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The Power of Testing:

Unlocking the potential of in vitro diagnostics to transform healthcare and improve lives

This report has been developed by Roche Diagnostics UK and Ireland in partnership with the Institute of Biomedical Sciences, and with support from the Royal College of Pathologists and the Association for Laboratory Medicine. This report has been funded solely by Roche Diagnostics.

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What are IVDs?

In vitro diagnostics (IVDs) are tests that analyse samples such as blood, tissue or fluid to detect disease, guide treatment and monitor health.[1] They are used throughout the patient pathway, from screening and diagnosis through to treatment response and long-term management.

IVDs vary in complexity and setting. Some are sent to laboratories for analysis by biomedical and clinical scientists, while others are analysed using point-of-care instruments in settings closer to the patient, such as GP surgeries, pharmacies, or homes. Their reach and versatility, supported by a skilled workforce make them a critical part of modern healthcare.

Foreword

In vitro diagnostics (IVDs) are the foundation of modern healthcare, enabling earlier and more precise diagnosis, informing treatment decisions, and supporting effective long-term management of health conditions. IVDs underpin over 70% of clinical decisions yet remain undervalued and under prioritised within UK healthcare investment and planning.

This report, supported by the Association for Laboratory Medicine and the Royal College of Pathologists, makes clear why this must change. Drawing on sector expertise, it sets out the critical role IVDs play in prevention, efficiency, and health equity, and outlines practical steps that government and health leaders can take now to unlock their full potential.

The NHS faces a period of unprecedented pressure, with rising demand, workforce challenges, and financial constraints placing strain on patient care. IVDs offer a cost-effective, scalable solution that can help address these challenges by shifting care towards prevention and early intervention, reducing the need for costly, late-stage treatment.

The government's NHS 10 Year Plan outlines a vision for a health system that moves from treatment to prevention, from analogue to digital, and from hospital to community-based care. As this report will set out, IVDs will be essential to realising this vision; enabling faster diagnoses, supporting personalised care, and empowering patients to manage their health.

Central to their success is the diagnostics workforce - biomedical scientists, pathologists, clinical scientists and support staff - who drive innovation, ensure quality, and champion the adoption of IVDs to deliver the NHS 10 Year Plan's vision of prevention, efficiency, and health equity.

Investing in IVDs is not only a clinical imperative but also an economic one, supporting a healthier, more productive population and reducing the long-term burden on the NHS.

Now is the time for decisive action, and we stand ready to work with the UK government and the NHS to implement the recommendations of this report and ensure the value of IVDs is fully realised for the good of patients and the health service.

By David Wells, Chief Executive of the Institute of Biomedical Science, and Matthew Johnson, Director of Access and Innovation at Roche Diagnostics UK and Ireland

Executive summary:

The government's 10 Year Plan presents an ambitious blueprint for NHS modernisation, which if implemented effectively, could deliver significant benefits for patients and the staff who make the NHS work. The coming months will be critical in laying the groundwork for this transformation and securing commitment across the sector as we work with the government on producing an implementation plan.

At the heart of the 10 Year Plan are three strategic shifts: from hospitals and communities, from analogue to digital, and treatment to prevention. These shifts aim to relieve pressure on NHS services, support the workforce, and put patients at the centre of care. But more than that, they are a response to what the government calls the "existential brink"[2] that the NHS finds itself at:

> "The choice for the NHS is stark: reform or die. We can continue down our current path, making tweaks to an increasingly unsustainable model - or we can take a new course and reimagine the NHS through transformational change that will guarantee its sustainability for generations to come."[3] **- NHS 10 Year Plan**

IVDs can support these three transformational shifts.

The transition from analogue to digital can be advanced by IVDs through integration with digital platforms, enabling real-time data analysis and personalised diagnostics for improved clinical decision-making. The shift from treatment to prevention can be facilitated through early detection and risk assessment which IVDs can enable, empowering proactive health management and disease prevention.

The move from hospitals to communities can be supported by portable and point-of-care IVD technologies used in the right settings, for the right person and at the right time. This can help overcome access barriers, improve patient outcomes and alleviate pressure on hospital resources, contributing to a more productive NHS.

> Central to this plan for transformation is the diagnostics workforce, whose expertise and leadership are critical to driving innovation, improving the adoption and use of IVDs, and delivering equitable care.

The plan for change set out in the 10 Year Plan has been supported by this government's recently published Life Sciences Sector Plan. Recognising the importance of a turbo-charged life sciences sector in supporting the NHS and driving economic growth is pivotal. The announcements set out in the 10 Year Plan that are designed to help get innovation in the medical technology space to patients quicker are welcome, and we are glad the Life Sciences Sector Plan will now build on these to deliver the necessary environment for the NHS to be supported.[4] The plan for a Rules Based Pathway for medical technology shows a positive direction of travel from this government towards recognising the value of diagnostics. It will be critical however to understand the scope of which products will be eligible for selection to this pathway, so that the positive impact will be maximised for patients.

There has been a welcome focus from government for investment in diagnostics, in particular the commitment to double the number of scanners.

However, IVDs have not received the same level of political capital as scanners and imaging, despite being equally essential to achieving these aims, and should be central to the government's reform strategy. IVDs are critical in detecting a broad range of conditions, including leading causes of death such as cardiovascular disease and cancer.

Early detection through IVDs can help to identify illnesses earlier, which can help to reduce the need for resource-intensive treatment. Despite their pivotal role, IVDs account for just 1% of NHS funding while informing over 70% of clinical decisions.[5] Barriers to access, uptake, understanding and implementation persist throughout the system. Unless these are addressed, realising the 10 Year Plan's ambitions will be extremely challenging. IVDs can also support measures that offer wider economic and social benefits, including keeping people in work, improving productivity, and reducing the need for costly NHS procedures.

More than just funding and innovation, however, is the need for a highly-skilled, well-resourced and well-funded workforce to enable the use of IVDs to support the pathology workforce. This would enable the diagnostics workforce to make accurate and informed diagnoses and treatment plans based on the use if IVDs. Long-term workforce planning that considers training and retaining of biomedical staff will be central to the successful delivery of the 10 Year Plan.

Innovation only truly matters when it gets to the patient. Without the necessary levers at all parts of the system to scale across the NHS, innovations in diagnostics won't reach the patients it is designed to help. This report sets out where barriers exist to IVD implementation and outlines how government, local health leaders, and industry can work together to unlock their full potential.

Recommendations

The recommendations from this report are as follows:

National policy actions:

1. Government should mandate equitable funding for diagnostics

The commitment in the 10 Year Plan to provide mandated funding for NICE-approved technologies is welcome. However, this must include a roadmap to setting out how this mandated funding can be gradually scaled-up to apply to all NICE-approved technologies and diagnostics, with the biomedical workforce leading in pathway redesign to ensure efficiency and equity. This would give these vital medical devices the same status and level of funding commitment as NICE-approved medicines.

