Future Blood Testing Network+

THE UK LABORATORY DIAGNOSTICS LANDSCAPE REPORT

University of Warwick and UHCW NHS Trust

D.K Grammatopoulos, E. Braybrook, N.A Anderson
Warwick Medical School and UHCW NHS Trust

Report Date: 06/03/2024

The UK Laboratory Diagnostics Landscape Report
FBTN-Project-Series: Landscape Report
Report Date: 06/03/2024
DOI: 10.5281/zenodo.13970649
Published by University of Reading

Network: Future Blood Testing for Inclusive Monitoring and Personalised Analytics Network+
This Network+ is EPSRC Funded under Grant No: EP/W000652/1
Principal Investigator: *Professor Weizi (Vicky) Li*
Co-Investigators: *Dr Robert Barker, Professor Jeremy Frey, Professor Serhiy Korposh and Dr Mark Elliott*
Network+ Coordinator: *Dr Samantha Pearman-Kanza & Rachel Mudzinganyama*

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1. Project Details

Title	The UK Laboratory Diagnostics Landscape Report
Funding reference	FBTN-FundingCall1_003
Lead Institution	University of Warwick
Project Dates	01/11/2023-30/4/2024
Keywords	UK diagnostics, current state of the art, challenges, opportunities

2. Project Team

2.1 Principal Investigator

Name and title Professor: Dimitris Grammatopoulos	
Employer name/University Department Name: Warwick Medical School	
Work Email: d.grammatopoulos@warwick.ac.uk	**Website Link:** http://www2.warwick.ac.uk/fac/med/staff/grammatopoulos

2.2 Co-Investigators

Name and title: Professor Neil Anderson
Employer name/University Department Name: UHCW NHS Trust
Work Email: Neil.Anderson@uhcw.nhs.uk

2.3 Researchers & Collaborators

Details of other team members:

Emma Braybrook, Senior Biomedical Scientist, UHCW NHS Trust [New], 1/6/2023

3. Executive Summary

Why do diagnostics and laboratory medicine matter? These services are critical components of modern healthcare, serving as the cornerstone of accurate disease diagnosis, patient monitoring, therapy selection and delivery of public health prevention policies and medical research. Demand for diagnostics services in the United Kingdom (UK) has increased over the past few years, but a chronic underinvestment in infrastructure and staffing means waiting lists are growing. This sector is now recognised as being a very high priority by the government and NHS England. The landscape report examines and reviews the current state of the sector, and identifies key trends, challenges, and opportunities. In particular, embracing digital technologies, fostering research collaboration, and addressing workforce challenges are pivotal for the sector's sustained success. All stakeholders identify the immense promise of digital diagnostics, AI, and personalized medicine for improving patient outcomes and healthcare efficiency and recognise fostering innovation as key for long term sustainable success. In parallel, collaboration between policymakers, healthcare providers, and industry stakeholders is essential to reinvigorate the sector, navigate changes successfully and ensure that diagnostics, and more specifically laboratory medicine services, remain accessible and of the highest quality for all the population in UK.

4. Key Findings

Consensus agreements the Diagnostics sector has been chronically under-funded; emphasis on costs savings not on delivery of a fit-for-purpose service
New service reconfiguration to uncover enablers
Staff shortage and currently staff under-skilled to deliver the technological advances
Better integration service to capture advantages of new technologies
Slow adoption of innovation
Digital technologies are identified as a major driver of improvements
Move towards direct patient access- benefits and pitfalls

5. Introduction to Diagnostics

5.1 Current Landscape

In the modern era, healthcare relies heavily upon diagnostics. This sector encompasses medical imaging, physiological sciences, pathology testing and genomic services, all critical to the detection and diagnosis of disease. Within the UK's current National Health Service (NHS) operating model, diagnostics is fully embedded within a clinical pathway-centric approach, with more than 85% of patients seeking NHS care requiring diagnostic tests.[1] Access to timely and effective diagnostic services to manage demand in screening, diagnosis, and prognosis, is critical to providing high-quality care, reducing waiting times for treatment, and improving health outcomes. Improved efficiency also has substantial economic benefits through both patient-related cost savings and the reduction in costs to diagnostic providers.[2]

Every year, the NHS spends around 6% of its budget carrying out more than 1 billion diagnostic tests. Demand continues to rise each year across almost all areas of diagnostics and between 2014 and 2019, an annual increase of 4–7% in activity for endoscopy, ultrasound, X-ray, computed tomography (CT), magnetic resonance imaging (MRI) and positron emission tomography (PET) – CT procedures were recorded. This was higher than other recorded aspects of NHS activity, such as emergency admissions and outpatient attendances.[3] Unfortunately, national data for some diagnostic services is not standardised in its collection (pathology, histopathology and physiological sciences) and so cannot be interrogated as easily. However, evidence from individual Trusts has demonstrated that substantial pressures year on year have also been experienced in these services.[4] In parallel, growth in the diagnostic workforce has not kept pace with demand and activity; there are now significant staff shortages across all specialties, with imaging, radiology, pathology and endoscopy notably under strain. The combination of increased workload and reduced workforce has severely impacted wait times for diagnostic tests. Across 2023, over 400,000 patients each month are regularly exceeding the 6 weeks wait target and more than 160,000 exceeded a 13 week wait. This is in comparison to respective averages of 40,000 and 5,000 recorded before the COVID pandemic (figure 1).[5]

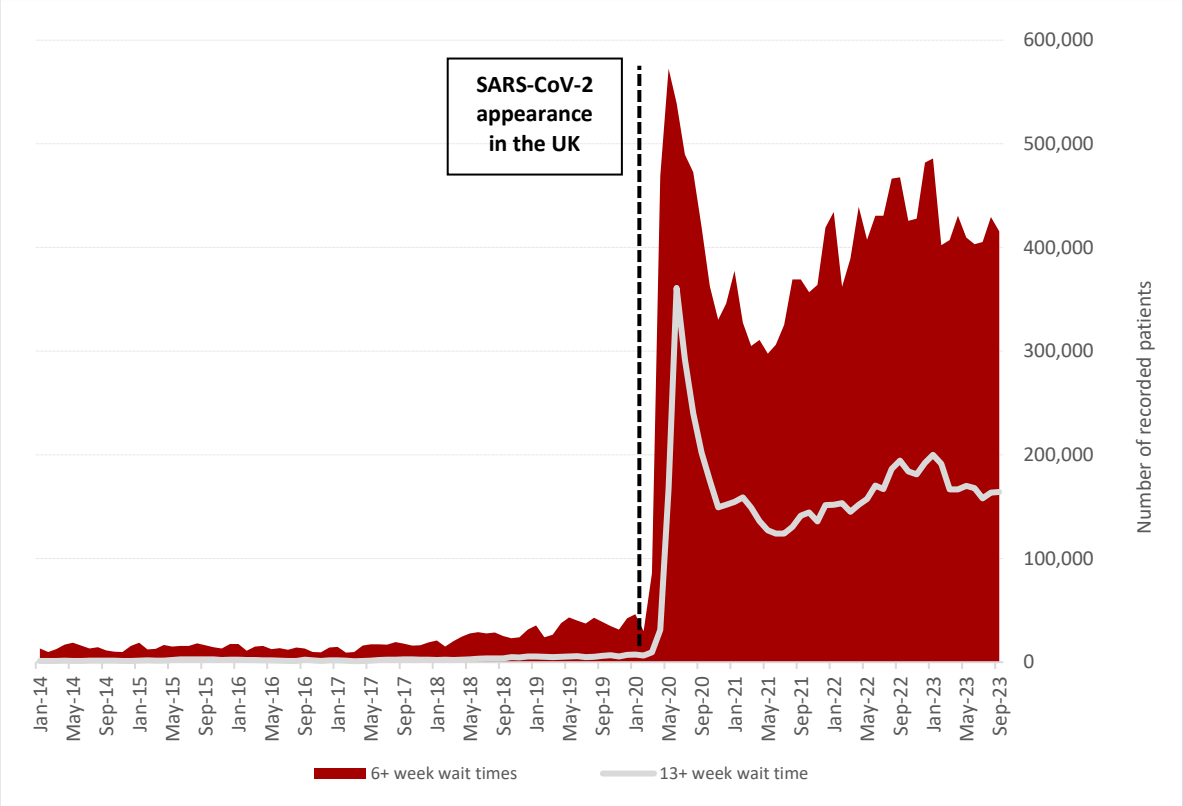

Figure 1: Patients waiting over 6 weeks and over 13 weeks for a diagnostic test (pre- and post-pandemic).

The laboratory medicine arm of diagnostics, often referred to as pathology, is a discipline that encompass a broad spectrum of services and sub-specialties. It is the bridge between science and medicine and alongside the analysis of a wide range of biological samples, such as blood, tissue and fluids, laboratory services also provide result interpretation, support in the development of national testing guidelines and are a source of clinical expertise and education to service users. Through early disease diagnosis, targeted timely treatment, or the reduction of risk for diseases that represent major public health challenges (e.g. diabetes or cardiovascular disease), laboratory medicine helps to promote a healthier population. In addition to the management of laboratory processes, departments such as mortuary, point of care and phlebotomy also fall under the management structure of Pathology. To ensure a high standard of service, many clinical laboratories are assessed by the UK Accreditation Service (UKAS) to an international standard for medical laboratories (ISO15189:2022) and all must ensure practices adhere to the Blood Safety and Quality Regulations 2005 and Human Tissue Act 2004. This is monitored through the respective regulatory bodies, the Medicines and Healthcare Products Regulatory Agency (MHRA) and the Human Tissue Authority (HTA).

Together, this comprehensive framework of regulation covers all aspects of diagnostic laboratories and service provision in the UK.[6]

This report explores the various facets of pathology and laboratory medicine in the UK, including drivers that have shaped current status, infrastructure, key players, regulatory frameworks, historical and current challenges and emerging trends alongside challenges and opportunities.

5.2 Pathology Services in the UK

Provision of *in vitro* diagnostic services in the UK is based on a well-established network of diagnostic laboratories, including the sub specialities: clinical biochemistry and haematology (collectively termed blood sciences), blood transfusion, microbiology and virology (collectively termed infection sciences), and cellular pathology. This network operates across 250 NHS hospitals, providing laboratory services for the 60 million people of the UK[7] and similar to many countries of Western Europe and the USA, the pathology and laboratory medicine services have been organised around a relatively small number of large central hubs. Traditionally, laboratories have provided a 24/7 service for blood sciences, whilst core laboratory services for microbiology and histopathology have been provided at most hospitals, although not always on a 24/7 basis. Specialised laboratory services such as molecular genomics or inborn errors of metabolic disease are available from a small number of expert centres, normally based in teaching hospitals or stand-alone reference laboratory sites. A small number of university hospitals with unique clinical expertise and methodological infrastructure also contribute to these services.

This overall testing activity involves a workforce of 28,000 that deliver around 1.2 billion tests per annum.[8] Most laboratories and diagnostic centres are part of the NHS, which provides comprehensive health care to everyone in the UK and is free at the point of delivery, although private diagnostic providers supplement NHS services, often offering specialised testing not provided by the NHS or recommended by NICE. The demand for private-led diagnostics has seen an exponential increase over the past few years driven by the COVID-19 pandemic and ongoing difficulties of patients in accessing NHS healthcare during the post-pandemic

recovery.[9] An important contributor in UK diagnostics is the globally recognised academic and biotech ecosystem offering cutting edge research with translational potential.

This model of pathology and laboratory medicine service provision has enabled all NHS laboratories to benefit from economies of scale. Moreover, it has fostered a collaborative community among senior professionals, encouraging cooperation rather than competition. The development of national workforce planning has been achieved through coordinated efforts of professional organizations, including the Association for Laboratory Medicine (ALM), the Institute of Biomedical Scientists (IBMS), and the Royal College of Pathologists (RCPath). Additionally, Health Education England (HEE) and the National School of Healthcare Science have played integral roles in shaping this coordinated approach.

Key developments of the UK laboratory diagnostics over the past 20 years that have shaped the current landscape include the modernization agenda[7], service reconfiguration and the influential Carter reviews[2,10,11] (see section 5.3) that guided current thinking about Diagnostic (Pathology) services in the UK, as well as implementation of Pathology networks[12] to minimise unwarranted variation, improve accuracy and turnaround times on tests, reduce unit costs and make best use of the expanding workforce.

As determined by all four Departments of Health in the UK, all pathology and laboratory medicine services are expected to be registered with an approved laboratory accreditation body. The overwhelming majority of NHS laboratories are registered with and accredited by United Kingdom Accreditation Service (UKAS), the national accreditation body for the United Kingdom, which uses standards benchmarked against ISO 15189. This is one part of a comprehensive framework of regulation that covers all facets of diagnostic laboratories and services provision in the UK (see also section 5.6).[6]

5.3 The Modernisation Agenda and the Carter Reviews

Despite the pre-existing collaborative approach, over the last twenty years there have been continuous efforts to ‘modernise’ laboratory services, citing improved quality, efficiency and cost effectiveness, whilst making them more patient focused and fit for purpose. Although ongoing since 1999, the modernisation journey for Pathology is not yet complete, with

continued policies from the Department of Health, bringing about national changes in structure and provision (an overview is presented in Figure 2). Although, the direction of travel towards consolidation has been cemented, as a result of the post-Covid era challenges to the diagnostic service, more recent changes are expanding diagnostic provisions outside the traditional acute care setting, supporting increased use of virtual consultations and community services.

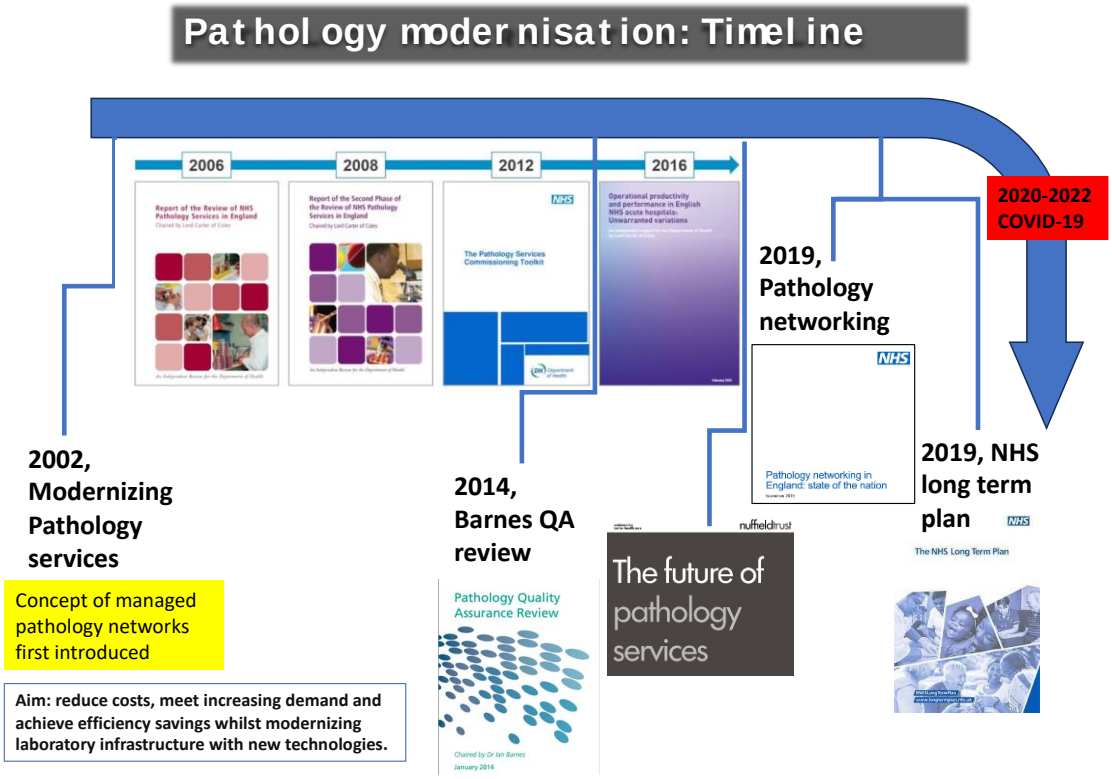

Figure 2: Pathology modernisation: a timeline.

