Medical Genetic Service Review and Re-procurement of Genomic Laboratory Services

1. Situation

The introduction of genomic medicine – particularly to inform the personalisation of treatment – is the most significant initiative to shape the future delivery of NHS care. In 2012 PM David Cameron launched the 100,000 Genomes Project and established Genomics England. In September 2015 the NHS England Board committed to the development of a Personalised Medicine Strategy for the NHS. The strategy defines personalised medicine

> ***a move away from a 'one size fits all' approach*** *to the treatment and care of patients with a particular condition,* ***to one which uses emergent approaches*** *in areas such as diagnostic tests, functional genomic technologies, molecular pathway, data analytics and real time monitoring of conditions* ***to better manage patients' health and to target therapies to achieve the best outcomes*** *in the management of a patient's disease or predisposition to disease.*

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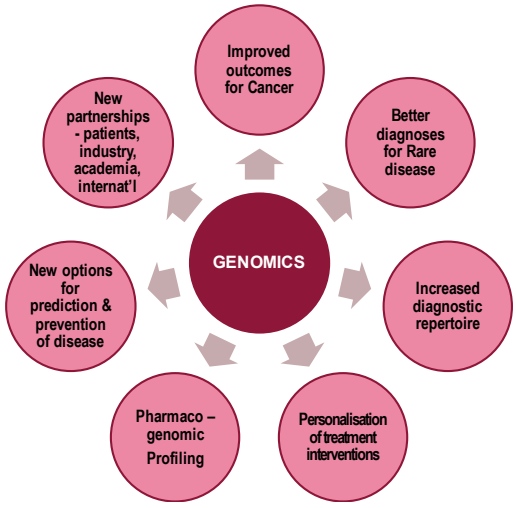
In November 2015, the government committed a further £250m to the 100,000 Genomes Project to ensure a lasting legacy for the NHS including the National Genomic Data Centre. This has been possible due to the decreasing cost of sequencing DNA and developments in computational power and data analytics.

By unlocking the power of DNA data, the NHS will lead the global race for better tests, better drugs and above all better care.



Where genomics is taking us

Tackling:

- Rare Diseases & Cancer
- Common Non-communicable disease (eg CVD, Diabetes)
- Other clinical priority areas (Mental Health, Dementia, LD)
- Infectious disease (inc AMR)
- Prevention & prognostics
- Pharmacogenetics

A Framework for the future

A network of high specification laboratories integrating Genetics and Genomics with broader Molecular Pathology (Public Health England):

- An **integrated Clinical, Laboratory** and **Academic** centre working with local genomic laboratories and the Whole Gene Sequencing provider partners;
- Focus on translation from **research to service;**
- Serving a broad population base, with strong **regional partnerships** and **networks to ensure patient access & knowledge flows;**
- **Unified centralised laboratories** bringing together all genomic applications and driving quality, clinical utility and enhanced interpretation.

2. The Task

NHS England Specialised Commissioning is reviewing the provision of genetic laboratory services to ensure alignment to the future vision and strategic approach.

Analysis of financial and activity-based clinical genetic service data was required to establish fitness for purpose and inform the future model and support service change and procurement across commissioning organisations, providers and specialist laboratories.

In 2016, Integral Health Solutions was commissioned to support NHS England in establishing the 'current state' relating to the provision of genetic laboratory services across over 100 NHS provider organisations. The purpose of this is to inform the future model of developing **integrated clinical, laboratory** and **academic** centres working with regional genetic laboratories and the Whole Genome Sequencing (WGS) provider partners. The work undertaken was complemented by Integral Health Solution's continual strategic challenge and assessment of the operational validity of a number of options throughout the project. Integral Health Solutions provides the financial and contractual advice to NHS England for the national genetic laboratory services procurement.

3. Action

Our Methodology

To establish the current state, we undertook a robust diagnostic assessment using our structured diagnostic tool including a detailed specification of the financial and activity genetics service data required to ascertain:

- the range and scope of existing laboratory genetic testing services provided by NHS and private laboratory centres;
- whether genetic testing services are commissioned in line with legislation;
- that funding and responsibilities are aligned to the correct commissioning organisation;
- a consistent service level is provided with defined patient outcomes, and;
- any contracting and payment process efficiencies, for both testing and clinical genetic services, that could be achieved.