We recognise that there are complexities around implementing new diagnostics given their ability to radically alter diagnosis and treatment pathways. It is therefore imperative that there is accompanying pathway transformation funding, to support local providers to evolve their services to support uptake of new IVDs into patient pathways.

2. Government should utilise expertise and infrastructure to support the adoption and implementation of innovation across the NHS

To maximise the potential of diagnostic technologies, including IVDs, the government should convene a cross-sector working group of stakeholders to collaborate on implementation plans. These plans should address key areas such as physical infrastructure, digital infrastructure, digital leadership, data interoperability, workforce, and skills, ensuring robust support for innovation adoption. Their role should be adapted to serve as one component of a comprehensive vehicle for implementing innovation, supported by consistent frameworks and resources. This could take the form of building on the existing Health Innovation Networks (HINs). They are an established, practical infrastructure with a track record of delivery. As such, it makes sense to continue to support them, evolving their role to become a vehicle to support the implementation of innovation throughout the NHS.

3. Government should champion the role of non-imaging diagnostics

Helping to drive awareness of their impact upon care should be part of a drive to support recruitment into the sector, which in turn would support delivery of the 10 Year Plan. This support should utilise the government's reach to extend and amplify the work of organisations – including the IBMS, Royal College of Pathologists and Association for Laboratory Medicine – who already work to champion the importance of the sector.

Local policy actions:

4. Each Integrated Care Board (ICB) should develop local diagnostics strategies that are embedded within the Neighbourhood Health Services promised in the 10 Year Plan

This will help to maximise the potential of diagnostics to enable a focus on local health priorities, informed by local biomedical workforce leaders. This work should be supported with funding as part of the 'inverse care law' outlined in the 10 Year Plan.

5. ICBs should collaborate strategically with industry and cross-sector partners to create the headroom for diagnostic innovation

For example, to pilot innovations, accelerate adoption, streamline administrative processes, and provide training to address workforce and commercial challenges in diagnostics delivery. Each ICB should appoint a diagnostics technology enabler to lead on, take responsibility for, and champion, the coordination and implementation of innovative practices in partnership with cross-sector partners. These enablers should work closely with their local diagnostics workforce to coordinate IVD adoption and streamline contracting processes to address commercial barriers, and ensure diagnostics align with local priorities and clinical requirements.

6. Stakeholders, including industry and ICBs, should collaborate with the diagnostics workforce to reform pathology contracting models

Simplified, standardised contracts will accelerate IVD adoption, reduce administrative barriers, and ensure equitable access across regions.

Wider system actions:

7. Stakeholders from academia, industry, the voluntary sector and those with lived experience should promote and share best practice

This will be vital in the successful implementation of the Neighbourhood Health Service and should be formalised as a national neighbourhood health forum.

8. The patient voice should be a key consideration in the development, adoption, and integration of IVD technologies

Engaging people with lived experience is critical in this process, as their insights help shape IVD services to be inclusive and effective, addressing specific challenges like accessibility, usability, and cultural sensitivity.

The current landscape

The NHS is undergoing significant reform, shaped by the 10 Year Plan and a shift from centralised structures toward more devolved, integrated models of care. ICBs now play a critical role in shaping local strategies, with a focus on prevention, responsiveness, and digital innovation.

In this evolving system, IVDs are vital to delivering earlier, more accurate diagnoses, guiding treatment decisions, and supporting proactive health management in communities. The skilled diagnostics workforce are the enablers of the potential of IVDs, delivering early diagnoses, guiding treatments and supporting community-based care.

The 29,000+ biomedical scientists,[6] with expertise across pathology disciplines, are critical to scaling IVD use, as demonstrated during the COVID-19 pandemic. With a significant portion of the pathology consultant workforce set to retire in the next 5 years, the role of biomedical scientists in advanced roles will be important in easing staffing shortages and delivering the 10 Year Plan.[7]

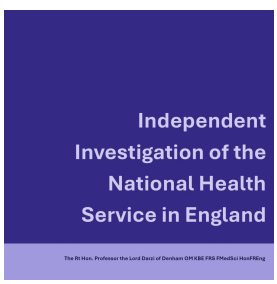
IVDs remain underutilised across NHS care pathways. Structural, organisational, and funding barriers continue to limit their full impact, hindering efforts to improve outcomes, drive efficiency, and support financial sustainability. Lord Darzi has called for action to address critical pressures like antimicrobial resistance, infection control, and early sepsis detection,[8] areas where IVDs deliver fast, reliable insights.

As Lord Darzi warned: “The last decade was a missed opportunity to prepare the NHS for the future and to embrace the technologies that would enable a shift from ‘diagnose and treat’ to ‘predict and prevent.’”[9]

Professor Mike Richards has similarly championed the role of IVDs in early cancer detection, screening, and the rollout of Community Diagnostic Hubs (CDHs) to bring testing closer to patients.[10]

However, commissioning and procurement of IVDs remain fragmented, with inconsistent approaches across ICBs creating variation in access and care quality. While diagnostics increasingly undergo NICE evaluations, the lack of mandated funding - unlike for NICE-approved medicines - has slowed the adoption of innovative technologies. The 10 Year Plan’s funding commitment will only make a difference if it applies universally to all NICE-approved diagnostics.

To achieve the 10 Year Plan’s ambitions - shifting care closer to home, prioritising prevention, and embracing digital tools - IVDs must be recognised as a core enabler. Policymakers and system leaders need clear guidance on how diagnostics can offer scalable, practical solutions to today’s health system challenges.



Top: Sky News (Youtube), **Middle:** NHS South-West London, **Bottom:** From Lord Darzi's Independent NHS Report

How IVDs can support the government's three shifts

The government's ambition to reform the NHS centres on three fundamental shifts: moving care from hospitals into communities, transitioning from analogue systems to digital solutions, and shifting the focus from treating illness to preventing it. Achieving these goals will require practical, scalable tools that support earlier intervention, improve patient pathways, support health equity and reduce system pressures.

IVDs should be at the centre of this transformation. By enabling timely, accurate, and accessible testing, they can help deliver care closer to home, support digital health integration, and empower a proactive and equitable prevention-focused health system across the UK.

Shift 1 — Shift 2 — Shift 3

From hospitals to communities

The NHS's commitment to delivering more care closer to home aligns with the strengths of IVDs. While many IVDs are currently used within hospital laboratories, their portability and adaptability make them well-suited for community and primary care settings, enabling timely diagnosis and treatment while reducing pressure on hospitals.[11]

Embedding IVDs in community care pathways can address disparities in access, reduce diagnostic delays, and align with the government's neighbourhood health model, which champions a "fundamental change in how health and care services in England engage with neighbourhoods and communities" to address the social and economic drivers of ill health.[12] Biomedical scientists and pathologists will play a central role in this move into the communities, and by adopting point-of-care testing and AI-powered analysis in community clinics, pharmacies, and mobile health units, the NHS can improve efficiency and ensure that patients receive the right care at the right time.

