, students and KCRs talked about the potential role of other adults in making decisions about children participating in research. School teachers at secondary schools, particularly where students were boarding away from home, were seen to have an information-giving and advisory role but were universally seen as not able to act as surrogate parents in this situation. Either the young person should decide on their own or – particularly if research was seen to involve any risks – either the student or the researchers should contact the parents.

The issue of guardians was briefly discussed in some student groups, for example, for children who had been orphaned. This topic was not explored systematically, although the challenges associated with increasing numbers of orphans, including for child-led households and grandparents acting as parents, are well recognised in Kenya¹¹. Where raised, students felt that a blood relative would be more trustworthy in acting in the child's interests than someone unrelated.

Cross-cutting/emerging issues

Conflating health research and health care

Amongst KCRs and students, during discussions on the perceptions of the value of research there was a common tendency to conflate the goals of health research with those of health care, as we have described in other publications from this setting¹². This confusion presented itself in different forms, from seeing research as *entirely* about providing services for the child only, to seeing that the child's involvement in research would give access to individual health care as *well as* generating new knowledge for the benefit of others in future:

¹¹ In 2005, the number of orphans was estimated at 2.4 million, 48% as a result of HIV/AIDS. Report on Orphans and vulnerable CHILDREN KENYA 2007 – 2010, Department of Children Services, Ministry of Gender, Children and Social Development, Kenya 2008. http://www.africanchildforum.org/clar/policy%20per%20country/kenya/kenya_ovc_2007-2010_en.pdf

¹² Including: Molyneux, C.S., N. Peshu, and K. Marsh, Understanding of informed consent in a low-income setting: three case studies from the Kenyan Coast. *Soc Sci Med*, 2004. **59**(12): 2547-59; Molyneux, C.S., N. Peshu, and K. Marsh, Trust and informed consent: insights from community members on the Kenyan coast. *Soc Sci Med*, 2005 **61**(7): 1463-73; Molyneux, C.S., et al., 'Even if they ask you to stand by a tree all day, you will have to do it (laughter)...!': Community voices on the notion and practice of informed consent for biomedical research in developing countries. *Soc Sci Med*, 2005. **61**(2): 443-54.

Okay, as a parent, I would want my child to participate in research because mostly, children are the ones who suffer from many illnesses of different types and if we look closely, under age children are not able to express themselves, so you as a parent will know that my child has a certain problem, so when she is involved in research, that problem will be known in terms of what type of illness it is and how it will get its solution. Through research, I know the solution will be found and the child can access treatment and cure. (P1 KCR4, female, 80y)

These perceptions were importantly linked to a common perception in this setting that *health care provided through research* is often of higher quality and more reliably available than that through *over-stretched public health resources*. At the same time, it was sometimes difficult to separate perceptions that the primary goal of research was to provide medical care for the child, as a 'therapeutic misconception' of research, from perceptions that the medical care provided in some types of research were highly beneficial to participant children. This confusion dominated discussions in one KCR and one student group, and were present to some extent in all groups (also see concluding comments).

Exaggerated fears

As described throughout the findings section, both KCRs and students – but particularly the latter – often described perceptions of risk related to research that were exaggerated in their magnitude (e.g. likelihood of dying) and likelihood (e.g. likely to affect many people). KCRs, having been in their roles for over a year, had more experience of talking about research with community liaison staff and researchers, and had attended a participatory training workshop on research and research ethics. Their views about risks were tempered by understanding more about processes of research governance, but many remained concerned about risks in trials.

Importance of information

KCRs and students commonly reflected on the importance of researchers giving clear and comprehensive information to allow parents and children to fully understand the nature of any proposed research, particularly the goals, procedures, risks and benefits. Information sharing was seen as important to inform and to build parents' and older children's confidence in making a decision about whether or not their child/they should participate. The information given should include any 'side effects' to look out for, including those that are minor and temporary and those that are more serious and the parent should act upon. Part of this confidence in research related to some level of understanding research review processes.¹³ A particular point made in many of these discussions was that researchers' failure to take back findings from earlier research was a source of frustration in the community likely to dissuade people from participating in research in future. In talking about 'findings', most commonly people were concerned to learn about results with direct individual implications.

