Public Consultation in the Introduction of a Laboratory Service Improvement

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Introduction

Laboratories carry out service improvement and new tests with the aim of providing a safe and quality service for patients. However, it is not standard practice for laboratories to engage directly with the public when planning or trialling service improvements.

In Wales the AWMGL is a partner organisation of Genomics Partnership Wales (GPW), and through GPW a patient and public sounding board (P&PSB) consultation was carried out for a planned service improvement-initiation of an RNA sequencing service to replace fluorescence in situ hybridisation (FISH) fusion gene testing, to capture issues concerning or affecting the public.

GPW Constituent Organisations

Genomics Partnership Wales is a programme board that was developed in line with the Welsh Government Genomics for Precision Medicine Strategy (2021) with the aim to manage the delivery of the strategy through engagement with all stakeholders (Figure 1).

Figure 1. Genomics Partnership Wales

Patient Sounding Board

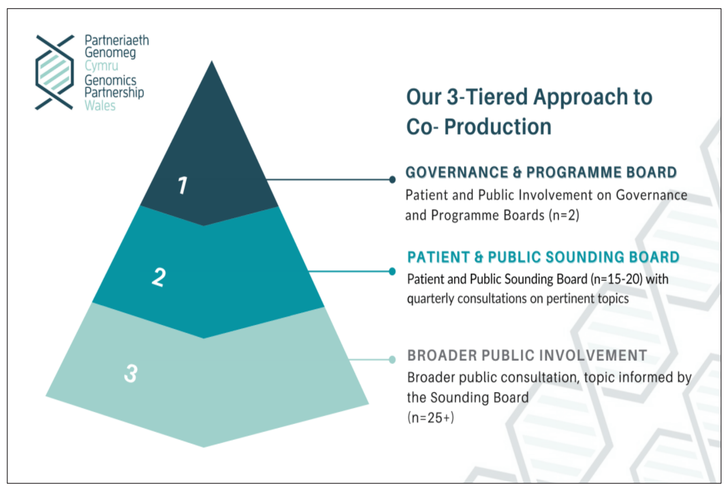
Regular P&PSB consultations are undertaken with a range of presenters and facilitators from the partner organisations after which the P&PSB are updated with progress / changes made following the sessions, through various channels of communication.

For this study a face-to-face session for the P&PSB was originally organised and designed to capture the potential impact of this service improvement project to the patients in order to attempt to capture issues concerning or affecting patients.

GPW has a mission statement to "Demonstrate a commitment to work in an open and transparent manner with patients and the public in Wales, using their collective experiences to shape and add value to the work of the Genomics Partnership and future genomics services in Wales."

In 2019 GPW established a Patient Sounding Board (P&PSB) which lies in the middle of their "3-tiered approach to co-production" (Figure 2) which meet with researchers, clinicians and policy developers regularly to consult and advise from a public and patient perspective on the development of their project, pathways and proposals.

Figure 2. 3-tiered Approach to Co-production



Methods

The session, carried out on Zoom due to COVID restrictions, consisted of a presentation split into 2 parts: an overview on the stages and considerations when a new test is developed and validated in the laboratory, and a brief presentation on the project for a lay audience. The P&PSB were split into groups and given a question to discuss (see break-out sessions). The findings were collated and a report generated by the GPW Programme Office.

