Transcript

Challenges in ethical approval for vulnerable groups and multi-centre

Wendy McInally:

Hello, we're here today to talk about the young lives interrupted by melanoma, exploring the experiences within relational context. So hello, and welcome to these two short podcasts. The first will be around challenges in ethical approval for vulnerable groups and multicentre. The second will be about the research study and its findings.

The first will explore the challenges and ethical approval for teenagers and young adults with cancer. And this will be delivered to you by Professor Susanne Cruickshank. Susanne Cruickshank is the strategic lead for applied health research at the Royal Marsden NHS Foundation Trust, London, and she has been there since May 2020.

She leads the health services research group, a diverse portfolio of research that covers all aspects of cancer care from the point of diagnosis, it's interdisciplinary and is always clinically applied. Her work uses qualitative and mixed methods approaches which builds on evidence in different kinds of care settings.

Her recent work has focused on psychological interventions. She qualified as a nurse in Edinburgh and has over 30 years of experience working in oncology and hematology. She has held several senior positions across the NHS, the higher education institutions and third sector, and was appointed as an honorary professor at the University of Stirling in 2021.

She is a PhD supervisor and examines nationally and internationally. Susanne is a member of the scientific advisory board for prostate cancer research, a mentor for the NIHR, and is an international cancer expert for the health sciences research unit, the nursing panel, Portugal, and the European Commission. And Susanne publishes widely.

Susanne Cruickshank:

Hello. As Wendy said, I'm Professor Susanne Cruickshank, and I'm going to talk about our study. And just to recap on the title of it, young lives interrupted by skin cancer, exploring the experiences within the relational context. And what I'm going to do is just some reflections on the ethical process site selection and recruitment.

And really talk a little bit more broadly about, how might that impact on research in populations where the samples of those populations can be smaller? And how do we actually successfully access people to be able to enable them to share their processes? Because it's quite a complex process now going through the ethical processes. And I'm just going to take you through some of our experiences, some of the learning from it, and how we could help others in the future.

I think first of all, I'd like to thank all our participants and health care professionals and also our funder because they supported this important work. And here's a quote from one of the participants, another partner just talking about the importance that they held in terms of sharing their experiences.
And that do you know what this is important? And I think we need to just reflect on the fact that we can have a lot of processes in place from our ethical pathways to really protect participants against any difficulties that they may experience by being participants within research projects. But What would you need to do? Is make sure that we can actually enable people to share their experiences and be part of research projects which where they see they're very, very important.

So, one of the things that we recognise when we started this study was that the population of young people with melanoma aged 16 to 24 are sometimes difficult to find. And that is partly because it's classified as a rare cancer. And so, the numbers across the United Kingdom are smaller and pockets of-- and it's difficult to understand exactly what the pathway is for these patients because some of them might come in through the dermatology service. And some of them come in through the young people and adults' services. And some of them come in through the adult services for melanoma.

So, one of the things when we went set out about applying the ethical processes is permission to speak to young people and their significant others. And by significant others we meant any family member friend or partner that they wanted to identify as somebody that had supported them at any point of their cancer journey.

But what we had to do was, we had to go and speak to the sponsor of study. And we decided that we would use the hospital processes to act as our sponsor. And this is quite a long process in itself because most NHS organizations are used to setting up large trials. And so, their processes are very much geared towards trials, and all the processes that need to be put in place for the regulatory approvals.

But this was a qualitative study. We were looking for a small sample up to 15 patients and people with melanoma. And we were also looking for up to 15 significant others. So, we also had a timeline where our funding was for 15 months. And sometimes what we found was some of the challenges of the hospital processes getting all the sign-offs in place, getting everything reviewed prior to it going to the health research authority for further ethical approval, was actually quite long.

And there is something about trying to speed up these processes for these very time-limited projects. Where you know you're taking two, three, four months to actually get internal sponsorship signed off so that then you can go to the Health Research Authority. Now, when you submit to the health research authority, this is an online application. You have to submit everything.

We were very, very fortunate that we sort of-- the parts of the application process require patient and public involvement, and we were very fortunate to have Jack on our application and our project, and he was able to look at all our documentation to ensure that it-- we were writing it correctly and also anything that we could improve upon in terms of making the materials and user-friendly for young people.

But through this application process, that in itself creates further delays. They decided early on that this couldn't be an a proportionate review. And they have two processes where the first one is proportionate review where they see that the project is quite low risk and they will allow it to be signed off independently within 10 days through their research processes.

And the other avenue is that you actually have to attend an ethics meeting. And in our case, we went to apply for an ethics meeting, but we had to wait six to eight weeks before a meeting became available. And we ended up going to an ethics meeting in Scotland. And all these different steps mean that you cannot recruit any participants to your study until such times as you've had all these approvals in place.

And obviously, this was taking longer and longer within a 15-month project. And I do think that reflecting on it, there are processes that take place for some of these smaller studies that could be speeded up. But we attended the ethics meeting and they were quite happy with all the measures we put in place to protect the young people and support them during the interview process.

But then we decided that we would like to have another site. And we added in a what's known as a patient identification site. So, this required further amendment to enable that to happen. And I suppose one of the reflections from this process is that it's really important to look at these things really from day one about where you're going to identify your patients from to approach them for interview.

I think we were under the impression that the hospital we had chosen for the patients to be recruited from as a second site actually had a significant number of young people with melanoma. And therefore, this was going to be a really good addition to our current hospital site where I worked to enable us to recruit. But actually, as it happened, we didn't end up recruiting from that site at all.