Gender as an influence

In some groups, gender influenced views on the acceptability of research in older children and young people. In relation to risks, a few KCRs and some students in most SEP groups - including female students - felt that older girls, beyond the age of menstruation, were more at

¹³ Building this understanding is part of the routine KCR participatory training workshops.

risk of physical harm from research participation. This was related to potential effects on fertility in future, being less able to tolerate blood sampling and risks to unrevealed or unknown pregnancies.

Particular gendered influences on the acceptability of research were described for Muslim families, by both Muslim and non-Muslim students, although contested by participants in the group attending a girls boarding school. Parents were seen as likely to protect their daughters from outside influences much more than their sons, leading to unwillingness to allow girls to be involved in research – particularly if this meant travelling outside the home and/or being in the presence of men outside the family. This protective attitude was described as increasing with the age of the child, affecting the movements of teenage daughters more than younger girls. As a Muslim student described ‘the older you grow the more difficult it becomes to get out of the house’ (P5, SEP3, 16 years).

At the same time many students saw an equal importance for involving boys and girls in research to ensure results were applicable to both. Girls in one school argued strongly that girls in general would be more (not less) keen to participate in research based on perceptions of their greater concern for children’s health in future, including their own future children. This group also felt that boys would be less likely to agree to participate in research given fears that certain concealed behaviours, thought to be more common in boys, would be uncovered, including sexually transmitted infections, such as HIV, and recreational drug use.

For a few KCRs in this consultation, gender influenced the extent to which young people were seen as sufficiently independent to make decisions about research participation on their own. In this case, it was felt that boys were encouraged to be more independent and might feel more confident about taking on this role; this was not interpreted as boys having greater capacity for decision-making however.

As described earlier, gender also influenced decision-making processes between parents, with mothers often being relatively disempowered to make independent decisions about their children’s participation in research¹⁴. This situation often presents a major practical obstacle for involving children in research (also see the questionnaire responses from other sites in Africa), as well as risking causing conflicts between parents which can be very damaging to mothers’ welfare.

The role of the research institution and trust

In all groups, in talking about the acceptability of involving children in research, KCRs repeatedly discussed the importance of *relationships and good communication* between researchers and families who might participate, as reflected in other publications from this setting¹⁵:

Like XX [name of a community facilitator] and XX [name of a local area] [Laughter]...now perhaps, maybe my child has been given those drugs and she took it, knowing XX will come, ‘How is she

¹⁴ As described in Marsh, V.M., D.M. Kamuya, and S.S. Molyneux, ‘All her children are born that way’: Gendered experiences of stigma in families affected by sickle cell disorder in rural Kenya. *Ethnicity and Health*, 2011a. **16**(4-5): p. 343-59; Gikonyo, C., et al., Taking social relationships seriously: lessons learned from the informed consent practices of a vaccine trial on the Kenyan Coast. *Soc Sci Med*, 2008. **67**(5): 708-20.

¹⁵ Gikonyo, C., et al., *ibid* note 12.

Angwenyi, V., et al., Complex realities: community engagement for a paediatric randomized controlled malaria vaccine trial in Kilifi, Kenya. *Trials*, 2014. **15**: 65; Angwenyi, V., et al., Working with Community Health Workers as ‘Volunteers’ in a Phase III malaria vaccine trial: practical and ethical experiences and implications. *Developing World Bioethics*, 2013. **13**(1): 38-47.

doing, no problem?’ ‘No problem. She is doing well’ and he passes by. Then we know we have someone in our midst who cares [Ps: Yes] for us. (P5, KCR4, female, 52 years)

Relatedly, positive or negative research experiences in the past would influence people's decision about future participation, including for their children.

CONCLUDING COMMENTS

The acceptability of involving children in research

From the findings of the consultations held with KCRS and students in Kilifi, the picture that emerges is one of mixed feelings and worrying tensions around perceptions of the acceptability of involving children in health research. The concerns and fears were closely tied to perceptions of risk, and therefore focused primarily on intervention trials of experimental products. They were also linked to perceptions of the susceptibility of young children to physical harms of various types, given their immaturity and related need for protection. For this younger group, there were also fears of physical harms related to non-intervention research, such as sample taking. At the same time, there was wide and strong recognition of the importance of involving children in research on conditions that were specific to their age groups, in order to benefit all children in future. Where individual children participating in research were thought to access valuable health benefits, this tension was resolved – both the participant child and ‘other children in future’ would be helped. In the absence of individual benefits, support for the involvement of children was in direct relation to perceptions of risk.

