Genomics Education Programme

NHS Health Education England

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

The competency framework for consent to genomic testing is designed around four categories of healthcare professionals, based on their training and experience with genomics. A Training Needs Analysis was conducted by the Genomics Education Programme (GEP) via the education and training leads in each Genomic Medicine Centre in 2016-17 during the delivery of the 100,000 Genomes Project, to identify current and future education and training needs of NHS staff. Results from this analysis have been used to outline four broad categories of healthcare professionals based on training and experience with genomics (Table 1).

The competencies have been mapped to these four categories, as clinical leaders and educators may find it helpful to develop training based on these groups, although individuals will have varying levels of experience.

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 for research projects. Also has experience in returning results for patients, which may 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.

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

	Competency	Category A	Category B	Category C	Category D
1	**Ensures the process of recording consent for a genomic test follows national and local processes and governance arrangements, and is appropriate for the test being requested.** • Demonstrates familiarity with the National Genomic Test Directory and adheres to this guidance when offering genomic testing, including the funding model, sample requirements and local requesting pathways. • Understands the 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). • Demonstrates familiarity with principles of the Human Tissue Act (2004), Data Protection Act (2018) and/or General Data Protection Register (GDPR, 2018) as they apply to the use of DNA and genomic data.	✓- however learning needs will change with incoming changes in the Genomic Medicine Service (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	**Demonstrates up-to-date knowledge of the conditions occurring within their specialist area for which genetic or genomic testing may be offered.** • Understands general genetic concepts, the inheritance and mechanism of disease. • Is able to elicit a family history to assess the risk of one or more conditions. • Understands how conditions may present and the variability of clinical presentations. • Knows the likelihood of the patient's presenting condition having a genetic basis, versus other possible factors (i.e. behavioural, social, environmental) that may contribute. • Recognises 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	**Assesses where genomic testing is appropriate in the patient's clinical pathway.** • Knows why a test may or may not be offered. • Considers ethnic and/or population-specific factors that may influence the type of test being offered. • Is aware of alternative tests to the genomic test being offered, if applicable. • Knows of possible future test options and choices, pending the results. • Recognises when it would be appropriate to offer genetic testing to children.	✓	✓/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

4	**Conveys to patients the purpose and process of the clinical test being offered.** • Explains the context of the test (diagnostic, predictive or carrier). • Outlines the scope and limitations of the test based on the technology being used. • Explains the possible results and the turn-around-time and feedback process for any results. • Describes the potential relevance of the test for that patient/family, including clinical actions that may or may not be taken. • Explains possible unexpected results (incidental findings). • Describes the potential uncertainty of genomic information, and the iterative nature of analysing results. • Describes how samples and data may be used, stored and accessed. • Outlines the familial implications of results and the importance of sharing results with relatives. • Understands the Code on Genetic Testing and Insurance.	✓	✓/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	**Explains and answers questions relating to the National Genomic Research Library* where applicable.** • Outlines the potential benefits and risks of data and sample use, storage and sharing on personal, familial and societal levels. • Describes how samples and data may be used, stored and accessed. • Explains the process of partial or complete withdrawal of consent for research at any time. *Based on research offer in the 100,000 Genomes Project and 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
6	**Applies core clinical skills to the genomic test conversation.** • Assesses capacity according to the Mental Capacity Act (2005) and other guidelines (such as Gillick Competency). • Establishes the patient's understanding and expectations of the genomic test being offered. • Employs effective communication skills to support decision making and enable patients to make a choice without coercion or bias. • Tailors provision of information based on the patient's cognitive ability, age and language. • Engages with all individuals present in the discussion and incorporates the	✓	✓/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

	potentially different views of family members. • Addresses the psychosocial impact of genomic testing and risk, taking into consideration the impact of disease on the individual and/or family. • Considers the factors that may influence an individual's choice to consent, including additional physical and mental health history; cultural, religious, familial and personal values; and timing of the conversation with respect to the patient's care and/or other life events. • Respects the patient's right to decline the genomic test, and is able to explain potential implications, limitations, and/or alternatives for the patient's care.				
7	**Recognizes one's ongoing responsibilities to the patient and acts when appropriate.** • Understands that duty of care may extend beyond the initial feedback of genomic findings. • Is able to inform relevant professionals involved in managing the patient's care and initiate onward referrals to other specialists. • Knows of patient resources, support groups, and eligibility criteria for research (where applicable).	✓ – 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
8	**Seeks further assistance where relevant based on scope of practice.** • Knows how to contact their local genomics laboratory, Clinical Genetics service and multidisciplinary review meetings if relevant. • Can recognize and understand one's professional responsibilities and boundaries, and when to refer to relevant specialists for further support or patient management. • Knows how to access educational resources to support learning where relevant (such as Good Clinical Practice training, Genomics Education Programme courses).	✓	✓	✓	X