

# Transcript of the Webinar 3 questions and answers

## Topic: Inclusion of people who can't consent

Date of webinar: Wednesday 17<sup>th</sup> May

### **Introduction**

Audio recordings were made of each of the webinars and transcripts were made of these. The following questions and answers are what was recorded in webinar 3 and are set out below. The only edits that have been made are to remove filler words (for example 'um') and repeat words. Some footnotes have been added which provide post webinar clarifications from the Spectrum 10K team.

**Question:** The survey explained by using both health related information provided by participants in the questionnaires and information on health, from electronic health records, Spectrum 10K can consider possible inaccuracy in medical records. Is it appropriate for the study team to spot errors in the participants medical records before they do, and may not even tell them about it?

**Answer:** The purpose of collecting data from two different sources - one is the electronic health records and on this using a questionnaire - is not necessarily to spot errors. And indeed, we have no reason to suspect that one is better than the other. But primarily because we know that electronic health records, even though they capture a whole lot of information, they can be quite incomplete. You can get certain types of information from electronic health records, and in the UK we're beginning to realise that they often are not as good in terms of capturing all the health information as we thought they were. But then, in addition to that, we also know, and this is from conversations with several people in the research space, autistic, non-autistic folks and clinicians, etc. that a lot of people might feel that they have a particular condition, especially a mental health condition, but may not have sought a diagnosis or may not have been diagnosed. People might also feel that they may have been misdiagnosed with something. So, for example, something may be recorded, but they may feel that actually that is not really what it is, but they might think it's something else. And it's essentially to include that information as well.

We want to create a space for people to report whether they think they have a diagnosis of something, or whether they think they have something but have not been diagnosed or they suspect that they have something. Capturing mental or physical health conditions is hugely complex, and we want to use multiple different streams of information. In no way do we think that if one source of recording says that someone has a condition and another source doesn't

say that, that one is correct and one is incorrect, it's just the nature of the fact that these things are incomplete, in general. We also know with self-report questions about different health conditions, we can't be quite exhaustive, because of people's time, and how much we remember, and so an electronic health record might do a better job on covering and may be more exhaustive in all the different set of conditions people may have been diagnosed with, with a self-report, we're focusing on perhaps some of the more common ones that people may remember.

**Question:** The consultation survey notes that the issue we're talking about in this webinar, having capacity to consent, is subject to further conversation, discussions with the Health Research Authority (HRA). Can you elaborate on what conversations you've been having with them? And what issues they have raised about this aspect of the study?

**Answer:** We have been in discussion with the HRA. So, one aspect of the discussions that we've had with the HRA has revolved around the possibility of professional capacity assessment within the project. Our original plan, because the project is online was to provide capacity assessment online with carers, family members, doing that. We spoke to the HRA who came back to us and asked, would we look at professional capacity assessment, which we said, that's absolutely fine. We reached out to 33 NHS sites, to ask them about this. Out of 33 sites, we got 11 back who said that they would be open to doing capacity assessment. And based on that, they would be able to look at that. However, they did express some concerns around resource and staffing. So clearly there's going to be an issue for an individual who's in one part of the country who might need capacity assessment, and there may not be a local solution available to them. That's a problem because if you're going to have capacity assessment done professionally, and it has to be available locally, it has to fit into people's lives. So we looked at having a dedicated capacity assessor within our team. For us to do that, we spoke to an individual about this and the specialist, and they recommended that it should be a member of the Spectrum 10K team. We are a very small team, only five people. So, in terms of resources, we also have difficulty. Practical things to think about in terms of capacity assessment, for example, we don't know the individual, we don't have access to their medical notes. There is context to capacity assessment that would be very difficult to perform for a member of our team to perform in that circumstance. So, we are speaking to the HRA, and we've raised this with them and we're waiting to hear their response. We've outlined the concerns and the issues that have been raised but we're still waiting for response.

**Question:** How are Spectrum 10K and the Autism Research Centre (ARC) ensuring that they have received consultation feedback - heard concerns - from those who cannot consent during this process?

**Answer Consultation Co-leads:** First off, we don't know who or who doesn't have capacity to consent to research when we're engaging in the consultation as they are completely different things. We don't know, but many of the people who can't consent to research also will have a learning disability and have some communication problems. We've tried to have many different ways of being involved, including the easy read survey. For people who have very limited communication, it is really challenging. And I've done this on other projects, and it's very hard, and takes a huge amount of time and resources that we don't have to do that. But we did ask for various different bits of demographic information for the people who volunteered for the co-design, including whether they had a learning disability, whether they were relative, or somebody had a learning disability. And so we try to get as wide as possible in that. So those are the things that were, and we also have interviews, so that people who can't engage in this time and social space will specifically look to include them by doing the interviews. But that's not to say that we've actually done a great job of getting a hold of and views from people who have limited communication ability, because that is actually just something that's very, very hard to do. So, we've tried, but that doesn't necessarily mean that we've done that we've achieved it or achieved any ideal.

**Question:** How can Spectrum 10K guarantee that children and adults without capacity to consent will not have their autonomy denied when parents can recruit their child if they do not fill in an assent form?

**Clarification of the question:** From the information we have, it says that children over six have the ability to understand that the simple form, the children's form, they'll be asked to give assent but that they can be included if they assent or if they don't do an assent form. So what about those who don't do a form? How can you be sure that they assent, or that you're not trampling all over their willingness to do it?

