recommendation 1: objective and measurable quality standards should be developed for pathology services, from sample request to delivery of interpreted result.

Steering group members’ considerations
For UKGTN member laboratories accreditation, currently with CPA, is mandatory giving quality assurance to Specialised Commissioning Group genetics commissioners; recognising that CPA has now been acquired by UKAS. Quality standards are already in place for genetics which are monitored by accreditation and external quality assurance.

The Clinical Molecular Genetics Society (CMGS) holds best practice meetings between genetic laboratories in order to develop and update guidelines for method of analysis and reporting. This is currently undertaken without funding on a voluntary basis; however the UKGTN is considering supporting this activity.

Electronic delivery of results to clinicians is not current practice in genetics. The current electronic system reports on absolute values which needs further refinement for genetics. This matter was raised during the collection of evidence for the House of Lords inquiry into genomic medicine. Further solutions are required in order for electronic reporting to be effective.

UKGTN requires and assesses clinical testing criteria for each new genetic test which is proposed for NHS service through the UKGTN Gene Dossier process, in order to ensure that a clinical appropriateness aspect of test quality is achieved.

recommendation 2: the accreditation process should be reviewed so that it inspects against the quality standards (once developed) referred to in recommendation 1.

Steering group members’ considerations
The accreditation process for genetic laboratories is for an independent inspector and a peer review assessor from the profession to carry out inspections. Membership to UKGTN is dependent on CPA accreditation. The full process and standards are available from the CPA website at http://www.cpa-uk.co.uk/. We are aware that CPA has been purchased by United Kingdom Accreditation Service (UKAS) but the changes this will bring are not yet clear.

recommendation 3: Pathology service providers - and, in future, consolidated networks - should be subject to mandatory accreditation by an organisation independent of the providers and the professions.

Steering group members’ considerations
For specialised services, such as provided in regional genetic centres, up-to-date professional expertise is required to carry out inspections for accreditation in order to have an understanding of the complex quality issues. Informal networks for genetic laboratories do exist (London consortium, SCOBEC [six genetic centres in South and West of England], GenLYNC [two genetic centres from Leeds and Newcastle]). Where formal network arrangements are in place, CPA, when assessing laboratories for accreditation, will scrutinise these joint arrangements, however accreditation is granted to the individual laboratories.
**UKGTN response to Report of the Second Phase of the Review of NHS Pathology Services in England**

**recommendation 4:** all providers of pathology services (including providers of point of care testing) should be required to participate in clinical audit and other clinical governance activities.

Steering group members’ considerations
Regional molecular genetic laboratories already participate in clinical audits decided at a local level and through EQA. Accreditation requires an audit cycle to be agreed each year.

**recommendation 5: IT connectivity should be put in place for NHS pathology services as a matter of priority.**

Steering group members’ considerations
IT connectivity could facilitate online ordering of tests and include access to UKGTN testing criteria at point of ordering test to facilitate appropriate test requests.

A number of regional genetic centre laboratories are currently collaborating to introduce a common Laboratory Information Management System (LIMS), namely StarLIMS, to process samples. However an integrated system across all regional genetics centres would be desirable. There is also a requirement for software to interpret results of an assay. All operating systems would need to communicate with each other and the requirement to establish standards in coding and classification is essential.

The National Genetics Reference Laboratory in Manchester is leading on standards, coding and classification in information technology.

**recommendation 6: Priority should be given to ensuring that pathology services are made more responsive to users’ requirements; and, in particular, that phlebotomy and sample collection services should be made more accessible and convenient.**

Steering group members’ considerations
The phlebotomy sample collection is not applicable to genetics. Blood samples are taken at the consultant clinic or by genetic counsellors, or by arrangement with the local GP surgery, usually as a one-off sample for diagnosis, rather than repeated sampling for ongoing monitoring of disease.

**recommendation 7: the Department of Health should formulate proposals for ensuring that more information is made available to service users about the quality and safety of services.**

Steering group members’ considerations
The UKGTN that was established by The Dept of Health has, through its membership criteria, enabled the quality and safety of genetic molecular laboratory services to be assured. A web site has been developed that enables service users to access information about the quality and safety of services for each laboratory member.
**UKGTN response to Report of the Second Phase of the Review of NHS Pathology Services in England**

**recommendation 8:** Specialist services should be consolidated through referral to specialist testing centres to assure quality and to address professional isolation.