Where KCRs had a better understanding of research – particularly research review processes – there was greater support for involving children in research. Many students did not seem to have much knowledge of review processes, leading to sometimes exaggerated fears about the type and likelihood of risks of harms involved in participating in research. In contrast, it was the students – although not all – that expressed the most positive and altruistic attitudes towards participating in research themselves. On this basis, one conclusion of this consultation is that creating a good understanding of the nature of research and how the acceptability of research is checked before any participants are invited, is essential to ethical research practice. Although not a novel understanding, this strongly emerging conclusion suggests an importance for wide forms of community and public engagement on issues of ‘safety in research’.

Similarly, the common conflation of the goals of health research and health care reflects a persisting challenge in disentangling these areas conceptually. As we saw here, the findings of a community consultation on the acceptability of involving children in research are likely to be particularly influenced or distorted by the extent and nature of this confusion. In other words, it is difficult to draw conclusions about attitudes to children's participation in research where these are underpinned by some degree of confusion about these goals. In practical terms, the consultation might have benefitted from more opportunities to explore these views in depth, and build understanding of the differences and overlaps between research and care before seeking opinions.

Throughout discussions on the acceptability of involving children in research, views on ‘what is special’ about children – leading to their need for particular protection for example – related mainly to their physical immaturity, increased susceptibility to harm, inability to express themselves and their dependency on parents and other adults to take care of their needs. For a

few participations, their 'specialness' was also linked to potentiality – for building their future lives, as well as future generations and that of the nation.

Decision-making and age

As in the UK consultations, children were clearly seen to gain in their capacity for decision-making about research participation as they grow older, but considerable variation was seen in the rates at which this would happen depending on many other influences – individual differences, experience of making decisions in normal life, exposure to formal schooling and parenting styles. An approximate categorisation by capacity was roughly agreed across groups, representing increasing control over decision-making by a child or young person, in place of a default parental responsibility at younger ages. However even in the oldest age groups (including some students who were 18 or 19 years in this consultation), some students believed that they would learn and make better decisions by taking account of their parents' views.

From a universal agreement that parents must make decisions for very young children, there was a similarly general view that children should be involved in decision-making as they become more aware of what was being proposed. Where decision-making capacities were seen as too low for this task, or too unstable, parents would still control decision-making, aiming to bring children into line with their decision through explanations, encouragement and small incentives. At quite a young age, for example, from 4 or 5 years, many parents did not feel that children should be forced against their will to join research if efforts to convince them failed. At a practical level, children were seen as simply 'hard to catch'. Respecting the child's choice, most parents were not comfortable with holding their child down unless the child themselves stood to benefit in important ways e.g. through accessing care, or (less often) the research was seen as of high importance. Once children were seen as old enough to understand, ask good questions and express consistent views, most KCRs and students felt that the child or young person should become the main decision-maker, but parents would still often be needed to support. Certainly they would have a right to refuse to participate, unless otherwise unavailable and needed health services were included.

There was much variation in the extent to which young people in this consultation¹⁶ described their willingness to seek out and follow their parents' views, with most in these discussions seeing their own views as the most important. Opinions were more divided for any research perceived as involving important risk, such as clinical trials, when bringing parents into the decision beforehand would both allow the young person to draw on additional experience and act as a type of insurance against future blame. The influence of children and young people's greater exposure to formal education and global communication, in comparison to their parents at the same age, was seen as important across these consultations. This factor tipped the balance in many cases towards older children and young people being given more responsibility for decision-making. The family context is therefore critical in this respect; the less 'worldly' parents are seen to be, the more independence young people are likely to assert. The Kenya Children's Act 2007, updated in 2010, was sometimes interpreted by KCRs to limit parents' rights to influence their children's decisions about research participation, particularly against their will. Nonetheless, it was common for students to respect their parents' views, for example, recognising the value of listening to these. Several young people expressed deep levels of trust in their parents' fundamental instinct to act only in their child's interests.