This approach not only advances the ambition of bringing more vital health services into the community but is also strongly supported by patients. According to a Patients Association survey, 61% of patients believe that home testing speeds up diagnosis, and 77% are willing to self-test at home - demonstrating clear public appetite for community-based care and highlighting the potential of IVDs to support this shift.[13]

For example, by using point-of-care testing to bring NHS services more quickly to the communities of people who need them, we can support efforts to identify illnesses earlier, reducing the need for more costly treatment in secondary services.[14] As one healthcare professional noted **"It just means that we can kind of nip it in the bud sooner rather than later and avoid any unnecessary secondary care admissions."**

Engaging people with lived experience is critical in this process, as their insights help shape IVD services to be inclusive and effective, addressing specific challenges like accessibility, usability, and cultural sensitivity.

Case Study 1: Rapid community testing for flu and COVID-19

Roche Diagnostics, in collaboration with the Innovation Agency Northwest Coast and Health Innovation Yorkshire & Humber.

Challenge

Every winter, overlapping symptoms of flu, COVID-19, and chest infections make timely diagnosis in community settings like care homes and community hospitals difficult. This can lead to unnecessary antibiotic prescriptions and additional pressure on the NHS. Delays in appropriate antiviral treatment can also increase complications, hospital admissions, and deaths.

Action

Community-based test-and-treat pathways were piloted, using rapid point-of-care tests that detected both flu and COVID-19, focused on patients in high-risk groups. Those testing positive received timely treatment, guided by test results. The pilots also tracked prescribing decisions, outbreak control, and overall impact on patient care.

Outcome

The pilots demonstrated that rapid testing improved early diagnosis and appropriate treatment, with the potential to prevent hospitalisations - including ICU admissions - and even deaths. Unnecessary antibiotic use was significantly reduced, helping to combat antimicrobial resistance. Healthcare staff reported improved outbreak control and faster patient recovery. This rapid testing changed prescribing decisions in over a third of cases, easing winter pressures on hospitals and the NHS. Overall, the pilots proved that community-based rapid testing can save money, reduce hospital strain, and improve patient outcomes.

Helping address health inequalities by reaching under-served communities

Patient populations are diverse, and expanding the use of IVDs in community settings can help tackle health inequalities by addressing disparities in access. The portability and flexibility of IVDs enable local health systems to tailor diagnostic strategies to the specific needs of their populations, supporting more targeted, place-based care.

For example, IVDs can help local health authorities prioritise testing for under-served groups, such as women with undiagnosed heart failure; or focus on high-prevalence conditions within specific communities. In Greater Manchester, where air pollution contributes to high rates of asthma and COPD,[15] Integrated Care System (ICS) leaders could commission point-of-care IVDs for early detection of lung function decline. Blood-based biomarkers, for instance, can flag COPD exacerbations before they become severe, enabling timely intervention and reducing the need for hospital care.[16]

It is clear that IVDs can support the wider shift of care from hospitals to communities. However, this transition must be coordinated and equitable. It requires close collaboration between local systems and national leaders, underpinned by clear, funded strategies that support the widespread deployment of IVDs outside traditional care settings.

To bring diagnostics closer to home, the system should enable local experts, like biomedical scientists and

pathologists, to champion the role of IVDs in their communities. This will help community systems educate patients on the importance of IVDs for detecting and managing health conditions, potentially increasing uptake. Only through strategic investment, clear national guidance, and empowered local leadership can IVDs realise their full potential in reducing inequalities and improving population health.

Case Study 2: Lived experience – in their own words[17]

Research from the Pumping Marvellous Foundation in partnership with Roche Diagnostics found that women were almost twice as likely to be misdiagnosed with heart failure than men (44.5% versus 22.7%).[17]

"My GP never mentioned that they thought I might have heart failure... In fact, one of them actually said, your symptoms are probably not to do with your heart because you're young and you're female."

Sarah from Hull, waited 10 months for a diagnosis of heart failure, despite multiple visits to her GP. She was incorrectly given diagnoses of rheumatological conditions and was told that her symptoms were unlikely to come from her heart, despite having family history and associated comorbidities.

"It would have been nice to have had some knowledge of heart failure because it changed my life dramatically," she says. "It really did have a massive impact on the way my life was. I was no longer able to work, no longer able to walk up the road, I couldn't go anywhere on my own. I had to have someone with me at all times for quite a long time. So, for me, it changed my life dramatically."

Beverly, from southwest London, who was 50 at the time of her diagnosis.

"My diagnosis took two years and eight months from the time I first went to my GP to complain that I was short of breath. The delay in the diagnosis caused me to be unreliable at work, which I hadn't been previously, and also to lose my independence," she says. "Whereas previously I was cycling 10 miles a day, now I was having to rely on other people to pick me up for work. For my family, it was extremely frustrating - I had grandchildren I couldn't pick up. I had to start sleeping downstairs; I couldn't get upstairs because I was so tired, having to rely on other people and eventually having to give up work."

Annette, a heart failure patient and member of The Pumping Marvellous Foundation

The role of biomedical scientists in advancing IVD adoption and improving community health outcomes

The biomedical workforce is pivotal in enabling the effective use of IVDs and improving health outcomes in communities. By leveraging their expertise, these professionals facilitate the adoption of IVDs, ensuring pathologists are able to make accurate and timely diagnoses. Through targeted community engagement and education, they address scepticism rooted in historical healthcare disparities, promote the benefits of diagnostic technologies, and empower individuals to embrace testing, ultimately driving equitable health improvements and better community health outcomes.

Bringing IVD expertise to service design

Community Diagnostic Centres (CDCs) can further leverage IVDs to expand testing capacity and deliver high-quality diagnostics outside hospitals. The potential of CDCs is maximised when they operate in partnership with ICSs, as they help ensure that pathology laboratories play a central role in regulating diagnostic services. The role of the biomedical workforce in helping facilitate this partnership is critical. This collaboration guarantees that testing aligns with clinical needs, maintains quality standards, and optimises resource use. For example, in the Greater Manchester Integrated Care Partnership, the ICS is commissioning clinical care services with direct input from key partners.[19] This ensures that diagnostic services are overseen by experts, preserving accuracy and reliability while integrating seamlessly into broader healthcare delivery, setting a benchmark for standardised, high-quality diagnostics across community settings.

The government should look to replicate such models across the wider NHS to maximise the potential of IVDs in community settings.

Shift 2 Shift 3

Making better use of technology in the NHS

Harnessing digital technology is essential to building a more predictive, preventative NHS. But without the right digital infrastructure, the health service cannot fully realise these benefits. Investment in digital systems must be prioritised on par with physical infrastructure.

IVDs enabling quicker test results for patients

Digitally integrated IVDs also speed up test results, enhance clinician collaboration, and provide a more connected view of the patient's diagnostic journey. Innovations such as remote testing, AI-driven analysis, and integrated lab systems improve diagnostic accuracy and encourage real-time, multidisciplinary teamwork between biomedical scientists, pathologists and technicians.