*Steering group members’ considerations*
The regional accredited genetic laboratories that are members of the UKGTN are already limited in number. The UKGTN working with the CMGS develops best practice across laboratories and therefore professional isolation is not an issue.

**recommendation 9:** Pathology networks should be developed on the lines set out in paragraph 43 [of the report of the Second Phase of the Independent review of NHS Pathology Services in England]

*Steering group members’ considerations*
Specialised Commissioning Groups (SCGs) are supporting laboratories to work in networks in specific geographical areas. UKGTN provides an umbrella of expertise and reference for all these networks which encompasses strategic developments in order to inform commissioning. UKGTN has patient representatives on the steering and working groups in order that their views are represented.

**recommendation 10:** each consolidated network should have a single integrated management structure, including a clinical director and commercial director, who would provide clear leadership and accountability.

*Steering group members’ considerations*
Regional Genetic Centres services are mainly provided from tertiary centres and within these tertiary centres colleagues from genetics often work within the Pathology Directorate. Different models for different disciplines need to be considered rather than a single solution.

**recommendation 11:** a national clinical director for pathology should be appointed, working in partnership with a national commercial director for pathology.

*Steering group members’ considerations*
The UKGTN agrees that there needs to be national leadership and collaboration with commercial partners and commissioners.

**recommendation 12:** our proposals for the reform of NHS pathology services should be reflected in the Department of Health’s operating framework for the NHS in England.

*Steering group members’ considerations*
The National Specialised Services Definition Set that is applicable to Specialised Commissioning Groups service commissioners includes genetic services and the laboratory component. The recently developed designation criteria for genetics includes relevant guidance for laboratories.
recommendation 13: the NHS pathology workforce should be reformed as set out in paragraphs 58-59 [of the report of the Second Phase of the Independent review of NHS Pathology Services in England].

Steering group members’ considerations
A new training scheme is being piloted and will be subject to careful evaluation to ensure that specialist knowledge is achieved and maintained in order to ensure appropriate service standards.

recommendation 14: Based on guidance and support from the Department of Health, each Strategic Health authority (SHA) should require the Primary Care trusts (PCTs) in its area to take the lead with providers (existing and - where known - potential) in drawing up cost-effective plans for implementation of this report's [the report of the Second Phase of the Independent review of NHS Pathology Services in England] proposals.

Steering group members’ considerations
Specialised Commissioning Groups of regional genetics centres undertake this role in respect of genetics.

recommendation 15: further work should be undertaken by the Department of Health to develop a tariff for community-based and specialist pathology.

Steering group members’ considerations
Regional genetic molecular laboratories are currently piloting activity currencies to evaluate a consistent method to count laboratory work load that could be used for tariff assignment.

recommendation 16: the Department of Health should determine the coverage and format of benchmarking data to be collected from all pathology providers, and procure the collection of such data.

Steering group members’ considerations
The UKGTN and the Clinical Molecular Genetics Society collects benchmarking data (UKGTN e.g. laboratory turn around times; Clinical Molecular Genetics Society e.g. number of tests, staff, number of reports). UKGTN is also collecting data to develop limited reporting on access to genetic tests geographically.

recommendation 17: the Department of Health should develop commissioning guidance as a matter of priority.

Steering group members’ considerations
UKGTN is developing a general genetic commissioning guideline and has developed, through the PHG Foundation, commissioning guidelines for Ophthalmology services for patients with inherited eye conditions.
recommendation 18: the Department of Health should consider the development of model contracts for pathology.

Steering group members’ considerations
Specialised Commissioning Groups have adopted the national contract for genetic services that encompasses the laboratory requirements. UKGTN would encourage specialised services commissioners to develop these contracts further so that there is a common approach in England.

recommendation 19: the Department of Health should ensure that a pathology ‘formulary’ equivalent to that used for medicines is introduced.

Steering group members’ considerations
The UKGTN has an online database within the web site that lists the UKGTN laboratories and the tests that they each provide. A Directory of Molecular Tests lists the tests that are available from the member laboratories. The Gene Dossier which demonstrates the clinical utility and scientific validity for the new tests evaluated by the UKGTN is integral to the database and Directory to give assurance to tests that are added to it. Testing criteria are also provided to assist appropriate referrals.

recommendation 20: the Department of Health should identify ways to facilitate the adoption of innovation in pathology.

Steering group members’ considerations
UKGTN was funded to enable innovation to be put into service in a quality assured manner. Further funding for translation in relation to genomics would be supported.