**How has design research shaped the Generation Study**

**Behind the Genes Transcript**

**Oznur:** Welcome to Behind the Genes.

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**Oznur:** My name’s Onzur Ozkurt and I’m the director of design and research at Genomics England. On today’s episode, I’m joined by Mathilde Leblonde, senior design researcher at Genomics England, Rebecca Middleton, and Sandra Igwe, CEO and founder of the Motherhood Group. Today we’ll be discussing how design research was used in the Generation Study by involving participant and users’ voices to address ethical considerations, implementation and consent. If you enjoy today’s episode, we’d love your support. Please like, share and rate us on wherever you listen to your podcasts.

**Oznur:** So, before we dive into our questions, would our guests like to briefly introduce yourselves to our listeners? Sandra, let’s start with you.

**Sandra:** Hi everyone, I’m Sandra Igwe and I’m the founder and chief exec at the Motherhood Group. The Motherhood Group is a social enterprise that supports black mothers, birthing people in their pregnancy and beyond.

**Oznur:** Great to have you on the podcast, Sandra. Rebecca?

**Rebecca:** Hi everyone, I’m Rebecca, I’m a rare condition patient, and I also have the pleasure of chairing the recruitment working group of the Generation Study.

**Oznur:** Fantastic, thank you, Rebecca. And over to you, Mathilde.

**Mathilde:** Hi, I’m Mathilde. I’m leading design research on the Generation Study, and I have had the pleasure of working with Sandra and Rebecca and many others, trying to shape the processes and materials of recruitment and consent in the Generation Study.

**Oznur:** Fantastic, thank you. Mathilde, let’s start with our first question. What is the Generation Study?

**Mathilde:** Sure. So, whole genome sequencing is a technology that’s improving. We’re finding new ways of using that, and there’s interest globally to explore the use of this technology to screen for rare genetic conditions in babies, so that we can treat them earlier on, so they’re not having two different departments trying to figure out what’s wrong with them. And because we can look for hundreds of conditions with whole genome sequencing, it’s really much more efficient, and we’re able to look at these rare conditions, so it’s really exciting. There’s still a lot of questions about implementing this operationally within the NHS, and so the Generation Study is aiming to explore this. We’re going to be aiming to recruit 100,000 babies across England to take part in this, and they will be staying on the Generation Study for 16 years, or until they withdraw, so that we can see how their health develops, and really understand how genes affect their health.

**Oznur:** Thanks Mathilde. And if you’d like to learn more about the Generation Study, you can listen to our previous Genomics 101 podcast called What is the Generation Study, and Which Conditions Will We Look for Initially in the Generation Study.

**Oznur:** Mathilde, can you briefly outline for us what we mean by design research?

**Mathilde:** So, design research is a design and research methodology, which involves users from scoping through iteration. So, even back when we didn’t know this would be called the Generation Study and we weren’t even sure of the boundaries of that, we were involving parents, NHS staff and other users of the service to try and understand what it might be. And later down the line it went all the way through to iterations once we started having materials and a better idea of what it could be like separating with users outside of the company to understand what their needs are, what would work well for them, and how we can shape the whole service to do things better.

**Oznur:** And how have we implemented design research in the Generation Study?

**Mathilde:** Yep, so we’ve also done a lot of engagement, which was bringing public views in the form of public dialogues, so understanding which conditions should be looked for, what principles should be guiding that work, but also we’ve been involving users in regular rounds of codesign and usability testing to understand what works and what doesn’t work. It’s been around 105 people now that have taken part, and it’s only going to be growing. Involving users has been shown to improve the implementation of interventions in the healthcare context, so we really hope that this will help the Generation Study when it launches. And regular rounds of codesign have had to be balanced with ethics, operations, feasibility, but I’m proud to say that user perspectives have been central to the decisions of the programme throughout.

**Oznur:** That’s fantastic to hear. I’m going to come to Rebecca and ask, why is it important for us to be guided by the patients and the participants?