The importance of digital infrastructure to digital pathology

However, these benefits depend on strong interoperability. A 2024 white paper from Microsoft and the Institute of Biomedical Science (IBMS) notes: *"The benefits of digital pathology come from the ability to easily collaborate and share workload. In the absence of interoperability between systems, this benefit ceases to exist. Pathologists cannot collaborate and request second opinions. Workloads cannot be easily shared. Clinicians cannot receive a single view of the patient across diagnostic services."* [20]

Investment in digital infrastructure is urgent. While large-scale transformation is complex, many UK health organisations have already undergone successful digital upgrades. By drawing on this existing expertise and working in partnership with industry, the NHS can co-design, scale, and embed digital diagnostic solutions, strengthening local care pathways and delivering faster, more connected care for patients.

Case Study 3: REVISE-HCC (liver cancer diagnosis)

Challenge

Liver cancer is often found too late, meaning many patients don't have access to potentially curative treatments. Current tests can miss early cases, especially in patients with cirrhosis, leaving NHS staff with less time and fewer options to treat. Hepatocellular Carcinoma (HCC) disproportionality affects people with underlying cirrhosis but is asymptomatic in its early stages; this means that those particularly susceptible to alcohol abuse, often from socially disadvantaged backgrounds, are more likely to be affected, adding to health inequalities.

Action

The REVISE-HCC project undertaken in partnership between the University of Manchester, Manchester University NHS Foundation Trust and Roche Diagnostics, tested an algorithm (known as the GAAD algorithm), which combines simple blood tests with age and gender to aid in the early diagnosis of HCC. This algorithm was added to routine checks to catch more cases early.

Outcome

The project found that using this algorithm helped identify liver cancer earlier, making more patients eligible for treatment, and easier management of patients. The algorithm shows promise for wider use in NHS liver cancer surveillance programmes.

Shift 3

From treating illness, to preventing illness

Shifting away from a health service that simply treats ill-health to one that prioritises preventing ill-health is a key ambition of this government. IVDs enable this shift by supporting early detection, risk stratification, and ongoing monitoring to prevent disease progression. Biomedical scientists, through advanced roles in cancer screening for example, drive the use of prevention-focused IVDs, ensuring equitable care and reducing pressures in the system.[21] From cancer screening to infectious disease management, IVDs provide the data needed for effective, proactive healthcare.

IVDs play a crucial role in the earlier identification of illness and allow for more treatment options and better patient outcomes. At their most transformative, they can shift the NHS to a future where more ill-health is prevented.

An example of this is the use of Placental Growth Factor (PIGF) based testing for pre-eclampsia, which has transformed ante-natal care by enabling earlier, and more accurate diagnoses and allowing for effective secondary prevention (Appendix 3, Case Study 11). Whilst PIGF testing is not a means to prevent pre-eclampsia from occurring, it is the critical first step that allows doctors and midwives to prevent the severe ill health and dangerous complications that pre-eclampsia can cause.

The benefits for both patients and the healthcare system are significant. By updating NICE guidelines to incorporate PIGF based testing, the NHS has helped women to manage their pregnancies with far greater confidence, thus alleviating many of their patient's anxieties. The ability to confidently rule out pre-eclampsia has a direct and positive impact on NHS efficiency through avoided hospital stays, reduced staff workload, and fewer follow-ups, which is vital at a time of acute pressure on secondary care services. This not only saves
NHS resources but also improves outcomes for mother and baby, demonstrating how IVDs can support preventive care and enhance patient well-being.

The potential of IVDs is understood and supported by patients too. When asked in a survey of patient experiences of diagnostics, 91% called for the prioritisation of investment in diagnostic technology to enable earlier, cost-effective interventions.[22]

Improving cancer treatment options through earlier diagnosis

The importance of identifying cancer as early as possible is well understood and has been one of the factors that has helped to improve outcomes for many different types of cancer. For example, a prostate-specific antigen (PSA) test can help to diagnose prostate cancer at an earlier stage, potentially reducing the need for costly and invasive surgeries.[23] When prostate cancer is detected early, patients may not require immediate treatment, allowing patients to avoid potential side effects and complications. Additionally, the 5-year survival rate for localised prostate cancer (cancer that hasn't spread beyond the prostate) is nearly 100%.[24]

Driving the fight against infectious diseases

In infectious disease, IVDs can provide accurate readings (e.g., flu, COVID-19, or strep tests) at rapid speeds, which can prevent hospitalisations and enable quick identification and inform a subsequent suitable measure of care.[25] Such measures were important during the COVID-19 pandemic, a period where most of the population became increasingly dependent on IVDs to manage their own response, and contribute to the wider public health measures.

Aiding diagnosis in heart disease

In cardiovascular disease, a type of IVD test called Troponin can diagnose heart attacks in hours, helping avoid complications such as heart bypass surgery, which can cost upwards of £10,000 per patient. In heart failure, NT-proBNP testing – a simple blood test – recommended by NICE, can save thousands of pounds in downstream costs by enabling earlier intervention and treatment. For example, a UK screening programme across 13 sites, including Liverpool, Birmingham, and Cardiff, tested 5,500 people using NT-proBNP
tests alongside checks for blood pressure and atrial fibrillation, identifying heart failure cases earlier and reducing hospital admissions (Appendix 3, Case Study 10). This initiative demonstrates how community-based testing can save NHS resources while improving patient outcomes. Similarly, in pre-eclampsia, IVD tests for placental growth factor can save £4m per year, as NICE suggests, by reducing hospital bed occupancy through better risk stratification.

It is clear that earlier diagnosis can both improve patient outcomes and further research and understanding in the effective treatment of major diseases, but the impact on patients' mental wellbeing should not be underestimated either. Rapid results and detailed answers can help to stop patients facing an anxious wait for results. A study by The Patients Association on the impact of delayed test results on patients found that 61% of people waiting for results feel nervous, and 17% people waiting for results report setbacks in long-term recovery.[26]

Case Study 4: Heart health event programme

Challenge

Heart failure often goes undiagnosed because its symptoms (like tiredness and swelling) are non-specific. This leads to unnecessary hospital admissions and higher costs for the NHS.

Action

A screening programme across 13 events in Liverpool, Stoke-on-Trent, Salisbury, London, Wensleydale, Birmingham, Newry, Kilmarnock and Cardiff tested 5,500 people using simple checks for blood pressure, atrial fibrillation, and heart failure symptoms. Those with symptoms had a quick blood test (an NT-proBNP test). If levels were high, they were referred to specialists.

Outcome

The programme found cases of heart failure earlier, allowing patients to get treatment sooner and stay out of hospital. By using quick blood tests instead of expensive scans, the NHS saved money and time. The programme is set to expand in 2025, showing how simple community checks can improve heart health and reduce NHS pressure.

"The widespread use of cost-effective diagnostic tools such as NT-proBNP must be our priority to save lives, reduce costs and improve patients' quality of life in the future."

