Updating the National Genomic Test Directory: Consultation response

NHS England and NHS Improvement

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Equality and Health Inequalities Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

• Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
• Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

Contents

1. Introduction

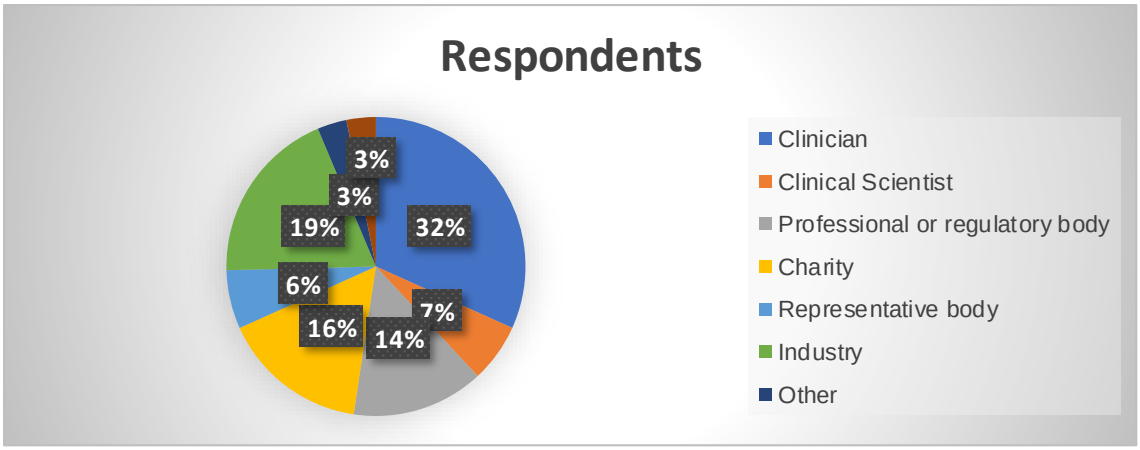
NHS England and NHS Improvement published a public consultation document outlining the approach to updating the National Genomic Test Directory. Stakeholder feedback on the approach was sought via the "Engage" hub[1] from 19th October – 17th November 2020. The consultation documentation and questions asked can be accessed via the "Engage" hub. This document outlines NHS England and NHS Improvement's response to stakeholder feedback.

2. Acknowledgments

NHS England and NHS Improvement extends its gratitude to those who took the time to engage with the consultation to provide constructive, detailed feedback on the proposed approach.

3. Respondents

A total of 65 responses to the consultation were received. Two responses were removed as no fields were completed. 63 responses were accepted and analysed. The figure below outlines the demographic of respondents to the consultation.



4. Next steps and communications

NHS England and NHS Improvement have updated the "Updating the National Genomic Test Directory" policy document[2] in line with stakeholder feedback and will implement the agreed process to support the 2021/22 update to the Test Directory (see section 4.1). Following the 2021/22 update, the full approach and annual timescales will be followed to inform future annual updates to the Test Directory.

Active engagement with stakeholders in relation to the process will continue and relevant updates will be communicated via email to our registered stakeholder list, via the NHS England and NHS Improvement website and additional communication channels as appropriate. Additional stakeholders can sign-up to the Genomics Clinical Reference Group (CRG) stakeholder list via the website[3] to receive updates in relation to the NHS England and NHS Improvement genomics programme. An annual review of the process to update the Test Directory will be undertaken to ensure that it is effective and appropriate.

[1] www.engage.england.nhs.uk/consultation/updating-the-national-genomic-test-directory/
[2] https://www.england.nhs.uk/genomics/updating-the-national-genomic-test-directory/
[3] https://www.england.nhs.uk/commissioning/spec-services/get-involved/crg-stake-reg/.

4.1 Updating the Test Directory for 2021/22

Applications to update the Test Directory for 2021/22 will be accepted from the date of publication of this consultation response until 31st January 2021.

Applications must be made by completing the relevant application form, and submitting via email to ENGLAND.testevaluation@nhs.net no later than 11.59pm on 31st January 2021. Stakeholders are encouraged to submit as soon as possible in advance of the deadline to support timely evaluation of applications prior to the 2021/22 publication of the Test Directory in April 2021.