**Rebecca:** It’s absolutely central, and the public dialogue that really underpinned this, which started in 2020, the messages from that have really come through to the whole codesign process of the project. The public consultation really told us that people were genuinely keen about the project, but wanted to ensure that they were part of the process, and that coproduction really began from day one. This is a new world leading project. This has not been done before, so we needed a whole new approach to how we produced and how we designed this with patients and with parents, and that’s exactly what we’ve done. And why we have done it is because we know ultimately it leads to trust within the project, within the research study, which is essential, as I say, ‘cos this is a world first. But it also leads to better consent, a better pathway through the study, a better results pathway as well, and all the way through, ensuring that expectations are managed, that there is transparency, and people are fully informed and can make the right decision for themselves and for their baby.

**Oznur:** Thank you. And would you like to add something, Sandra?

**Sandra**: Yeah, so I know from my community that we represent black mothers and black ethnic minority patients and participants, and we have very unique lived experiences that many research may not be privy to or just do not understand. And so engaging with patients from the community ensures that research is grounded in real authentic community needs and priorities. And also involving women like myself and those from my community, it can really help to identify and overcome barriers to inclusion or getting mums involved. I know I always hear, you know, “Sandra, black mothers are so hard to reach, they don’t really get involved in research.” Well, if you include those from the community to lead in the research or support in engagement, you will have a lot more uptake, and it leads to more accessible inclusive research, which of course everyone really, really desires to have more of.

And then also participants from the community can flag issues and suggest solutions that researchers may miss, because it’s not knowledge, it’s experience. It’s, you know, having someone go through the experiences without necessarily studying it, but again lived experience to me, it’s more crucial than any other experience that you could possibly have.

**Oznur:** 100 percent, lived experience is really, really crucial for us to make the services that we’re making really speak to the actual context of our users. Thank you for that. And Rebecca, how has this process been different to the 100,000 Genomes Project? What was your experience?

**Rebecca:** I was consented onto the 100,000 Genomes Project back in 2015, and I can remember that experience very vividly, on a cold, wet December afternoon, going off to meet my genetic counsellor, and receiving the consent form for the 100,000 Genomes Project, which was very much like War & Peace. Scratching my head at the time, going, “Gosh, I’m going to have to put a couple of hours aside to go through this.” And then going home that evening and sitting on the sofa, and, you know, considering myself an educated woman, just realising I had so many questions. I really didn’t understand it, and I needed somebody to help me unpack this, and translate it. And I’m pleased to say that our consent process and our recruitment process is very different to this, which is a fantastic thing.

And what’s really key about the lessons that we have learnt from the 100,000 Genomes Project is that, to really build trust in a research programme and a new research programme, you need to manage expectations, and that’s wrapped up in building trust around the programme as well. And with the 100,000 Genomes Programme, there have been challenges and issues around that expectation management, and some expectations weren’t managed. And even now nearly ten years on, we are still feeling the effects of that, and patients and families are still feeling hurt because of that. So, we have learnt from that and therefore we have designed a process with patients and with parents. We know that no two experiences are the same, that we have to ensure that we remain flexible, and we have to ensure that we are addressing any misconceptions, any misunderstandings.

Perception and reality have to be treated the same. We have to understand how people are understanding genomics, because outside of pockets, genomics is not a standard NHS piece of healthcare. So, people come to this study with different assumptions, and we have to learn to go beyond them. We have to understand what their health literacy needs are, and how we can help manage that, how we can help translate, so that nobody is stuck at home on a cold, wet December evening, scratching their head, going, “Well, I don’t know what this actually means.” We are ensuring that the NHS professionals and everybody involved in the pathway is fully aware of how to explain the project, explain the risks, explain the benefits, and be fully transparent. And we know what the risks and the benefits are that need to be addressed because we’ve asked parents and patients as well.

So, we know the challenges and we’re trying to address them head on, and that’s essential. It’s essential in building trust, and that’s one of the key learnings from the 100,000 Genomes Project. And it has been brilliant to be involved in this project and really kind of learn from that past experience, but move forward in such a unique and fresh way that really will have benefit to those new parents.

**Oznur:** Thank you, Rebecca.

And we have been talking about the consent process in the context of newborns, and we know that, while consent given for newborn screening is really high in the UK, parents often leave this conversation relatively uninformed. Sandra, can you tell us a little bit about what you think the risks of not designing this consent moment appropriately might be?

