Partneriaeth Genomeg Cymru
Genomics Partnership Wales

Patient & Public Sounding Board Newsletter

Issue 1, April 2019

I have been committed to establishing a strong patient and public involvement strategy to shape the work of Genomics Partnership Wales, since the day I was appointed to my role as Head of Programme. Over the past 12 months, whilst establishing a number of other work streams, I consulted with a number of individuals and organisations to ensure that my initial ambition to create a Patient and Public Sounding Board was informed and supported by patients and the public.

I was delighted to welcome you all to the first two-day event, and was greatly enthused by the way you formed a strong and trusting group so quickly. This enabled a constructive and diverse discussion on the theme of 'Consent to Research Studies', which will greatly help to inform the next steps considered by members of the Consent Implementation Group.

A great strength of this group is its diversity; collectively you represent a range of patient experiences - from rare diseases and cancer, to genetic testing during pregnancy, and you also represent a geographical spread across Wales. Some of you are experienced in Patient and Public Involvement and others are new to it. These are some of the reasons that I am excited to see this co-production evolve, building on strong foundations set by this Sounding Board.

I'd like extend my sincere thanks to you all for your contributions and ongoing commitment, and look forward to our next meeting already!

Dr Catrin Middleton
Head of Programme
Genomics Partnership Wales

Day 1: Welcome and Induction

Welcome to the Genomics Partnership Wales Patient & Public Sounding Board! Members travelled from North, South, East and West Wales to meet for the first time in Cardiff for a two-day residential event; a chance to get to know one another, to meet the team, and to begin on the work of co-production!

You heard a few key introductory presentations from Rhys, Catrin and Michaela, providing you with a background to Genomics, the Genomics for Precision Medicine Strategy and how this Sounding Board provided the foundations to the Co-production theme.

We then enjoyed a session led by Emma, discussing the Terms of Reference for the Sounding Board. Thanks to you all for your contributions; it's important that these reflect your expectations and ambitions for what the group can achieve!

We concluded the day with a 'Glossary Game' – how well had you all been listening to the presentations throughout the day?!

Day 2: First Consultation – Consent Models

Time for Co-Production!
We were grateful to Professor Angus Clarke who set the scene with an engaging presentation about the journey to understand the genetic basis to the rare disease Ectodermal Dysplasia (ED), a process to find a treatment which has taken several decades and is still ongoing!

We sought your input on multiple scenarios that explained how a patient was being asked to take part in a research study which involved a genetic test. How did these scenarios make you feel? Were the approaches acceptable, or were there elements that made you feel uncomfortable?

There was a general consensus that 'consent' is a highly complex subject, and that the individual circumstances played a big role in deciding whether something was appropriate or not.

Three models of consent were considered – turn the page for a re-cap!

Research Consent Scenarios – Group Discussion

Scenario 1

Parents with a child with an undiagnosed genetic condition, all investigations to date have found no explanation. Sample and data de-identified and available for further research as required. Results emerge – one likely to provide a diagnosis and one additional relating to cancer risk so having family implications – but cannot be passed back to family as no longer a link to personal details.

General feedback

You felt sad and disappointed that these results could not be related back to the individual, and that it was a missed opportunity to provide answers to the family about the child's condition and additional findings where action could be taken to mitigate the risk.

What you liked…

The use of clinical samples and data in research was a good thing; in this case results would benefit future children and this particular family may benefit from the research in a broader sense.

What you felt uncomfortable about…

There were mixed views about additional findings – some of you would only want to know about actionable results, whereas others would want to know everything that was found. You felt that there should be a "key" held so that general research results can be reported back to individuals and families even if they have not given direct consent and their information has been used anonymously; the benefits to the family are huge as these results could affect management of condition or risk. It was felt that there should be a change in the current process to reflect this.

Scenario 3

A young woman with skin cancer consents to genetic testing to select best treatment. During appointment she is asked to give consent to be contacted later about becoming involved in research. Some time afterwards she is contacted by the biobank to arrange separate appointment to discuss consent to research

General feedback

You were broadly supportive of this approach as it gave the patient time to consider research and separates this from the clinic appointment; may reduce the risk of an emotive response.

What you liked…

The most positive aspect was that the patient was given more time to consider providing research consent, away from their clinical care process, with the flexibility of changing their mind.