But because every time that you do something, you have to go through a very large machine of ethics in a big organization. It adds another further delay to you being able to start recruitment. So, I think it's just one of the things that we've learned from this is terms of planning ahead with your ethical processes, really understand what's required at each stage.

For us, for the study, we approached 12 participants and we'd interviewed in the end we interviewed 11 participants. So, our sample of participants that agreed to be interviewed was very high. And I guess that's kind of one of the reflections. We went through a lengthy process to understand to identify the ethical concerns that we had and others may have about approaching young people to talk about their experiences.

And to share those experiences with us, they believed that the work was very important. They had not had that opportunity to share their experiences. But actually, to get to actually approach them, the gatekeepers along the way including clinical staff, NHS pathways, the way that you have to go about approaching them, asking if they want to participate, can sometimes create an additional barrier to these young people being able to participate in the study.

And as you can see, of those that were approached, we had a very high number of them that agreed to participate. So, we knew that people wanted to participate in the study, it's just that we had to find a way of navigating between the clinical areas, the clinical services, the ethical processes to enable us to ensure we were doing everything correctly but also actually enabling the person to know that the studies are actually happening.

We also need to work across teenage young adults and adult melanoma services. And that's really important because of the age range. In the UK, teenage young adult services are up to 24, 16 to 24. But in fact, many of these individuals weren't treated through those services that actually been referred through the adult services and didn't always know about the teenage young adult services in place.

The other thing that we wanted to ask them about was their significant others. Now, this was a slightly unusual study in that we were asking them to identify who the significant other. And what we learned from this was that most of the people that we recruited into the study were in their early mid 20s at interview.

That perhaps they had moved away from home, they were living at a distance from parents. So, we might have thought initially they would identify their parents. But in fact, many of them were working independently living away and didn't identify their parents at the time. And their significant others were maybe-- it was quite far on since they'd had the diagnosis and therefore, they didn't identify anybody.

But in fact, those that we did interview were very happy to participate. The other thing that I think is really important to consider about when you're interviewing young people is what their preferred method is. And what we found was that most of the young people wanted to be interviewed on an online platform.

One had a phone call, but the rest were-- but nobody wanted a face-to-face interview. And that was really important in terms of how you plan and engage with people who are younger. Who may-- they've got busy lives, they're often working, and they may live some distance away from the hospital especially those participants who were part of the teenager and young adult services. They're not always local to where people live, and they have to travel and the geographical area associated that's quite large.

So, as I say, most of them wanted to be interviewed. And that's maybe been a change since the COVID pandemic where we've prior to that we've always had seen everybody face to face. But now people are much more comfortable, and especially young people they're very comfortable with these social platforms, these online platforms and it's quite natural for them.

One of the things that I think is quite important, especially when you're thinking about this population and recruiting them, is how they engage with you as researchers and how they access you. And in our case, it was very much about accessing us through a mobile phone. And that was really, really important for us because they don't really pick up the telephone.

Many of them don't often use email. They use social media platforms, and they're used to being on their mobile phone either through WhatsApp or through text messaging. And that was the way that most of the interviews were set up was they were engaging, they were contacting us by mobile phone.

So how does this sort of inform us? And how do we kind of learn from some of the experiences we've had? Well, there's no doubt about it in the NHS. And the number of gatekeepers in place that create barriers to patients to being able to participate in studies that are non-drug studies is quite sensitive. And I think what we would advocate is that we need to look at limiting the number of gatekeepers to enable individuals with melanoma opportunities to participate in non-drug studies.

I mean, one of the important things about anybody who has cancer is that it's not just a cancer and a disease, we have to look at the person holistically. And we have to think about what they young person requires both their physical, their psychological, their emotional needs, social, financial needs may be. And the only way we're going to understand what kind of interventions are going to support these individuals at different stages of the cancer pathway is actually by listening to them, hearing their experiences, and actually working with them to develop effective interventions.

So, it's really important that we don't just focus on the huge advances we've seen in drugs, but we also listen and hear their experiences. And so, we need to really think about how we reduce some of the gate-keeping around deciding whether somebody's going to be approached or not to participate. And what we found with our participants was that we had participants at all stages of the pathway. Some of them had a recurrence, and therefore that didn't negate their interest in wanting to participate.

Also identifying sites carefully, I think that's really very important. And really investigating early on and about the numbers. Choose the right pathways are to recruit the patients, and maybe not sort of assuming that it's going to be one particular individual. And actually, look at how we share knowledge about the studies within the teams I think that we very much learned from this work that we have to work across the teenage young adults, the adult, and the dermatology services to actually maximise our opportunities to meet and enable in this age group to participate in these studies.

The other thing is the opportunities for the third sector to be involved in disseminating and sharing these opportunities. And also think about social media. I think we had some really interesting discussion about the use of social media at our stakeholder event. And what came from that was that actually, social media is such a sort of busy landscape as well. And because we know that this group of people with cancer there are less of them that actually maybe this social media may not be a good solution.

And actually, we do continue to work with the NHS TYA Adult and Dermatology Services, but actually think about our communication early on so that they are aware that the studies like this are available for individuals to participate. So, thank you very much, I'm Professor Susanne Cruikshank, a strategic lead for applied health research at the Royal Marsden NHS Foundation Trust in London.

Speaker:

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