¹⁶ Mostly 16 and 17 years old, but some 18 and 19 years and one 14 years (see Appendix A)

In summary, in relation to the work so far in the working group, we noted concordance over:

- Views about the centrality of research in building better health services for the future, including for children, but far short of seeing research as an acceptable component of health care given the perceptions of risk associated.
- Views about the specialness of children in relation to their need for parental protection and support, linked to a fragility associated with immaturity and their potentiality.
- The importance of considering children within their family situations in many respects, including for decision-making processes, in which they may act as both beneficiaries and contributors to families learning about research.
- A gradual shift of control over decision-making about research participation from parents to older child or young person as the latter mature, without clear ‘cut off’ age groups and with many personal and contextual influences on the rate at which control is seen to shift.
- Support for the ‘principles’ we are using to underpin arguments about assent and consent: that is, parents’ responsibility to respect even very young children’s personhood; for a pedagogical role in helping children to learn how to make decisions/develop attitudes of solidarity; and for supporting the wellbeing and welfare of children. For children seen as partially autonomous, and where parents supported participation, the parents’ roles were described as both:
 - ‘Persuading’ or giving small incentives (sweets, biscuits) to avoid psychological harm, that is, a wellbeing argument;
 - Building understanding of the importance of research to further ‘persuade’ but also to build the child’s capacity to understand research and their role in contributing to the welfare of others, that is, a pedagogical role.
- Recognition that some children without parental/strong adult support may be in a particularly difficult situation – but not explored in depth here.

Important differences emerged in the following areas:

- In low income countries, challenges experienced in accessing health care through often over-stretched public health services have a major effect on the perceived acceptability of research that includes the provision of health care.¹⁷ While this factor affects research involving adults and children, children are particularly affected given their higher rates of morbidity and uptake of public health services.¹⁸
- Unfamiliarity with health research and science is more common in many low income country settings, where exposure to formal education is not universal. This unfamiliarity includes low awareness of regulatory systems for science and research ethics, contributing to unrealistic fears and hopes about participation. While clearly relevant to all types of clinical research, not just that involving children, this phenomenon has a major influence on the acceptability of research involving children. In relation to ‘familiarity’, we note the importance of ensuing

¹⁷ Also see Molyneux, S., et al., Benefits and payments for research participants: Experiences and views from a research centre on the Kenyan coast. *BMC Medical Ethics*, 2012. **13**: p. 13.

¹⁸ This situation generates particular responsibilities for researchers in developing partnerships with government health authorities to support long term care and capacity development, building effective community engagement to strengthen understanding of research and finding reasonable ways to contribute to structural inequalities that underpin low access to health care.

that neither too much nor too little trust is placed on researchers in making decisions about children's involvement in research.¹⁹

- Relatedly, perceptions of the age at which decision-making control should shift from parents to their older children are influenced by increased access to formal schooling and global communication amongst many children, in comparison to their parents.
- In contrast to regulations in the UK, there is a perceived importance of *both* parents being involved in making decisions about their child participating in research, and associated challenges in gaining this type of consent where many fathers work away from home but carry traditional paternal responsibilities for control of domestic resources that limits mother's independence.
- In comparison to UK based consultations so far, we noted differences in perceptions of the role of gender and religion on the acceptability of, and decision-making for, research involving children and young people. Perceptions of gendered differences may present important practical challenges in designing processes for information-sharing and informed consent. In particular, in some situations mothers and young women may need particular support from researchers to ensure that their views are heard and respected.

Appendix A: List of participants, codes and characteristics

<i>Group type</i>	<i>ID</i>	<i>Gender</i>	<i>Age (yrs)</i>	<i>Years schooling (current class)</i>	<i>Urban/rural home</i>	<i>Religion^a</i>
Girls' boarding school students	SEP1 P1	F	16	11 (F4)	R	C
	SEP1 P2	F	18	11 (F4)	U	M
	SEP1 P3	F	17	11 (F4)	U	C
	SEP1 P4	F	16	11 (F4)	U	C
	SEP1 P5	F	16	11 (F4)	U	M
	SEP1 P6	F	17	11 (F4)	U	M
Mixed day school students	SEP2 P1	M	20	11 (F4)	R	M
	SEP2 P2	M	19	11 (F4)	U	M
	SEP2 P3	M	18	10 (F3)	U	M
	SEP2 P4	M	19	10 (F3)	U	C
	SEP2 P5	M	18	10 (F3)	U	C
	SEP2 P6	M	20	10 (F3)	U	C
Girls' day school students	SEP3 P1	F	17	10 (F3)	U	C
	SEP3 P2	F	16	9 (F2)	U	C
	SEP3 P3	F	16	10 (F3)	U	M
	SEP3 P4	F	16	10 (F3)	U	C
	SEP3 P5	F	17	9 (F2)	U	M
	SEP3 P6	F	16	9 (F2)	U	C
Boy's day school students	SEP4 P1	M	19	10 (F3)	U	C
	SEP4 P2	M	18	9 (F2)	U	M
	SEP4 P3	M	18	10 (F3)	U	M
	SEP4 P4	M	14	10 (F3)	U	C
	SEP4 P5	M	17	9 (F2)	U	M