The Pathology Modernisation Programme was first launched in 1999[13] and led to the appointment of a National Pathology Adviser alongside the initiation of pilot projects across England. These demonstrations were predominantly focussed on the introduction of information technology (IT). A further consultation paper published in 2002, proposed future principles, goals and objectives for NHS pathology services. Amongst these proposals the introduction of managed pathology networks was identified as a priority. The expectation was that this change would reduce costs, meet increasing demand, and achieve efficiency savings, whilst modernizing laboratory infrastructure with new technologies. The outcome of this consultation was the policy document, 'Modernising Pathology Services'[14] which incorporated a blend of local strategies and national support mechanisms.

A follow up document published in 2005 by the Department of Health[15], aimed at 're-energising' the modernisation program and promoting a patient-centric service using new technology and new ways of working. This paper also announced a radical independent review of pathology services under the chairmanship of Lord Carter of Coles.

The Carter review supported the modernisation program in England. A practical guide to service improvement was published[16] as a toolkit for use by individual laboratories alongside workshops to encourage the local use of LEAN and Six Sigma methodologies. This phase achieved some progress; a number of network laboratory services were developed with a sharing of resources and a rationalisation of services across a number of sites. Successful networks were actively managed with management support from the hospitals. Unfortunately, the prevailing scenario involved informal federated networks where laboratory medicine professionals tried to drive the networking agenda without active support from the employing authority. The parallel push for self-managed, competitive, Foundation Hospital Trusts that did not fit comfortably with networked laboratories offered another level of complexity and so several informal networks failed to consolidate and develop in tangible entities.

Despite this, many examples of good local practice in the modernisation of laboratory medicine services were achieved through the *action learning program*. These examples were collated and published in two practical, hands-on documents. These published case studies were focused on: workforce development and re-profiling; protocol-guided investigations using patient wristbands; network development; standardisation of reference intervals; improving primary care diagnostics.[17,18] Similar activities also took place in the other three devolved countries of the UK.

A key focus of the Carter review team was a deep and systematic evaluation of pathology and laboratory medicine services in England. In shaping recommendations for the future, the team drew insights from global examples of good practice. The scope of pathology and laboratory medicine services in England was defined for the first time. The report estimated that 70–80% of all health care decisions affecting diagnosis or treatment are influenced by

laboratory medicine results. Over 500 million clinical biochemistry and 130 million haematology tests are carried out, over 50 million microbiology requests are processed and over 13 million histopathology slides and 4 million cytology slides are examined each year. Overall laboratory services were estimated to cost the NHS in England £2.5 billion per annum and rising, of which the single largest element is workforce.[10]

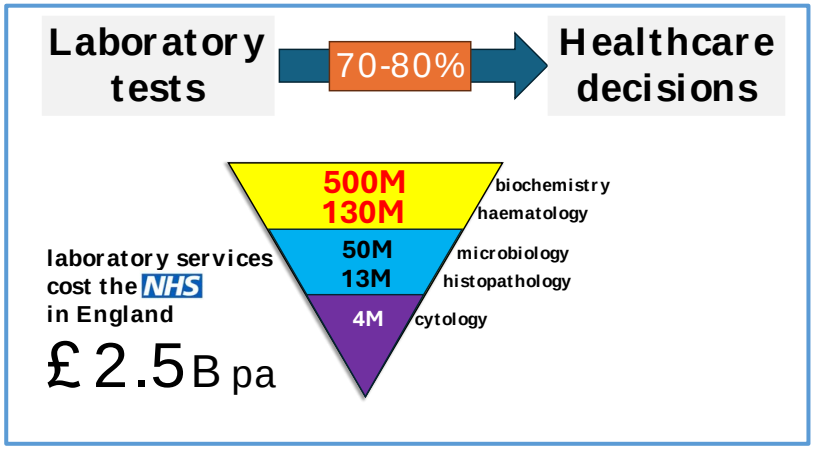

Figure 3: Summary of laboratory costings in the NHS

The first Carter review report in 2006 advocated for managed pathology networks as the optimal model for service delivery. Table 1 describes the key drivers and barriers identified for change to pathology and laboratory medicine services.

Table 1: Introducing change to pathology and laboratory medicine services in England: The Carter review

Drivers	Barriers
Greater need for patient focused services	Fragmentation of arrangements for collecting and transporting samples
The need to embrace competitiveness and plurality of provision	A complex workforce lacking in appropriate planning and development
A requirement to re-profile the workforce to make it better suited to new technology and modern ways of working	A lack of end-to-end information technology (IT) connectivity
The need for the definition of core data to create a framework to measure efficiency and effectiveness	Variability in test repertoire, investigation protocols and reference ranges
Recognition of the status of a core clinical service in relation to impact on the patient's journey leading to a requirement for laboratory services to be commissioned and delivered as part of an integrated health care system	A lack of knowledge and understanding of laboratory services amongst commissioners and senior managers
The need for strong clinical leadership	Uncoordinated use of point of care testing (POCT)
	A lack of knowledge and understanding of laboratory services amongst commissioners and senior managers

In making its recommendations the Carter review team identified the following priorities for change and set the framework for future developments.

- **The development of a national specification for improving quality.**
- **The creation of stand-alone pathology service providers.**
- **End to end IT connectivity, including where possible POCT.**
- **A national tariff system for reimbursement.**
- **Integrated service improvement and large-scale workforce change.**
- **Development of stronger clinical leadership.**

The report from the Carter review team contained several recommendations that required action from laboratory professionals, NHS hospital trust providers, those responsible for commissioning services and from the Department of Health in England. However, the two major recommendations were:

⇒ Creation and use of managed pathology networks favouring of pathology and laboratory medicine services that are 'joined up' and clearly part of integrated healthcare.

⇒ Establishment of pilot projects to gather data in a standard format that can be used to inform a national specification and a national system for reimbursement.

A number of recommendations were consolidated in a second Carter report in 2008[11] accepted by the DoH as there were estimated savings of £250-500 million. The Carter recommendations built on Lord Darzi's vision of a patient-focused, more accessible NHS.[19] Senior leaders of the UK laboratory medicine such as Dr I. Watson and Dr J. Barth, ex-Presidents of ACB, commenting on this report[20] highlighted the three key areas to improve service, built around to *adoption of new technology*, *ways of working* and *extensive*

consolidation of services into networks. Their view was that key recommendations to enable changes in service while supporting quality, should involve improvements in:

- **Logistics and information technology for laboratory communications.**
- **Knowledge for patients to enable better patient engagement in their care.**
- **Design of community laboratory testing.**
- **Development of laboratory networks with integrated management to take advantage of economies of scale, modern technology and shared expertise and experience.**
- **Optimal design of specialist services.**
- **Development of national quality standards.**
- **Advocacy and development of national clinical leaders.**
- **Modernising Workforce skills and career pathways fit for purpose.**

It is fascinating that these recommendations made in 2008 provide a blueprint that is still relevant 15 years later as UK diagnostics and the whole national healthcare is trying to recover from the COVID-19 pandemic. These identify the key pillars that underpin the UK diagnostics sector and requirements for best laboratory medicine practice.

For many these recommendations are considered as crucial to deliver an integrated care focusing around the needs of patients and service users. Doing so will require a move away from single institutions towards a systems-based approach organised around networks of care, a model of delivery that is currently delivered by integrated care boards (ICB). These relatively new bodies, are statutory NHS organisations responsible for meeting the health needs of the population, managing the NHS budget and arranging for the provision of health services in a geographical area. The Nuffield Trust, investigating the future of service delivery in various specialisms within the health service, identified the following opportunities and emerging trends for Pathology and Laboratory Medicine.[21]

- **Improve efficiency and effectiveness and in many areas, savings should be reinvested to fund additional activity and achieve the quality improvements that are needed.**
- **Encourage and promote initiatives such as the National Laboratory Medicine Catalogue (NLMC) that provide a useful language and standards for testing and reporting. The Royal College of Pathologists has endorsed the 'Choosing Wisely' campaign, which is designed to ensure only the most appropriate and effective investigations are used. Translating these into routine practice will be a substantial and at times difficult undertaking.**
- **Contribute to the commitment to improve early diagnosis of diseases such as cancer and cardiovascular disease. Patient pathways could also be redesigned to provide improved care out of hospital, extending the life of existing infrastructure, which will struggle to cope with expected population increases without major investment.**
- **Address acknowledged gaps in provision in the fields of molecular testing and genomics, centred around a network of 13 genomic centres.**
- **Benefit from the pace and scale of innovation in the biosciences which is significant; developing the sector is seen as a national priority. POCT (see section 7) and digital health and biosensor applications are starting to enter health care.**

Experts within the profession widely expect that delivery of the above will require:

⇒ Informed leadership at all levels – including boards, clinicians, commissioners, and the national leadership of the NHS to champion these opportunities and emerging trends. But far greater opportunities exist for systems that want to be ambitious.

⇒ Emphasis on innovative integrated approaches that addressing the whole patient pathway together with pathology.

⇒ Exploring impact of systematic collaboration between sites and potential to yield greater benefits than consolidation into larger-scale centres.

⇒ Maximising benefit for patients from advancements in biomedicine and data science. The NHS must not only evaluate effective practices but also invest in developing care models that leverage available innovations. New contracting approaches should encourage innovation.

⇒ Addressing the need for better-supported interoperable IT allowing easy access to data for patients and other institutions. The National Laboratory Medicine Catalogue is an important foundation for this initiative and appropriate IT support is vital for ensuring high-quality, safe pathology services. As the quantity of digital information increases, the ability to store, retrieve and analyse data will become increasingly important.

⇒ Fostering the creation of a highly skilled and proficient workforce is a crucial imperative. Concerns have been raised regarding an aging workforce, with 40% of pathologists aged over 55, and the majority anticipated to retire within the next five years. While evolving technology may necessitate the development of new skills, this alone is unlikely to entirely offset the associated risks. There is rising demand for bioinformaticians and data scientists, underlining the pressing need for training and education to empower the broader clinical workforce to keep pace with field advancements.

As consolidation of laboratory services is on-going, there are already attempts to assess and evaluate the impact of change, especially around cost-savings which represented a major focus. Recent reports[22] suggest that consolidated units have on average achieved larger cost savings than non-consolidated units. However, the consolidation of services has opened the pathology market to the private sector, with an increased number of private laboratories operating in the last 5 years. Authors have been unable to directly prove that the greater cost savings are due to the consolidation process, but savings were achieved with negligible redundancies. It is concluded that the long-term impact on the pathology workforce and the quality of pathology services is worth further investigation.

In addition, a recent RCPath report[23] reiterates support on NHS Trusts taking measures to reduce unwarranted variation and encourages departments to consider closer collaboration and networking to ensure optimal provision of pathology services. The focus should be on the value of the services provided, ensuring that the quality remains high while cost savings are sought. Like many other previous documents, the report highlights focus on IT and workforce. Most importantly, a consistent theme across several reports and authors were concerns around the lack of re-investment to modernize the sector and insufficient overall funding in R&D related to Diagnostics for new product development and strengthen clinical research capacities, a point that compromised UK and global preparedness to pandemics.

5.4 Service Reconfiguration Post-COVID and Beyond

The COVID-19 pandemic has been a turning point to the Diagnostics sector in the UK and globally. On one hand UK diagnostics entered this unprecedented healthcare emergency from a position of limited strength; underfunded, with shortages in staff numbers and skills, for many years focusing on 'just deliver the core service' and unable to process quickly technological and scientific innovations.

On the other hand, there is consensus that the UK diagnostics sector successfully mobilised resources and delivered mass diagnostics at an impressive scale following government's plans and policies. Despite concerns around the accuracy of lateral flow devices (LFD) and the impact of false reassurance, UK infrastructures and data systems delivered up to 4 million LFD-based results per day. On the international stage the UK is highly regarded as a pioneer of mass testing. It is widely accepted that looking ahead, this must harness every positive, and built on the momentum developed. This involves recognition of (a) the social and healthcare impact the development of novel diagnostic approaches has had to benefit the sector's and the nation's health and (b) the need to develop innovative ways to deliver diagnostics-driven health, outside traditional settings including home and high street and involves extensive patient engagement.

5.4.1 Academic and industry collaboration

Various reports published post-pandemic recognised that mobilising resources and focused approach to diagnostics during the pandemic by industry, academia, NHS and government led to development of infrastructures and data systems in the UK that massively uplifted national capacity for remote testing as well as centralised PCR testing to an unprecedented scale (for example see Chris Molloy, CEO, Medicines Discovery Catapult Blog)[24]. This response was supported by training an exceptional number of young scientists in clinical-quality level diagnostic lab skills. Even more impactful was the effect on the public; for the first time, they had taken control of their own diagnostic assessment and acted based upon the results. Furthermore, key positive changes identified following the pandemic include remote GP appointments, virtual wards, AI-enabled and other digital process improvements. Diagnostics available in the home and high street are one major agent of change, offering complementary

access to diagnostics. There is expectation that these changes will result in growth of private sector remote diagnostics providers as well as the development of new structures within the NHS; we already see development of new units such as Community Diagnostic Hubs, encouraging a more patient engaged, sustainable healthcare future. Most importantly, the response to pandemic catalysed a growing range of remotely delivered products and services, which provide choices to public; this is considered as an opportunity to offer greater choice to disadvantaged or disengaged communities and encourage public to take control and be responsible of their health. This might also encourage a different mindset focusing on screening and early diagnosis to drive a collaborative healthcare model of private-public co-operation through various models of synergy: for example, the public sector might provide demand signalling, provided by the private sector. Alternatively, the private sector-led innovations might result in adoption from the public sector.

As proposed in a recent impactful *BMJ Global Health* article[25] improving diagnostics services to develop a robust service for future pandemic preparedness will require a coordinated approach to implement "a holistic approach to diagnostics preparedness." Key areas identified include:

- **Boosting diagnostic capacity, staff skills and establishing surveillance of priority pathogens across defined laboratory networks.**
- **Development and adoption of diagnostics technologies that require minimal sample preparation, and 'clever' platforms that can rapidly adopt new assays.**
- **Formalising pathways for dedicated diagnostic funding to meet demands and maintain preparedness including incentives for industry involvement.**
- **Expanding the network of expert personnel and labs to enable knowledge sharing and a rapid response during outbreaks.**
- **Learning from solutions developed to address similar challenges in vaccine development could be expanded to cover diagnostics.**

These are crucial to counter future threat of a hypothetical 'Disease X" which, according to the WHO definition[26], "represents the knowledge that a serious international epidemic could be caused by a pathogen currently unknown to cause human disease.'' There is an established need to enable early cross-cutting R&D preparedness that is also relevant for an unknown Disease X.

Other points raised by Chris Molloy, CEO, Medicines Discovery Catapult[24] commentary include:

- ⇒ Acknowledging that diagnostic tools and services operate on a global scale is crucial. Consequently, depending solely on the NHS for testing innovations represents a narrow perspective that is progressively dismissed by investors and the global healthcare community.
- ⇒ Redirecting public sector high capacity in laboratory settings developed during the pandemic. This could be applied to distinct cancer and infectious disease mass testing programmes for specific biomarkers, capitalising knowledge around multiplexed PCR, serology or LFD. Especially if we are to ripe benefits of early diagnosis these must be steps to deliver more digitally-enabled tests capable of being used outside the traditional laboratory setting. There is an opportunity to establish purpose and responsibility shared by patients, health providers and payers.

