Risk Prediction in the Clinic

I come at CanRisk from two viewpoints: one as a health services researcher, and secondly as a health psychologist. When we did the usability and acceptability studies, we knew that to make CanRisk more usable and more acceptable, we needed to develop a patient-facing add on to help patients collect data. If you're in primary care and you've only got 10 minutes anyway, you want to spend all of that time telling people about what to do once they've had their risk calculation and organising what happens next.

We're actually going to make a separate add on tool that's going to be called CanRisk-P or CanRisk-Patient. Now, this is a user centred design process, working out what it is that patients, might be patients who are turning up to their GP and saying: “I'm really worried, my mummy and my aunt and my granny have all had breast cancer”, and CanRisk-P would allow patients to collect all of this data. So when they come in for the clinical consultation, the GP can sit down with them and say: “thanks for getting all this information together, I've run a CanRisk calculation, your risk is moderate risk, this means I'm going to send you for early screening, I'm going to prescribe you some chemo prevention, and I want to see you again in 12 months to think about how you’re getting on.”

The first thing that we're going to do is speak to people who might reasonably use a tool like this and find out what it is that they want. We know that the hardest thing that we're going to have to work out how to do is collect family history information, because it's complex, how far do you go, how much information do you need? So, we’re going to spend a lot of time in this early phase working out how we're going to do that.

Then in phase two, we're going to make a prototype, and we're going to have this iterative testing cycle, so we’ll take it back to people, say: “what do you think of this, have a go, how can we improve it?” And then we move into phase three, once we have a good working prototype, giving all of these data to a healthcare professional in a simulated clinical consultation; do we get the same amount of data, the same quality of data, the same accuracy of data, by getting patients and the public to do this before they come into clinical practice?

Once we have this, we're going to combine it with the normal CanRisk, and we're going to test whether CanRisk can be used in clinical practice, and we're going to do this in two settings. First in primary care, second in clinical genetics. There'll be an initial assessment, to see whether a woman is affected or unaffected. If they're unaffected, they'll be sent the patient-facing CanRisk tool and consent for the study.

Those who do consent to be entered into the study, they're going to be randomised either to the control arm or to the experimental arm. For the control arm, they'll get care as normal, and then we're going to follow them up at one, three and twelve months via post, and we're going to ask them about the different elements that I showed on the initial site. So; uptake of any risk reduction option, psychosocial impact, patient experience, and we'll be monitoring their health services use so that we can do the economics impact assessment.

For those who go into the randomized arm, the genetic counsellors will start collecting information about any cancers that have already been in their family so that we can get the fullest picture as possible. We will also be asking patients to do a saliva sample so that we can work out their polygenic risk score, because that's one of the risk factors that is included in the multifactorial model. But it will give us the most comprehensive, most complete risk. Once we have all of these data, we’ll run the risk stratification using CanRisk and people will be allocated to one of the three risk groups.