All information and documentation regarding the process to update the Test Directory for 2021/22 can be access via the NHS England and NHS Improvement website[2].

5. NHS England and NHS Improvement response

NHS England and NHS Improvement have reviewed all responses to the consultation and identified key themes. Section 5.1 summarises the key changes made to the process, which are outlined in further detail in section 5.2. Section 5.3 provides responses to additional themes identified from the feedback received.

5.1 Summary of key changes to the process

The following key changes have been made to the process, which can be found on the following pages of the policy document[2]:

1. Removing the application submission window and accepting applications at any time, publishing annual timelines, including, dates at which applications submitted prior to would be considered for the upcoming annual update (page 11);
2. Introduction of a Fast Track process for applications that meet certain criteria and require implementation more urgently than through the annual update (page 15);
3. Incorporation of a quarterly review and update of NHS GMS virtual gene panel content (page 15);
4. Addition of a dedicated Equalities and Health Inequalities Impact Assessment stage for each annual update to the Test Directory and when appropriate for any additional in-year updates (page 14);
5. Introduction of a notification form for stakeholders to notify NHS England and NHS Improvement of activity which may result in a proposed change to the Test Directory to support horizon scanning (page 5).

Materials to support the process have been developed and amendments to the evaluation and scoring materials have also been made (see section 5.3.3 for evaluation and scoring).

5.2 Themes resulting in changes to the process

5.2.1 Timelines

Respondents supported ensuring timelines allowed for the appropriate governance and commissioning decisions to be made and that the process remains robust. The annual process will also provide stability and clarity for the NHS Genomic Medicine Service (GMS) in implementing genomic testing.

Particular reference was made to the submission window for applications, facilitating urgent updates, and allowing certain categories of amendments to be considered for update more frequently. Three key changes have subsequently been made to the process:

1. The defined submission window has been removed and the submission of applications will be accepted on an ongoing basis. To support the process, each year timelines for the annual process will be published, including defined dates at which applications submitted prior to would be considered for the annual update occurring within the annual cycle. Any applications submitted after this date would be accepted but would not be fully evaluated within the current annual cycle and would be progressed in line with the next update to the Test Directory.

2. To support amendments that require implementation more urgently than through the annual update, a Fast Track process for applications has been introduced. Stakeholders who identify an amendment which may require implementation more urgently than through the annual update should complete the usual application form and also complete a Fast Track cover sheet to outline the rationale for requiring the amendment outside of the annual update.

   Fast Track updates will be considered if they meet one of the following criteria;
   - An error is identified that needs to be corrected to ensure correct delivery of testing
   - An urgent change is needed to address an unmet patient need that has limited financial impact
   - An urgent change is needed to benefit operational implementation in the NHS Genomic Medicine Service that has limited financial impact
   - Newly emerged guidance or clinical policy mandates the amendment (including NICE guidance)
   - An urgent change is needed as a result of the COVID-19 response.

3. The process has been revised to incorporate a quarterly update of NHS GMS virtual gene panel content. To facilitate this, proposed amendments to the content of NHS GMS virtual gene panels should be submitted as evidence reviews via the Genomics England PanelApp platform[4]. All evidence reviews associated with NHS GMS virtual gene panels submitted via PanelApp will be reviewed on a quarterly basis, (dates to be published each year). This process does not apply to NHS GMS panels which are not virtual (e.g. wet lab panels) as amendments to these will require further impact assessment as per the annual process. Amendments to NHS GMS panels which are not virtual should be submitted via the relevant application form as per the annual process.

5.2.2 Health equalities

Respondents welcomed the aim of the process and associated dedicated funding aimed to ensure equity of access and improve health equalities.

An Equalities and Health Inequalities Impact Assessment (EHIA) will be undertaken for each annual update to the Test Directory and any additional in-year updates as appropriate, to assess the impact on all protected characteristic groups. In addition,

[4] www.panelapp.genomicsengland.co.uk

information on potential impacts on health equalities can be provided via each application form directly by stakeholders to inform the evaluation and EHIA.