¹⁹ Also see C.S. Molyneux, N. Peshu, and K. Marsh, Trust and informed consent: insights from community members on the Kenyan coast. *Soc Sci Med*, 2005 **61**(7)1463-73; Participants at an International Workshop on Informed Consent and Community Engagement, *J. Emp Res Health Res Ethics*, 2013 **8** (4), 1-18

	SEP4 P6	M	17	9 (F2)	U	M
KCR 1	KCR1 P1	M	37	8	R	C
	KCR1 P2	F	51	7	R	C
	KCR1 P3	M	45	4	R	C
	KCR1 P4	F	36	8	R	C
	KCR1 P5	M	41	12	R	C
	KCR1 P6	M	46	8	R	C
	KCR1 P7	F	44	8	R	C
	KCR1 P8	M	60	12	R	C
KCR 2	KCR2 P1	M	32	12	R	C
	KCR2 P2	M	-	-	R	C
	KCR2 P3	M	59	12	R	C
	KCR2 P4	M	57	12	R	C
	KCR2 P5	F	37	16	R	C
	KCR2 P6	M	54	12	R	M
	KCR2 P7	F	35	8	R	C
	KCR2 P8	F	43	12	R	C
	KCR2 P9	F	40	11	R	C
KCR 3	KCR3 P1	M	55	7	R	C
	KCR3 P2	F	31	7	R	C
	KCR3 P3	M	-	0	R	T
	KCR3 P4	F	51	5	R	-
	KCR3 P5	M	36	8	R	C
	KCR3 P6	M	57	11	R	C
	KCR3 P7	F	38	7	R	C
	KCR3 P8	M	30	12	R	C
KCR 4	KCR4 P1	F	80	10	U	C
	KCR4 P2	M	55	16	U	C
	KCR4 P3	M	40	7	U	T
	KCR4 P4	F	49	8	U	M
	KCR4 P5	F	52	10	U	M
	KCR4 P6	F	43	11	U	C
	KCR4 P7	M	65	12	U	C
	KCR4 P8	F	26	12	U	M

^aC=Christian; M=Muslim; T=Traditional

Appendix B1: Focus group discussion guide for parents/wider community

Background

KEMRI Wellcome Trust Research Programme researchers are working in partnership with a UK-based organisation called The Nuffield Council on Bioethics to find out more about what people think about taking part in health research. This is part of a project to look at ethical issues that come up when carrying out clinical research with children and young people – from babies up to 17 year olds – how can we do the research in the best possible way? The aim of the project is to produce a report to advise researchers on these ethical issues and ways of handling them. Although the report will be produced in the UK, the aim is to ensure that it is relevant to research in other countries in the world. For this reason, we are keen to listen to your views on how research that involves children and young people should be carried out.

In Kilifi, we are asking four different KCR groups to discuss some of these issues. The four KCR groups, including yours, were chosen on the basis of being interested in participating, being based in urban or rural areas of the County and having meetings at the times this activity has been planned. We're grateful that your KCR group has agreed to contribute to these discussions, but it's important to know that you are free not to discuss any subjects you don't wish to talk about. Your views will be recorded anonymously, that is, by using codes rather than real names in any report so that anything you say cannot be linked to you personally in future. As long as all participants agree, we will voice record the group discussions to help us to capture all the views put forwards, but these will be permanently deleted once summaries of the discussions have been made.

In our work we are using the term 'clinical research' to mean research projects carried out in places like hospitals or clinics, where the main aim is to obtain knowledge that will help improve the health care of all children in the future. This means that the research does not aim to improve the health of each participant in the study directly, although in some clinical research this may happen. Some clinical research studies will be closely related to the child's treatment, whereas others will be quite separate and may involve healthy children or additional procedures. Examples are studies where researchers:

- only ask questions about a person's health;
- only do blood tests (e.g. taking half a teaspoon);
- or try out new treatments to see how well they work - these generally also require taking small blood samples and asking questions.