5.4.2 Service integration and discipline collaboration

There is an on-going discussion around the future diagnostics set-up suitable to capture healthcare priorities and technological developments. A key challenge of transformative innovation in healthcare is how to harness technology to reshape healthcare delivery, step change towards prevention and need to exploit the advances around data science. This is happening in parallel to efforts of migrating to a more progressive healthcare ecosystem. Regional stakeholders, organised as integrated care boards (ICB), will assume collective responsibility for managing resources, delivering services, and ensuring improved health of the population they serve. This fundamental change in the ways that the NHS works, and interacts with patients, clinical users and other stakeholders provides the opportunity for shifting the pathology paradigm from the transactional and inward-looking constraints of pre-COVID pathology systems to the value and outcome-based transformational service model next generation pathology is expected. Such approach can positively affect the bottom line of the system as a whole. It has been highlighted[27] that this is journey will enable pathology to evolve and transform to exceed its traditional organisational, operational, scientific and clinical restrictions and learn to proactively create and deliver high quality, innovative

solutions for its users and patients. Having the laboratory medicine in the driver's seat of innovative multidisciplinary solutions for clinically excellent and cost-effective management of patients. Such Initiatives provide opportunities to depart from a focus on cost centre-based targets that require squeezing out yet another percentage of its own 5% share and instead endorse the long view.

Blood Sciences disciplines within Pathology and Laboratory Medicine are well placed to underpin and lead delivery of scientific, methodological, and operational innovations: laboratories routinely detect or quantify diverse circulating targets (such as blood cells, chemical compounds, nucleic acids, proteins, and enzymes) to provide information used for the prevention, screening, diagnosis, treatment and management of diseases. Capturing and decoding this data is key to characterise complex pathophysiological phenotypes and deliver personalise diagnosis and treatment of patients. Retaining the ability of Clinical Biochemistry, Immunology and Haematology etc to adopt innovations and drive translation of powerful multidiscipline methodologies and novel biomarker concepts into routine patient care across the whole of the NHS, is of fundamental importance if precision medicine is to become the exemplar practice across the 21st century NHS.

NHS Diagnostics commitment to deliver word-class diagnostic services whilst maximising cost efficiencies is central in shaping thinking. The aspiration to deliver more beyond efficiency savings through consolidation but to grasp the unique opportunity to facilitate and lead innovation back into the operational planning of routine diagnostic services, appears to be an exciting opportunity post-pandemic. It is stated that this ambition aligns with delivery of the new NHS long-term plan[28] that places research translation and innovation as key enablers of improvement. Lord Carter's report clearly identifies that transformation of pathology service is necessary so that they can respond swiftly to the challenges presented by innovation (particularly from the technological advances in mode of diagnostics delivery as well as genomic, -omic signatures and data revolution), system reform across the NHS and reorganization of the workforce. Service consolidation could support the rapid adoption of innovative new technologies and new approaches to the delivery of pathology.

Concerns have been raised, when service consolidation drives attempts to ringfence services and therefore knowledge, this could develop silos and frustrate attempts to integrate the full spectrum of diagnostic innovations into patient care. Several opportunities have been identified, for example, frontline Diagnostic services can interact with Genomic Laboratory Hubs (GLHs) to embed relevant 'molecular' knowledge and methodologies into routine diagnostic laboratories where appropriate.[29,30] This can maximise the benefits of new advances in molecular pathology and genomics and deliver diagnostic tools and solutions that introduce powerful new concepts.[31] Such approaches could, and some argue should, involve suitable and evidence-based predictive risk algorithms for polygenic diseases that combine analysis of multisource phenotypic, genotypic and environmental data. Also, interaction of diagnostic laboratories with academic and industry experts in health data analytics can develop new concepts and facilitate translation of recent advances in Artificial Intelligence (AI). An ambitious investment programme to accelerate innovative use of data sciences in medicine and health[32], has already generated necessary infrastructure to support this ambition. Such interactions can support the direction in the NHS of multidiscipline integrated care but will also facilitate adoption of rapid and potentially disruptive changes that are happening in other parts of the biomedical ecosystem.

To develop infrastructure to meet the operational quality requirements of the users of the consolidated pathology networks, and in parallel support a world-class evidence-based

- **Prioritisation of development and signpost roadmaps that will bring cutting edge technological advances and innovation back in the NHS laboratory space.**
- **Enabling staff, through appropriate up-skilling, to lead implementation of the new technologies and concepts to deliver the necessary diagnostic applications. This is crucial since the workforce of the next generation laboratories will be required to operate and manage highly automated platforms that integrate complex chemistries for a wide array of tests with support from appropriate AI-based interpretative risk algorithms. Evolving technologies may lead to certain skills redundancy while requiring new ones responding to needs of the wider clinical workforce to keep up with developments in the field.**
- **Embracing innovation in order to address emerging national healthcare challenges associated with increasing numbers of ageing patients with chronic diseases, such as dementia and mental health and multimorbidities, related to established health priorities such as obesity, diabetes, cardiovascular disease and cancer. These represent intriguing but challenging examples of common diseases that fit the gene x environment (lifestyle) interaction paradigm. It is expected that this will be addressed by diagnostic testing transformation based on –omics and protein-molecular fusion technologies and advances in pathology digitalisation and molecular imaging.**

healthcare system, at the forefront of clinical science and innovation, it is conceivable that the consolidated Pathology networks and Clinical Biochemistry departments within it, should focus on the following:

For many experts, decoding the genome alone is not sufficient to explain polygenic disease phenotypes and frequent discrepancies between phenotype and genetic data do occur. Therefore, specialities such as Blood sciences and Genetics together with healthcare data sciences will need to establish an effective working interface to bridge information gaps around the patients' phenotype as determined by genetic background and lifestyle-environmental influences. Optimising use of diagnostic methodologies and ultimately clinical data and pathways will become the key lever to deliver the commitment to establish rapid precision diagnosis and treatment and clinical laboratory teams shift testing emphasis towards prevention and screening. Thus, a crucial challenge is how investment in genomic medicine can also catalyse transformation of diagnostic services and offer wider benefits across a wide and expanding range of common but heterogeneous diseases NHS diagnostics asked to screen, diagnose, and monitor progression and response to treatment. Detection of genetic background and epigenetic clues will be important for managing and treating each patient individually and design appropriate testing protocols to investigate heterogeneous phenotypes employing sophisticated data approaches and algorithms. Spreading the benefits of genomic medicine across the NHS diagnostic networks could potentially include diffusion of molecular expertise across suitable pathology settings. Especially for Blood Sciences and genetics services, the case of stronger interaction is indeed compelling to 'future-proof' diagnostic services and maximise benefits of the investment to address increasing and changing demand and meet patient and clinical expectations associated with development of more personalized and preventative medicine.

5.4.3 Staff training and development

Pathology departments require their staff to have a high degree of expertise and possess specific skills related to the service provided and processes they perform. As a result, there are a variety of roles typically seen, from laboratory assistants in supporting roles through to medics that have specialised in their training within a pathology discipline. The majority of the workforce within pathology is made up of biomedical scientists and clinical scientists, both

of whom require professional registration. The duties and responsibilities of these roles vary according to both staff grade and disciplines, but all are required to complete prescriptive training pathways supported by the relevant professional bodies (IBMS, Health Education England and RCPath). In addition, as a requirement of professional registration for both scientific staff groups, continued professional development is vital. For some specialisms, namely histopathology, advanced qualifications through the IBMS have allowed biomedical staff to move into roles in dissection and reporting, traditionally duties performed by medics.

Through the achievement of both academic and professional qualifications, laboratory experience and CPD, the current healthcare science workforce across the UK has a vast amount of transferable knowledge and skills that can be utilised for sector improvements. This includes knowledge of the regulatory systems, good lab practice, good clinical practice, research principles, test methodology, quality, safety and scientific knowledge, both generalised and specific to their chosen discipline. HCPC registration ensures scientists operate to high standards and work within their scope of practice, but does not place definitions on practice, allowing workforce flexibility where needed.

One of the biggest challenges to addressing the current and future needs of diagnostics, as recognised by the IBMS chief executive David Wells[33], is being able to train enough individuals with the appropriate skills and experience. Over the last 8 years, a number of reports and surveys from key stakeholders have identified the shortfall in the workforce. In 2017, Health Education England launched a draft workforce strategy 'Facing the Facts, Shaping the Future – a draft health and care workforce strategy for England to 2027'.[34] This identified that if growth in healthcare demand remained on its current course, 190,000 new posts would be needed by 2027. In 2023, the new NHS long term workforce plan published by NHS England, predicted an increased shortfall of between 260,000 and 360,000 by 2036/37.[35] The area of cancer diagnosis is one that poses a particular challenge in terms of testing demand and workforce, and there have been a number of publications in recent years specific to this field. Cancer Research UK's document published in 2016 'Testing times to come? An evaluation of pathology capacity in England', estimated that with aging populations and increased cancer incidences, cancer cases could increase to 514,000 new cases per year by 2035.[36] This is more than 40% above current levels. More specifically on workforce, a 2017 survey by the Royal

College of Pathologists of its histopathology members evidenced a lack of sufficient qualified staff, a large percentage of the workforce reaching retirement age within the next 20 years, insufficient bodies in training posts and additional costs of around £17m across the UK on locums to cover vacancies.[37] In 2023, NHS England reviewed cancer targets across the NHS and rationalised them, with the focus shifting to a 28-day faster diagnostic standard. Within this diagnostic pathway, Histopathology is crucial and accounts for a significant portion of the 28 days. To try and ensure this new target is achieved, NHSE have put together the Transforming histopathology – six-point plan and the first area targeted within this plan is workforce. From the information released so far, this again reinforces the need for advanced training and extended practice roles, widening the skill mix and the need for retention of staff.[38,39]

Although these reports all identify ways to address the long-standing issue of workforce, a number of practical challenges remain that can be a barrier to change. These include:

- ⇒ Insufficient staff numbers and a lack of supernumerary roles for the purpose of training.
- ⇒ Lack of funding for the long-term workforce plan, unable to pursue further professional or academic qualifications.
- ⇒ Resistance to scientific staff having additional responsibilities.

Diagnostic services are undergoing a science and technology revolution that require a fully staffed workforce to acquire new skills and work outside of the traditional roles and disciplines. In support of this, the IBMS published their workforce plan in September 2023.[40] Within this, there are several recommendations from the professional body and steps they are taking to tackle some of the challenges and support the workforce to meet the goals published in recent NHS plans. Amongst these are:

- ⇒ New qualifications to support work across disciplines,
- ⇒ New courses for POCT,
- ⇒ Extended practice qualifications in haematology and microbiology
- ⇒ Training bursaries to support the registration portfolio.

One novel approach at early stages of development, is the creation of regional Pathology academies, following other examples such as regional imaging and endoscopy training academies. The collaborative approach shares the burden of training and can be a tool to centralise and standardise the content delivered.[41]

Table 2: Summary of findings and recommendations related to training from key reports

Report Title	Date	Associated Body	Key Findings/Recommendations
Testing times to come? An evaluation of pathology capacity in England[36]	2016	Cancer Research UK	• Projected to be 514,000 new cancer cases per year in 2035, up 40% on current figures. • A need to utilise BMS staff to cut up specimens. • Ensure widespread use of BMS in a reporting role after completion of required specialist training.
The Pathology Workforce[37]	2017	RCPath	• 3% of departments had sufficient staff to meet the growing clinical demand. • 25% of histopathologists are aged 55 or over and there are insufficient trainee doctors to fill future gaps. • Extrapolated costs from responses indicate around £17m a year is spent on locums.
Facing the Facts, Shaping the Future[34]	2017	Health Education England	• 190,000 new posts in healthcare needed by 2027. • Continued support of HSST programmes for clinical scientists • Expansion of STP training to include bioinformatics and genomics. • Investigate why there is lack of demand for the PTP pathway. • Support apprenticeships in healthcare science at levels 2, 4 and 6.
Science in healthcare: Delivering the NHS Long Term Plan[42]	2020	NHS England	• A need to improving recruitment, retention, training • Investigate new roles and training routes for technology adoption specialists, bioinformaticians and data scientists. • A need for leadership training programmes
NHS long term workforce plan[35]	2023	NHS England	• Shortfall of 260,000 to 360,000 staff by 2036/37 • Lack of workforce with required skill mix • Current workforce issues impacting service capacity and patient care
IBMS Long Term Workforce Plan[40]	2023	IBMS	• Need for registration training grants to support completion of IBMS registration portfolio. • Increase number of BMS training position • Recognition of progressional qualifications and expanded practice roles. • The need for NHSE and Government support in training and upskilling workforce
Time to Test[43]	2024	IBMS and Astra Zeneca	• The need to invest in and train a pipeline of talent. • BMS and clinical scientists operating in specialist and expert roles

5.4.4 Key opportunities for service staff and development in novel technologies

Some key opportunities and drivers identified, are presented below, highlighting areas where innovation in service models, in training and development, in staff engagement and opportunities and finally in discovery of novel diagnostic tests, their development and application is expected to improve patient care:

- **Development of 'molecular' skills and technology infrastructure in frontline diagnostic services in tandem with development of the genomic medicine advances. Shortages of staff with appropriate skills during the recent pandemic resulted in delays and reduced capacity, highlight this point and the urgent need to develop a robust network of expert staff and labs to enable a rapid response during outbreaks.**
- **The current 'limited' ability of Diagnostics labs to employ molecular technologies alongside established chemistries or immunoassays should be addressed. Across the sector, it is expected that advances in automation technology could lead to incorporation of molecular platforms alongside chemistry and immunoassay analysers. There is a unique opportunity for the diagnostics Industry to support this direction. The GLHs and Genomic Medical Centres could provide valuable guidance especially in areas of governance and setting professional standards.**
- **Molecular testing and diagnostics are only one example, where technological advances are accelerating better health outcomes delivered through precision medicine. Through more complex –omics and advanced analytics, the signature of an individual's 'personal health blueprint' can be generated, making it possible to identify susceptibility of individuals to disease(s) and to detect disease(s) in pre- or even a- symptomatic stage – even to predict the onset of disease. At the same time, treatment can be personalised, enabling the efficacy of the intervention to be individually optimised. It is likely this trend will create demand for more advanced investigations.**

A framework that ensures strong multidiscipline interaction can accelerate horizon scanning approaches for development and rapid implementation of innovative testing approaches and better patient outcomes.

5.5. UK Diagnostics and Seeking the Value Proposition

Advances in analytical and information technology significantly improved productivity of laboratories over several decades. While this has undoubtedly contributed to improvements in patient care and laboratory operations, it has also led to a focus on the analytical activities and costs within the laboratory itself rather than a broader consideration of the impact of testing on patient care. There are obvious and well-described difficulties in identifying and

quantifying medical tests as an intervention; the so-called commoditisation of laboratory and medical testing in general has been identified by many as an important issue.

Following this trend, for many years much of the thinking of the Diagnostics and Laboratory Medicine sector in the UK (and globally) was centred around a fundamental question: What should be the focus of efforts and overall direction of the discipline: reducing cost or identifying and enhancing the value of laboratory services? In general, laboratory services underpin modern healthcare at a cost of <5% of the NHS total budget. The value of that spend lies in the *effective application of laboratory outputs within processes designed to deliver healthcare benefits to the population served*.[44]

Processes are often complex and dependent upon laboratory services delivering the right test results, to the right place, at the right time to deliver the right impact. This defines a value proposition (VP) for laboratory services.

Many activities reflecting best practice laboratory medicine, contribute to the overall value of testing with particular emphasis on the importance of minimising error of requesting and reporting processes to the overall value.[45] Efforts to classify possible sources of error, in particular cataloguing causes of diagnostic error, have been spearheaded by Paul Epner from the Society to Improve Diagnosis in Medicine.[46,47] These include errors around ordering inappropriate tests; an appropriate test is not ordered; an appropriate test result is misapplied; an appropriate test is ordered but a delay occurs somewhere in the total testing workflow; or the result of an appropriately ordered test is inaccurate.

Using the above to identify and classify errors, a formula has been proposed[48]: the value of laboratory medicine (V) can be described as the 'aggregate delivered benefits (B) offset by both the harms delivered (H) and the missed opportunities (MO)'; so in summary: V = (B – H – MO).[49] Epner 's work led to the development of a framework using the above concepts which would define the structures and processes that are required for a high value laboratory service.