5.2.3 Horizon scanning

Horizon scanning between NHS England and NHS Improvement and NICE will take place in line with the NICE Topic Selection process. NHS England and NHS Improvement will coordinate identifying potential policy decisions which may impact on the Test Directory. Regular engagement has been established with NICE to ensure that any potential impacts to the NHS that may result from NICE processes are communicated. Horizon scanning will also take into account other relevant policy changes and requirements, e.g. FDA, EMA, MHRA and EAMS recommendations.

NHS England and NHS Improvement is also involved in the NICE Topic Selection process to identify medicines which may proceed through the NICE technology appraisal process and include a genomic test as part of the patient pathway. Where relevant medicines are identified, the impact of implementing the genomic testing element of the patient pathway will be included as part of the technology appraisal.

To further support robust horizon scanning, NHS England and NHS Improvement have additionally introduced a notification form for stakeholders, including industry representatives, to notify NHS England and NHS Improvement of activity which may result in a proposed change to the Test Directory, e.g. the submission of a NICE Technology Appraisal by industry to NICE.

5.3 Additional themes

5.3.1 End-to-end Process

Respondents were supportive of a comprehensive and dedicated process by which the Test Directory is evaluated and updated. Respondents made particular reference to resubmission of applications, decommissioning of tests and engagement with NHS Genomic Laboratory Hubs (GLHs).

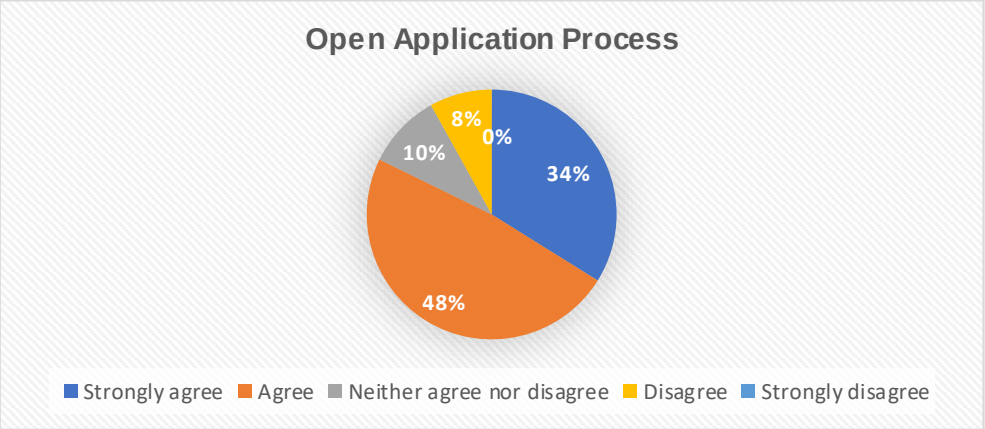
The end-to-end annual process to update the Test Directory is independent of any alternative NHS England and NHS Improvement service development processes and is overseen by a dedicate governance structure. Due to the continual nature of the application process and commercial sensitivity of applications, NHS England and NHS Improvement are not able to publish the applications and proposed amendments under consideration. The updated Test Directory will be published each year to confirm the accepted and actioned amendments to the Test Directory.

Proposals to decommission tests will undergo the same evaluation process as all other proposed amendments and be subject to the same stakeholder and public consultation and relevant impact assessments as required.

As part of the process, an impact assessment of the proposed amendments will be carried out in collaboration with the NHS GLHs to consider the operational, workforce and financial implications of implementation, prior to review and prioritisation of amendments by the Genomics CRG. Following formal decisions on the amendments and finalisation of the updated Test Directory, the amendments will be linked to NHS GLH Planning Guidance to support implementation and the Test Directory published in December each year, to ensure full implementation of the updated version by April each year.

5.3.2 Open Application Process

Most respondents agreed or strongly agreed that the process should not be restricted to certain groups of stakeholders and that applications should be accepted from any stakeholder wishing to propose an amendment to the Test Directory.