**Sandra:** I guess not designing appropriately can break down trust. So, I think engaging in a variety of parents in this research and design is crucial for trust. And that’s a topic that’s come up many times in our community is that they believe that there is a lack of trust between research practitioners and this wider system as a whole, and the community of marginalised patients, parents, mothers. So, I think it’s really important that communities have this. But also researchers must make the effort to meet parents where they are at, not just physically but also conceptually, as well as emotionally. So, hosting conversations in familiar, comfortable community spaces is essential. We had our session in our hub, our community hub, and mothers were really familiar with the space and with each other as well. And so partnering with local grassroots organisations and leaders to create inroads is so beneficial, and I can hand on say that when you connect with the community, you’ve already done the first step in building trust.

And consent conversations should be guided by what matters most to each parent within each community, ‘cos every community’s different and every patient is different as well, and so that may require different focuses or different formats, or different messengers for different groups. And so we like to have people with lived experience from the community representing that, and also driving the uptake of consent as well. But failing to engage diverse voices can lead to perpetuating inequalities in access and uptake, so it’s really important to have representation because the lack of it in research can overlook communities’ specific concerns and needs.

**Oznur:** Absolutely, and that inclusion is really important for the study. Is there anything you’d like to add, Mathilde?

**Mathilde:** Yes. When we talk about consent, oftentimes we think about that one moment, the moment of conversation with a clinician, and signing on the dotted line, and I think what we have done here in the Generation Study is to consider recruitment from the very first time that they hear about the Generation Study all the way down to that moment. And it’s been really important because, yes, the moment of consent - you know, during pregnancy, you’ve got a lot of information coming in, a lot of different priorities, so you may be a little bit all over the place and not understand specific things, or not have the time to really spend thinking and understanding jargon, etc. And that presents a big risk because, when you may receive results, there may be confusion. There may be a loss of trust if there’s media coverage that talks about the Generation Study in a way different from what you had understood it. So, these are some of the risks that we’re trying to avoid.

But the big risk is also, as Sandra has said, the risk of not engaging a wide variety of parents, not just in the moment of consent but the whole process. So, if we’re thinking about where we’re using the word genomic and how are we using that, this is a word that’s actually really scary for a lot of people. And we might be very proud of the cutting edge technology that we’re using, but actually it can sound very science-y and almost sci-fi to people. So to us, the moment of consent is really from the first time that you hear about the Generation Study, you start creating a mental model about what that means, all the way down to the consent moment, when the samples are taken, the results and beyond. It’s really been looking at this whole journey holistically.

**Oznur:** And that language point is a really interesting one. I know that the study is obviously being communicated to the public through posters, leaflets, websites, which speak to how the study works, you know, the conditions we test for, and the benefits and risks of joining. There’s a lot of language. There’s written words in there, there’s audiovisual content, videos, images. How did we inform what type of content is needed to communicate the depth of the study?

**Mathilde:** I think the example of the introduction video is a really good one, and I want to discuss this a bit with Sandra, because actually it was quite a crucial turning point. We tested the video several times in user research before and after the Motherhood Group workshop, but the thoughts that her community gave us really helped change the tone of this video from something very professional to a conversation between parents raising questions. I wonder, Sandra, if you remember what your community’s feedback had been, and if you can talk a little bit about that.

**Sandra**: Yes. So, the mothers from our community at the Motherhood Group definitely gave lots and lots of feedback that the initial posters didn’t really resonate with mothers from our community. They said that the visuals and the language felt a little bit generic and also too clinical, and it didn’t speak directly to our community. They also expressed that seeing more black parents and more black families represented signals for us too as well – so, seeing people like look like us in the posters and the media would have allowed a lot more uptake. So, narratives and videos featuring real people that looked like members of our community, they expressed that would go a lot further. And also it made them feel a lot more relevant, and again it goes back to the notion of having more trust and feeling less abstract, but more like an authentic way of engaging or directly communicating with our community.

They also appreciated the effort to be more upfront, but the risk and also the downside, not just selling only the positives. You know, members from our community were saying they wanted to know the real deal. And also our community have been misled in the past. You have to understand that. The history kind of shows that there has been a breakdown in trust, and so transparency, they shared, was really, really key to rebuilding that trust, as well as materials that are culturally tailored and designed for different formats for our community.