- Dr Jim Moore, General practitioner with special interest in cardiology, Gloucestershire Heart Failure Service[27]

"Even in the hospital setting NT-proBNP is underused – the NCEPOD report showed that although NT-proBNP was available in 90% of Trusts, only 17% of new heart failure cases had NT-proBNP testing."

- Dr Lisa Anderson, Heart Failure Consultant, St. George's University Hospitals NHS Foundation Trust[28]

Supporting better antimicrobial stewardship

The faster and more accurate identification of infections that IVDs can deliver can be an important tool in the fight against antimicrobial resistance. By quickly being able to differentiate between bacterial and viral infections, the inappropriate – and ineffective – use of antibiotics can be reduced, a key aspect of good antimicrobial stewardship. Antimicrobial resistance (AMR) threatens to be a problem not just for patients whose infections can become more difficult to treat, but also to health systems in the UK and globally - AMR is projected to cost health systems $1 trillion globally by 2050.[29]

The shift towards prevention is now essential to the sustainability of the NHS, and early diagnosis through technologies like IVDs is a critical enabler of that transformation. As treatments continue to advance, the ability to identify conditions earlier—and intervene sooner—will become even more vital. To make prevention a reality, technological progress must be matched by system readiness. This means ensuring ICSs are accountable for adopting proven diagnostic innovations, supported by dedicated funding mechanisms, robust digital infrastructure, and locally tailored diagnostics strategies. Without focused investment and leadership at both system and national level, these advances risk remaining theoretical, delaying benefits for patients and placing greater strain on NHS services.

The economic case for IVDs

The Secretary of State has set out a clear ambition for the Department of Health and Social Care to drive economic growth. The UK life sciences sector will be central to achieving this, supported by the measures in the government's Life Sciences Sector Plan. IVDs are a key part of this opportunity. By enabling earlier diagnosis and targeted treatment, they not only improve health outcomes but also reduce healthcare costs and help people stay in work, directly supporting both the NHS and the wider UK economy.

Keeping people in work and reducing NHS costs

Early and accurate diagnosis through IVDs directly supports economic productivity. For example, a 2020 study of heart failure patients found that 44% experienced a negative impact on their ability to work, 30% faced financial losses, and 32% reported hindered career progression.[30] With 2.8 million people currently out of work due to long-term sickness, IVDs can play a critical role in mitigating these impacts. By identifying conditions like diabetes or cardiovascular disease early, IVDs enable timely, cost-effective treatments that prevent disease progression, reduce the need for expensive scans or specialist referrals, and help lower secondary care costs. This not only saves NHS resources but also ensures individuals remain economically active, contributing to the wider economy.

Unlocking economic value from IVD data

The data generated by IVDs is a powerful economic asset. When aggregated and analysed, IVD data provides insights into disease trends, supports predictive public health models, and enables targeted interventions. For instance, longitudinal data on chronic conditions like diabetes and cardiovascular disease, which are major drivers of NHS costs in an ageing population, can inform the government's strategies to help move towards a preventative model of healthcare that can help reduce long-term healthcare spending in hospitals as outlined by Lord Darzi, and help unlock more funding elsewhere in the system such as in scaling up community infrastructure.[31] By identifying at-risk populations early, IVDs help shift the NHS toward efficient, proactive care, delivering significant cost savings and improving population health outcomes.

Designing equitable diagnostic pathways for maximum impact

To fully realise the economic potential of IVDs, the NHS and government must work to ensure that access to diagnostics is equitable. This means designing care pathways that bring the right IVD tools to patients – whether through main laboratory services, CDCs, GP practices, or community pharmacies at the right time, to the right patient, rather than requiring patients to navigate complex systems. The biomedical and wider pathology workforce should be central to the designing of these pathways due to their clinical expertise and understanding of patient needs. By enabling faster, decentralised access to diagnostics according to patient need, IVDs can help reduce delays, ease pressure on acute services, and lower the demand for costly secondary care.[32] This approach enhances equity of access and outcomes for under-served communities, whilst optimising resource allocation and economic efficiency.

Barriers to implementation

Despite the clear value of IVDs to patients, the health service and the country, there are significant barriers at a structural, organisational and social level which hinder the adoption and integration of IVDs. For the ambitions of the 10 Year Plan and the government's three shifts to be realised, these must be addressed.

Resource barriers:

Capacity constraints
The NHS faces significant capacity constraints that limit the expansion of diagnostic services, particularly in community settings. Demand for diagnostics continues to outstrip available resources, with insufficient infrastructure to support the widespread deployment of IVDs outside traditional hospital-based laboratories.

Insufficient funding model for medical technologies
Currently, diagnostic technologies do not receive mandated funding from the goverment to ensure their adoption and rollout in ICSs. Despite NICE approval, uptake of innovative IVDs is slow. Whilst there have been commitments for increased funding, this is not mandated funding as it is for medicines. Without mandated funding, the adoption of IVDs is likely to remain limited. This disparity risks fewer patients receiving a timely, life-changing early diagnosis, and instead shifts burdens to further down the patient pathway with the need for costlier and often more invasive interventions. A mandated funding mechanism for NICE-approved diagnostic technologies would put diagnostics on par with medicines. This can and should include the means for central government to allow capital to flow from central budgets to support ICBs, to allow local services to adopt innovation effectively.

Workforce challenges
Insufficient training and a dwindling diagnostics workforce compound the challenges of IVD implementation. The UK's biomedical workforce are world leaders in their field, but data from the IBMS Long Term Biomedical Scientist Workforce Plan states the UK is facing a projected shortfall of 260,000–360,000 NHS staff by 2036/37.[33] The biomedical workforce requires specialised training in the use of advanced IVD technologies and only through this vital workforce can the potential of IVDs be fully realised. By leading the adoption of IVDs, upskilling through IBMS qualifications and streamlining contracting processes, biomedical scientists can alleviate pressures on pathologists, reduce reliance on costly locum staff (£17m annually UK-wide),[34] and support the 10 Year Plan's goals of prevention, community-based care, and digital integration.

These workforce shortages, driven by recruitment and retention difficulties, place further strain on NHS services. Competing pressures, such as managing backlogs and addressing urgent

care needs, divert attention from diagnostics innovation. A new workforce plan must account for comprehensive training programs and workforce planning to build capacity and resilience for the diagnostics workforce.

Organisational barriers:

Infrastructure and digital challenges
There are variations in the modernity of NHS infrastructure, and fragmented digital systems present substantial obstacles to maximising IVD implementation. Many NHS facilities require upgrades on ageing laboratory equipment and siloed IT systems that lack interoperability and prevent better integration with IVDs. Insufficient digital connectivity further complicates data sharing and real-time result reporting. Modernising infrastructure across the whole NHS estate, with a specific focus on digital interoperability, as is set out in the 10 Year Plan, is central to enable IVDs to deliver their full potential and bring the NHS into the 21st century.