***Description of laboratory VP*:** For service providers, the VP describes what is to be delivered by their service model to users; for service users, the VP describes what is expected from and seen to be delivered by providers. Delivery of the VP therefore requires a common whole system focus from service providers, users, and other stakeholders in processes (e.g. clinical pathways) and co-working to define and validate the term 'right' within the VP. Once defined, component services within a care system will enable configuration of delivery models and outputs that are optimally aligned to deliver desired outcomes with identifiable whole system value. In this framework the concepts of Triple Aim and Triple Value are important in defining the value of Diagnostics: the term Triple Aim provides a framework that can be used to assess the benefits and impact of services across the wider system. Moreover, documentation of benefits in terms of Triple Value, which incorporates all the elements of the Triple Aim concept, provides a method of quantifying the whole system value and impacts on total cost of care more suited to the UK healthcare model.

For many applications of the value of Diagnostics, the Triple Value concept stands out as the preferred approach within the context of the 'application and impact domain' of the whole system value paradigm (WSVP). It facilitates a holistic evaluation of the benefits of services throughout the broader healthcare system, categorizing impact into:

- ⇒ ***Allocative value***: resources should be allocated to different groups equitably to maximise value for the entire population.
- ⇒ ***Technical value***: quality and safety of healthcare should be improved to amplify the value derived from resources allocated to services.
- ⇒ ***Personalised value***: decisions should be based on the best current evidence, thorough assessment of an individual's clinical condition and consideration of individual values.

The Value Proposition (VP) also mandates addressing the challenges hindering the broader adoption of certain value-based pathology practices. Without a comprehensive understanding of these barriers, developing effective strategies to overcome them becomes challenging, and the transition to a more value-based pathology practice may remain a theoretical academic endeavour. Some examples are shown in box 1

Box 1. Challenges That Hinder Adoption of Diagnostic Services Value Proposition

1. **Lack of resources and skills:**
   Highly productive laboratory testing models with a focus on cost savings can result in limited resources. Economic analysis of laboratory testing is often driven by authors without a laboratory background. There needs to be a better appreciation and development of useful skills to enhance awareness of the need and capability to make a business case for introduction of new tests and an understanding of how to apply tools such as economic modelling.

2. **Achievement of collaboration outside the laboratory, particularly clinical teams:**
   Often the laboratory functions as an isolated silo, and this barrier is exacerbated by the fact that it offers services, while the benefits of these services are delivered by other departments or silos. Requirement to quantify the benefits and drawbacks across all the stakeholders (or silos). This challenge sometimes contributes to technology failure. Need to involve clinical users is crucial as measurement of patient outcomes is a key requirement of a more value-based service. Outcomes measurement is traditionally seen as difficult when it includes the traditional measures of morbidity and mortality. There are other short-term, more operational measures identified as key performance indicators (KPI) and turnaround times (TAT) which have economic consequences, and which can show the value of testing. Difficulties in capturing these measures exist, in part due to inflexible health information systems that cannot be adapted to automatically collect the requisite data. Changes in this area are crucial to demonstrating value-based practice.

3. **Developing sustainable funding pathways:**
   Obtaining funding for evidence collection and outcome measurement presents a substantial hurdle in adapting global evidence for practical use in local contexts—an essential aspect of laboratory services. Exploring funding opportunities might entail leveraging Clinical Decision Support (CDS) tools for primary care requests and information gathering to ensure the software remains current and aligns accurately with evolving practices. These approaches offer value by facilitating the identification and reduction of unnecessary testing. When coupled with audit and outcomes research, they hold the potential to deliver enhanced value to the healthcare system and its stakeholders.

5.5.1 Whole system models and the VP of laboratory tests

Similar to various systems around the world, the UK diagnostics face opportunities and challenges as new models of care, emerging technologies, rapid expansion of medical knowledge, and advances in information, data and knowledge management appear as dominant drivers for transformation of laboratory services. They also present opportunities to provide higher impact services that result in the delivery of better care. In a series of talks and reports many authors proposed that:

'Moving forward, laboratory medicine must redefine its positions, not only acting in its classical role as provider of laboratory results, but also adopting new roles and responsibilities in the clinical dialogue'.[49]

Adopting the above framework requires whole system thinking and involvement by lab professionals with an emerging drive to develop tools such as key performance indicators (KPIs) that assess service impact on quality of care and total cost of care. The UK diagnostics are considered a key global leader in delivering this concept. An important benefit is that it moves quality ***focus away from a traditional introspective focus on lab quality that is of little interest to most service users since it provides no measure of clinical value***. It also proposes that adoption of this new quality construct for laboratory services, with healthcare targeted KPIs co-owned by service users held jointly accountable for their delivery, could facilitate the necessary whole system and wider stakeholder focus on value. It is suggested that adopting this innovative quality framework for laboratory services, incorporating *healthcare-centric* Key Performance Indicators (KPIs) co-owned by service users with shared accountability, has the potential to promote a comprehensive system-wide perspective and draw the attention of a wider spectrum of stakeholders towards value. This approach is expected to cultivate a mutual interest in the structure and functionality of laboratory services.

This approach recognises that the costs of laboratory tests are a fraction of whole system cost of care (<5%), but they impact significantly upon the overall healthcare spend (the other 95% of the budget). It has been recognised that inclusion of laboratory service providers in healthcare teams tasked with improving quality of care through optimisation of processes within the 95% spend, will exert a bigger impact on total cost of care. This statement is linked to the concept of Deming's chain reaction that identifies the principle that improving quality of processes increases quality and reduces cost of healthcare.[50] The key emphasis lies in addressing the suggested primary driver, which is enhancing the quality of processes, rather than solely focusing on costs. It supports the view that overall healthcare budgets are best managed by considering overall clinical care costs, can be improved by elimination of waste, and improving clinical outcomes, and can be reduced by eliminating need. Laboratory services

committed to the VP previously identified, have an important role in the delivery of impacts in each of these areas. Therefore, by adopting this strategy, *specialists in laboratory medicine should strengthen roles as advocates for change within the broader healthcare system*. Through driving this process, they can harness the advantages offered by both existing and emerging science and technologies. Embracing this perspective, positions laboratory services as value centres and frontline operations rather than mere 'cost centres' or back-office functions, ultimately resulting in tangible improvements in patient care.

As described by Bill Bartlett and colleagues in a recent RCPath bulletin communication[44], the recognition and adoption of healthcare-specific KPIs by laboratory services enables their value as clinical services to be objectively assessed and, in turn, provide an evidence base to challenge historical views that laboratories are costly 'back office' services. As diagnostics is dynamic and constantly evolving, it is now conceivable that new KPIs should move away from the efficiency-based KPIs to focus on key clinical pathway parameters, for instance, on turnaround times (TAT) to diagnosis, impact on patient flow and bed capacity, and influence length of stays and drug usage (e.g. antibiotics). A key element of the VP – right impact – identifies the need for laboratory services to be more outwardly oriented and integrated within clinical teams, with new roles and responsibilities within the wider system.

Experience from previous service transformation work undertaken across different diagnostics organisations helped to shape the distributed laboratory service (DSM) model. This supports the design and delivery of a system that can demonstrate the following characteristics:

- ⇒ Efficiency of processes.
- ⇒ Effectiveness of outputs.
- ⇒ Equitability of access.
- ⇒ Resilience and affordability.

To enable a value-driven transformation requires adoption of the VP and a potential improvement model described as the whole system value paradigm (WSVP). Within the overall architecture of WSVP four domains influencing the value of a service can be identified:

interface, laboratory service model, application and impact, fitness of purpose reporting. Each comprises discrete but interlinked high level attributes. Implementing the Delivery of Service Model (DSM) involves configuring services to align with the characteristics of the population area served by the healthcare system. Achieving this, requires consideration of service stakeholders to each of the four domains of the WSVP to enable definition of optimal service configurations and realization of the VP.

While it is anticipated that stakeholders' focus may differ across individual domains, achieving desired healthcare outcomes will require a collaborative effort to co-develop and refine the final model. This approach encourages a comprehensive perspective, prompting exploration of broader benefits to substantiate the investment. The model is versatile, allowing for granular application, whether at the macro level of an entire service or the micro level of a single test, with a consistent focus on the ultimate goal of value.

5.5.2 Current diagnostics considerations: the VP of laboratory tests and emerging technologies

Similar considerations are relevant for discrete laboratory outputs, where the VP identifies importance, worth or usefulness of a test. For example, a test could have the potential to be, more accurate, less invasive or reduce time to diagnosis. This has been recognised by the UK healthcare science system, who attracted investment in developing expertise within the National Institute of Healthcare Research (NIHR) network of In vitro Diagnostics Co-operatives for Care pathway analysis to identify the VP.[51] This involves definition of a care pathway and outlining the sequence of interactions a patient experiences as they navigate through a healthcare system with the symptoms of a particular medical condition. Mapping out the care pathway captures the points of contact, actions, decisions, and potential outcomes associated with the patient's care. This helps to identify unmet clinical needs and scenarios where a new test could be integrated into the pathway to improve patient care.

For individual tests an example of the framework requirements for describing the value proposition is shown in Table 3 adapted from the Test Evaluation Working Group of the European Federation of Clinical Chemistry and Laboratory Medicine.[52] There are multiple ways to determine the value of a laboratory test, particularly if one takes into consideration

its impact upon the complete clinical pathway. These include use of the concept of a VP that describes in detail the pathway of test implementation by measuring its clinical, operational and economic impact. In addition to professional leadership, there is a need for research that related to translating global evidence into local practice, a key challenge facing laboratory medicine and healthcare generally.

Table 3: Description of a value proposition for a diagnostic test: Framework requirements

1. **The unmet clinical need**
2. **Patient population that will benefit**
3. **Identity of the test and its properties**
4. **Test intervention purpose**
5. **Expected outcomes**
6. **Location of where test is performed**
7. **Quality of evidence available**
8. **Part(s) of the care pathway in which the test will be used**
9. **Stakeholders – potential beneficiaries**
10. **Benefits to each stakeholder in relation to the outcomes**
11. **Potential limitations and risks and proposed migration strategy**
12. **Resource/activity contributed by each of the service lines involved in the care pathway with and without the test intervention**
13. **Reimbursement received for delivering the care pathway before and after the test**
14. **Proposed implementation plan, including the metrics for monitoring appropriate adoption**

***** questions 1–7 of the framework are essentially the principles of evidence-based medicine while steps 8–14 are primarily focused on how the test will be implemented on a local basis*

Requesting the correct test is one of the key attributes of improving value of laboratory testing. Rates of blood testing requests have increased over the past two decades especially in primary care, however, the reasons for this pattern are not easily identifiable. In parallel, rate of undertesting and over-testing for specific diagnostic tests against national or international guidelines is also increased.[53,54] The lack of relevant data identifies the need to develop and introduce in routine practice clinical decision support (CDS) tools to provide better evidence-driven guidance to requesters and particularly to primary care as this inappropriate diagnostic testing has enormous resource implications. There is increasing emphasis on the AI-based concepts to support development of such tools.[55] This is now

recognised as a key priority together with collection of better supportive evidence of interventions designed to improve the appropriateness of requesting and use of CDS.

Such automated laboratory test recommendation systems can provide rapid and appropriate test selection, potentially improving the patient management workflow. Some examples are described in box 2.[56-58]

Box 2. Examples of CDS in Diagnostics

1. To explore inappropriateness of tumour marker testing in an outpatient setting; models based on comparison between the actually ordered and expected requests of tumour marker, can be calculated according to recommendations of clinical practice guidelines (CPGs)[56] Such models can recognize very high rate of overordering of tumour markers. The model can further focus by a dedicated algorithm to be adapted to different clinical conditions or organizational settings by applying performance indicators to cohort-wide structured information in electronic health records (EHRs).

2. Laboratory tests are performed to make effective clinical decisions. Deep learning-based automated systems developed to automatically predict accurate and efficient laboratory tests using simple variables available in the electronic health records (EHRs).[57] This can be integrated into the EHR to recommend personalized laboratory tests.

3. Global prediction models developed to treat laboratory testing as a series of decisions by considering contextual information over time and across modalities.[58] The method was validated in a critical care database; the deep-learning model made real-time laboratory reduction recommendations and predicted the properties of lab tests, including values, normal/abnormal (whether labs were within the normal range) and transition (normal to abnormal or abnormal to normal from the latest lab test).

5.5.3 Future of laboratory medicine and the role of AI in transforming medical lab operations

As the world becomes data-driven artificial intelligence (AI), machine learning (ML), and data analytics (DA) are becoming crucial tools in laboratory operation. In the healthcare industry, AI refers to developing intelligent computer systems that can perform tasks that traditionally require human intelligence. AI in healthcare technology includes machine learning, natural language processing, computer vision, and robotics. The potential of AI in medicine to revolutionize healthcare by improving diagnostic accuracy, personalized treatment, and medical research is becoming more evident. Diagnostic laboratories are rapidly going through digitization by implementing LIMS and RIMS. Labs have taken up roles of data capturing and acting as reliable data generating centres. The Essential Diagnostic List (EDL) released by WHO mentions around 120 tests.[59] Billions of diagnostic tests are performed annually by labs

worldwide, creating an enormous amount of data. The world population, types of disorders, and demand for healthcare all together add up to massive data. Diagnostic labs must function optimally to manage such a huge amount of data and stay ahead in the business. Machine learning algorithms offer the potential to analyse this vast amount of medical data. ML technology can then identify patterns that signify a particular disease or condition.

Key Performance Indicators (KPI) as metrics of Diagnostic Labs performance

The operations in a medical lab are complex, as various processes combine to affect the lab's throughput. Key Performance Indicators (KPIs) metrics that measure the quality, effectiveness, and efficiency of a diagnostics laboratory. KPIs can help to track and analyse a lab's performance, some examples of which can be found in table 4.

Table 4: Examples of key performance indicators (KPIs) applied in medical laboratories	
Sample turnaround time	Measurement of time taken to results delivery
Test volume per instrument	Measurement of the efficiency of lab instruments and equipment
Test cost per unit	Measurement of the cost-effectiveness of testing
Repeat rate	Measurement of the percentage of repetition of tests
Quality control metrics	Measurement of accuracy and precision in test results
Test result accuracy rate	Measurement of the accuracy of lab test results
Staff productivity	Measurement of the productivity of lab staff
Test result reporting and documentation time	Measurement of the time it takes to report and document test results

Recent trends indicate that labs are implementing AI, ML, and DA solutions to improve the operational accuracy and KPIs of labs. It is expected that these technologies will in the future perform tasks and automatically make decisions requiring human intelligence. Medical laboratories can benefit from AI, machine learning, and data analytics in several ways, including increased accuracy and speed, predictive analytics, individualized treatment plans, lower costs, better patient outcomes, and better research and development. With new tools and insights, these technologies are transforming the healthcare sector and enhancing patient care.

Introducing AI in the operations of a human-led laboratory operation can lessen the possibility of mistakes or misdiagnoses, assist healthcare providers in making better judgments, and

deliver more individualized care. With AI supporting and strengthening human capabilities rather than replacing them, humans and AI can work together to provide better healthcare. For example, AI can automate repetitive processes, lowering the possibility of human mistakes and freeing laboratory employees to concentrate on more crucial tasks like research and development. As this technology develops, it can influence the future of AI in laboratory diagnostics, opening new possibilities for advancement and innovation. Thus, AI with human inputs would solve real-world problems faster.

The Power and The Future of AI in Diagnostic Labs

AI-led transformation of the diagnostic lab and healthcare industry involves improvements in diagnostic accuracy and reduce turnaround time for lab tests. It also aims to reduce human errors in diagnostic laboratory testing and in parallel to provide cost-effective healthcare solutions. It can also improve data management, enabling better tracking of specimens and patient health data. A significant step change is also in predicting disease patterns and outbreaks, allowing early warnings and adequate preparation to healthcare systems. Overall, it is expected that AI will improve patient outcomes and healthcare diagnostics in its entirety. Several publications and various sources[60] provide statistics related to the application of artificial intelligence in medicine and the clinical laboratory setting. A few examples are shown below in table 5.

