Presentation of a referral tool and patient information to support the implementation of the 2021 NHS England national genomic testing criteria for breast cancer patients

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Introduction
From April 2021, NHS genomic testing in England will be delivered through seven regional Genomic Laboratory Hubs (GLH) according to mandated eligibility criteria in the national genomics test directory, as per NHS England and NHS Improvement. Breast multidisciplinary teams (MDT) will be able to request BRCA1/2 and PALB2 germline mutation testing for eligible patients diagnosed with breast cancer, without referral to their regional genomics service.

**Benefit to patients**

*Broadened inclusion criteria for germline mutation testing*

- Clear inclusion and exclusion criteria
  - Should improve equity of access to genetic testing

*Timely diagnosis and treatment planning*

- Results available within 6 weeks
  - Will enable patients to make an informed decision between breast conservation surgery and mastectomy, according to their genomic test result
  - May allow patients to avoid radiotherapy, if they are progressing to mastectomy following a positive germline mutation test
  - May allow more targeted systemic anti-cancer therapy

*Preservation of regional genetics team capacity for those patients who need specialist input*

Methods
A multidisciplinary group, coordinated by the Greater Manchester Cancer Alliance, in collaboration with the North West Genomic Laboratory Hub and the Manchester Centre for Genomic Medicine, identified potential barriers to implementation of the new guidance, which informed the development of a genetic testing toolkit for Breast MDTs.

**Challenge for breast multidisciplinary teams**

1. The eligibility criteria in the National Genomic Test Directory was not easily accessible
2. Non-genetic specialists had concerns about consenting patients for germline mutation testing
3. Appropriate patient information about genetic testing was not available at local breast services
4. Local breast services required a safe and efficient pathway to send blood samples and receive test results

Results
The toolkit presents the eligibility criteria in an accessible format for non-genetics specialists, with prompts to prevent exclusion of patients with rarer genetic causes of breast cancer (e.g. CDH1 mutation, Lynch Syndrome). The toolkit also provides patient information and a consent form, developed by service user representatives and a genetics counsellor, for use outside specialist genetics clinics. The genetic testing toolkit has been approved by all seven breast services within Greater Manchester, resulting in an agreement to mainstream referrals from April 2021.

**Toolkit contents:**

- Eligibility assessment and referral algorithm
- Manchester Scoring System support document
- Patient Information leaflet
- Patient Information video
- Standardised consent form
- Education video aimed at breast specialist nurses about obtaining consent for genetic testing
- Test request form
- ‘Frequently Asked Questions’ document for clinicians

Conclusions
We have developed a toolkit that will enable rapid upskilling of local MDTs to successfully implement the national eligibility criteria for germline mutation testing in patients with breast cancer. This will facilitate equity of access to genomic testing across the region. The resources have been developed to allow adaptation for use by other cancer alliances.

For further information please contact Claire Goldrick, claire.goldrick@nhs.net or visit www.gmcancer.org.uk/genetictest for access to the toolkit.