Assessment criteria and siloed budgeting
Current evaluation frameworks are often designed around interventions that deliver direct and measurable health outcomes, whereas IVDs typically generate value by enabling earlier or more accurate clinical decision-making, streamlining care pathways, and preventing unnecessary procedures. Furthermore, siloed budgets in the NHS reduce the incentive to rollout IVDs in one setting when the benefit or financial saving of that test is only realised in another setting, further along the patient pathway. As such, these indirect and system-wide benefits are frequently overlooked in standard assessments, which tend to prioritise short-term clinical or financial outcomes. As a result, IVDs with the potential to improve patient care, increase efficiency, and reduce overall system burden are often undervalued or delayed. This misalignment between how tests deliver value and how value is assessed slows the adoption of innovation and limits the NHS's ability to deliver more proactive, personalised care. Another key issue lies in the fact that pathology services are predominantly based in secondary care, yet a large percentage of their workload stems from primary care referrals,[35] a disconnect exacerbated by the separation of primary and secondary care budgets. Addressing this mismatch is essential for sustainable IVD implementation. It should not be acceptable that accounting processes are being allowed to impact upon patient care.

Health inequalities
Regional disparities in access to diagnostic services exacerbate health inequalities. Rural and under-served areas often lack the infrastructure, workforce, and digital connectivity required to implement IVDs effectively, leading to uneven care quality. We welcome the 10 Year Plan's commitment to moving funding towards these under-served regions, and hope that investing in

diagnostic infrastructure will be a key part of this funding. Targeted investments in under-served regions informed by the needs of those with lived experience will be crucial to addressing this challenge.

Social barriers:

Low public awareness

During the pandemic, the UK public had an increased awareness of both the importance of, and effectiveness of testing for respiratory viruses as evidenced by the availability and access of lateral flow testing for COVID-19 and other respiratory conditions. This heightened public awareness helped reduce the impact of COVID-19, allowing people to take measures to protect themselves and other members of the public from the spread of disease. However, this awareness of testing has not carried across to other major diseases such as heart failure, leading to delayed presentation and worse outcomes. Without greater public awareness of IVDs and their vital role in detecting and helping prevent ill-health, there remains a challenge in helping move to a preventative model of healthcare.

Lack of policymaker understanding

Whilst there has been an increased focus on diagnostics in recent years, evidenced by the commitment to double the number of CT and MRI scanners in the NHS, IVDs have not received parity of recognition in policymaking. Many policymakers are not aware that when used in the right setting and at the right time in the patient pathway, IVDs have the potential to reduce demand on wider NHS services that are often under significant pressure. Echocardiograms are used to diagnose heart failure, but waiting times are highly variable and the cost per scan is variable to each NHS Trust depending on their location. And yet, there is a simple blood test for triaging patients, which can be used to rule out heart failure even in community or primary care settings, in turn reducing demand on echocardiograms.

This ability to triage is made more valuable in light of the Royal College of Radiologists' report underscoring the significant challenges faced by workforce shortages and limited availability of large scanners,[36] highlighting the critical value of IVDs in optimising diagnostic pathways and alleviating pressure on imaging resources.

Conclusions

To ensure the transformative potential of IVDs are fully realised, we urge all touchpoints of the system – policymakers, those with lived experience, professional organisations, clinical staff and industry to actively engage with this report's findings, consider their implications for NHS reform, and commit to driving forward the necessary change with stakeholders across the healthcare ecosystem. By prioritising these recommendations, policymakers can help unlock the potential of IVDs – diagnostics tools with the potential to deliver positive outcomes for the system, align with the 10 Year Plan's vision, and deliver equitable, efficient, and prevention-focused healthcare that improves patient outcomes and strengthens the health system for the future. We welcome the opportunity to work with you to unlock the true potential of IVDs and help make them a vital solution to address the challenges set out in the 10 Year Plan.

Appendix 1 - How IVDs are enabling the shift from hospitals to communities

This appendix presents case studies demonstrating how in vitro diagnostics support the transition of healthcare from hospitals to community settings, improving access and efficiency. We extend our thanks to the organisations that contributed these case studies, which have helped shaped this report and its recommendations.

Case Study 1 - Rapid community testing for flu and Covid 19

Roche Diagnostics, in collaboration with the Innovation Agency Northwest Coast and Health Innovation Yorkshire & Humber

Challenge
Every winter, overlapping symptoms of flu, COVID-19, and chest infections made timely diagnosis in community settings like care homes and community hospitals difficult. This can lead to unnecessary antibiotic prescriptions and additional pressure on the NHS. Delays in appropriate antiviral treatment can also increase complications, hospital admissions, and deaths.

Action
Community-based test-and-treat pathways were piloted, using rapid point-of-care tests that detected both flu and COVID-19, focused on patients in high-risk groups. Those testing positive received timely treatment, guided by test results. The pilots also tracked prescribing decisions, outbreak control, and overall impact on patient care.

Outcome
The pilots demonstrated that rapid testing improved early diagnosis and appropriate treatment, with the potential to prevent hospitalisations - including ICU admissions - and even deaths. Unnecessary antibiotic use was significantly reduced, helping to combat antimicrobial resistance. Healthcare staff reported improved outbreak control and faster patient recovery. This rapid testing changed prescribing decisions in over a third of cases, easing winter pressures on hospitals and the NHS. Overall, the pilots proved that community-based rapid testing can save money, reduce hospital strain, and improve patient outcomes.

Case Study 2 – The health inequalities exposed by those with lived experience – in their own words[13]

Research from the Pumping Marvellous Foundation in partnership with Roche Diagnostics found that women were almost twice as likely to be misdiagnosed with heart failure than men (44.5% versus 22.7%).[14] In addition, 43.9% of respondents aged under 45 received the incorrect diagnosis, compared with 31.2% of those aged over 55.

“My GP never mentioned that they thought I might have heart failure... In fact, one of them actually said, your symptoms are probably not to do with your heart because you’re young and you’re female."

Sarah from Hull, waited 10 months for a diagnosis of heart failure, despite multiple visits to her GP. She was incorrectly given diagnoses of rheumatological conditions and was told that her symptoms were unlikely to come from her heart, despite having family history and associated comorbidities.

“It would have been nice to have had some knowledge of heart failure because it changed my life dramatically,” she says. “It really did have a massive impact on the way my life was. I was no longer able to work, no longer able to walk up the road, I couldn't go anywhere on my own. I had to have someone with me at all times for quite a long time. So, for me, it changed my life dramatically.”

Beverly, from southwest London, who was 50 at the time of her diagnosis.

"My diagnosis took two years and eight months from the time I first went to my GP to complain that I was short of breath. The delay in the diagnosis caused me to be unreliable at work, which I hadn't been previously, and also to lose my independence,” she says. “Whereas previously I was cycling 10 miles a day, now I was having to rely on other people to pick me up for work. For my family, it was extremely frustrating - I had grandchildren I couldn’t pick up. I had to start sleeping downstairs; I couldn't get upstairs because I was so tired, having to rely on other people and eventually having to give up work.”

