Genomics Education Programme

NHS Health Education England

# A cross-professional competency framework to facilitate consent for genomic testing

**Genomic testing in the NHS**

Advances in genomic technology and its applications to clinical care have led to increased utilisation of genomic testing across a growing number of specialities. The NHS is implementing a Genomic Medicine Service (GMS) including National Genomic Test Directories, outlining the tests that will be commissioned by NHS England for more equitable access. Later this year, whole genome sequencing will be available for certain rare disease indications and cancers, and will involve a 'patient choice' model of consent which covers both the clinical implications of a test as well as a research offer within the clinical pathway. There is therefore a growing need to provide a framework to support the development of the workforce who will be having these conversations with patients. Health Education England's Genomics Education Programme (GEP) is responsible for ensuring that the NHS workforce has the knowledge, skills and experience to deliver genomic medicine, and has already developed a number of evidence-based resources.

**What is the framework?**

This cross-professional framework identifies the core competencies required to facilitate consent for genomic testing. The framework has been designed as a guide for best practice for healthcare professionals offering genomic testing, which may include whole genome sequencing, microarray or single gene tests for diagnostic, carrier or predictive testing purposes. We are also aware that conversations about genomic testing may be led by different individuals depending on the context of the test and clinical pathway. It is therefore imperative that professional judgement based on an individual's scope of practice is considered when reflecting on these competencies. A Training Needs Analysis was conducted by the GEP in 2016-17 during the delivery of the 100,000 Genomes Project, to identify current and future education and training needs of staff. Results from this analysis have been used to outline four categories of healthcare professionals based on training and experience with genomics, and is incorporated into the competency framework with regards to the varying levels of competence each group is broadly anticipated to have (Table 1).

**How will this framework be used?**

This framework aims to provide a comprehensive foundation for training to enable the consent conversations around genomic testing to be delivered in a safe and effective way for patients across specialties. It will enable professional groups and clinical leaders to consider how the competencies fit within the education and training needs of their specific workforce group or specialism, and can be used as a guide for individual healthcare professionals to identify additional learning needs. This framework will also guide the development of future tools made by the GEP to support the workforce.

**What input do we need?**

The methodology for reaching consensus on this framework is founded on the nominal group technique. An initial framework was developed based on existing literature and experience of the authors in the GEP. On 12th February, a one-day expert consensus meeting with healthcare professionals in various disciplines reviewed clinical scenarios in iterative rounds, mapped themes to the framework and voted on areas of inconsistency. Before this framework is finalised, we are inviting individual healthcare professionals and professional bodies to review the current framework. The final version will be published along with case studies of how the framework can be used in practice.

**Table 1. Healthcare professionals categorised based on previous experience with consent to genomic testing**

| | Category | Examples of healthcare professionals | Comments regarding experience |
|---|---|---|---|
| **A** | Genetic/Genomic specialists | Clinical Geneticists, genetic registrars, genetic counsellors, specialist nurses in clinical genetics | Experience consenting for complex genetic and genomic testing, as well as often for research projects. Also experience returning results for patients, which will influence their consent practice. |
| **B** | Consenters for genomic research projects (i.e. 100,000 Genomes Project, NIHR BioResource - Rare diseases) | Research nurses, bio-bankers, research trials coordinators, mainstream clinicians | Familiarity with the process of consent to a genomic test, although varying levels of competence expected depending on the nature of the research study and familiarity with clinical pathways. |
| **C** | Mainstream clinicians | Specialist consultants and registrars, specialist nurses, midwives, community paediatricians, GPs | Includes diagnostic tests to confirm a clinical diagnosis within area of expertise. Will have experience in consent for genetic/genomic tests, but level of complexity and experience returning results may vary. Overall less extensive training than Category A, and may or may not have been involved in research including genomic testing. |
| **D** | Healthcare professionals who have never consented for a clinical or research genetic/genomic test | Healthcare professionals as listed in C. | May have some or no knowledge of genomics and how it relates to their role. |

Based on findings from a Training Needs Analysis conducted by the GEP in 2016-17

✓ = expected to already have competence; X = does not yet possess this competence (although expected variance in expertise among members in each group)