Table 5: Statistics related to the application of AI in medicine and the clinical laboratory

- **AI in healthcare will grow from 23 billion in 2020 to $194.4 billion by 2030, with a compound annual growth rate (CAGR) of 38.1% between 2021 and 2030.**
- **AI-assisted diagnosis improved diagnostic accuracy of CT and mammograms.**
- **Use of AI in laboratory medicine will increase by a CAGR of 8.9% between 2020 and 2025.**
- **AI can reduce laboratory testing time by up to 60% in some cases, resulting in significant improvements in patient care.**
- **AI can help improve the accuracy and speed of laboratory tests and reduce errors and variability in results.**
- **AI can assist in diagnosing various diseases, such as cancer, by analysing medical images and patterns in large data sets.**

AI-Powered Diagnostic Labs: Overcoming Five Challenges

Some of the operational laboratory challenges identified where AI can add value can be found below in box 3.

Box 3. Operational Challenges in the Clinical Laboratory.

1. **Inaccurate and Inconsistent Results:**
   By utilizing algorithms to evaluate data and find patterns not easily recognized, AI might assist in reducing mistakes and variability in laboratory test results.

2. **Large Volumes of Data:**
   It can be difficult or time consuming to examine and interpret vast medical data. AI in healthcare can speed up and improve the processing and analysis of enormous amounts of data.

3. **Time-Consuming Tasks:**
   Laboratory operations like manual counting or interpreting images take much time. AI can automate these tasks, and reduce the time needed for analysis and increase the productivity of labs.

4. **Limited Expertise:**
   A shortage of skilled laboratory professionals may limit labs' capacity to interpret complex data. AI in medicine can offer expertise and assistance, particularly in pathology and image analysis, by automating the interpretation of complex data.

5. **Cost and Resource Constraints:**
   Labs frequently deal with budget restrictions and limited resources. By automating tasks and increasing productivity, AI can lower costs and enable labs to use their resources better.

5.5.4 The role of CQC and regulation

This explosion in machine learning approaches and tools has been identified by regulatory organisations such as the Regulatory Horizons Council and CQC, who issued reports and guidelines around the clinical application of such approaches via development of a regulatory sandbox pilot.[61] A 'regulatory sandboxing' is a way of working proactively and collaboratively to understand new types of health and social care services, agree what appropriate quality looks like, and develop a suitable approach to regulation.

The CQC sandbox developed is focused on the use of machine learning applications for diagnostic purposes in healthcare services. Part of this work involved building a consensus on what is needed to deliver high-quality care in services that use these applications. The findings

of this sandbox identified and consider where an update of current regulatory methods is required, and what work is needed to get this right, which will offer better regulation of these services. The key findings are shown below:

Key findings and recommendations from the relevant CQC sandbox[61]

- **Providers that use machine learning in diagnostic services need to have appropriate governance in relation to the clinical, information, technical and human aspects of the application. We still need to develop our approach with providers to get this right.**
- **Most suppliers of machine learning applications in diagnostics will not need to register with CQC. Only those suppliers that deliver clinical activity themselves within the scope of a regulated activity need to register. Some parts of the market are developing quickly, and we anticipate having to register the first organisation that uses an autonomous machine learning system in routine clinical service before the end of 2020.**
- **To effectively regulate these few suppliers that become registered providers and assure the public that their services are safe and effective, CQC will need other national bodies to develop technical standards and assess against them.**
- **There are two key gaps around the assurance of machine learning systems that national bodies need to address, particularly for autonomous systems: firstly there is a need for more guidance and infrastructure to support clinical validation of algorithms, both at the CE kitemarking stage and when implementing in a new site; secondly we need more clarity on how hospitals should implement machine learning devices within clinical pathways to ensure high-quality care.**
- **Technology suppliers need to clearly communicate what their products, solutions and devices do and how they perform. Suppliers do not always accurately state whether their products use machine learning. This makes it harder to implement devices safely and poses a risk to patients.**

5.5.5 Choose wisely UK

Recognising the need for a more coordinated approach to request and deliver the right tests to the right patients, stakeholders have developed and pursue various initiatives. From the point of view of patients, they should be able to understand that some tests or treatments can be invasive and have undesirable side effects. In the UK, the Choose wisely framework, championed by the Academy of Medical Royal Colleges and RCPath is one such example.[62,63]

The Choosing Wisely initiative developed in the US but is now a global initiative that seeks to encourage both doctors and patients to have a conversation about the value of treatments.

The purpose of this initiative is to change doctors' practice to align with best practice by getting them to stop using various tests, treatments and procedures that are:

- ⇒ Not supported by evidence
- ⇒ Not free from harm
- ⇒ Truly unnecessary, including those that duplicate tests or procedures already received.

5.6 Regulatory Landscape in Diagnostics

This section provides a brief overview of the bodies and processes regulating diagnostic services in the UK as it is extensively covered by a number of official documents.

In the United Kingdom, the NHS diagnostic services are regulated through a combination of legislation, professional standards, and oversight mechanisms.[6] The regulation of diagnostic services is essential to ensure;

- ⇒ Quality,
- ⇒ Safety
- ⇒ Effectiveness in healthcare delivery

The regulation is delivered by **Health and Social Care Act 2008 (Regulated Activities) Regulations;** the Health and Social Care Act 2008 provides the legal framework for the regulation of health and social care services in England. The Act sets out the fundamental standards that providers must meet. Diagnostic services fall under the category of "regulated activities," and providers must comply with the associated regulations. Several bodies are involved and follow a stringent framework to maintain high standards in the development, manufacturing, and usage of diagnostic products and services. Some key aspects of the regulation of NHS diagnostic services and professional bodies involved are described below.

5.6.1 Regulatory bodies

Medicines and Healthcare products Regulatory Agency (MHRA): key regulatory body responsible for regulating medical devices and in vitro diagnostics in the UK. It ensures that diagnostic tools meet safety and performance standards before they are placed on the market.[64]

Health and Care Professions Council (HCPC): regulates and sets standards for various healthcare professionals involved in diagnostic services, including clinical scientists and biomedical scientists (BMS). These bodies set standards for professional practice and conduct and can take action against individuals who do not meet these standards.[65]

Care Quality Commission (CQC): The Care Quality Commission is the independent regulator of health and social care services in England. It monitors, inspects, and regulates all healthcare providers, including those offering diagnostic services. The CQC assesses services against a set of fundamental standards, which include criteria related to safety, effectiveness, and quality of care.[66]

National Institute for Health and Care Excellence (NICE): NICE provides evidence-based guidance and advice to the NHS on the most effective ways to diagnose and treat medical conditions. NICE guidelines influence the practice of healthcare professionals and may be considered in the regulation and provision of diagnostic services.[67]

Patient Safety and Incident Reporting: The NHS has systems in place for reporting and learning from patient safety incidents. Diagnostic services are expected to adhere to these reporting mechanisms to ensure continuous improvement in quality and safety.[68]

5.6.2 Regulatory framework

CE Marking: Most diagnostic devices used in the UK must be CE marked, indicating conformity with European standards. post-Brexit, the UKCA (UK Conformity Assessed) mark may be used for products intended for the UK.[69]

IVDR (In Vitro Diagnostic Regulation): The EU's IVDR, although initially under the European Union, impacts the UK's regulations, emphasizing more rigorous conformity assessment, stricter clinical evidence requirements, and traceability of devices.[70]

Laboratory Accreditation: Laboratories conducting diagnostic tests are often accredited by bodies such as UK Accreditation Service (UKAS) to ensure they meet specific quality standards.[71]

Data Protection and Privacy Laws: The handling of patient data collected during diagnostics is regulated under laws such as the General Data Protection Regulation (GDPR), ensuring patient privacy and security.[72]

It's important to note that the regulatory landscape evolves over time, and additional or modified regulations and standards may be introduced over time to enhance the quality and safety of NHS diagnostic services as newer technological approaches or innovation enter the diagnostic testing repertoire. An example is the recent report with recommendations from CQC's regulatory sandbox around use of machine learning in diagnostic services.[61]

The impact of regulation on diagnostic services development and delivery has been the subject of intensive discussions on a few reports.[73-75] The key points (challenges and opportunities) identified are highlighted below:

5.6.3 Regulatory challenges, opportunities and considerations

- **Evolving Regulatory Landscape Post-Brexit:** regulatory autonomy, which might lead to changes in conformity assessment and regulatory requirements for diagnostics.
- **Innovations and Emerging Technologies:** rapid advancement of technology, such as AI and genetic testing, poses challenges in adapting regulations to address these new developments.
- **Global Harmonization:** As the UK remains a global player in the healthcare industry, harmonization with global standards while ensuring public health and safety is essential.
- **Adherence to Stringent Quality Control:** Ensuring that diagnostic products and services consistently meet high-quality standards is essential for patient safety and confidence in healthcare.

Opportunities:

- **Collaboration and Consultation**, between regulatory bodies, industry, healthcare providers, and researchers. This can lead to more adaptive and effective regulations that foster innovation while maintaining safety.
- **Agility and Flexibility:** A regulatory framework that can adapt swiftly to technological advancements while maintaining stringent quality standards can encourage innovation in diagnostics.

- **Research and Development Incentives:** Encouraging investment in R&D by providing incentives for innovation that complies with regulatory requirements can drive progress in diagnostic tools and procedures.

The fitness-for-purpose evaluation of diagnostics regulation in the UK is a multi-faceted assessment. While the current regulatory framework maintains certain strengths, there are areas that could benefit from enhancement to keep pace with the rapidly evolving landscape of healthcare technologies and diagnostic advancements. Table 6 below summarises the areas identified in various reports:

Table 6: Diagnostic regulation in the UK

Strengths of Diagnostics Regulation	Areas for Improvement	Recommendations and Opportunities
Patient safety	Adaptability to technological advancements	Flexible regulatory framework
Quality assurance	Complexity and clarity	Collaboration and consultation
Expert oversight	Post-Brexit transition	Education and support for innovation
	Global alignment	Global harmonization
		Continued review and improvement

6. Diagnostics Evolution and Development

As described above the urgent need to reform the diagnostics sector in the UK has been described in many reports post-pandemic.[76-81] This followed recognition of the need to apply innovative ways of using pathology services, as a focus solely on local test production misses opportunities for pathology services to: work in different ways to enhance care pathways enable patients to take control of their chronic disorders and save resources outside the laboratory and across health economies.

6.1 Trends and Drivers

A major drive on diagnostics is required to (a) develop a fit for purpose sector to address health priorities of an ageing population with increased prevalence of chronic conditions and mental health issues, (b) deliver the personalised/precision medicine ambition as well as the long-term NHS plan commitments to address many of the specific conditions such as cancer, heart disease, respiratory diseases, stroke and musculoskeletal conditions. Several drivers can be identified in relevant strategy documents and think-tank publications from UK government and stakeholders as crucial motivators and are often shaped by the need for improvement, advancements in technology, changes in healthcare demands, and responses to global health challenges. These include:

1. **Public Health Imperatives:** Addressing established and emerging public health crises, such as the COVID-19 pandemic and mental health as well as emphasis of the healthcare system on prevention and early detection, highlights the need for robust and adaptable diagnostic systems. During and post-pandemic, there's a heightened awareness of the critical role diagnostics play in managing public health crises. The urgency to develop robust systems for early detection, contact tracing, and monitoring the spread of infectious diseases has become a key driver for reform.

2. **Technological Advancements:** Rapid advancements in diagnostic technologies, including genomics, artificial intelligence, and digital health, present opportunities for more accurate and efficient diagnostics. Advances in diagnostic technologies, such as high throughput affordable next-generation sequencing, point-of-care testing, and AI-driven analysis of laboratory data, offer the potential for more accurate and timely diagnoses and development of novel biomarkers suitable for diagnostic applications. The drive for reform stems from the desire to leverage these innovations to enhance the diagnostic capabilities of the healthcare system and deliver some of the key promises around precision medicine.

3. **Improved Patient Outcomes:** Enhancing diagnostic capabilities and deployment of technological advances can lead to earlier detection of diseases, improving treatment outcomes and overall patient health. Early detection and diagnosis enable timely

interventions, leading to better treatment outcomes, reduced morbidity, and improved overall health for patients.

4. **Economic Efficiency:** As diagnostics is a key discipline for delivering healthcare in the NHS, streamlining diagnostic processes and adopting cost-effective technologies can contribute to cost savings by preventing unnecessary treatments, hospitalizations, and complications associated with delayed diagnoses.

5. **Demographic Changes:** Managing the health of an aging population and increasing prevalence of chronic diseases require diagnostic systems that can handle the growing demand for healthcare services. Reforming diagnostics addresses the need for a scalable and efficient system capable of handling the growing complexity and volume of diagnostic procedures.

6. **Patient-Centred Care:** Patient expectations for quicker, personalised and more convenient diagnostics are increasing, and reform efforts can focus on delivering more patient-centred care, with an emphasis on accessibility, convenience, and involving patients in the decision-making process.

7. **Data-Driven Healthcare:** The emphasis on data-driven decision-making in healthcare calls for improved diagnostic information systems and analytics to enhance patient care and population health. Such efforts may include implementation of advanced health information systems, interoperability, and data analytics to harness the full potential of diagnostic information for patient care and population health management.

8. **Global Health Threats:** Preparedness for global health threats, such as pandemics and emerging infectious diseases, is a critical driver for diagnostic reform to ensure a rapid and effective response.

9. **Personalized and Precision Medicine:** The goal of delivering precision medicine and the move towards personalized treatment plans necessitate sophisticated diagnostic tools capable of tailoring healthcare interventions to individual patients. Advances in

genomics and decoding large biomarker datasets require diagnostic capabilities that can provide detailed information about an individual's health. There are already reform efforts in development that focus on integrating genomic and molecular diagnostics into routine healthcare to tailor treatments to individual patients.

10. **Strategic Innovation:** Encouraging innovation in diagnostics aligns with broader healthcare strategies, fostering a culture of continuous improvement and technological advancement. This will require efforts and systems in place that encourage the adoption of new technologies and methodologies in diagnostics. This can include incentives for research and development, collaboration with industry, and support for startups in the healthcare technology space.

11. **Workforce Development:** The need to attract, train, and retain a skilled healthcare workforce with expertise in the latest diagnostic technologies is a crucial determinant of reform success. As diagnostic technologies become more complex, workforce development is a critical factor. Training programs, continuing education, and strategic recruitment initiatives are implemented to ensure a skilled and adaptable healthcare workforce capable of using advanced diagnostic tools and new technologies.

12. **Health Inequalities:** Recognizing and addressing health disparities and inequalities in access to diagnostics can be a driving force for reform efforts. The NHS has identified this as a strategic priority addressed under the initiative Core20plus5.[82] Strategies may include targeted outreach programs, community-based diagnostic services, and policies aimed at reducing barriers to access in underserved populations.

13. **Government Policy Initiatives:** Policy changes and government initiatives can drive diagnostic reform by providing funding for research, regulatory support for innovative technologies, and strategic plans to guide the evolution of diagnostic services.

14. **International Benchmarking:** Comparing the UK's diagnostic capabilities with those of other nations can help identify areas for improvement and can drive efforts to ensure

that the country remains at the forefront of medical innovation and healthcare delivery. Benchmarking can drive investments in cutting-edge technologies and best practices.

15. **Public and Stakeholder Expectations:** Meeting the expectations of the public, healthcare professionals, and other stakeholders for high-quality, accessible, and timely diagnostics is a fundamental driver. Public and stakeholder feedback can shape policies and initiatives to align with the needs and preferences of the people the healthcare system serves. Increasingly, the public appears to be a significant factor in promoting diagnostics reform; post-pandemic there is increased awareness and Importance in the role of diagnostics, as well as understanding around innovations of rapid resting development and remote Diagnostic. This is enhanced by increased awareness to long term health and access to educational sources and information coupled by struggling healthcare unable to meet demand post-covid and clear backlogs.

