



**Comments on the Department of Health
Review of UKGTN – January 2014**

1. What are the requirements in genetic testing over the next 3-5 years for:
 - Providing assurance to patients on the quality of clinically appropriate testing services?

Diagnostic genetic tests should be appropriately validated and providers should be monitored as a mandatory requirement of CPA and ISO accreditation

The most challenging aspect will be delivering meaningful results to patients. Specifically the reported output from extended analysis such as next generation sequence panels & whole exome sequencing should be fully interpreted, assessed in context of the patients needs and communicated appropriately. This will require better outcome & performance monitoring and clinical audit that feeds back into the testing process.

- Ensuring services are fit for purpose, comparable and efficient?

As above plus the development of the NLMC and data standards should facilitate more data sharing and comparison between providers and more robust audit. At present we are continually comparing apples with pears..

- Evaluating new tests for scientific validity and clinical utility and making recommendations to commissioners?

Requirements for assessing the validity of new tests should be part of the remit of laboratory accreditation (UKAS). Recommendations to commissioners should be part of a NICE-allied process and take a more holistic perspective.

- Overseeing choice, evaluation and prioritisation of NHS funded tests?

Genetic testing needs to be considered in the same way as other diagnostics. The test will need to be assessed in terms of performance, cost, accessibility, availability etc. As well as the testing element, we need to consider how results/data will be stored, retrieved and shared to avoid duplication, re-investigation and assist management and future family follow-up..

This is also part of the remit of the Clinical Reference Groups/NICE HTA

- Advising commissioners on medical genetic service developments?

We need a better understanding of the clinical benefit. Specifically which patient groups might benefit from easier access to tests directly from other services and which patients need to be seen within medical genetics.

Again this is also part of the remit of the Clinical Reference Groups/NICE HTA



2. With genetic technologies informing the pathway from DNA to RNA to proteomics, should UKGTN only have oversight of genetic and genomic testing or should it include somatic (non germline) DNA and RNA (i.e. genomics and proteomics and transcriptomics) providing a broader clinical approach?

A more joined up and harmonised approach would be beneficial. UKGTN should have a wider scope but work more closely and in association with other specialty and advisory bodies such as NICE and UKAS.

3. As we move to broader applications of life sciences technologies to support the spread and adoption of stratified medicine, how should their clinical utility, value and quality be assessed in order to inform the commissioning process for both new and established services? Is there a role for UKGTN?

There appears to be potential duplication with the role of NICE, CRG's and HTA. UKGTN could offer advice as part of one of these groups.

4. How do UKGTN's recommendations now fit within the wider clinical advice and commissioning mechanisms available, including speciality / service based clinical reference groups and clinical commissioning groups

This seems unclear and needs to be addressed both in relation to genetic tests delivered by specialties other than Genetics and by non-NHS England providers. There seems inconsistency and confusion especially as UKGTN is not a commissioner or accreditation body.

5. What should be the future remit of UKGTN?

It would be less confusing and more transparent if UKGTN was an NHS England body that works as part of a specialist unit within NICE. It could be commissioned to take on various projects such as genomic testing, pricing and workload measures including international work. At present its work seems to overlap with too many other bodies and these relationships need to be clarified

6. How does UKGTN need to evolve to meet future service needs and retain its relevance?

It needs to cover a wider scope of tests/services than it currently covers and more formally align its processes to those of NICE and UKAS

7. Are there any competition considerations associated with UKGTN's membership and its resulting recommendations to both providers and commissioners;

UKGTN is often perceived to have a conflict of interest as it reports to Commissioners, is part of the Commissioning framework and also approves who can do what Genetic test via the "Gene (test) Dossier process. Many services have now developed tests outside this framework which no longer seems fit for purpose.

8. Should UKGTN's role be extended to cover genetic tests undertaken outside of the UKGTN membership for NHS patients (such as non UK providers);

There are divided views here dependent on addressing concerns around a conflict of interest.

9. Should UKGTN have a role in the development of genetic testing pricing and currencies;

UKGTN could have a role but in collaboration with other bodies such as the HRG so it is consistent with all other NHS pricing.

10. Where should UKGTN sit and within which governance framework (e.g. within the NHS or outside, government/public body, other)

UKGTN should sit with a body that would address concerns about potential conflict of interest. The most obvious would seem to be NICE

11. What is UKGTN's role in respect of the devolved administrations and should this be formalised;

This is up to the devolved countries to determine alongside a contribution of the funding of UKGTN. As UKGTN is currently funded by NHS England, then its principal remit is to England.

12. Should UKGTN remain a UK-wide organisation or England only?

As above, depends on its funding. As there is no UK wide Health Body it is not clear who they would report to if they remain a UK wide body.

13. How should the UKGTN be funded in the future?

There was a view that UKGTN should be self-funding. They could be part of NICE and obtain some funding from the devolved countries.

14. What other developments or organisations in the wider landscape could have an impact on UKGTN's future direction?

Organisations - principally DH, NHS England, UK NSC, NICE, BSGM, RCPATH, UKAS, ESHG, CRGs, HFEA, HPA, Cancer networks, Rare Disease, Genetic Alliance UK & other patient groups, PHG foundation & other charitable organisations, Genomics England
Developments - privatisation (providers and customers), consolidated service configuration not requiring a network approach, mainstreaming, EU legislation around IVDD and data protection

15. Do you have any other comments?

- a) Whilst the UKGTN admin team, is quite lean, a lot of support is provided by other NHS professionals. The overall cost needs to be assessed in terms of sums involved. For example the work that goes into some gene dossiers seems disproportionate to the financial value involved and out of step with other processes. The gene dossier process does need a separate review with respect to effectiveness.
- b) On the UKGTN website it says that for rare genetic disorders there are 27 labs providing unique testing services for 69% of conditions on the directory and that there are <10% conditions where testing is available at more than 3 labs so I would agree that generally speaking pricing and competition could be key issues for the future
- c) The fertility field is a relatively small part of a huge area with particular focus on PGD / PGS - embryo testing and also investigation of recurrent miscarriage (Karyotyping etc), male infertility testing being the main areas.
The idea of a network to advise on what tests are available and where this can be accessed is essential to avoid duplication and encouragement of best practice and faster implementation of novel techniques / tests for the whole population. Definitely wary of a closed system that is entirely NHS / centrally controlled as this can lead to a loss of market competition. Competition encourages improvement and development and ultimately this should lead to better results for patients. Many NHS 'services' are outsourced to private providers including pathology and genetics services.
No idea on future demand but can only agree that it is going to be bigger. It is essential that there is a system combining expertise from public and private sector bodies and staff as well as a fair and open system to allow engagement with both public and private sector medical centres and laboratories. Unfortunately there is still ignorance across the healthcare profession about genetic testing / embryo biopsy etc. and a relatively closed market on who can provide services. It is easier for commissioners to stick to existing providers than open up the field
- d) There will be a massive increase in the demand for genetic testing/screening over the next 5 years, especially as the cost of these tests reduces and the possibilities and range of testing increases
UKGTN is an advisory organisation, providing support to patients and commissioners and NHSE/DH.
Does the HFEA have any view on this? As it may impact or limit some PGD requests, and we should bear in mind that this may relate to specialised commissioning, which no longer covers IVF treatment.