**Mathilde:** It’s really exciting how much this feedback has pushed all of us in the team and the designers – pushed us to think about how to talk about the Generation Study, what narratives to use, what tone of voice, but also you’ll see on the posters there’s space there to have photos of several different family types and people of different backgrounds. It’s not just one photo. And there’s also some very small tweaks, it seems like, but it actually has a very big impact, about what it is that you’re trying to say and what people understand in a split second when they’re seeing that.

**Oznur:** Absolutely, and that open dialogue is definitely key to keeping on bringing those perspectives in, and keeping updating and moving the language of the study as well. Obviously, the study will keep being shaped. I’m curious about how will design research continue to shape the Generation Study going forward.

**Mathilde:** Yep, so we will have an iterative process, where we’re still listening to the sides as they’re launching to hear what are the questions that are being raised, what are some of the challenges that they’re facing. At the same time, we have a survey that parents will be able to fill in, and we have an evaluation partner, UCL, who is doing an independent review of how well all of this is landing, and evaluating the work that we’ve been doing to see is it really hitting all of these points, and what we may need to be iterating or changing as we learn.

**Rebecca:** I should also point out that the recruitment working group is very much in the background, but we are still very much alive, and we will come back to look at those first pieces of feedback and to look at what the experiences have been, and how we can learn and how we can help kind of shape what comes next. Because it’s critically important that we have this always learning philosophy. It’s critically important that now, you know, the rocket has launched, how will it land, and we don’t know until we’ve actually had that feedback. So, we can plan and absolutely plan to the nth degree, but actually how it exists out there in the real world, we won’t know until the project goes live and that feedback comes through. And that’s what we’re also really excited about is to actually learn those first lessons and see how we can support going forward, and see what needs a tweak here, a change there. And again, it’s that dialogue that started with the public dialogue back in 2020, and here we are in 2024 and that dialogue will still continue, and we are still listening and we are still learning.

**Oznur:** Thanks Rebecca. I’d like us to reflect on the importance of continuous learning. What’s the importance of continuous learning in this project? I’ll start with Sandra.

**Sandra:** Continuous learning to me and my community really means listening to the voices that are often seldom heard. It means trusting and placing trust in the community to be a part of or lead or be involved in research, changes that affect our community. It also means actively and proactively working to rebuild that trust, because there’s been a lack of trust from the community, and that means transparency. It also means honesty, and it also means continuous involvement as well. There’s no point in involving us at the end of a study for our feedback, but at the very start to show that you are trying to be authentic.

**Rebecca:** Ultimately, genomics is the science of people. Genomics is people, so we have to keep talking to the very people that we are looking to try and support, help, care for, and ultimately impact them and their families as well. So, I completely agree with Sandra, continuous learning, it’s a continuous dialogue, and understanding how our opinions differ, how our opinions may shape and grow as the general conversation about genomics continues as well in the public discourse. So, we have to understand and we have to stay sort of on our feet, that this is a dynamic conversation, therefore we need to change and we need to remain flexible as well. And if we keep our ears open and if we keep our minds open, then we will continue to build that trust, and we will continue to ensure that we have a robust study that will ultimately fulfil its research aims.

**Oznur:** Thank you. And Mathilde?

**Mathilde:** I think there’s only so much that we could really cover in theory before we launched, and now, you know, it’s going to go out into the world, and there’s many things that we couldn’t have predicted that will happen. We have that humility to understand that. And what’s super important going forward is that we have a team there to keep kind of staying on our toes, listening to what’s happening, to make sure that we respond to that, so that, as Sandra said, it’s not enough to just ask people afterwards. It’s also not enough to engage just at the beginning and then stop listening once we’re live, once it gets hairy and a bit difficult. So, we are very excited to find out all the things that we hadn’t considered before we launched, and just continue to learn.

**Oznur:** We will wrap up there. Thank you to our guests, Rebecca Middleton, Sandra Igwe and Mathilde Leblonde for joining me today as we discussed the use of design research in the Generation Study. If you’d like to hear more episodes like this, please subscribe to Behind the Genes on your favourite podcast app. I’ve been your host, Onzur Ozkurt. This podcast was edited by Bill Griffin at Ventoux Digital, and produced by Naimah Callachand.