**Answer:** The key point here is, and I think this will be a key part of the working group is that we should aim to make this compulsory. Actually, there should be both parental consent, and child assent. Because obviously, for any child who takes part in the project the parent obviously gives consent. We provide assent and we provide age-appropriate information sheets, the child can decline if they choose not to assent. That needs to be respected. But obviously, we say if you're not happy, please don't sign this. But I think to answer the question directly, the key here is to have required assent plus parents' consent for all children over six years of age.

**Question:** There are things in child's environment that can be captured that are not controversial. Like where they live, other things could be more controversial, like their socioeconomic status, or mental health issues, or whatever. And what's the team's views on

capturing the more sensitive types of information? And on how to get parents' consent, to providing the information about the children and themselves?

**Answer:** There are two questions here but one of them is what we think about capturing very sensitive pieces of information. So of course, if the parent signs up, and then the whole family signs up, then we would know whether someone is autistic or not, I think that we do capture, but we don't really have a way of capturing how that might affect, in terms of environment, how that might affect a child's development. I don't think we're capturing that and I don't think there would be a way of doing that with the questionnaires we have at the moment. There are some sensitive questions about vulnerability, bullying, things that are important. And we think these are, first of all, they're optional. So, we've made these questionnaires optional. The participants can either skip a question, or they can skip the whole question, especially for the optional questionnaires. And we want to capture that information, mainly because we know that a lot of these variables like vulnerability or bullying, for example, can affect the child's mental health. And I think that would be important to collect when we're looking at co-occurring conditions in in autism.

First of all, I don't think we are necessarily looking at how parents with autism affects the child's development in any way that was not a part of it. And there are some areas that are ostensibly sensitive. Whether the child has been unfortunately maltreated, or has had experienced sadly, had experience of bullying and things like that. But from a mental health perspective, we know that these things are hugely important factors to understand mental health. And, when we were talking to various people about it and about what are the sort of variables we want to collect, there was a general feeling that even though these are sensitive, these are important variables to investigate. And if these are not investigated, we won't have an idea of what the impact of some of these sensitive aspects are on mental health.

And the second part of the question was about our views on how to get parents' consent to providing the information about their children and themselves. I don't know what this exactly means. I think most of most of you will know, but when a parent registers a child, one of the things we do provide for the child is age-appropriate participant information sheets. And maybe it [assent] should not be optional. And maybe the wording can also be worked on with the co-production group. But yes, apart from that, I don't know how to answer that question, because I don't know what it alludes to. But our views are that there should be safeguarding in place when you're recruiting children. And I think with this and the age-appropriate information, that's one side of it. The other side is that, of course, a child can withdraw. So, for example, the child can withdraw their assent before they're 16. And they can also withdraw their participation when they turn 16. So, there are safeguards in place for that, in terms of the child being able to decide on what is done with their data.

**Question:** There are autistic people without the capacity - or recognised capacity - to consent, express their viewpoints or advocate for their interests. It's often said that their families are the only representatives of the viewpoints. Are such autistic people included in the research? And if so, to what extent do Spectrum 10K believe that their families accurately represent their viewpoints and interests.

**Answer:** I don't think it's appropriate for us to comment on how families represent each other or how parents represent their children. I don't think it's possible for us to actually know that, absolutely. But obviously, we set things up so that the people can make an informed decision. We have included adults without capacity and people without capacity to consent, it was very important to us that we were to include people without capacity because the situation is that for a lot of adults with intellectual disability or adults who lack capacity, there has historically been under representation and research. So, what you see is lack of science that reflects the needs of this population. It was very important to us that we work to do this to make sure that we represent the full spectrum through the results of Spectrum 10K. And we provide an opportunity for people without capacity too, because the needs of that aspect of the community may differ from other autistic individuals. We have worked to do that. And we did that through building in the British Medical Association capacity assessment tool into the study website. So, capacity assessment could be performed online. And having specific questionnaires for adults without capacity, and obviously children without capacity may be consented by their parents. So yes, to answer question one, yes. And number two, the second question is not possible for us to comment on the representation of individuals.

**Question:** I've watched parents of autistic children on television who seemed to be autistic themselves, but unaware of the fact. So I was interested in how you'd get the parents to self-reveal. I think you answered by saying that that would depend on whether the family as a whole would participate in the study.

**Answer:** As a part of the child's questionnaire, there could be questions pertaining to family background in general, which could provide information about parent's diagnosis, or perhaps parent's autistic traits. If we have just a child participating, and the parents decide not to participate, we are more interested in a child's history. But we don't really collect anything beyond basic things, like you know, basic things like SES and or things like that. We don't really collect any information about parental diagnosis or parental autistic trait scores? So yes, I think what we said earlier is just correct that it would very much depend on whether the family as a whole would participate in the study, or whether one of the parents decide to participate in the study. And even if there could very well be a possibility that one or more or both the parents could be autistic, but they don't have a diagnosis. But really, without, we have no clear-cut way of seeing that just using any of the questionnaires. So, for example, we have a measure of autistic traits called the AQ. And we know very well you could score high on that,

and you need not be autistic. Or you could score lowly on that and you could be autistic as well. So that in itself is not necessarily a good proxy for autism, if someone is undiagnosed. But if the parents are participating, I think they have an option to say, I have not been diagnosed as autistic, but I suspect I am or I think I am that option is there. But again, it ultimately boils down to what parents feel about themselves and if they are participating.