



Diagnostics · In Vitro ·
 Empowering patients · Self monitoring ·
 Accurate · Patient care ·
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 More efficient NHS · Early detection · Better
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The Value of IVDs

The contribution of the
in vitro diagnostics industry
 to patients, the NHS and
 the UK economy



BACKGROUND

In vitro diagnostics (IVDs) are an essential part of the NHS. They are used to both enable diagnosis and to rule out causes of ill health. They are also used to monitor, screen and assess people for any potential health problems they might have. Increasingly, they also allow people with chronic disease to manage their own conditions. There are three main types of IVDs:

- 1) **CLINICAL LABORATORY TESTING** – The majority of IVD tests are still performed in a laboratory. Many specialties now have fully automated equipment that produces a result within minutes of a sample being loaded onto the system. Even the more ‘hands on’ specialties such as microbiology are gradually becoming more streamlined as equipment is developed to reduce time to result and allowing scientists and pathologists to focus on interpretation of results and individual patient care. An important development is the use of IVDs to identify patients who will benefit from drug treatment.
- 2) **NEAR PATIENT TESTING** – Also known as Point of Care Testing, these are IVD tests which can be performed outside of a laboratory setting. This could be within a hospital such as on a ward, at an out-patient clinic or in A&E. Alternatively the testing can be done in a community setting such as at a GP surgery or within a pharmacy. Some tests are simple, colour-change formats, while others may be done on miniaturised versions of laboratory equipment using simplified procedures. They do require the relevant healthcare professionals to be trained in routine managing, monitoring and maintenance of the test equipment to ensure laboratory quality results are produced.
- 3) **SELF-TESTING** – Self-testing can be broadly divided into two purposes – self-testing or self-monitoring. Self-monitoring using an IVD test enables a patient to help manage their own condition with support of their healthcare practitioner, for example someone with diabetes. Self-testing involves tests or testing services which are bought by an individual to enable them to learn about their own health or physiological condition, for example a pregnancy test kit.

It is estimated that 70% of clinical decisions are made using IVDs. They are a vital component of all NHS front line services and an integral part of almost all patient pathways. As such, their contribution to healthcare systems around the world, and to the health and wealth of our nation should not be underestimated.

£117.229bn
NHS England Budget
(2015/16 in real terms)

>

£850 million
NHS spend on IVDs

>

70%
Yet 70% of clinical decisions
are made using IVDs



Effectively used, IVDs help to reduce hospital stays, support patients to look after their own health and release resources for use elsewhere in the NHS, resulting in a healthier population and stronger economic growth. Through molecular diagnostics, the industry also contributes to the natural evolution of medicine and more personalised treatment.

Research and Development (R&D) by our industry has led to the creation of many new and innovative IVDs across a wide range of disease areas. However, the sector still faces a glass ceiling when it comes to the uptake and diffusion of IVDs within the NHS. This is due to:

- **BUDGET SILOS** – Currently the budget for testing and general pathology in the NHS is separated from the rest of the budget for a medical pathway. This can often provide a disincentive to introduce cost-saving and potentially life-saving new tests because while the up-front and ongoing costs are borne by the innovators, the savings accrue further down the patient pathway.
- **UNDERSTANDING** – Use of IVDs can lead to a more effective, rapid and accurate diagnosis, which in turn enables tailored patient care. However, when being commissioned, the benefits of diagnostics are often either misunderstood, or worse, not considered at all.
- **FLEXIBILITY** – Currently, the NHS is too inflexible when it comes to adopting new IVD tests. Typically, solutions are still thought of as pharmaceuticals and consideration is not given to how IVDs could be adopted in the system to improve outcomes.

Delivering benefits for patients and the NHS is at the heart of the IVD industry. However, it should be acknowledged that the industry also makes a valuable contribution to the UK economy, employing more than 8,000 people, generating annual sales of approximately £850million to the NHS and playing a significant role UK exports; £1.1billion were exported in 2013.

Through this publication, we hope to demonstrate the value of the IVD industry to patients, the NHS and the UK economy. While many of the accompanying examples and case studies to this report are England focused, the wider issue concerning adoption are applicable across the UK.