Respondents particularly highlighted the benefit of involving a broad range of stakeholders to ensure;

- A comprehensive range of perspectives are considered, including patients and the public;
- The process remains fair, equitable and accessible to anyone with an interest in engaging with the process;
- All applications are considered equally.

Stakeholders will not be required to sign up to a stakeholder list as part of the process.

5.3.3 Scoring and Evaluation

Amendments to the application and evaluation forms and supporting materials have been made to reflect comments received. This includes;

- Clarification of mandatory and non-mandatory sections of application forms
- Fields to identify if an application or evaluation relates to a prognostic, diagnostic or predictive test
- Clarification of definitions e.g. “benefit to patient” and “test”/“clinical indication”
- Benefit to patient to be evaluated as an independent section
- Clarification regarding amendments to gene panel content and its evaluation

Scoring alone does not determine the outcome of an application but is indicative to guide the Test Evaluation Working Groups in their holistic review, discussions and decisions on each proposed amendment. The Test Evaluation Working Groups will use their expertise and experience to assess each application with the relative evidence provided to give their recommendation on the proposed amendment. Each application will be considered in its own context, e.g. patient population size, evidence base, disease area etc.

5.3.4 Governance

Respondents were supportive of the governance structure principles, the utilisation of expert groups with a range of specialist expertise, and involvement of clinical oversight to support the process, and welcomed further clarification regarding the

recruitment and membership of the Genomics CRG and Test Evaluation Working Groups.

The standard NHS England and NHS Improvement open recruitment process was undertaken for the Genomics CRG and Test Evaluation Working Groups, which was open for external applications during October 2019 via the British Medical Journal.

Patient and public voice (PPV) roles were advertised on the NHS England and NHS Improvement participation hub website and were promoted through various NHS England and NHS Improvement patient bulletins and communication channels. The full membership of the Genomics CRG and terms of reference of the Genomics CRG and Test Evaluation Working Groups will be published on the NHS England and NHS Improvement website shortly.

To ensure the evaluation of applications are conducted on a UK-wide basis and all UK nations are informed of the outcomes of this process, recruitment to the Test Evaluation Working Groups was undertaken from each UK devolved administration. Each UK nation determines their own commissioning decisions, therefore any review of impact of implementation as part of this process is conducted for England only, and each nation will implement their own methodology for determining which tests are commissioned for their populations.

During the process, each Test Evaluation Working Group will have the ability to seek additional expert input to contribute to the review of any application where deemed necessary, including for example, from clinical experts, professional bodies, patient representative groups or groups representing a specific condition or clinical area.

5.3.5 Funding

Respondents were supportive of centralised and designated funding for updates to the Test Directory to further support equitable patient access to genomic testing in England but welcomed further detail in this area.

NHS England and NHS improvement will set aside a portion of its budget each year to fund the implementation of changes to the Test Directory. The total funding envelope for updating the Test Directory will be determined on an annual basis, utilising the spending from the previous year as a baseline, and taking into account other spending commitments within the year. Additional funding may be allocated outside of this funding allocation to support mandatory in-year updates as a result of NICE processes or clinical policies. NHS England and NHS Improvement continue to work with NICE on funding associated with NICE processes and implementation of genomic testing.

All funding decisions will be made at the end of the evaluation process against all amendments recommended by the Test Evaluation Working Groups, when no further applications are being considered for the relevant year, and not on a first come first served basis. The funding envelope will be allocated to the proposed amendments based on the recommendations from the Test Evaluation Working Groups.

Funding for each amendment will be agreed prior to implementation in the NHS GMS in line with the costing model for the NHS GLHs, who are commissioned to deliver a national genomic testing service. NHS England and NHS Improvement does not assess or commission specific technologies as part of these arrangements.

5.3.6 Genomics Unit resource

Respondents welcomed clarification on the NHS England and NHS Improvement resource supporting the process. The Genomics Evaluation Team within the Genomics Unit will be responsible for full administration of the process to update the Test Directory, including;

- Triage and management of applications from stakeholders;
- Communication to stakeholders of progress and outcomes of applications;
- Direct support and coordination of the Test Evaluation Working Groups.