What you felt uncomfortable about…

You recognised that extra resources would be needed – two separate appointments, careful planning and co-ordination. Flexibility is needed as depending upon circumstances an individual may change their mind about research consent between the two appointments, so the ability to withdraw consent must be available with the understanding that care and treatment is not affected. You also felt that the limitations of the possible research should be made clear to the individual; for example, not receiving individual research results back. You also felt that some regular information about the research studies using the biobank would be useful.

Scenario 2A	Individual with family history of bowel cancer attends Clinical Genetics department and gives consent for genetic testing. During appointment also asked to give consent to provide samples to biobank for research
Scenario 2B	Individual attends Oncology clinic and given breast cancer diagnosis with possibility of condition being inherited; agrees to genetic testing to determine treatment and risk for relatives. During appointment also asked to give consent to provide samples to biobank for research

General feedback

You broadly agreed with research consent taking place in clinic so long as full understanding of information given was achieved. You felt that the risk of this approach is that the response from the patient at the time may be an emotive one depending upon their clinical situation. The need to give patients the time to process the information was paramount.

What you liked…

You felt that less resource was required as both clinical and research aspects were dealt with in a single appointment and the response was immediate removing any time delay.

What you felt uncomfortable about…

The emotional impact of the clinical situation could lead to any consent obtained not being fully informed; these scenarios do not give any time for the individual to reflect and digest the research information. You also highlighted that there could be some confusion for the individual between clinical and research consent.

Online recruitment to research

Recruiting patients after the clinic using an online method was also raised.

You felt that giving consent online seemed a reasonable option, and provided an opportunity to those individuals who are online to participate in research. However it does limit recruitment as not everyone is online.

You were concerned about lack of face to face contact and ensuring sufficient understanding that the consent given was informed. It was suggested that an online knowledge test could be used to address this, and also giving people the option to talk to someone if they wish.

Opt-out / Presumed Consent model

An opt-out model, similar to that in place for organ donation, was discussed. You raised some issues with this approach including defining clinical surplus for genetic samples, and when clinical use ends. Additionally, there would be no default ‘debriefing’ pathway with an opt-out model and no way to feedback to individuals as samples would be used anonymously. The need to consider the impact on the wider family was seen as critically important. However this approach was supported with robust safeguards and governance. It would remove the need for difficult conversations at difficult times, and be good for time-critical samples.

Summary & Next Steps

Your Say

You felt that ideally all research needs to be approved with the correct governance

There was some wariness around commercial companies' use of data for research. Some of you felt that a cost recovery model was appropriate rather than profit

Some of you highlighted particular views you have about certain types of research (e.g. animal testing) and any consent model must accommodate these different opinions

Some of you felt that there needs to be the ability for individuals to change their mind about involvement in a study

The broad consensus of the group was that consent is important

Understanding of the extent, and limitations of a given study needs to be made clear at the outset

You felt that any samples leftover once their clinical utility was complete should not be wasted and should be used for research

You felt that it was useful to link anonymised samples back to individuals should additional findings of clinical significance arise during research (and if the participant has consented to being informed of research results)

Your Impact

The feedback you gave as part of this consultation will be passed onto the Consent Group to inform policy development

Following further work by the Consent group to refine the options for research consent based on the Sounding Board consultation, a revised paper will be produced

This document will be disseminated amongst the Sounding Board members, by email, for final comments

Once this final remote consultation is complete the options will be presented at the GPW Governance Board to help inform the official Welsh position on genomic research consent

Your contributions are therefore pivotal in shaping the high level government position on consent to research

We very much value and appreciate your input and look forward to cultivating our relationship with this Sounding Board in the future

Dates For Your Diary

2nd Patient & Public Sounding Board
18th June 2019, 10:30 – 15:30
Venue – to be confirmed (Cardiff)

Outline Agenda:

- **Pre-lunch – public facing website content development**
- **Post-lunch – considerations for designing clinic waiting areas and clinic rooms**

Your input is sought for the 3rd and 4th consultations – where can your experiences add value?

The Genomics Ball

Celebrating two years since the launch of the Genomics for Precision Medicine Strategy in Wales!

We would like to extend a warm invitation to you all to join us for the Genomics Ball on Friday 19th July at the Exchange Hotel in the heart of Cardiff Bay.

This will be an excellent opportunity to hear from, and meet with, senior Welsh Government representatives and a wide selection of Genomics Partnership Wales partners.

Tickets available by emailing the GPW team – tables of 10, and partners are very welcome!

Feedback so far….

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