The Royal College of Pathologists
Pathology: the science behind the cure

RCPath response to the draft NHS Genomic Medicine Service: Service Specification, 2025

The College welcomes the opportunity to review the draft guidance on the future of the Genomic Medicine Service (GMS). The expansion and embedding of genomic testing in standard patient care has been transformational but has also brought challenges in terms of ensuring quality, timely delivery and equity of access across NHSE. Pathology is at the core of genomic medicine, and its members have been, and remain, committed to ensuring that these challenges are met. We hope we can work closely with the NHSE Genomics Unit (GU) to ensure this is achieved.

The College understands that the proposed increased centralisation of testing to Genomic Laboratory Hubs (GLHs) offers some advantages in terms of economies of scale and increased range of tests. However, we have listened to our members in differing subspecialties who are of the opinion that this is not a universal solution and a broader portfolio of testing strategies, aligned specifically to patient needs, is essential. The retention of local testing in certain situations provides the best solution for patients and indeed would be in alignment with the Government's 3 shifts in its 10-year plan – i.e. supporting national priorities for faster and earlier diagnosis closer to the community, providing personalised care and embedding innovation and AI into clinical practice.

The retention of local testing would reduce the risk of fragmentation of patient-focused pathways, where the following considerations are required.

- **Timely delivery of test results**: audits across multiple trusts in England demonstrate more rapid turn-around-times (TATs) from local testing compared to GLH testing. In some clinical scenarios, these differences in TAT have significantly impacted on patient safety and care.
- **Equity of access**: not all samples (e.g. tiny fine needle biopsies with low DNA yield) are suitable for large-panel testing whereas clinically important results can be achieved using 'salvage' pathways in excellent UKAS-accredited (ISO 15189) local

labs. Mandating large panel testing for all risks no results for some, which is unacceptable for many reasons, including treatment delay, due to repeat biopsy requirements.

- **Quality of service**: rapid results cannot come at the expense of quality. For decades, pathology laboratories have led the way in quality assessment and quality control of tests, establishing and participating in many EQA programmes. Local testing does not necessarily compromise quality and can be, and indeed is, regularly monitored.
- **Costs**: The College is concerned that there will be increasing costs of transport and logistics involved in moving work involved in cancer testing further away from the patients. Further, the cost for patients of more centralisation is longer waits for definitive tailored treatment with likely even poorer outcomes.
- **Research initiatives**: Centralisation of all testing to GLHs will lead to a reduction in clinical trials and national research initiatives, which drive improvement in healthcare forward via the interaction of the NHS with academia and industry. This risks new drugs that are untested on UK populations being deemed of unproven efficacy and risks approval for use being denied.

These considerations affect all patients, and the clinical and laboratory team should be empowered to undertake the most appropriate test in any circumstance. Tumour-specific expert committees draw up guidelines for best practice and these should be adhered to. Specifically, the College would like to highlight the proposals for centralised analysis in haematological malignancy, which contravenes the NICE NG47 Guideline and therefore requires urgent reconsideration.

We also emphasise the considerable expertise in molecular pathology that exists across pathology departments in England, providing high-quality responsive services that enhance patient care. The proposed GMS configuration threatens this highly skilled workforce and seriously compromises service resilience.

The College is committed to the ongoing expansion and development of genomic medicine and precision care. However, this requires collaboration between NHSE GU, the GMS and the pathology workforce. We propose that this could best be achieved through a pause in the implementation of Section 24 guidance, and through constructive discussion with all parties affected, including (and particularly) patients. The College could facilitate this with the establishment of a short-life working group with regular discussions with yourselves, to reach

solutions acceptable to all, and most importantly, achieving the best quality, cost-effective, fit-for-purpose and ambitious genomic medicine service.

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