The list of drivers includes a number of innovative enablers that have been identified as critical for a shift towards more efficient, accessible, and technologically advanced diagnostic methods. These are:

- **Advancements in Rapid Testing**
- **Remote Diagnostics**
- **Point-of-Care Testing**
- **AI and Machine Learning in Diagnostics**
- **Wearable Diagnostic Devices**
- **Multipurpose Diagnostics**
- **Home Testing Kits**
- **Environmental and Pathogen Monitoring –surveillance**
- **Personalized Medicine and Diagnostic**
- **Data Integration and Interoperability**

By introducing these enablers policymakers, healthcare providers, and stakeholders can work collaboratively to shape and implement effective diagnostic reform strategies in the UK. There is consensus recognition that this will involve addressing challenges that have emerged during the pandemic while also leveraging new opportunities for improvement. Table 7 below summarizes various key recommendations proposed:

Table 7: Reforming diagnostics in the UK: Key recommendations	
Invest in Technology and Infrastructure:	• Upgrade and modernize diagnostic equipment and facilities. • Embrace digital health technologies, such as online access and remote monitoring, to enhance accessibility and efficiency. • Implement centralized data systems for better information sharing and coordination among healthcare providers.
Workforce Training and Recruitment:	• Invest in training programs for healthcare professionals involved in diagnostics. • Address workforce shortages by increasing funding for training and recruitment initiatives. • Explore partnerships with educational institutions to ensure a steady supply of skilled professionals.
Streamline Pathways for Diagnostics:	• Develop clear and standardized pathways for diagnostic testing, ensuring a smooth and timely process for patients. • Implement triage systems to prioritize urgent cases and reduce waiting times for critical diagnostic procedures.
Enhance Primary Care Diagnostics:	• Strengthen the role of primary care in diagnostics to ensure early detection and intervention. • Provide additional resources and training for primary care providers to conduct preliminary diagnostic assessments.
Utilize Artificial Intelligence (AI):	• Integrate AI tools for faster and more accurate diagnostics. • Implement AI algorithms for image analysis, diagnostics, and data interpretation to support healthcare professionals.
Patient Engagement and Education:	• Increase patient awareness about the importance of early diagnostics and preventive screenings. • Provide resources and tools for patients to actively participate in their healthcare, such as digital health apps and patient portals.
Public-Private Partnerships:	• Foster collaboration between the public and private sectors to leverage resources and expertise. • Encourage partnerships with diagnostic companies and technology providers for innovation and efficiency.
Address Inequalities:	• Identify and address health inequalities in access to diagnostic services. • Implement targeted interventions to reach underserved populations and reduce disparities in healthcare outcomes.
Outcome Measurement and Continuous Improvement:	• Implement robust systems for monitoring and evaluating the effectiveness of diagnostic services. • Use data analytics to identify areas for improvement and adjust strategies accordingly.
Prepare for Future Pandemics:	• Develop contingency plans for maintaining diagnostic services during public health crises. • Ensure the resilience of diagnostic infrastructure to withstand future challenges. • Implementing these recommendations will require collaboration between government agencies, healthcare providers, technology companies, and other stakeholders. • Regular evaluation and adjustment of strategies will be crucial for the ongoing improvement of diagnostic services in the UK.

6.2 The Innovative Devices Access Pathway (IDAP)

Interest in developing a framework to manage and promote technological advances led to the development and introduction of The Innovative Devices Access Pathway (IDAP)[83] recently launched in the UK.

'The Innovative Devices Access Pathway (IDAP)

This scheme is set to accelerate the development of cost-effective medical devices and their integration to the UK market and ensure timely access to innovative medical technologies, create opportunities for real-world data collection, enhancing the value proposition of products and giving businesses a competitive advantage by allowing innovators to rapidly penetrate the market and build a strong patient base.

This initiative also recognises the importance of safeguarding these ground-breaking innovations through patents and other forms of intellectual property protection by rewarding those that have patents in place. In doing so, it seeks to strike a balance between nurturing innovation and improving market access, to ensure the long-term sustainability of businesses. The program aspires to offer faster access to cutting-edge medical device innovations for patients through targeted support for innovators in exchange for allowing the National Health Service (NHS) to have access to their technology. Moving forward, laboratory medicine must redefine its positions, not only acting in its classical role as provider of laboratory results, but also adopting new roles and responsibilities in the clinical dialogue.

This initiative seeks to streamline the regulatory process, and reduce delays and bureaucracy, bringing medical technology solutions to patients who need them faster than ever before.

6.3 The Case for Early Diagnosis

Early diagnosis makes clinical and economic sense. It is often highlighted that diagnosis is too slow and can result in much higher financial and non-financial costs. Early diagnosis may not always deliver healthcare cost-savings in the short term, as early detection is likely to mean earlier treatment. Nevertheless, the benefits of early diagnosis such as increased range of treatment options, improved long-term survival and improved quality of life, have been

demonstrated in research findings in a wide range of disease areas and are supported in a number of NICE standards and guidelines and the NHS long term plan, especially in areas such as cardiovascular disease, stroke, dementia and cancer.[84-86]

Diagnostic testing is an integral part of the healthcare system efforts for early diagnosis, providing essential information to enable providers and patients to make the right clinical decisions. Demand for access to quicker, more accurate diagnosis is rising at a rate of 10% per year, increasing costs and putting pressure on the capacity capability of diagnostic providers. Improving the efficiency of testing and the speed and accuracy of diagnosis can provide a substantial contribution to the NHS ambitions for early diagnosis. A large body of research links early diagnosis to measurable health gains such as approval survival rates and lower treatment costs. However, effective implementation of early diagnosis varies widely across the NHS and lags behind many European countries. Furthermore, the Department of Health estimates that if cancer patients in the UK were diagnosed at the equivalent stage of the disease, as in other European countries, up to 10,000 deaths could have been avoided.[87]

A number of charities, including Cancer Research UK has been working in the field of early diagnosis, initially as part of the National Awareness and Early Diagnosis Initiative (NAEDI) introduced following the Cancer Reform Strategy for England in 2007. Reducing late stage/advanced stage cancer is a key part of their strategy to improve outcomes for people affected by cancer. This initiative champions an evidence-based approach to identifying and embedding the developments that are needed to secure a meaningful reduction in the diagnosis of late-stage disease through earlier disease detection. Approaches are developed across the entire diagnostic pathway, and with researchers, the public, patients, health professionals and key opinion leaders to drive high-quality research and the implementation of evidence into policy and practice.

6.4 Obstacles to Change

Over the past 15 years, dealing with the financial challenges and wide scale reforms around reconfiguration of pathology services and improved efficiencies have distracted attention

away from considering how the NHS might harness technology and use existing NHS capacity more efficiently.[88,89]

Box 4. Obstacles to Access.

Widespread adoption of new diagnostic tests typically takes around 10 years.[88] Adoption is hampered by a lack of clarity about the research evidence required by those involved in the approval process around use of new diagnostic tests. At the same time, quite often clinical needs are not always matched by the technological advances and there is poor evidence of clinical utility in peer-reviewed literature making difficult to obtain commitment to change clinical practice.

EXAMPLES:

1. **SLOW UPTAKE:**
   While the UK has been successful in developing new technologies, level of uptake has been low compared to many other countries such as Switzerland, Canada Sweden Norway. The UK is consistently ranked below European average in per capita spent on medical technology.[89]

2. **INCREASED DEMAND:**
   In the UK the ageing population and rising incidence of chronic disease fuels a 10% increase per annum in demand for blood and tissue tests.[88]

There are few measures trying to establish the impact of diagnostics on disease prevention patient outcomes and overall healthcare expenditure. It is widely accepted that investment in new, more sensitive blood tests could save money and save lives.

The five main barriers identified to improving access to diagnosis and obtaining a diagnosis in an efficient and effective way are:[74]

1. **Organisational**: poor communication between primary and secondary care, variable referral management practises, delays in reconfiguring pathology services to encourage adoption of innovation, confusion over responsibility for technology assessment. There are examples of successful initiatives but there is lack of wider adoption plans to help deliver immediate improvements.

2. **Financial**: No fit for purpose payment incentives and the lack of an effective activity based payment system, the short term nature of any test budgeting and poor understanding of the cost benefits of diagnostic testing. There is no allowance for population increase,

demographic pressures (obesity, ageing population, dementia), service provision improvements (drugs, treatments), increases in healthcare cost.

3. **Operational**: Capacity constraints, including variations in opening times, variable progress in automation, lack of trained staff and uncertainty over future demand.

4. **Cultural:** failure to engage frontline staff, risk aversion at board level and inadequate collaboration with industry and other providers.

5. **Regulatory**: Better understanding of the regulatory framework requirements for medical diagnostics.

6.4.1 The case for access for emerging diagnostic technologies

Diagnostics a key part of the solution to some of the pressures facing the NHS. It is increasingly recognised amongst NHS leaders that new diagnostic technologies could help to reduce increased demand and pressures on the healthcare system. Indeed, the NHS Long Term Plan[28] makes a commitment to accelerate the uptake of selected innovative diagnostic technologies. Yet, achieving market access in the competitive and complex UK landscape is never easy.

Various marker surveys and industry leaders identified some of the common challenges (box 5) faced by market access and commercialisation when bringing a new diagnostic to the NHS and make recommendations for overcoming some of these hurdles (box 6).[90-99]

Box 5. Key UK market access challenges faced by diagnostics companies.

- **Understanding the dynamic nature of the NHS:**
  The evolving environment and shifting priorities of the NHS creates a significant challenge to keep up with and understand their perspectives. Different areas of the NHS are likely to vary in their level of preparedness for innovative diagnostic technologies.

- **Staying up to date on policy, procedure, and regulation:**
  Understanding new and established policies, technology assessments, standard operating procedures, and regulatory landscapes is key to align value messages and communication strategy with policy, regulator, and other assessors' needs.

- **Identifying the diagnostic's place in the pathway:**
  It appears much easier to make the case for diagnostic, and demonstrate its true value to the healthcare system, if one can demonstrate where and how the diagnostic will support and enhance the existing pathway of care. This only works when the pathway outlined is accurate and resonates with the decision maker. As a result, understanding local and system pathways and service provisions becomes a key challenge.

- **Understanding funding landscape and drivers:**
  A key hurdle for any new technology is identifying appropriate funding streams. There are several evidence generation and funding pathways available within the UK for diagnostics, including:
  - ⇒ Digital Technology Assessment Criteria (DTAC)[91]
  - ⇒ Artificial Intelligence in Health and Care Award[92]
  - ⇒ NHS Innovator Accelerator[93]
  - ⇒ NICE's Evidence Standards Framework for Digital Health Technologies[94]
  - ⇒ NHS Payment Scheme[95]
  - ⇒ Medical Technologies Evaluation Programme [96]
  - ⇒ NHS Accelerated Access Collaborative: Medtech Funding Mandate:[97] The NHS Accelerated Access Collaborative has launched the 'Health Technology Navigation Pathway Tool' to support innovators. This includes helpful guidance for both innovators and larger companies looking to navigate the access pathways into the NHS.[98]

- **Identifying key stakeholders:**
  In the NHS, time is limited, and so it is important to identify the right people to speak to. A key challenge to market access is identifying those responsible for planning, commissioning and delivering services in diagnostics, and then understanding their roles and responsibilities within the healthcare and pathology system.

- **Scaling up:**
  A great way to develop proof of concept evidence of a new diagnostic technology into the NHS is via a small, short-term pilots with a local Primary Care Network (PCN) or through Academic Health Science Network (AHSN). This approach can enable to prove the concept and generate real-world evidence to support the innovation. Following completion however, there is a risk that the local care system moves on or that it remains an entirely local phenomenon. Scaling up from a small, short-term pilot to a long-term place, system and ultimately nation-wide footprint can be a real challenge. When exploring system and national routes to market access, it is important to present the value demonstrated in the pilot in a way that showcases the impact the diagnostic could have at this system/national level.

Box 6. Approaches to overcome common market access challenges for diagnostics launching in the NHS.

- **Engagement with NHS experts:**
  Engage with NHS and best practice experts to understand the landscape and identify and optimise opportunities. Seek support from experts from across the NHS, who hold strategic, operational, and clinical leadership roles.

- **Policy, funding and regulation:**
  Monitor changes in new policy and the evolving funding and regulatory landscape in the NHS and understand any changes to identify the right decision makers, understand the funding flows and pathways, and craft a communication strategy that resonates.

- **Solution-focused value proposition:**
  Development of strong value propositions that demonstrates an awareness to the key challenges facing the NHS, such as reducing diagnostic backlogs, emergency admissions and hospitalisations.[99]

- **Case for Change:**
  Building a Case for Change is key to scaling up and moving beyond a pilot study to ensure technology can be disseminated outside local pathways and is also taken forward and accepted at a national level. During initial engagement supporting of key stakeholders in the NHS with data collection is essential. These data can be used to build a Case for Change, develop case studies, build business case templates, and help NHS customers secure continued funding.

- **Map out the care pathway:**
  Map local pathways to understand service provision and identify opportunities where proposed technology could be used across an integrated system approach, e.g. across primary, secondary, and community care.

- **Key stakeholders:**
  Identifying and understanding stakeholder mapping is crucial to understand the roles, responsibilities, objectives, and challenges of those within the healthcare system able to bring diagnostics into the care pathway. The approach needs to be holistic including those with responsibility for planning, commissioning, implementing, and assessing services.

7. Direct Result Access

As the population continues to live longer and the burden of chronic disease increases, the demand for diagnostic testing is reaching new heights and new modes of access and healthcare delivery are explored. Six-week waits for diagnostic services have increased by 17% each year since 2010 leading to delays in the patient pathway, however moving towards a direct access model and encouraging patients to take control of their own health requires improvements in healthcare access.

The shift of both patient care and delivery of diagnostic testing to a more community-based approach, was first proposed in the 2019 NHS long term plan[28] and highlighted again in Sir Mike Richards' Diagnostics: Recovery and Renewal report published in 2020.[77] The latter report recommended that acute workflows be separated from elective, that community diagnostic hubs be utilised for elective care and it highlighted the importance of near patient testing in achieving these goals. Further to this, a community pharmacy framework for Point of Care Testing (POCT) was released in early 2022. This agreement demonstrated a commitment by NHS England to explore the delivery of POCT through community pharmacists and the resulting guidance gave important information regarding procurement, operational management, legislation and clinical governance.[100] However, responses by key professional bodies raised concerns that there were no recommendations for collaboration or consultation with local Pathology Services.[101]

Building on this drive to deliver diagnostics outside the traditional model, the 2022 NHS delivery plan for tackling the COVID-19 backlog of elective care, highlighted the critical role of community diagnostic hubs and suggested expansion of both the number of centres and range of diagnostic tests available to reduce wait times.[102] As part of this plan, it was recognised that the workforce would need to grow and be supported in terms of training. However, there was no mention of key scientific roles requiring support and development to achieve the plan. In response to this, the relevant professional bodies advocated the importance of training more HCPC registered scientists and that the expertise of Pathology staff should be utilised in the selection of equipment, quality assurance and governance of diagnostic devices when used for patient care.[103] In May 2023 the same professional bodies collaborated in the production and release of a National Strategic Guidance for at Point of

Need Testing[104]. Aimed at those responsible for commissioning and developing diagnostic services, the guidance gave a number of key recommendations when considering and developing POCT services.

All these reports agree that equitable and timely access to diagnostics is critical to successfully delivering effective healthcare, and the national delivery plan for recovering urgent and emergency care services, including its initiatives around urgent community response (UCR) and virtual ward services such as hospital at home, emphasise that Integrated Care Boards (ICBs) consider POCT as a way to achieve this.[105] For this purpose, updated guidance released in August 2023 provides information on the key requirements to support integration of IVD POCT devices into these services.[106] Taking on board previous criticisms, the new guidance outlines the role of pathology and considers organisational governance and clinical safety responsibilities.