We are determined that the sector will continue to thrive in the UK post-Brexit, but in order for the industry to grow and improve patient outcomes, it is vital that steps are taken to increase the adoption of IVDs.



LANDSCAPE: 2017-18

The current landscape facing the IVD sector is challenging. On the one hand, there is an increasing demand for tests; it is expected that there will be a 10% annual increase in demand for blood and tissue tests over the next ten years due to an ageing population and rising incidence of chronic disease.

On the other, the final report of the Carter Review stated there was an opportunity for the NHS to save around £200 million in the provision of pathology services. This is despite the fact that the NHS only spends about £850 million annually on IVD products – less than 1% of the total NHS budget, yet around 70% of clinical decisions are made using IVDs. Research has also recently been published that found pathology services in the UK are struggling to cope with the increasing demand for samples to be tested, in part due to workforce shortfalls¹.

Perhaps unsurprisingly, considering the challenge facing pathology services and NHS finances, the IVD industry continues to face a glass ceiling when it comes to the uptake and diffusion of new tests and technology across the health service. In fact, uptake of new IVDs within the NHS typically takes about 10 years².

In addition to the pressures on pathology services, adoption is often slow due to budget silos and inflexibility within the NHS. However, critically, adoption is also being undermined by a lack of understanding, meaning that during the commissioning process, the **use and value** of diagnostics is either misunderstood, or worse, not considered at all.

The pressures on the NHS's time, resources and finances are well documented, but it is little understood that IVDs are in a unique position to offer improved patient outcomes while also ensuring efficient use of NHS resources. In fact, IVDs are well placed to deliver on many of key ambitions from the **Five Year Forward View** including:

- Prevention
- Empowering patients
- Implementing new models of care
- Driving efficiency savings

Also, with the future of healthcare focused on personalising medicine and ensuring the right person gets the right treatment at the right time, innovations in diagnostics will be critical to achieving this ambition. However, in order to make this a reality, the challenges preventing greater uptake and diffusion of diagnostic tests need to be addressed.

There have been a number of initiatives recently that we hope will increase the adoption of IVDs, including the;

- Accelerated Access Review
- O'Neill Review into Antimicrobial Resistance
- Life Sciences Industrial Strategy

As an industry, we will continue to support these initiatives to ensure the voice of the IVD industry is heard loud and clear. With Brexit on the horizon and the uncertainty that will bring, it is vital that the IVD industry is strongly supported in order for it to play its part in demonstrating the value, innovation and importance of the UK life sciences sector on the global stage.

Ultimately, to invest in IVDs is to invest in an efficient and improved future for patients, the NHS and wider UK economy.

IVDs: DELIVERING IMPROVEMENT, IMPACT AND INVESTMENT

Outlined below is an overview of how IVDs are delivering better outcomes for patients, the NHS and the UK economy.

For practical examples of how IVDs are making a difference, look out for our case studies that correspond with our three focus areas:

Improvement, Impact and Investment.



1) IMPROVEMENT: EMPOWERING PATIENTS FOR BETTER OUTCOMES, DIAGNOSIS AND TREATMENT

The most important aspect of IVDs is the role they play in delivering patient care and improving outcomes.

Innovations in IVDs are resulting in faster, accurate testing and are allowing the NHS to target treatment more precisely and effectively, improving patient pathways and enabling earlier intervention.

IVDs can also have a positive effect on the treatment and quality of life of patients, particularly those with long-term conditions (LTCs) by:

- Allowing patients to manage their conditions themselves at home
- Regular self-management allows for early detection of changes in health status, reducing the likelihood of dangerous and costly complications
- Empowers the patient with greater understanding of their LTC, reducing anxiety



2) IMPACT: INCREASING EFFICIENCIES AND SAVINGS WITHIN THE NHS

At its core, the IVD industry enables the NHS Pathology Service to manage its workload – this equates to approximately 900 million tests each year in UK or 300,000 tests each working day.

