The Tissue Genomics Pathway: Ironing out the bumps

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**Driver For Change:**
The NHS is the first healthcare system globally to offer whole genome sequencing (WGS) as part of routine clinical care. Patient Choice will see genomic analysis inform the clinical and research databases, furthering understanding of molecular mechanisms underlying cancer, and driving innovation in anti-cancer therapy. The National Genomic Medicine Service (NGMS) will enable increasingly accurate diagnoses, and personalised treatments guided by big gene data (1). Better clinical outcomes will extend lifespan and improve quality of life, for everyone living in England with cancer.

**Method:**
Face-to-face meetings were held by Cancer Genomics Project Managers Deborah Lakeland and Steve Jones, with local cancer clinical and laboratory leads in Greater Manchester, and Lancashire & South Cumbria. The concepts of the GMS, and the NHSE-commissioned Genomic Test Directory (2), were introduced. Feedback and data was gathered on molecular activity over a six month period in 2019, and common themes were explored, to inform delivery of the National Genomic Test Directory.

**Purpose:**
An exercise was undertaken to engage cancer health professionals and audit existing molecular testing activity around the North West. Findings would increase understanding of local testing strategies, inform expanding capacity at the North West Genomic Laboratory Hub (NWGLH), and facilitate alignment of local services with the NHS England (NHSE) Genomics agenda (2), which delivers centrally-funded tests from the region, in the region. Conversations would identify the existing level of molecular testing, and expose barriers to the regional centralisation of genomics analysis required in tumour pathways.

**Findings:**
Whilst cancer clinicians and laboratory leads understood that centralisation of molecular analysis and whole genome sequencing in the NHS was progress, many concerns were raised.

**Clinical concerns:**
Clinicians wanted detail on the implementation strategy and key players, plus guidance on using the genomic test directory, consenting patients, and communicating results. Clinicians also wanted to know how WGS fitted in, who could request tests, and whether redirecting existing molecular testing to the NWGLH would adversely impact cancer pathways. There was a perception that the NWGLH could not deliver a service that met expectation of Haematologists in Lancashire and South Cumbria, who already had strong links to Leeds HMDS.

**Laboratory concerns:**
It was noted that Pathology Departments had practices unique to their site. Generally, managers wanted information, on whether tests were UKAS-accredited, test requesting, sample volume, fresh frozen and FFPE tissue handling, result reporting, and connectivity of IT systems. There was confusion over prioritising, so they wanted to see SOPs, and to understand what would happen outside of routine working hours.

Whilst most of the Genomic Test Directory was already delivered by the NWGLH, duplication of service provision, use of other funding streams, and plans to increase the test repertoire with tests already provided by the GMS, were identified in local laboratories. A few molecular investigations offered by the NWGLH were being referred to test facilities outside the North West or even abroad. It was noted that some of these referred tests also included tissue processing by the testing facility, creating local capacity for other aspirational activities. Laboratories expressed a wish to retain and in some cases expand local molecular service provision. Some managers viewed the genomics agenda as deskilling, destabilising, removing income and kudos, and would likely increase TATs.

**Clinical and Laboratory concerns:**
All consultations highlighted the level of upscaling required, and the financial constraints on increasing local capacity. They emphasized that existing arrangements with other test facilities were already effective, and had concerns about TATs. Everyone desired a means of communication with the NWGLH, ring-fenced funding both for education to implement changes and to retrieve stored samples.

**Conclusions:**
There is now greater awareness of activity outside of the NWGLH, and engagement of cancer leads with Genomics. Closer alignment with the GMS, of molecular service provision outside of Greater Manchester, is necessary, in order to follow the funding, remove duplication, standardise pathways, and to improve equity of Genomic analysis for cancer patients. The NWGLH would need to expand capacity and the workforce to repatriate all molecular activity in the region. There is a need to determine the impact that TATs have on clinical decision making. Greater understanding of IT interoperability around the network is required.

**Outcomes:**
- Findings from this audit have been presented to NHSE and are reflected in other regions.
- Responses to FAQs are being written by the NWGLH.
- New regional cancer pathways including WGS are being designed by the NWGLH in collaboration with cancer leads.
- Capacity is growing both at the NWGLH and in local Histopathology laboratories, including the creation of new Genomics Specialist scientific roles.
- Parallel testing of lung molecular markers at the NWGLH and local laboratories to inform the testing algorithm has begun.
- Mapping of IT systems is underway, to identify breaks in communication of Genomic requests and reports.

**References:**