As increased availability and access of POCT technologies and testing has been consistently identified as a key enabler of future diagnostics in UK, some key concepts are described in Section 7.1.

7.1 In Vitro Diagnostic Point of Care Testing

POCT is defined as any analytical medical testing that is performed at, or near to, the site of the patient, aiding rapid clinical decision-making and potentially leading to a change in the care of that patient. Examples of how POCT may be utilised in patient care can be seen below.

Reasons for POCT Testing

- **Rule a specific disease in or out.**
- **Enable general examination, providing clues to the cause of a patient's symptoms.**
- **Help with disease staging, assessing how advanced or severe the disease is.**
- **Monitor a patient's condition over time to identify changes.**
- **Screen asymptomatic patients for a specific condition.**

Typically, POCT results are available at point of care within seconds up to about 20 minutes. The purpose of a POCT service is to enable the delivery of high quality, accessible diagnostics at the point of need for clinical services, improving clinical outcomes and enhancing patients' healthcare experience.

During early phases of implementation, POCT has had a role outside of the laboratory to support clinical care. Common examples of testing and devices that have fallen within this remit include blood gas analysers, glucometers and urinalysis. Over recent years, the demand for POCT has increased reflecting development of novel models of healthcare delivery as testing often falls outside the remit of a traditional clinical laboratory. Examples include self-testing (glucose), home testing (SARS-CoV-2 and pregnancy tests) and clinical settings (GPs, ambulances, pharmacies, CDCs and virtual wards etc).[104] There is strong evidence to suggest that the availability of rapid results from IVD POCT devices used in the community can support better clinical decision-making, including helping to avoid unnecessary hospital admissions.[107-111] There is increasing confidence that compared to laboratory testing, IVD POCT devices are as accurate and reliable, as long as the devices are used in the way they are intended to be, and there is understanding of the tolerances and limitations of devices and results. All POCT devices are regulated by the Medicine and Healthcare products Regulatory Agency (MHRA) and should carry a UKCA mark.

Recommendations around optimal use of POCT and improved outcomes are focusing on the purpose of diagnostic tests and in particular, the information that is required, the speed the result is required to be able to make the best clinical decision for patient's care well as the clinical setting. A typical example involves supporting assessment by urgent community response teams that often deal with frail adults that can be complex to assess and present in similar ways, despite distinct underlying conditions. In this setting, using POCT to support community assessment of frail adults can significantly improve speed of clinical decision-making and patient outcomes.[112] The purpose is to aid clinical decision-making when it is not clear from standardised assessments whether a patient should be transported to hospital, treated on scene, admitted to a virtual ward or discharged to primary care.

The following tests have been identified by experts as the priority tests for implementation:

Priority Tests for POCT Implementation

- **Blood glucose**
- **Ketones**
- **C-reactive protein (CRP)**
- **Haemoglobin**
- **Haematocrit**
- **Lactate**
- **Renal profile, commonly known as urea and electrolytes (U&E)**
- **Venous blood gas analysis (VBG)**

A summary of the evidence for the benefits of using POCT devices in the community is presented below in table 8:

Table 8: Benefits of POCT in the community

Benefit	Evidence
Improved confidence in clinical decision-making	• 84.6% increase in clinician confidence in decision-making • Enables a change in decision-making
Quicker clinical decision-making	• Faster decision-making and clinical intervention
Significant reduction in conveyance to hospital	• Quickly detect or rule out serious illness • Make faster, better decisions about care and management • Increased clinician confidence in deciding not to admit
Enable good clinical management on a virtual ward at home	• Enable management of patients at home, and avoid the need for escalation to hospital care
Reduction in re-contact rate following discharge on scene	• POCT devices are used to aid clinical decision-making, those discharged on the scene have a lower re-contact rate in comparison to usual care
Supports antimicrobial stewardship	• Distinguishing a likely bacterial infection from a viral one, reducing over prescribing of antibiotics and risk of antimicrobial resistance • Deliver right treatment sooner • NICE's guideline [CG191] on the diagnosis and management of pneumonia in adults recommends that POCT CRP testing should be considered for people with symptoms of lower respiratory tract infection in primary care if a diagnosis is unclear after clinical assessment, and that antibiotics should be prescribed based on the result.
Increased patient satisfaction and QoL	• Patients reassured and help inform personalised care decisions and shared decision-making on next care steps
Cost savings to the NHS	• Using POCT at scale, the NHS can save overall £138 million a year

7.2 The Issue of Over- and Under-Utilization of Laboratory Tests

Appropriateness of diagnostic testing can be conventionally described as prescription of the right test, using the right method, at the right time, to the right patient, with the right costs and for producing the right outcome. Across the spectrum of healthcare over- and under-utilization of laboratory tests is an on-going challenge depending on the investigated parameters and the respective setting, and there is active debate about the real burden of inappropriateness in laboratory diagnostics. Overall, there are concerns this could become a major issue over the coming years, possibly affecting patient safety as well as health care budgets.[113] This is increasingly recognised as a major challenge not only for laboratory professionals, but also for healthcare in general. Alarmingly, it appears that inappropriate laboratory utilization is rapidly growing; recent studies estimate the amount of inappropriately used laboratory tests to be 20–70% of all ordered tests.[114]

Several attempts have been made to describe and catalogue the over- and under-utilized laboratory tests. Examples of most common tests are shown in figure 4 below. Recognising the importance of this issue, there are now efforts to develop interventions to manage the inappropriate use of laboratory resources, focusing mainly on the effectiveness of interventions aiming to reduce inappropriate testing. Recommendations on managing inappropriate use of laboratory resources or differences in test requesting depend on the clinical and diagnostic settings.[115,116] Existing strategies to reduce inappropriate tests and improve the efficiency of ordering clinical laboratory tests include feedback and reminder, clinical decision support tools, education, practice guidelines, and condition-specific algorithms. The performance of these interventions varies, depending on how these interventions are applied. These interventions might sometimes offer limited impact and the effect is mostly short-term. To develop long term interventions there is a need to better understand the mechanisms underlying this phenomenon.

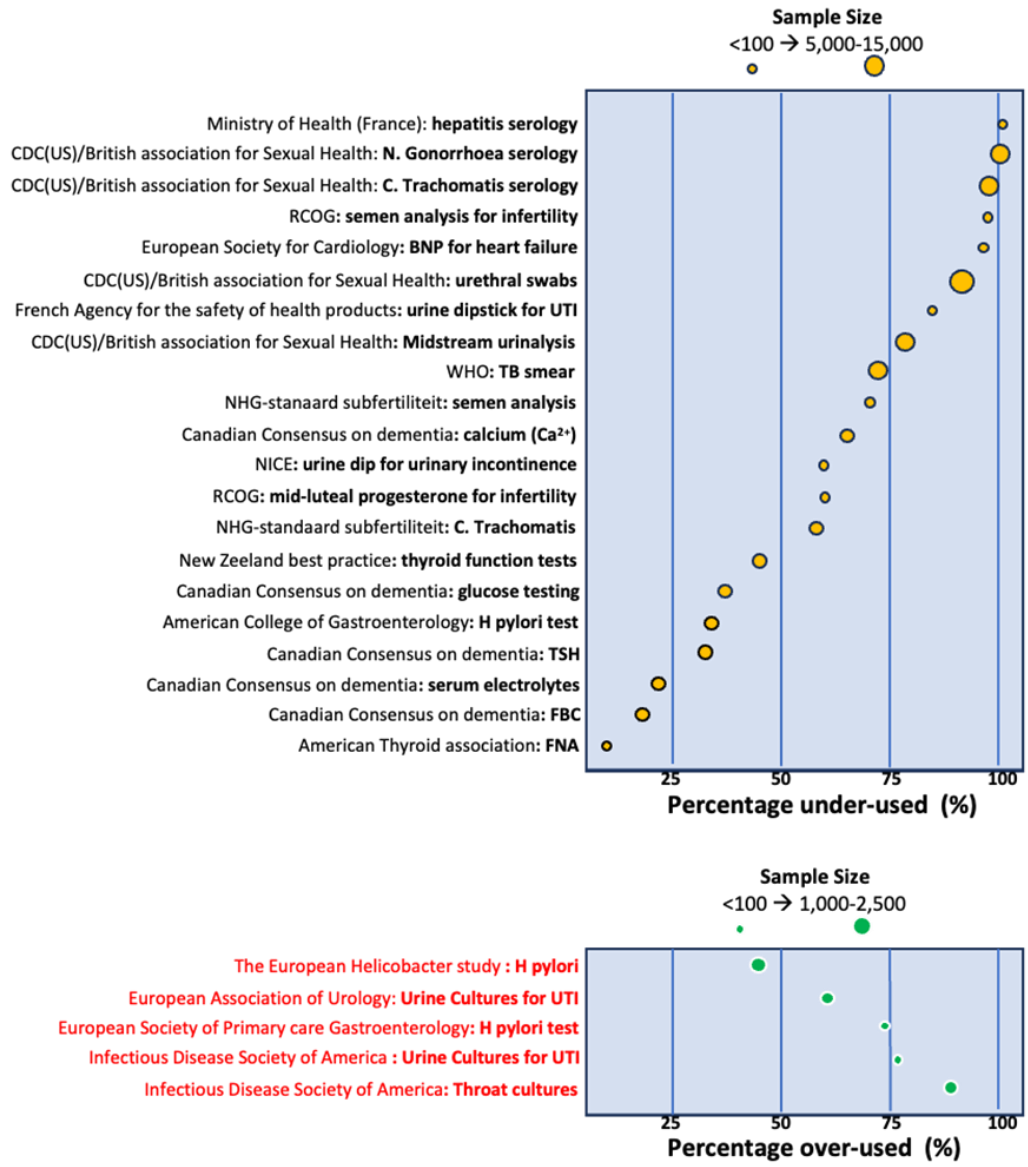

Figure 4: Summary of most common tests over and underutilised. Adapted from O'Sullivan et al.[54]

Many reasons for the inappropriate use of laboratory resources have been proposed like inadequate knowledge of laboratory tests, availability of higher numbers of new tests, fear of diagnostic errors, and lack of education. Other reasons include using so-called laboratory ordering profiles, increased workload, defensive medicine, or the lack of understanding of the diagnostic value of a test to name only a few.[117] Some studies for example identified laboratory misuse to varying quality of guidelines,[118] which is often used as marker of healthcare and laboratory testing appropriateness. Several factors also increased the rate of inappropriate laboratory testing, such as increasing patient satisfaction, fear of liability.

Perhaps the most prominent reason for laboratory overutilization is the ever-increasing day-and-night availability of high-quality analytics at a very low TAT. Innovations in analytical technology and IT solutions catalysed the provision of larger laboratory test portfolios at higher quality and with TATs as low as 45 min or even faster. These possibilities shape practices like the use of laboratory ordering profiles (LOPs), where selected tests can be bundled together and ordered simultaneously as a single item. These profiles may be helpful in standardizing laboratory diagnostic workup when correctly implemented in collaboration with clinicians and based on current reliable evidence. Nevertheless, when these LOP are used to simplify diagnostic processes, regardless of individual patients' condition (e.g. "routine panel"), they may contribute to a considerable overuse of tests. Therefore, it seems reasonable to replace such LOPs with condition specific profiles.[118] Other reasons might also be relevant such as insecurity, curiosity, patient pressure, question of accuracy of a prior result, hospital policy, frustration or just pure habit as well as personal education.[114]

In many countries in Europe and Americas, an educational gap in using and interpreting tests and their results has been identified,[119] possibly due to inappropriate or insufficient academic education. Although test availability and plethora of information (not always correct or backed by robust evidence) available across the internet has been proposed as a reason for the inappropriate use of laboratory tests, the evidence for a causal relationship between the availability and the demand for a particular test has yet to be provided.

7.3 Direct Access and Managing Demand

Over the last few years, the diagnostic landscape in the UK is experiencing fundamental changes in the ways that diagnostic services are delivered. Increased exposure of public to information around diagnostic testing and demand for immediate test availability combined with an exponential rise in off-the-counter diagnostic solutions to 'democratise healthcare', have led to a substantial rise in testing activity outside the NHS-delivered established channels of standard of care involving patient symptoms assessment followed by requesting of appropriate tests based on evidence-based approaches. This 'distortion' in testing is increasingly recognised as a major challenge not only for laboratory professionals, but also for healthcare in general. In the UK post-pandemic, there is an explosion of companies

offering private tests for a range of conditions and deficiencies. Some make claims that exceed the evidence base, and experts support implementation. Of tighter regulation measures to protect patients.

A unique glance in the future of diagnostic testing activities relevant to public expectations based on new technologies has been offered by Prof Jo Martin ex-President of the RCPath in 2020.[120] This hypothetical journey in the future diagnostics which captures many of the 'blue skies thinking' in diagnostics today is summarised below:

'The future use and value of point of care testing will be expanded, leading to explosion of near patient testing solutions. These tests will be overseen by laboratory personnel expert in quality assurance, many tests will be redesigned to align with care pathways and meet consumer needs. For many, information will be available from Health Bots about appropriate tests to consider before seeing a health professional in non-emergency situation.

Despite availability of free testing for convenience, individuals will be able to buy most of the diagnostic tests that are needed, or indeed those that they would like, at the local pharmacy or via a number of private online healthcare providers. This could include genetic as well as blood and urine tests for a wider range of conditions available for direct purchase. Results interpretation will be delivered via phone apps. This availability will reflect the exponential expansion of the direct consumer (DTC) diagnostic market, built on the sustained economic success of genetic providers. In the future it will a lot easier to get a cholesterol test at any local pharmacy than it is to do it via the health service. Since there is no requirement for an appointment and the test is very cheap in relative terms, regulation will be expanded to cover the disease, diagnostic testing services and associated quality assurance, so they will enhance confidence about the quality of testing.

Expansion of the public education programme will lead to a better-informed market. Increases in DTC testing will also exert a positive economic impact on the diagnostic industry, with a wider market and more investment in innovation and infrastructure related testing. It is expected that focus will be on least invasive testing solutions such as breath tests and finger prick blood tests to be carried out at local chemist in the superstore. Such technologies will provide instant readouts with commentary to what the result means.

Use of AI and electronic general practitioners, available 24/7 on phones or tablets is another innovation that is expected to be widely available and relieve the burden of primary care backlogs. Test can be ordered via this route through personalised note in visuals explaining what is being looked for and what to do if there's an abnormal result. These will likely be personalised, but actually populated from a series of established diagnostic and care pathways. The advice is likely to include links to start explanatory videos and other information, including the interactive voice activated lab test online, which is likely to become the international standard for diagnostic test information.

Need for further investigations will be managed by rapid diagnostic centres, where additional scans and imaging will be offered in a one stop clinical setting with immediate reporting with input from AI algorithms. Quick access to results will enable same visit initiation of additional procedures, biopsies as well as blood, urine or breath-based specialist tests. Again, AI-based decision support systems will ensure personalised treatment can be decided and initiated on the same day. Updates will load directly on the phone and health record as well as any online support and contact phone number for help.'

7.4 Direct to Consumer Testing

Increased exposure of public to information around diagnostic testing and demand for immediate test availability combined with an exponential rise in off-the-counter diagnostic solutions to 'democratise healthcare', have led to a substantial rise in testing activity outside the NHS-delivered established channels of standard of care *involving patient symptoms assessment followed by requesting of appropriate tests based on evidence-based approaches*. This distortion in testing is increasingly recognised as a major challenge not only for laboratory professionals, but also for healthcare in general.[121] In the UK post-pandemic, there is an explosion of companies offering private tests for a range of conditions and deficiencies. Some make claims that do not follow the evidence base, and experts are raising concerns that effective regulation is needed to protect patients.[122]

Through intense advertisement to 'take health into your hands", many companies encourage multiple blood tests a year using 'highly advanced blood analysis technology' making sometimes exaggerated claims. The market for direct-to-consumer testing (DTC) is booming; research predicts that the global blood testing market will rise by 60%., from around £80.5 billion in 2021 to £128.45 billion in 2028.[121] Experts are concerned that many companies are making misleading claims. In many cases increased availability of DTC triggers the demand in laboratory testing. There are also concerns, around the lack of regulation to ensure that consumers are fully informed and know what test results mean.[122] On occasions there is a simplistic assumption that more information is better, so why shouldn't you get the test done? Yet sometimes there is emphasis on the value of testing without showing any of the disadvantages.