5.3.7 Stakeholder engagement and patient and public voice

Respondents welcomed the level of, and continued involvement of, patients and the public throughout the process, but welcomed any further clarification on the development of the patient and public voice and continued stakeholder engagement.

Ensuring patients, the public and communities are at the heart of developing the NHS GMS is a central focus of the work of the Genomics Unit. PPV representatives sit on all governance groups that take decisions on changes to the Test Directory including the Genomics Programme Board, Genomics CRG and Test Evaluation Working Groups.

A Genomics People and Communities Forum has been established to bring together all genomics PPV representatives, Genomics England's Patient Participation Panel and NHS GMS Alliance regional PPV partners (to be recruited), and influences policy development in the genomics programme, and will consider and make recommendations on feedback from this consultation relating to stakeholder and patient engagement. The group has links with NHS Citizen[5] which provides opportunity to draw on additional patient experience to ensure inclusion of all patient groups. NHS England and NHS Improvement will consider the need for additional roles as the NHS GMS develops.

Mechanisms to ensure changes to services that impact on patient care are assessed against our duty to involve the public in commissioning decisions[6] are set out in the Participation Framework for Specialised Commissioning and will drive decisions to engage or consult on future changes to the Test Directory. How and when people can get involved in future engagement on changes to the Test Directory will be published at the appropriate stage in the process.

5.3.8 In-year Updates and horizon scanning

Respondents welcomed the provision for in-year updates to the Test Directory in response to policy decisions, noting the positive impact on reducing delays in access to new treatments and interventions for patients.

The process to update the Test Directory is an independent process and does not duplicate any existing processes, including NICE processes, but is aligned to ensure that the outcomes of NICE processes are actioned in relation to the Test Directory. Industry partners will engage regarding their treatment, medicine or technology via NICE processes. An additional application to the process to update the Test Directory should not be submitted for amendments for which the medicine or

[5] https://www.england.nhs.uk/participation/get-involved/how/nhs-citizen/
[6] Section 13Q of the Health and Social Care Act 2012 (as amended)

treatment etc is already being considered via a NICE process. Further evaluation of any genomic testing elements and subsequent impact assessments through the process to update the Test Directory are to assess the impact of implementing an associated genomic test on the NHS GMS only.

In-year updates will be made outside of the annual update, and therefore will be made as soon as possible in line with the required timelines for the associated process e.g. NICE Technology Appraisals require implementation within 90 days. NHS England and NHS Improvement always aim to meet the requirements for implementation; however, each process has provisions to ensure suitable implementation plans and interim arrangements can be made if timelines cannot be met, ensuring minimal impact to patients.

Stakeholders and the NHS will be notified of in-year updates via direct notification including publication of policy statements, issuing of Provider Letters and Commissioning Circulars, media and a social media posts/campaigns and emails to key stakeholder groups.

5.3.9 Out of scope responses

Some comments provided were out of scope of the consultation topic and purpose, therefore are not responded to (see below for out of scope topics).

Respondents commented on the design and structure of the Test Directory. Whilst out of scope of this consultation, NHS England and NHS Improvement would like to confirm that development is planned to implement an Online Test Directory tool to replace the current format, improving usability and functionality.

Specific proposed amendments to the Test Directory content are out of scope of this consultation and have not been captured or actioned. Any amendments to the Test Directory should be submitted via the process (see section 4.1).

Appendix 1 - Out of scope responses

Out of scope responses to the consultation were received on the following topics;

- Third party/private companies approaching the NHS
- Evaluation or appraisal of specific technologies or platforms
- The introduction of the NHS whole genome sequencing service
- Genomic testing undertaken prior to or outside of the NHS GMS
- Education and training of NHS clinical staff
- Engagement via other governance processes within NHS England and NHS Improvement outside of the proposed process
- Processes not operated by NHS England and NHS Improvement e.g. by NICE
- Implementation of the National Genomic Test Directory by local NHS Trusts
- Quality assurance of Genomic Laboratory Hubs (GLHs)
- Requesting and receiving results of tests listed in the National Genomic Test Directory
- Impact of COVID-19 on genomic testing
- Structure and design of National Genomic Test Directory
- Proposals for specific amendments to the National Genomic Test Directory