ICR The Institute of Cancer Research

Accessing biomarker tests on the NHS

Position Statement from

The Institute of Cancer Research, London

Summary

The Institute of Cancer Research (ICR) believes that expanding access to biomarker testing is crucial to enabling cancer patients to benefit from precision medicine. We believe that it should be standard within the NHS to perform molecular profiling of all cancers. More needs to be done to expand access to biomarker testing – including both genetic testing and various types of non-genomic testing. We need large-scale implementation studies to evaluate the best way to roll out testing. The current National Genomic Test Directory is too limited and needs to be updated more regularly. We need to see a broader directory of tests established to create a clearer route to the NHS for non-genomic tests.

We believe it is of the highest priority for the Medicines and Healthcare products Regulatory Agency (MHRA) to develop new UK regulations for the use of *in vitro* testing. We would like these regulations to enable and encourage exploratory biomarker research to increase our knowledge of cancer and enable new biomarker tests to be developed. Currently, NHS institutions are able to share access to tests defined as 'in house' tests, which is a key mechanism of providing access to innovative testing. Usually, in order to place a medical device or *in vitro* diagnostic (IVD) on the market, it needs a mark to show that it conforms to relevant regulatory requirements, this is a CE mark. UKCA marking replaced CE in January 2022 following the UK exit from the EU. 'In house' tests are not required to have a CE or UKCA mark. It is important future regulations include a broad definition of 'in house' biomarker tests so that NHS institutions are able to continue using tests that have been through rigorous in-house validation and quality control, without requiring a CE or UKCA mark.

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Background information

The new era of precision cancer medicine is increasing the effectiveness of treatment and changing the way in which drugs are developed and marketed for cancer. Advances in technologies such as gene sequencing have driven huge progress in our understanding of the genetic and molecular causes of cancers, providing exciting new avenues for treatment.

Increasingly, treatments are now selected for patients based on the molecular make-up of an individual's disease. To target medicines in this way, we first need to gain detailed information about a patient and their cancer. Biomarker tests, including genetic tests and gene expression profiles, protein expression tests and immunohistochemistry, can help identify the type of cancer a patient has and crucially inform judgements on the suitability of a treatment and how a patient is likely to respond.

NHS England's 'Next Steps on the NHS Five Year Forward View', published in 2017, signalled its intention to create a national NHS Genomic Medicine Service. As part of this, a new National Genomic Test Directory was designed, intended to address the variation in the approach to commissioning and funding genomic tests across England and eliminate disparities in access.

Rolled out in April 2019, the National Genomic Test Directory specified which genomic tests are available for inherited rare diseases and cancer, the patient eligibility criteria, the medical specialties that are able to order specific tests, and who pays for the tests. As a result, only the tests included in the directory can be commissioned and funded by the NHS. A national genomic testing service is now delivered through a network of seven regional Genomic Laboratory Hubs (GLHs). However, the directory only covers genomic tests and there is no defined route for taking non-genomic tests to the NHS or a national system for providing them.

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Key ICR positions on accessing biomarker tests on the NHS

- We believe that it should become standard within the NHS to perform molecular profiling on all cancers. We need a broad expansion of biomarker testing for people with cancer – both wider cancer testing and testing for inherited mutations which may confer an increased risk of developing cancer – as an essential step to delivering truly personalised medicine.

- Every patient with advanced cancer should be able to access broad biomarker panel tests, to open up the possibility of treatment with approved precision medicines associated with their test results, or enrolment on a stratified clinical trial. Testing should occur at the point of diagnosis and during treatment, to monitor cancer evolution and help guide treatment.

- We welcome the attention that NHS England is bringing to genomics through the Genomic Medicine Service and believe that the National Genomic Test Directory will help standardise access to tests across the UK. However, we feel the current list of tests outlined on the National Genomic Test Directory is too limited and would like to see more regular updates of the directory.

- We welcome the updated guidance that the National Genomic Test Directory will accept applications on an ongoing basis. However, as there is still an annual evaluation cycle, and we are concerned that it may still take up to two years for a biomarker test to be made available on the NHS. This may have subsequent impacts on patients' ability to access the most innovative and personalised medicines.

- We welcome the guidance from the National Genomic Test Directory that companion diagnostic tests for drugs will be added to the directory automatically when the drug receives approval by NICE. However, ideally diagnostic tests would be made available on the NHS in England even before the associated drug has gained approval. We believe that tests could be categorised as 'essential' or 'desirable'; tests that are verifiable and proven to work in a clinical setting would be categorised as 'essential', and tests for biomarkers with companion drugs that are still in late-stage clinical trials, but that have plenty of experimental evidence to validate them, classed as 'desirable'. These 'desirable' tests could then be fast tracked to inclusion in the national directory – allowing, for example, identification of genomic alterations for rare cancers in children where the associated drug has not yet been approved.

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- We need large-scale implementation studies to evaluate the best way to roll out genetic testing and recommend that the clinical utility of whole-genome sequencing be carefully evaluated.

- We believe there needs to be a clearer route to the NHS for non-genomic biomarker tests, such as transcriptional, protein expression and immunohistochemistry tests. It will be important to create mechanisms to certify and centrally fund such biomarker tests, just as is currently the case for genetic biomarker testing.

- We need to ensure there are additional pathways for non-genomic biomarker tests to be made available through the NHS. The National Genomic Test Directory has a clear path for genomic tests, but other biomarker tests such as protein expression and immunohistochemistry fall outside of this. It will be important to create mechanisms to certify and centrally fund such biomarker tests, just as is currently the case for genetic biomarker testing. Currently, variation in availability exists for these non-genomic tests and we, therefore, need a broader directory that lists wider tests that the NHS will provide so that they are accessible to all patients.

- We believe that it is essential that NHS institutions should be able to use genetic tests that have been through rigorous in-house validation and quality control, without requiring a CE or UKCA mark. When new post-Brexit regulations are drawn up, it is important that a broad definition of ‘in house’ is used so that tests devised and validated by academic institutions such as the ICR and its NHS partners can be accessed across the health service. The science of biomarkers and in vitro diagnostics is constantly evolving and researchers often update tests as their understanding of the biology and genetics of cancers advances – whereas commercially available tests can quickly become out of date. The criteria needed for an institution to be exempted from the requirement to use quality-marked commercial tests must be as permissive as possible and should include efficiency and value for money – since an academic institution may decide that it will be more efficient to run a gene panel test developed in house than 20 individual commercial tests.