Many of the treatments and vaccines we use today were developed in this way through research done in the past. But children are very different from adults in the kinds of health problems they have and in the way their bodies handle different treatments. This means that research in children is important because otherwise it will not be possible to develop good new treatments for children in future. At the same time, clinical research in children raises some difficulties. While adults may choose to undergo any inconvenience, discomfort and potential risks that may be involved in clinical research, it is much harder for parents to make such decisions on behalf of their children. Many people feel that children should be protected from anything difficult as much as possible, but if children do not participate in research, how will we ensure they can be well treated if they become unwell in future?

In all the questions we will discuss in the groups, there aren't any 'right' or 'wrong' answers – we're interested in knowing *what* you think and in finding out more about *why* you think it. Thank you for taking part!

Feelings about your child taking part in research

1. If you were asked if a child of yours (of any age) could take part in research, how would you feel? What might you feel pleased, annoyed or worried about, and why? [Look for 'hopes and concerns']
 - [Probe for direct experience] For anyone, is this on the basis of your own experience of participating in research in the past? If so, what was that research about, what did it involve and how old was your child?

Influence of type of research

2. Do you think your views would be different for different types of research? Earlier, we talked about research that involved only asking questions, or only taking blood, or also trying out new treatments (including some blood sampling) to see if they worked. Do the differences between these types of research change the way you think about your child participating? In what way? Are there other differences in the type of research that would change your point of view?

Influence of age of child (introduce and follow up in Q 5 & 6)

3. Would the age of your child when asked to participate make a difference to you?
 - If so, what kinds of ages would make a difference? [e.g. differences between young babies, young children and older children but listen to these ideas about age groups without promoting]
 - What is it about those ages/age groups that make a difference?

Who should make the decision about taking part?

4. Who do you think should decide whether your child takes part in clinical research? [E.g. just you/both parents or guardians? The child & parents/guardians together? Someone else?]
 - What role should the researcher/doctor who is looking after you and running the study have? (parents? Someone else?) Why?
 - What do you think should happen if you want your child to take part in research but they disagree with you? Why?
 - What if you don't want your child to take part in research, but they want to? Why?
 - What if you and your spouse (husband or wife) don't agree with each other about this?
 - Where studies are taking place only in schools, with the support of the DEO, does this make a difference to who should make the decision? (*Probe for role of teachers vs parents and of students; probe for studies that only include asking questions and those that include taking finger prick blood or urine/stool samples; take account of whether boarding or day school*)
5. Influences on making decisions:
 - [Link to earlier discussion on role of age] How would the age of your child affect your views on who should make the decision about taking part? (e.g. babies, young children or older children)
 - What about the gender of the child? Would that make a difference & how? Any relationship to age (e.g. boys considered more able to make independent decisions than girls of same age, or vice versa?)
 - Do you think religion plays a role in making a decision on child participation?

Should children participate in research that will not benefit them as individuals? [If time]

6. If you were told that the research probably wouldn't help your child directly but might help other children in the future, would you still agree for them to take part? Why/why not?
 - [Linked to Q3] Would the age (of the child) make a difference? i.e. if the child asked was older or younger, would this make it seem more or less reasonable? In what way?
 - Would the type of study make a difference?

Emerging recommendations

7. For concerns brought up during these discussions (Q 1-6) what could be done to deal with these? (E.g. ways in which the research might be carried out that would feel better/more comfortable for children and their parents/guardians?)

Encouragement to take part (if time)

8. Rewards (such as books, vouchers, cash or other goods) for children may be welcomed as an appropriate way of saying 'thank you' or criticised as making participation too attractive – such that children will agree without thinking about the research and/or any disadvantages to them and their families of participating. What forms of reward or compensation do you think are acceptable for children and young people, and why?

Appendix B2: Focus group discussion guide for students

Background

KEMRI Wellcome Trust Research Programme researchers are working in partnership with a UK-based organisation called The Nuffield Council on Bioethics to find out more about what children and young people think about taking part in health research. This is part of a project to look at ethical issues that come up when carrying out clinical research with children and young people – from babies up to 17 year olds - how can we do the research in the best possible way? The aim of the project is to produce a report to advise researchers on these ethical issues and ways of handling them. Although the report will be produced in the UK, the aim is to ensure that it is relevant to research in other countries in the world. For this reason, we are keen to listen to your views on how research that involves children and young people should be carried out.

In collaboration with the Kilifi County Education Officer, we have chosen four secondary schools in the County to visit as part of this project. They have been chosen on the basis of their involvement in the KEMRI Wellcome Trust Research Programme Schools Education Programme last year. In each school, we will meet with a group of students (about 6) for about one hour to listen to their views on research involving children and young people.