**Table 2. Competencies to facilitate consent for genomic testing**

| | Competency | Category A | Category B | Category C | Category D |
|---|---|---|---|---|---|
| 1 | **Have a working knowledge of the process of requesting a genomic test.**<br>• Familiarity with the National Genomic Test Directories and the criteria for these tests<br>• National and local processes for obtaining and recording consent, including requirements for clinical testing and participation in research where relevant<br>• National and local processes for changes to consent (i.e. at age 16, with capacity, for additional tests, when a patient changes their mind about having the test)<br>• National and local processes for ordering a test from a genomic laboratory, including submission of relevant clinical information<br>• Sample requirements, how the sample will be taken and the transport pathway<br>• Awareness of the funding model and where that may restrict requesting a test<br>• Awareness of the Code on Genetic Testing and Insurance<br>• Awareness of the Human Tissue Act (2004) as it applies to use of DNA for genetic tests<br>• Awareness of the resources available to patients and healthcare professionals to access further information about these processes | ✓- however learning needs will change with incoming changes in the GMS | ✓/X - may vary depending on type of genomic research study, and learning needs will change with incoming changes in the GMS | ✓- however learning needs will change with incoming changes in the GMS | X |
| 2 | **Have a working knowledge of the conditions occurring within their area of work for which genetic or genomic testing may be offered.**<br>• General genetic concepts, the inheritance and mechanism of disease<br>• Ability to elicit a family history to assess the risk of one or more conditions<br>• Understanding of how conditions may present and the variability of clinical presentations<br>• The likelihood of the patient's presenting condition having a genetic basis, versus other possible factors (i.e. behavioural, social, environmental) that may contribute<br>• The different implications of somatic versus germline analysis | ✓- however learning needs will change as new tests and technology changes | ✓/X - may vary depending on type of genomic research study and familiarity with clinical pathways | ✓- however learning needs will change as new tests and technology changes | X |
| 3 | **Be able to assess where genomic testing is appropriate in that patient's clinical pathway.** | ✓ | ✓/X - may vary depending | ✓- however learning needs | X |

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| | • Knowledge of why test may or may not be offered<br>• Awareness of ethnic and/or population-specific factors that may influence the type of test being offered<br>• Awareness of alternative tests to the genomic test being offered, if applicable<br>• Possible future test options and choices, pending the results<br>• Awareness of when it would be appropriate to offer genetic testing to children | | on type of genomic research study and familiarity with clinical pathways | will change as new tests and technology changes | |
| **4** | **Be able to explain the purpose and process of the clinical test being offered.**<br>• Context of the test (i.e. diagnostic, predictive, carrier)<br>• The technology used, it's technical accuracy and limitations<br>• Clinical limitations of the test<br>• Possible results, the turn-around-time and feedback process<br>• Clinical actions that may or may not be taken<br>• Possible unexpected results (i.e. incidental findings)<br>• The potential uncertainty of genomic information, and the iterative nature of analysing results<br>• How samples and data may be used, stored and accessed<br>• Familial implications of results and the importance of sharing results with relatives that may be at risk | ✓ | ✓/X - may vary depending on type of genomic research study and familiarity with clinical pathways | ✓- however learning needs will change as new tests and technology changes | X |
| **5** | **Be able to explain and answer questions relating to the National Genomic Research Library* where applicable.**<br>• The benefits and potential risks of data and sample use, storage and sharing on personal, familial and societal levels<br>• How samples and data may be used, stored and accessed<br>• The process of partial or complete withdrawal of consent for research at any time<br>• Familiarity with principles of the Data Protection Act (2018)<br>*Based on research offer in the 100,000 Genomes Project, initially only applicable to whole genome sequencing indications in the GMS | ✓/X - may have some knowledge depending on experience with 100K Project | ✓/X - may have some knowledge depending on experience with 100K Project | ✓/X - may have some knowledge depending on experience with 100K Project | X |

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| **6** | **Be able to apply core clinical skills to the genomic test conversation.**<br>• Establish patient(s) understanding and expectations of genomic test being offered<br>• Employ effective communication skills to enable patients to make an informed choice without coercion or bias<br>• Tailor provision of information based on the patient's knowledge, education, age and language<br>• Attempt to engage with all individuals present in the discussion while incorporating different views of family members<br>• Address the psychosocial impact of genomic testing and risk<br>• Assess capacity according to the Mental Capacity Act (2005) and other guidelines (i.e. Gillick Competence) | ✓ | ✓/X - based on experience with other research tests/decisions | ✓/X - based on experience with other clinical tests/decisions | ✓/X – based on experience with other clinical tests/decisions |
| **7** | **Awareness and consideration of the factors that may influence an individual's choice to consent.**<br>• Individual's physical and mental health history<br>• Cultural, religious, familial and personal values<br>• Experience and impact of disease on the individual and/or family<br>• Timing of the conversation(s) about consent, with respect to the patient receiving a diagnosis, other procedures and treatment, or other life events | ✓ | ✓/X - based on experience with other research tests/decisions | ✓/X - based on experience with other clinical tests/decisions | ✓/X – based on experience with other clinical tests/decisions |
| **8** | **Have a working knowledge of one's ongoing duty of care to the patient.**<br>• Awareness that duty of care may extend beyond the initial feedback of genomic findings<br>• Informing relevant professionals in the patient's circle of care<br>• Onward referrals to other specialists<br>• Awareness of patient resources, support groups, eligibility for research | ✓– however learning needs will change with incoming changes in the GMS | ✓/X - based on experience with other research tests/decisions | ✓– however learning needs will change with incoming changes in the GMS | X |
| **9** | **Be able to seek further assistance where relevant based on scope of practice.**<br>• Awareness of contacts in local genomics laboratory, Clinical Genetics service and multidisciplinary review meetings if relevant<br>• Recognition of one's own limitations and when to refer to relevant specialists (i.e. clinical genetic services, psychological support)<br>• Awareness of educational resources to support learning (i.e. Good Clinical Practice training, Genomics Education Programme courses and tools) | ✓ | ✓ | ✓ | X |