Annette, a heart failure patient and member of The Pumping Marvellous Foundation

Case study 3 - Revise REVISE-HCC (liver cancer diagnosis)

Challenge
Liver cancer is often found too late, meaning many patients don’t have access to potentially curative treatments. Current tests can miss early cases, especially in patients with cirrhosis, leaving NHS staff with less time and fewer options to treat. HCC disproportionality affects people with underlying cirrhosis but is asymptomatic in its early stages; this means that those particularly susceptible to alcohol abuse, often from socially disadvantaged backgrounds, are more likely to be affected, adding to health inequalities.

Action
The REVISE Hepatocellular Carcinoma (HCC) project undertaken in partnership between the University of Manchester, Manchester University NHS Foundation Trust and Roche Diagnostics, tested an algorithm (known as the GAAD algorithm), which combines simple blood tests with age and gender to aid in the early diagnosis of HCC. This algorithm was added to routine checks to catch more cases early.

Outcome
The project found that using this algorithm helped identify liver cancer earlier, making more patients eligible for treatment, and easier management of patients. The algorithm shows promise for wider use in NHS liver cancer surveillance programmes.

Case Study 4 - Heart health event programme

Challenge
Heart failure often goes undiagnosed because its symptoms (like tiredness and swelling) are non-specific. This leads to unnecessary hospital admissions and higher costs for the NHS.

Action
A screening programme across 13 events in Liverpool, Stoke-on-Trent, Salisbury, London, Wensleydale, Birmingham, Newry, Kilmarnock and Cardiff tested 5,500 people using simple checks for blood pressure, atrial fibrillation, and heart failure symptoms. Those with symptoms had a quick blood test (an NT-proBNP test). If levels were high, they were referred to specialists.

Outcome
The programme found cases of heart failure earlier, allowing patients to get treatment sooner and stay out of hospital. By using quick blood tests instead of expensive scans, the NHS saved money and time. The programme is set to expand in 2025, showing how simple community checks can improve heart health and reduce NHS pressure.

Case Study 5 - Supporting equitable access through education and trust-building

Challenge
Successful adoption of IVDs in community settings depends on public trust and understanding, particularly in populations sceptical of healthcare innovations due to historical inequalities. Fear and distress, especially among young patients and families undergoing frequent diagnostic tests, can hinder engagement with IVDs and delay timely diagnosis.

Action
IBMS's Harvey's Lab Tours, led by biomedical scientists in over 100 laboratories, offer an innovative approach to building trust. These tours engage young patients and their families, providing hands-on education about the diagnostic process. By demonstrating how samples are processed and introducing the professionals behind the tests, the initiative transforms anxiety into understanding, fostering confidence in IVD technologies.

Outcome
At University Hospital Southampton and NHS Dumfries and Galloway, the tours have successfully reduced fear and distress associated with diagnostic procedures, particularly needle-based tests, improving patient cooperation and engagement. By increasing transparency and public understanding of IVDs, the initiative has built trust in communities wary of healthcare innovations. This model of community education supports the broader adoption of IVDs, aligning with the NHS's goal of delivering accessible, equitable diagnostics closer to home. This case study underscores the importance of patient and public engagement in overcoming social barriers to IVD adoption. By prioritising education and trust-building, such initiatives ensure that underserved communities are better equipped to benefit from diagnostic innovations, supporting the NHS's ambition to deliver equitable, community-based care.

Case study 6 - Heart failure point-of-care testing in Everton, Merseyside

Challenge
The BEAT Breathlessness campaign at Everton in the Community's People's Hub, a partnership between Everton in the Community, the Pumping Marvellous Foundation, Liverpool University Hospitals NHS Foundation Trust, Us2ai, Edge Hill University, NHS Health Innovation North West Coast, and Roche, focused on improving the time to diagnosis of heart failure by reducing the need for patients to make multiple appointments or wait six weeks. Symptoms like breathlessness and exhaustion can be vague and non-disease-specific, making it hard for doctors and nurses to confirm heart failure quickly. This leads to stress for patients, unnecessary hospital visits, delays in starting treatment and reduced health outcomes.

Action
A new community-based pathway called BEAT-to-TREAT was set up. Patients with suspected heart failure were referred by local GPs. They were tested at Everton in the Community's People's Hub using a simple blood test that identified a need for an echocardiogram. Results were available in just 15 minutes. Those with a high result were offered an AI-assisted echocardiogram that was checked by a heart failure consultant cardiologist. Based on the results, patients were diagnosed, given education about heart failure, treated with guideline-directed medical therapy, and referred into the local heart failure service with a further referral to a hospital-based echocardiogram.

Outcome
Evidence shows that if heart failure is found sooner and treated with guideline-directed medical therapy, mortality is reduced, quality of life is improved, and costs to the NHS reduce. The new pathway slashed the waiting time from months to just 60 minutes. Patients received faster diagnoses and started treatment sooner. The approach also helped doctors quickly rule out heart failure in other patients, cutting down on unnecessary referrals, thus reducing waiting times and unplanned hospital admissions. Because of its success, the model is now being used within the East of England, showing how quick tests and smart use of technology can enable rapid clinical decision-making to transform care, ease pressures on the health system and improve the lives of patients.

Appendix 2 - How IVDs can enable and unlock the full potential of technology in the NHS to improve outcomes

Case study 7 - IVDs unlocking the future of personalised medicine

Challenge
Pathology departments are under pressure to provide quick and accurate diagnoses, especially for cancer patients. With the rise of personalised treatments that specifically target cancerous cells, doctors need precise information about each patient's disease and biomarkers before treatment can commence.

Action
Pathologists examine tissue samples from biopsies and surgeries to confirm diagnoses and look for key disease markers. For breast cancer, they check for hormone receptors and other biomarkers that help guide treatment choices. For bowel cancer, they test for genetic changes that can affect chemotherapy responses. In inflammatory bowel disease (IBD), they help doctors understand disease activity and watch for complications.

Outcome
Thanks to the careful work of pathology teams, patients receive the right diagnosis and targeted treatment quickly. This means more effective care, fewer unnecessary treatments, and better patient outcomes. For IBD, pathology also helps monitor the disease and catch issues early, improving quality of life and outcomes.

Appendix 3 - How IVDs keep people healthier for longer and reduce clinical and financial burden on the NHS

Case study 8 - Blood biomarkers boosting dementia diagnosis in the NHS

Alzheimer's Society, in partnership with the National Institute for Health and Care Research (NIHR), and supported by Alzheimer's Research UK

Challenge
Diagnosing dementia in the NHS takes a long time, with some patients waiting up to a year. This delay happens because current tests, like PET scans and lumbar punctures, are expensive, invasive, and resource-heavy, making them harder for patients to access. As more people develop dementia, the NHS is struggling to keep up.