Although we will seek the advice of class teachers to identify possible participants for the groups, participation will be completely voluntary. Students who participate are also free not to discuss any subjects they don't wish to talk about. Their views will be recorded anonymously, that is, by using codes rather than real names in any report so that anything participants say cannot be linked to them personally in future. As long as all the participants agree, we will voice record the group discussions to help us to capture all the views put forwards, but these will be permanently deleted once summaries of the discussions have been made.

In our work we are using the term 'clinical research' to mean research projects carried out in places like hospitals or clinics, where the main aim is to obtain new knowledge that will help improve the health care of all children in the future. This means that the research does not aim to improve the health of each participant in the study directly, although in some clinical research this may happen. Some clinical research studies will be closely related to the child's treatment, whereas others will be quite separate and may involve healthy children or additional procedures. Examples are studies where researchers: only ask questions about a person's health; only do blood tests (e.g. taking half a teaspoon); or try out new treatments to see how well they work - these generally also require taking small blood samples.

Many of the treatments and vaccines we use today were developed in this way through research done in the past. But children are very different from adults in the kinds of health problems they have and in the way their bodies handle different treatments. This means that research in children is important because otherwise it will not be possible to develop good new treatments for children in future. At the same time, clinical research in children raises some difficulties. While adults may choose to undergo any inconvenience, discomfort and potential risks that may be involved in clinical research, it is much harder for parents to make such decisions on behalf of their children. Many people feel that children should be protected from anything difficult as much as possible, but if children do not participate in research, how will we ensure they can be well treated if they become unwell in future?

In all the questions we will discuss in this group, there aren't any 'right' or 'wrong' answers – we're interested in knowing *what* you think and in finding out more about *why* you think it. Thank you for taking part!

Feelings about taking part in research

1. If you were asked, how would you/do you feel about participating in clinical research? What might you feel pleased, annoyed or worried about, and why? [Look for 'hopes and concerns']
 - [Probe for direct experience] For anyone, is this on the basis of your own experience of participating in research in the past? If so, what was that research about, what did it involve and how old were you?
 - [For any worries] What could be done to deal with any worries? (E.g. ways in which the research might be carried out that would feel better/more comfortable for children?)

Influence of type of research

2. Do you think your views would be different for different types of research? Earlier, we talked about research that involved only asking questions, or only taking blood, or also trying out new treatments (including some blood sampling) to see if they worked. Do the differences between these types of research change the way you think about participating? In what way? Are there other differences in the type of research that would change your point of view?

Influence of age of child (introduce and follow up in Q 5 & 6)

3. Would the age of the child asked to participate make a difference to you? If so, what kinds of ages would make a difference?
 - [*Probe where needed*] For example, most of you in this group are between (aa) and (bb) years – what if the children needed in the research were much younger than you, or older than you? What difference would this make, why?
 - What is it about those ages/age groups that make a difference?

Who should make the decision about taking part?

4. Who do you think should decide whether you take part in clinical research? (E.g. just you? You & your parents/guardians together? Your doctor & your parents? Someone else?) Why?
 - What do you think should happen if you want to take part in research but your parents or guardians disagree with you? Why?
 - What if you don't want to take part in research, but your parents or guardians think you should? Why?
 - What if your parents don't agree with each other about this?
 - Where studies are taking place only in schools, with the support of the DEO, does this make a difference to who should make the decision? (*Probe for role of teachers vs parents and of students; probe for studies that only include asking questions and those that include taking finger prick blood or urine/stool samples*)
5. Influences on making decisions:
 - We talked earlier about how issues might be different for children of different ages – how would this affect your views on who should make the decision about taking part? (e.g. babies, young children or older children – see responses to Q3)
 - What about the gender of the child? Would that make a difference & how? Any relationship to age e.g. boys considered more able to make independent decisions than girls of same age, or vice versa?

- Do you think religion plays a role in making a decision on child participation? If so, in what way?

Should children participate in research that will not benefit them as individuals? [If time]

6. If you were told that the research probably wouldn't help you but might help other children in the future, would you still take part? Why/why not?
 - [Linked to Q3] Would the age (of the child) make a difference? i.e. if the child asked was older or younger than you, would this make it seem more or less reasonable? In what way?
 - Would the type of study make a difference?