The initial stages of our work involved the facilitation of group sessions (stage 1 below) to discuss the service specifics and identify and develop a strategic approach that would provide NHS England with the knowledge and information required for the planned re-procurement (stage 4).

Stage 2

Due to the absence of an existing framework it was necessary to conduct a data collection exercise to cover the larger regional laboratory services. This required working with regional laboratories distributed nationally across England.

Throughout the project a level of fluidity in the future service requirements often led to a change in our work-plan and deliverables for which a revision of the current strategy was needed. In January 2017, Molecular Cancer Diagnostics (MCD) was introduced into the procurement scope, which necessitated a new data collection exercise.

This was predominantly aimed at an additional, wider cohort of providers as well as looking to provide further detail on the MCD already collected as part of the initial exercise (223 organisations in total). To minimise the resource impact on those laboratories that had already submitted it was necessary to develop algorithmic mapping to reverse engineer this output. Despite this aim it was often necessary to ask for a resubmission.

Following the data collection exercise, we established a national dataset. We have continued to improve this through validation of data to address data quality issues. We also undertook an assessment of any block contract values, establishing an apportionment methodology, to allocate financial and activity data to the appropriate commissioner.

Stage 3

Due to the need to identify all the funding sources for these services, one of the main issues identified was reconciling the national data received from laboratories with the data held by the 10 area hub commissioners.

To support the data collection exercise, we provided two support sessions for the 10 area hubs. The importance of agreeing triangulation at this stage was largely to mitigate the risks of using inaccurate financial and activity values for the future procurement. This data-set is the basis for the financial and activity envelope to support the national genetic laboratory procurement process.

The evaluation of current Clinical and Laboratory services and the identification and recording of the finance structures was an essential foundation to the future development and introduction of a new model.

4. Results – what we have achieved

The Challenge

From the onset of the project we identified inconsistencies in the data due to the lack of a national data framework. This presented the programme with a significant challenge, which meant that there was no detailed knowledge of current market and provision of services.

There was considerable disagreement between commissioners and providers around the tests carried out, agreed test nomenclature and structure or parent grouping. In addition, there was a disparity of test provision across the country which in many cases conflicted with the relevant legislation.

Our Solution

To address the challenges above, we provided strategic consultancy and advice, establishing a robust operational programme management approach, ensuring the objectives of the review were achieved through:

- development of guidance and production of templates for ensuring accurate data collection;
- process timetabling to co-ordinate and control the project with minimal disruption to the laboratories;
- collation of laboratory data returns and produced a national data-set for genetic laboratories;
- on-going communications through webinars with provider laboratories;
- production and circulation of a regular technical bulletin (including Q&As);
- weekly conference calls with the NHS England central team;
- support in the production of the service specification for medical genetics;
- data collection and validation to highlight inaccurate data;
- data reviews with providers to continually improve the integrity of the national dataset;
- assessment of any block contract values, application of apportionment methodology;
- reconciliation between the 2016 Identification Rules (IR) exercise and the 2017-19 contract planning data;
- worked with the 10 specialised commissioning area hubs and NHS providers on the triangulation of data to mitigate the risks associated with utilising inaccurate values for the procurement financial envelope.

Outcomes

The main outcomes of this programme of work resulted in the compilation of an extensive national dataset and analysis of the financial and activity-based genetic service data to inform the future service model. This work supports the national procurement of genetic laboratory services, improved patient level data quality, and informed a new national data collection template.

Integral Health Solutions is continuing to support NHS England in the re-procurement of these services in line with the future vision, due for completion in summer 2018.

The initial regional genetic laboratory data collection is largely complete but continues to be validated and the quality improved by working closely with providers. Work to complete the MCD dataset is currently being undertaken, due to be completed by June 2017. Integral Health Solutions continues to offer both strategic and operational advice and guidance to NHS England to support the national procurement.