
DIAGNOSTICS: A FUTURE ROADMAP

DEVELOPMENT OF A UK DIAGNOSTICS CAPABILITY AS A STRATEGIC PRIORITY

The future of Diagnosis in the UK

Testing for SARS-CoV-2 and screening for COVID-19 antibodies are widely acknowledged as key tools to manage both the human and economic impact of the global coronavirus pandemic. The diagnostics industry, both multinational organisations and smaller companies, has mobilised to make tests available in the UK. The Government acknowledges that the UK went into the pandemic with a shortfall in testing capacity and capability due to less investment in diagnostics compared to other countries such as Germany. Today, strong partnership working between industry and Government, delivers nearly 250,000 tests each day.

At the Life Sciences Council meeting held on 8th June 2020, members praised the ongoing collaboration and highlighted the need to maintain and build on progress achieved so far. The Council requested that the HTP consider recommendations for a strategy which will deliver a resilient, scalable and holistic diagnostics capability for our country.

Diagnosis today

"In the UK, we do not make the best use of available diagnostic tests...if a new promising diagnostic came out tomorrow, the NHS is not equipped to get it into front-line use quickly." [Tackling antimicrobial resistance, 2019–2024](#).

[The NHS Long Term Plan](#) rightly acknowledges throughout, the importance of early diagnosis, a sentiment reinforced through the subsequent prevention Green Paper. Approximately 70% of clinical decisions are influenced by in-vitro diagnostics (IVDs), yet only 1% of the NHS' budget is spent on IVDs. The situation is echoed in in-vivo diagnostics, for example data from the [JAG 2019 census](#) showed that the NHS was struggling to cope with the increase in demand for bowel cancer screening colonoscopy, even prior to the limitations enforced by COVID-19. There has been significant under investment in diagnostics (technology, infrastructure, and people) over many years.

The COVID-19 pandemic has highlighted the integral value of diagnostics to a well-managed health and care system. Significant capacity and capability continues to be built to support COVID-19 Test and Trace services. However, as routine NHS activity was put on pause, [patients face long waits](#) for routine tests and imaging, and an already overstretched workforce is under further strain. For example, the Radiologist workforce alone is thought to be understaffed [by 43%](#). Similarly, [only 3%](#) of histopathology departments said they had enough staff to meet clinical demand. Government must now continue the strong partnership working between the NHS, academia, and industry to learn lessons from COVID-19 and build a diagnostics industry of the future.

Diagnosis tomorrow

For diagnostics to play its role within a broader health system, its value must be placed at the centre of disease and patient pathways, to detect diseases as early as possible and accurately guide the right treatments.

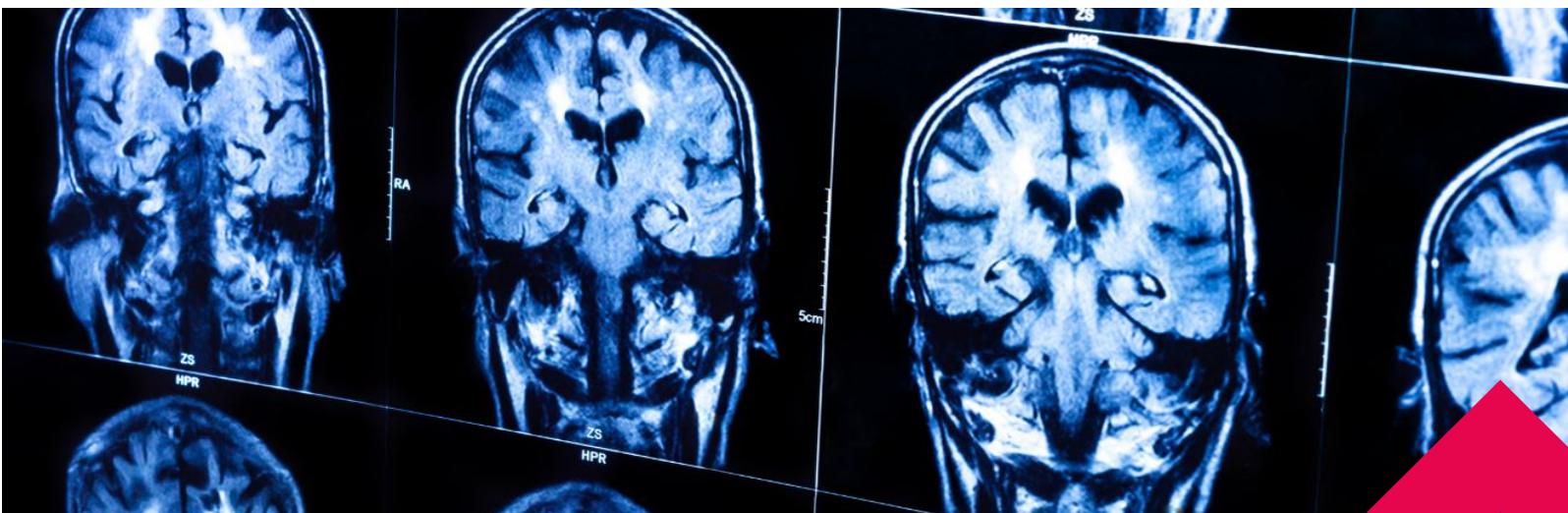
The Government must now set out a diagnostics strategy with clear deliverables to achieve by 2025. To measure success, we recommend Government aims for:

1. An increase in the per capita spend on diagnostics as compared to other European nations
2. Equity of testing access across all regions of the UK including the devolved nations
3. An increase in the level of investment in both manufacturing and Research and Development in the UK
4. A significant shortening of the technology adoption timeline
5. Full implementation of MedTech Funding mandate for all NICE approved diagnostics
6. Recovery of waiting times for diagnostic testing to pre-COVID levels and meet the various targets laid out in the Long Term Plan related to early diagnosis.

THE RECOMMENDATIONS

To achieve these deliverables, the HTP makes recommendations in **five key areas**:

1. Develop national oversight and leadership of a holistic approach to diagnostics, aimed at reducing fragmentation and aligning and co-ordinating outputs
2. Place diagnostics at the centre of population health management by developing expertise and increasing investment in the sector
3. Ensure systems and resource is in place to retain and build upon the existing partnership and collaboration
4. Retain the infrastructure built to support COVID-19 testing to accelerate adoption of new diagnostic delivery models
5. Put in place critical enablers so that patients have access to innovative and lifesaving diagnostics



RECOMMENDATION #1

Develop national oversight and leadership of a holistic approach to diagnostics, aimed at reducing fragmentation and aligning and co-ordinating outputs

The opportunity that diagnostics presents in supporting health improvement and management is now, we contend, strongly recognised by the public. However, the system in which diagnostics operates is complicated and disjointed with decision making markedly slower and more disparate than in other countries.

Leadership and resourcing is much needed to ensure alignment and strong co-ordination of strategy implementation.

- › Appoint a 'National Diagnostics Director' operating jointly from the Department of Health & Social Care (DHSC) and NHS England
- › Deliver clear guidance on the intended roles and responsibilities between different Governmental departments and NHS Authorities
- › Ensure there is close working between devolved nations on a national diagnostic strategy so learnings can be shared
- › Accelerate the consolidation of the national pathology networks across England and the IT infrastructure and connectivity that will need to underpin their work.

RECOMMENDATION #2

Place diagnostics at the centre of population health management by developing expertise and increasing investment in the sector

The full benefits of diagnostics are realised when they are positioned as a key enabler for the delivery of population health management. Investment is key, and needed to recruit talent, upgrade infrastructure, and adopt new technologies. Expertise is crucial for the success of population health management, however staffing and resource constraints in radiology and pathology are well documented. There is a need to develop and implement an NHS diagnostics workforce plan to boost this expertise.

NHS laboratories are integral in delivering high quality tests, they conduct circa 80% of in-vitro analysis. They have high standards of accreditation, governance, and data connectivity to patient records. Yet, they have been under-invested in. Alongside this, new technologies and partnerships are changing how all diagnosis happens, for instance through digitalisation and application of machine learning techniques, and these factors must be taken into account when recruiting, training or up-skilling. This modernisation drive provides an opportunity for new systems and processes to take hold and productivity to increase over the long-term.

- › Boost expertise by developing and implementing an NHS diagnostics workplace plan.
- › Provide up-front investment to modernise infrastructure and equipment through a capital investment fund. Public-private partnerships can support this and help bring new capital and manage financial risk. Partnerships should be built in such a way as to bring in multiple suppliers, including SMEs, who provide significant innovation and resilience to the system.
- › The consolidation of laboratories to form [29 pathology networks](#) must continue. However, the outcome should not be cost-containment, but modernisation, productivity and innovation.



RECOMMENDATION #3

Ensure systems and resources are in place that will work to retain and build upon existing partnerships and collaboration

Central to the UK's COVID-19 testing response, has been collaboration between different organisations within the diagnostics ecosystem, public and private laboratories, NHS England, Department of Health and Social Care (DHSC), Public Health England, academia, and industry, small and large. Whilst national leadership will help with alignment and co-ordination, a broader forum to ensure the different groups continue to co-ordinate, share learnings, and work collaboratively will be crucial to ensure the achievements and progress made are not lost. Trust is key to facilitating partnership working and a broader forum will continue to help in this regard.