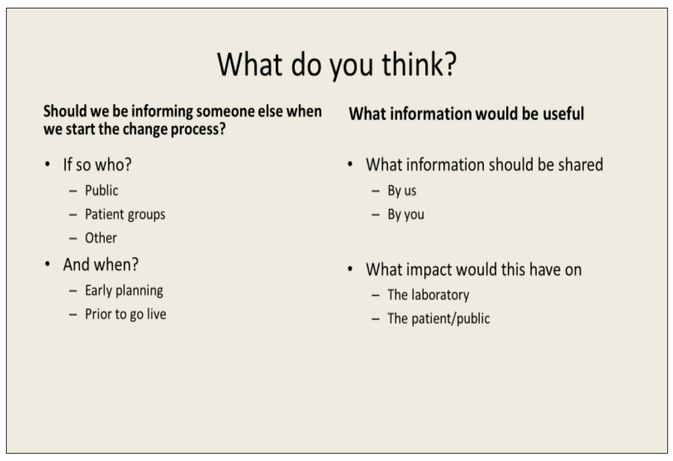
Pre-reading sent to P&PSB

FISH to Fusion: Change of technique for testing blood cancers

In the All Wales Medical Genomics Laboratory (AWMGL) a large portion of our work is the development of new tests. Those tests may be completely new, for a disease or gene that we haven't tested for before, or it could be that we want to change or update a test to improve it in some way. We will often gather help, advice and direction from Clinicians and other partners (academia, industry, other labs) but patients and the public are not usually directly involved. In this session I intend to give a brief outline of the work that is necessary to develop a new test and then an overview of one particular new test I am developing. I will be asking a lot of questions to try and capture your thoughts, views, worries, recommendations and anything else you want to feedback to me! In preparation for this you may want to consider the following question

If you read an article announcing a new test on the news what information is of particular interest to you, and is there ever/often information you think should be included that isn't?

Breakout sessions



The following conversational points were also used to stimulate conversation:

Cost of various tests-one test may give lots more information but be much more expensive-how would they feel if the test was available to fewer people because of it?
Incidental findings: a more comprehensive test may have a greater yield of results but what if some of them had unknown consequence?
Turnaround times: is there a trade of between speed and the amount of information?

Public & Patient Sounding Board Closing Report: FISH to Fusion

Key messages picked out by the authors are as follows:

1. Importance of trust. It was clear that the P&PSB felt that there was an expectation for the scientific community to provide services that were of benefit to patients and the public. It was not clear if this referred to the scientific community as part of the NHS or as a whole. The latter is more likely as there was a general lack of understanding from the public members of the board of how different scientific bodies relate to the NHS. For example, there was an assumption (from more than 1 member) that Cancer Research UK was part of the NHS and a confusion as to different pathways that a patient or patient sample may follow i.e. diagnostic testing (via an NHS laboratory) and research testing (via a trials facility). It may be that the public are more aware of organisations such as CRUK than a specialist NHS diagnostic organisation as they have a heavily promoted media presence and a clear message and name. Public engagement, via bodies such as the P&PSB, to fully understand the confusion, assumptions or lack of knowledge is the key to being able to inform the wider public in a way that is both clear and reassuring.

2. The impact of any laboratory change to the patient population and the public must be carefully considered and this used to inform exactly what information is to be disclosed to the public and when. It was clear from the consultation that, as was the case with public information regarding COVID 19 testing, confusion can easily take hold when various types of information are released without clarity of the intention of the sharing of it.

3. Along with clarity of message and intention, timing is a crucial part of successful communication. Again COVID 19 was used as an example of information shared too soon (vaccine updates months before there was likely to be a successful candidate ready and licenced for the public) leading to confusion, anxiety or eventual disinterest and boredom. Discussion was had around the complexity of validating some of the new genomic tests available for patients in the NHS following on from the presentation (appendix 3) and indicated that board members were generally unconcerned with being kept abreast of laboratory developments whilst in process.

4. The pathway the sample may take and the data that is generated. There was clear support for a reduction of the number of times a patient has to be "sampled" or donate tissue for a test in particular if it meant that a test could give more information in a shorter time period. It was also accepted that such tests may be at a higher cost initially but lead to efficiencies through a reduction in other tests and cost burdens due to a more accurate and clinically useful result. Support was also high for the retention of tissue for future testing due to a clear message that one of the most frustrating and negative experiences that patients share is multiple appointments and sampling when a more efficient pathway may be possible.

5. Incidental findings was touched on briefly as there is a potential for almost any test involving interrogation of a range of cancer genes to illuminate a finding that may have wider implications for the patient and their family. It was felt strongly that the implications and subsequently clinical pathways to deal with these instances should be "baked in" to any new test developed.

6. Communication in the community should be carried out for a new test in the same way as any other change-accessible through different languages and on different platforms, e.g. leaflets as well as websites and the board members felt it particularly vital that technical information about the test change should be communicated to those medical professionals who are most likely to be responsible for providing the patients with information-GPs and consultants.

7. The board members were happy with a new test being more expensive than a current one if it led to a cost saving elsewhere or in the long term.

8. Ethical considerations were important to the board members with misuse (either real or misconceptions) of genomic data highlighted as an example of the need to communicate test changes and the information yielded carefully and clearly and where possible to learn lessons from previous public "successes". An example of a perceived success was the 100k project and in particular how patient choice on information gathered and shared was tailored to individual families and circumstances.