Action
The Blood Biomarker Challenge is trialling new blood tests that can identify Alzheimer's and other forms of dementia more easily and more affordably. These tests are less invasive and can be used at scale, and assessments are now being made as to how well these blood tests work, and how to bring them into everyday NHS care.

Outcome
Blood tests could transform dementia diagnosis - speeding it up, cutting costs, and helping patients get treatment sooner. Early results show promise, and the next steps involve building NHS capacity to make sure local services can use these tests, helping patients get the care they need without long waits.

Case study 9 - Improving the level of care and health of pregnant women and unborn babies in their locality

Challenge
Women at risk from pre-eclampsia would need to be referred to a specialist to confirm a clinical assessment and a clinical diagnosis. This often meant referring women into hospitals to monitor their blood pressure and get blood tests. For many women the risk of pre-eclampsia is a discouraging factor in having children. One patient noted that "the anxieties from suffering from pre-eclampsia are still there" and stated that "being able to get tested earlier would help take away those anxieties".

Action
To alleviate the burden on both patient and clinician time, NICE guidelines were updated to allow for Placental Growth Factor (PLGF) testing. Where before PLGF testing was only recommended for ruling out pre-eclampsia.

Outcome
This update improved outcomes for mothers and babies, as clinicians could make more accurate diagnosis of pre-eclampsia using the PLGF test. This also helped reduce unnecessary appointments for both the women, and the NHS, and improves the level of care they can receive in their locality. This helps give women confidence to plan ahead for the future without fear of pre-eclampsia and gives clinicians confidence that they can make accurate diagnosis, and better focus its resources.

Case study 10 - Advancing precision in cellular pathology

Challenge
Cellular pathology plays a vital role in diagnosing and managing conditions such as cancer and inflammatory bowel disease (IBD). Increasing demand for personalised medicine means pathologists must provide precise diagnoses and deliver detailed biomarker data to guide targeted therapies, while maintaining efficiency and accuracy. Delays or capacity issues can impact patient care.

Action
Pathology departments analyse a wide range of specimens, from biopsies to surgical resections, using microscopy and advanced testing. In breast cancer, pathologists confirm the diagnosis and assess key biomarkers (oestrogen, progesterone, HER2, PD-L1) to guide treatment. For colorectal cancer, molecular tests help identify hereditary syndromes and genetic mutations (KRAS, NRAS, BRAF) that inform chemotherapy decisions. In IBD, biopsies are used to distinguish Crohn's disease from ulcerative colitis and monitor for complications such as dysplasia. Departments collaborate with clinical teams to ensure results drive personalised treatment strategies.

Outcome
Cellular pathology provides timely, accurate diagnoses, enabling safe, tailored treatments for patients. Biomarker and genetic profiling allow clinicians to select effective therapies, improving outcomes and reducing unnecessary treatments. For IBD, pathology supports accurate diagnosis and early detection of complications, enhancing patient care. Integrating advanced pathology testing and close collaboration with clinicians helps ensure the delivery of personalised medicine while optimising NHS resources.

Case study 11 - Predicting risk through targeted profiling

Challenge
Meningiomas are the most common adult tumours of the central nervous system (CNS). World Health Organisation (WHO) grading, based on the study of cells and tissues, is limited to being able to predict the likelihood of recurrence. While there are other molecular tools that can help to profile risk in patients, they are costly. This raises a key question; which meningiomas should be prioritised for testing to maximise value for clinicians and patients, while balancing the cost?

Action
To address this challenge, the Division of Neuropathology at The National Hospital for Neurology and Neurosurgery in London analysed over 1,000 meningioma cases. The study integrated the WHO grading with other classifications including DNA profiles. A risk model was applied and this allowed the researchers to group cases into low, intermediate, and high-risk categories.

Researchers then assessed which features most consistently aligned with higher-risk cases, and were able to identify cases with different risk profiles. Even those tumours that were ungradable benefitted from the profiling, particularly in cases where

tumours were suspected of spreading into the brain.

Outcome
The study confirmed that using diagnostic tools to help profile cases provided greater clarity over the prognosis of particular cases. As a result, the researchers proposed a cost-effective, clinically meaningful algorithm for profiling different types of meningioma tumours. This research also highlighted the need for further research into affordable biomarkers - such as AI-based predictors - to better target their testing. While some limitations remain to be overcome, this research offers a practical pathway to improve patient care within economic constraints. This case exemplifies how diagnostic data, when used smartly, can enhance the way patients are treated, managed and monitored. This potentially allows the most urgent cases to be triaged so they can be delt with more quickly, a vital tool in highly strained health system such as the NHS; a tool that would ultimately enhance clinical decision-making and patient outcomes.

Case study 12 - Improving infection control and bed management at Harrogate NHS Trust

Background
As winter 2024 approached, Harrogate and District NHS Foundation Trust (HDFT) anticipated increased patient footfall in the Emergency Department (ED) and Same Day Emergency Care (SDEC) due to respiratory viral symptoms caused by Flu A, Flu B, COVID-19, and RSV. Concerns arose about the capacity of existing clinical pathways to manage this surge effectively while preventing onward transmission and ensuring hospital beds were available for those most in need. The availability of the Sterilab Combi Antigen Lateral Flow Test (LFT) for these four viruses, paired with Testcard's electronic smartphone reader, offered an opportunity to enhance infection control and bed management.

Challenge
The primary challenge was managing increased patient volumes presenting with non-specific respiratory symptoms, which risked overwhelming ED and SDEC while increasing the potential for in-hospital viral transmission. Traditional reliance on PCR tests, which are resource-intensive and slower, often led to unnecessary testing, delayed clinical decisions, and inefficient bed management. This strained hospital resources, including side rooms and ambulance bays, and posed risks to both patients and staff through potential infections and the need for frequent deep cleaning.

Action
HDFT implemented a rapid clinical decision pathway, developed by Consultant Microbiologist Dr. Lauren Heath and Acute Medicine Consultant Dr. Richard Mayers, integrating the Sterilab Combi Antigen LFT with Testcard's smartphone reader. The pathway enabled ED and SDEC staff to quickly test suitable patients for Flu A, Flu B, COVID-19, and RSV, delivering results in 10 minutes. This facilitated immediate streaming decisions, such as discharging stable patients with positive results for self-care or isolating infectious patients. PCR tests were reserved for clinically indicated cases, optimising resource use and guiding treatment and discharge decisions.

Outcome
The pathway significantly improved infection control and bed management, enabling rapid streaming of patients, with stable short-of-breath patients discharged for self-care when appropriate, saving time and resources. Rapid LFT results reduced staff exposure to infections, lowering sick days, and improved patient flow by minimising unnecessary deep cleans and optimising ambulance bay and side room use. The initiative enhanced clinical decision-making, protected patients and staff, and ensured efficient resource allocation. By demonstrating the effectiveness of rapid LFTs in a high-pressure setting, HDFT's approach offers a scalable model for managing respiratory virus surges, reducing hospital burden, and improving patient outcomes.

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