- › Formalise a diagnostics group, under the Health Technology Partnership, to bring together the different organisations in the system and build supporting resource and capability within the Office for Life Sciences and broader Government as necessary.
- › Forge new partnerships to improve analytics and information sharing so that the utilisation of diagnostic technologies informs population health management, screening and surveillance.
- › Build a model for 'speed dating' between different parts of the system to deliver collaborative and innovative projects. Such a model should be aware of ongoing initiatives, learn lessons from the Precision Medicines Catapult and not add complexity to the system.
- › Develop and support industry-NHS-academia accelerator programmes that identify innovations to deliver diagnostics in different locations closer to the patient.
- › Continue the development of the 'Accelerating Detection of Disease', Accelerated Access Collaborative and [CONDOR network](#) programmes.

RECOMMENDATION #4

Retain the infrastructure built to support COVID-19 testing and go further by utilising those to accelerate the adoption of new diagnostic delivery models

Diagnostic delivery models have been changing over many years. The “place” where diagnosis occurs is moving closer to the patient, point of care in-vitro tests are an example, as are smaller, more portable imaging devices which can be used in community settings. Earlier disease detection can help shift health focus from intervention to prevention.

The COVID-19 pandemic has seen an acceleration of the implementation of some of the new ways to conduct tests. The distribution and management of home testing kits, assembled from scratch, is an example of an effective channel to reach citizens. Work is also underway to smooth IT connections so that data capture and test analysis by Lighthouse Labs is linked to personal health records.

It is well understood that the silo nature of funding in the NHS and the need to show same-year savings slows traction of these new models. Addressing this will mean a greater push by Government to expedite the move to ICSs and shared budgets.

We have also seen [a dramatic increase](#) in the use of virtual GP appointments. The process to order COVID-19 test kits online has proven that different models for providing diagnostics can, and should, be implemented. There is now an opportunity to facilitate more diagnosis to be conducted in an equally convenient and efficient manner, without the need for patients to attend a physical consultation.

- › Facilitate change and adoption of innovations by moving to whole system, outcomes-based payments that recognise the value and benefits of diagnosis across the entirety of a patient pathway.
- › Review the current diagnostic assets and how they are best utilised i.e. NHS Laboratories for instance could arguably have been utilised in a more productive way.
- › Review the systems asset management, equipment tracking and warehousing and logistics in order to maximise utility from that which already exists and has been built during the pandemic. Industry expertise could be used to complete this review.
- › Ensure appropriate resilience planning is in place to protect critical screening programmes during subsequent waves of COVID-19 or another future pandemic.
- › The use of community settings, e.g. pharmacies, to deliver diagnostics to support the increase in virtual GP appointments.



RECOMMENDATION #5

Put in place critical enablers so that patients have access to innovative and lifesaving diagnostics

Fundamental to building indigenous industrial capability, is having a receptive local market to new technologies. This demand supports return on investment and spurs further innovation. To do this, the UK must increase the adoption of diagnostic technologies across the system. This can be achieved in part by:

- › Ensuring the Accelerated Access Collaborative (AAC) and NHS funding mandate for devices and diagnostics is supported by the necessary funding and infrastructure to expand the adoption and diffusion of a significantly greater number of diagnostic technologies than the few it currently allows.
- › Developing an early access scheme for diagnostics equivalent to that for medicines that is now well established to allow for early access to innovative testing.
- › Improving routes to market with greater flexibility to help smaller businesses gain commercial traction with the NHS.
- › Further developing a UK-wide national, standard set of contractual requirements for Pathology Managed Services based on clinical need that represents an equitable balance of risk expected both for the NHS organisation/s and suppliers. Focus then needs to be given to ensure the standards are fully utilised.
- › Continue to invest in the Academic Health Science Networks and Medtech and In-Vitro diagnostics Co-operatives (MICs).
- › Ensure that digital diagnostics are enabled by the availability of data and the necessary IT infrastructure, information governance and cyber-security arrangements.
- › Work with the investment community to ensure appropriate incentives are in place to encourage support for the diagnostics sector.
- › Digitally supported patient pathways should become the norm to provide better care for people with major health conditions, with diagnosis at the core.
- › As part of the innovative regulations project, consider opportunities, for both medical device and invitro diagnostics regulations, as to how MHRA can develop as a next generation, world leading regulatory body building on its existing international standing and agility demonstrated during the pandemic.

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