Do benefits outweigh the harm? Consumers are promised that such tests will help them take control of their health and spot problems early. Frequently, there are offers a quarterly subscription for tests of cholesterol, an HbA1C, thyroid, hormones, kidney and liver function, testosterone, vitamins D and B12 folate and ferritin. However, in the case of vitamin D deficiency, in the absence of clinical signs or symptoms, the advice based on national Guidance on Minimum Retesting Intervals is not to retest at all.[123] For patients with low risk for cardiovascular disease, the advice is to carry out lipid checks every three years and even for high-risk patients or those on stable treatment, only annual testing is recommended.

The UK National Screening Committee has well defined criteria, for assessing whether screening is appropriate that have been in place for many years.[124] These include whether the condition being screened for is an important health problem and there is a detectable early stage of the disease, and the physical and psychological risks are outweighed by the benefits. The view of the committee is that screening tests are not for people with symptoms. In addition, NHS screening programmes offer care or treatment for people who needed it.
Some of the health checks from high street companies are not recommended by the National Screening committee because it is not clear whether the benefits outweigh the harm.

Impact on GPs work: Many testing companies sent a clinician-reviewed report to the patient. Most of the online tests will send the results to the patient usually with an * next to the ones that they are abnormal, with advice to seek support from a health professional, or their own GP. There are concerns that this will increase the workload of publicly funded primary care at a time in when is already extra stressed.[125] In 2019, the Royal College of General Practitioners published a position statement about private health screening, warning that the organisation initiating the screening should not assume that GP's will deal with the results.[126] This puts GP's in a challenging position, as patients are asking to address results of private screening tests that they're not indicated or requested. In addition to the risk of false positive results, which may lead to a catalogue of unnecessary and potentially invasive tests and anxiety for the patient, things may be missed. Some believe that that there is a risk of a patient being falsely reassured because they're told there's nothing wrong, but they haven't had the right test, and they then delay seeking help.

The companies selling DTC believe there is a role for private testing in the health ecosystem, if they adhere to strict clinical governance criteria.[121] One key driver identified is that customers seek an alternative to NHS either because they're having trouble accessing NHS services, or because the NHS does not provide the service they're looking for. Moreover, people are directed to the GP after private testing in about 7% of the cases. For many in the private testing sector, the perceived drive is in ‘democratising healthcare testing’ because there are around 1,000,000 people with undiagnosed type 2 diabetes and countless asymptomatic people with high cholesterol, thyroid disorders and vitamin D deficiency.

Regulation: There is a widespread view that better regulation of the DTC area is required.[127] The Care Quality Commission in theory, overseas service in England that perform test analysis, but marketing, consumer outreach and the sending of home kits are all outside its remit. Some laboratories are accredited to UK Accreditation Service, but this is voluntary.

The Advertising Standards Authority does investigate misleading claims, However, no many complains are received and fewer than a quarter are investigated. Most agree on the need for clear guidelines of what staff should be expected to do after patients have opted for private tests. The advertising could be regulated much better, so companies have to describe about the harms as well as the benefits of each testing available.

7.5 Genetic Tests and Polygenic Risk Scores - Creating Demand

As the cost of gene sequencing continues to decrease thanks to advances in next-generation sequencing (NGS), more companies have started to offer direct-to-consumer (DTC) genetic testing services. Simultaneously, an increasing number of people are electing to submit their DNA for testing.[128] This is primarily driven by adverts inviting the public to understand their genetic health risk. Unfortunately, when it comes to current DTC genetic testing methods, this statement is more fiction than fact. There are some key differences between clinical and DTC genetic tests.

Unlike clinical genetic testing, which is usually ordered by a health care professional to investigate a specific medical question, DTC genetic testing is an elective test marketed directly to consumers that can be ordered and completed by anyone in the general public without the involvement of a health care provider. DTC tests are usually completed by mailing in a sample of DNA, usually a swab or saliva sample containing cheek cells, then receiving the results in the form of an online report through a website. DTC genetic testing is also known as at-home genetic testing, consumer-initiated genetic testing, direct-access genetic testing, home DNA testing, as well as ancestry/genealogy testing when the service aims to answer questions about family history.

There are several companies active in the US, UK and globally that offer different types of non-diagnostic DTC genetic tests, including tests for ancestry, disease-causing genes (genetic variants), genetic health risk and carrier status, and pharmacogenetics, i.e., genetic differences that can affect a person's response to medications. Results from DTC tests should be reviewed with a primary care provider before making any health or lifestyle decisions.
Though not diagnostic, DTC tests have the potential to act as relatively inexpensive, large-scale population health screening tools to find people who will be potentially affected by genetically-linked conditions but who may not have direct contact with a health care provider. In the US there are many health professionals that see a certain value in this activity as there are many people slipping through the cracks. But one of the risks is when consumers, usually inexperienced non-experts, believe that DTC and clinical genetic testing are interchangeable.

The differences between DTC and clinical genetic testing include access, cost, and accuracy, though the number one difference is that only clinical genetic tests are diagnostic. DTC tests are not regulated by the MHRA, FDA or other national regulators—most DTC genetic tests are lab developed tests (LDTs), and currently, only one company in the US has received marketing authorization from the FDA for some of its DTC tests.[129]

In comparison to fully approved genetic diagnostic tests offered by diagnostic services, DTCs are characterised possibly by less rigorous or no analytical and clinical validation and standardisation with questions around methodologies used and whether they are fit for purpose to answer some of the clinical questions investigated, in the field of Genetics where understanding the genetic origins of disease is work in progress. In most cases, many genes or gene variants, in addition to other factors, may contribute to a disease, so it may not be possible to calculate someone's risk of disease without a thorough medical history and also understanding ethnic specific patterns of genetic disease. This is important as most databases have been created using data from people of European descent.[130] Therefore, results generated might be inaccurate and less informative. Most importantly, these non-endorsed tests would not benefit from extensive comparison of analytical and clinical performance and standardisation that is available for HRA and NICE approved tests used across the NHS diagnostic services.

Potential for more harm than good: The main motivation to undergo DTC genetic testing is usually its perceived health benefit, but whether DTC genetic testing produces tangible health benefits for the masses isn't clear. Studies following people who underwent DTC genetic testing for six months found that those received elevated cancer risk estimates weren't more likely to change their diet or exercise or engage in cancer screening to reduce the risk of developing disease any more than those who weren't found to be at risk.[131] On the other hand, DTC pharmacogenetic tests also pose a risk, the biggest being that people may be encouraged to stop taking a medication based on their results before appropriate consultation. A study found fewer than 1 percent of people who underwent DTC testing changed their medication without proper consultation, however 1 percent is still a significant number when placed on a global scale.

Thus, whether DTC testing has clear health benefits is uncertain, especially considering the potential risk of receiving misleading results. One of the biggest risks associated with all types of genetic testing is a false sense of security or reassurance. For many DTC genetic testing services, this risk isn't insignificant, as they may only cover a subset of the known genetic variants that contribute to human disease. A negative test result is never truly negative—there is always post-test residual risk i.e., the chance that someone may carry a disease-causing genetic variant that was not detected by a test.

7.6 Wearable Diagnostic Devices

Within the area of DTC and POCT, fall a range of personalised diagnostics in the form of wearable devices. These biosensors are non-invasive and can measure a variety of parameters, which could facilitate patient monitoring outside of the usual primary or secondary care setting. More than 500 health-related sensors are now available, with an annual growth rate in the sector of more than 20%.[132] Devices can be placed on various parts of the body such as the limbs, torso and ear and can be used in biomedical research, for clinical care and personal health. Depending on the sampling method used, wearables can be categorised as skin-based or biofluid-based and typically are comprised of two basic functional units, a "bioreceptor" (enzyme, antibody, DNA, nucleic acid, peptide, etc.) and a physicochemical transducer (optical, electrochemical, piezoelectric or thermal). The various

biological fluids and matrices that can be sampled include sweat, interstitial fluid, breath, saliva and tears.[133]

The four fundamental functions of these devices can be broken down as:

- ⇒ Monitoring
- ⇒ Screening
- ⇒ Detection
- ⇒ Prediction

Monitoring is currently the most common function wearable devices are utilised for, this includes monitoring pulse, heart rate, physical activity, and oxygen saturation. This information is primarily used by the wearer for information purposes, as part of possible lifestyle changes or to monitor the effects of diet and exercise. Outside of monitoring, specific studies have demonstrated the use of sensors to screen for individuals suffering from sleep apnoea,[134] the detection of atrial fibrillation from heart rate[135] and prediction of COPD from respiratory rate data.[136] A wider review of current research related to wearables and digital diagnostic tools by *Chakrabarti et al*[132], identified solutions targeting a much wider range of conditions including neurological diseases, fatty liver diseases, metabolic disorders and psychological illnesses. The SARS-CoV-2 pandemic and COVID disease has been identified as a crucial catalyst in the expansion of wearable sensors.[137]

Within the NHS, wearable continuous glucose monitors have only recently been made available for type 1 diabetics,[138] despite the technology existing for over 25 years.[139] The devices allow for improved glycaemic control, have a positive impact on quality of life and can predict increases in blood glucose. This change has been made possible as a result of unit cost reduction, NICE endorsement and aligns with the NHS Long Term plan to ensure 20% of people with type 1 diabetes benefit from such monitors by March 2021.[28] In the UK, the Government have pledged to support innovative technology in the NHS through both investment[140] and the publication of their medical technology strategy.[141] Trials are underway for further wearable technologies, such as continuous measurement of vital signs in cancer patients[142] and NICE have recently published conditional recommendations for devices that monitor motion and muscular activity in those with Parkinson's disease.[143]

Although the expanded role of such devices remains unclear, recent clinical trial data from across the globe is evidencing the value of such technologies in conditions such as diabetes[144,145] and cardiovascular disease.[146-148] Preliminary indications are that personalized data-driven interventions and objective measurement of treatment effects can often lead to improved outcomes when compared to standard care in some settings. However, several concerns about their use in patient care have been raised[132,137,149] and are briefly summarised below in table 9.

Table 9:	
Standardization	• Lack of data standardization between the many different commercially available devices • Different sensor locations contribute to variation. • Numerous reports have identified significant variation in results obtained wearable devices and not all devices show agreement to conventional diagnostic methods.
Data Quality	• Need to ensure there are ways to integrate data into a patient's electronic health record. • There also needs to be an agreed clinical workflow as to how the data collected will be used.
Energy and Connectivity	• Devices need to be comfortable and light enough to wear but have a suitable enough power supply. Often, sensor size can be limited as a result of this. • Wearable devices require internet access. Any disruption in connectivity or lack of signal will impact the data collected.
Health Equity	• Collection of low-quality data about severe health problems can be a very serious burden, leading to unnecessary anxiety. • Wearables can improve access to healthcare, but wearable technology might constitute the main health service available for some users and poor data quality will unequally impact them more than others.
Data Processing	• Often will be multi-variate time-series data, there needs to be a meaningful way to analyse. This may fall to machine learning algorithms and AI.
Data Privacy	• Often, wearables have poor data encryption. • How is the data secured? Often cloud-based storage is used, and this may not be UK based. • Who has ownership of the data collected? Is it the patient, the healthcare practitioner, the device company, or the owner of the data storage/processing software?
Informed Care	• Healthcare professionals need to ensure literacy of patients, in their understanding of both the technology and the data. • What can be determined from the collected data, accuracy and any limitations must be clear to allow for an informed choice. • There needs to be clear patient instructions not only for use of the device, but also in interpretation of the results.
Cost	• There needs to be a clear understanding of cost and that there will be a return on investment for healthcare providers.
Evidence Base	• Clinical utility and acceptable positive and negative predictive values will vary according to disease and context used. • Much of the current evidence collected is through commercial partners. As a result, very little information on how the data are collected, classified, and interpreted by the device is shared throughout the process. • More contextual information is needed.

From a recent workgroup on the clinical application of wearables organised between the Mobilize Center at Stanford University and the Mobile-Sensor-to-Knowledge Center (MD2K), key features responsible for success in digital health programmes were identified.[150] Many of these are similar to the ways in which to determine the value of a laboratory test (table 3).

Key features of successful digital health programs involving wearables

- **Clearly defined problem and disease state**
- **Integrated system of healthcare delivery**
- **Technology support**
- **Personalised experience**
- **Enhanced end user experience**
- **Clinical champions**
- **Stakeholder support**

The recent advancements in wearable technology have enabled a rapid expansion in both the types of sensors utilised and the analytes that can be tested for. Further adoption of continuous self-testing by NHS could allow for more digital, personalised, preventive medicine. Although further technological improvements and regulation are needed to overcome the current limitations, these tools could be a way to expand healthcare to patient groups identified in both the NHS Long Term Plan[28] and Core20PLUS5 initiative[82] and reduce health inequality.

8. Future Perspectives and Challenges

Post pandemic the UK diagnostics is now facing new challenges as well as opportunities. In particular, embracing digital technologies and AI, fostering innovation and achieving rapid translation of promising research, and addressing workforce challenges are pivotal for the sector's sustained success. There is an established goal to improve health needs of a population that is older and is becoming less healthy; this demands better outcomes and healthcare efficiency. Fostering innovation is key for long term sustainable success to deliver the promise of precision and personalised medicine. Being able to navigate changes

successfully is crucial to ensure that diagnostics, and more specifically laboratory medicine services, remain accessible and of the highest quality for all the population in UK.

9. Summarising Common Themes Across Key Opinion Leaders

Below is a summary (table 10) detailing the main themes found throughout the report and the published opinions of both NHS England and the professional bodies across the sector. These groups are identified as: The Royal College of Pathologists, The Institute of Biomedical Science and the Association for Laboratory Medicine (formerly the Association of Clinical Biochemistry)

Table 10: Agreement of themes by key opinion leaders	
Workforce	All 4 of the key opinion leaders identified that the Pathology workforce is an important challenge that needs to be addressed. The need for skilled, registered staff was recognized as were the difficulties currently faced in terms of recruitment, retention and training. Achieving a sustainable workforce model through increased numbers in all roles, with all working to a new agreed scope of practice, is vital to tackling the diagnostic backlog and to adapt to the changing needs of the service.
Digital and AI	All key opinion leaders have made statements around digital pathology and AI and its importance for the future delivery of diagnostics. One has even gone as far as to say that the NHS should be a world leader in the development and use of AI in Pathology. However, these areas require significant investment, and they are not the sole answer to reducing the backlog. These tools will contribute to future developments in medical safety and efficiency in the medium term, but upskilling and training of the workforce must occur for this to be realized.
POCT	There has been collaboration between all three of the key professional bodies in this area to produce the 2023 national POCT guidance document, highlighting its shared importance. In addition, POCT is given in multiple NHS England reports as a key tool, vital to the delivery and expansion of the diagnostic service. This includes its use in community diagnostic hubs, virtual wards and GP surgeries. However, there are specific concerns by all three professional bodies regarding the unregulated direct to consumer testing industry.
Collaboration	Two of the four opinion leaders have made statements around the importance of Pathology working collaboratively with the independent sector, particularly to address service delivery challenges and the adoption of new diagnostic strategies. Laboratories and the diagnostic industries share a symbiotic relationship and IBMS identified in its long-term workforce plan that working with industry will drive improvement and can speed up adoption of effective technologies and diagnostic tests.

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