IVDs provide enormous value to healthcare, both in terms of how they can transform care but also in terms of the cost to the system to achieve this. The NHS spends approximately £850 million annually on IVD products, less than 1% of the total NHS budget, yet around 70% of clinical decisions are made using IVDs.

When utilised efficiently, IVDs can also be a key driver in delivering both efficiencies and financial savings for the NHS by:

- Reducing downstream treatment costs
- Reducing avoidable/inappropriate interventions
- Lowering hospitalisation rates
- Save staff time



3) INVESTMENT: CONTRIBUTION TO THE UK ECONOMY

IVDs have obvious benefits for the NHS and improving patient outcomes. However, it is also important to recognise that the IVD industry has a vital role to play in contributing to the economic prosperity of the UK.

For example, the IVD industry delivers benefits in areas such as:

- Employment
- Trade
- Growth
- Productivity
- R&D

BUILDING ON OUR SUCCESS

The IVD industry is clear that it wants to continue to grow, develop and innovate, offering benefits for the NHS, economy, and most importantly, patients.

While the IVD sector is already making a significant difference in these areas, we have identified five priority areas that need to be addressed in order for us to be able to build on our success:

1) SECURING A MORE EFFECTIVE AND EFFICIENT NHS BY INCREASING THE ADOPTION OF IVDs

The adoption of innovative IVD tests within the NHS is still taking too long. Typically, widespread adoption of new diagnostic tests takes approximately 10 years.

Over the coming months, the Government will be implementing the recommendations of the Accelerated Access Review (AAR) and the Life Sciences Industrial Strategy. We hope this will provide a vital stepping-stone to faster adoption, so that patients of the future have access to the right IVDs, at the right time.

However, it is also vital that IVDs receive the same status as medicines, specifically by making it mandatory that positive NICE Diagnostics Guidance is funded and implemented within 90 days.

2) PLAYING A LEADING ROLE IN OVERCOMING GLOBAL HEALTH CHALLENGES

The importance of IVDs in overcoming the challenge of antimicrobial resistance (AMR) cannot be overstated. While the widespread use of broad-spectrum antibiotics has helped to create multi-drug resistant strains of bacteria, greater adoption of IVDs would lead to a reduction in cases of unnecessary antibiotic prescribing by reducing time to appropriate treatment decision and allowing for a more targeted use of therapy against infection.

Understanding of the beneficial role IVDs have to play in this area is increasing among both clinicians and policymakers. To build on this progress, BIVDA wants the Government to work in conjunction with industry and NHS England to ensure extensive use of IVD tests to support the prescribing of antibiotics in both primary and secondary care and prevent over-prescribing and unnecessary treatment.

3) SECURING A NEW MECHANISM FOR THE FUNDING OF IVDs

A key factor that limits the wider adoption of IVDs is the way the NHS budget works. The budget for testing and general pathology in the NHS is separated from the rest of the budget for a medical pathway. This can often provide a disincentive to introduce cost-saving and potentially life-saving new tests because while the up-front and ongoing tests are borne by the innovators, the savings accrue further down the patient pathway.

BIVDA is calling on the Government to introduce a funding mechanism, which does not disincentive the uptake of IVDs, thereby encouraging the NHS to increase the adoption of IVDs and enabling better patient access to diagnostics.

4) GUARANTEEING PATIENT ACCESS TO MOLECULAR DIAGNOSTICS

Advances in personalised medicines have helped to transform the way we understand and treat health conditions in the UK today. Patient access to these treatments is reliant on the availability of appropriate molecular diagnostics tests. However, the availability of molecular diagnostic tests is variable due to a fragmented commissioning structure.

In oncology, some progress has been made to overcome this challenge. For example, NHS Improvement introduced a clear mechanism for funding an initial six specific molecular tests for cancer within the 2016/17 National Tariff Payment System (NTPS).

However, this is only part of the solution. BIVDA calls on the Government to work with NHS England to introduce a national commissioning framework for molecular diagnostics, starting in oncology, ensuring widespread patient access to such tests and allowing more patients to benefit from personalised treatments.

5) ESTABLISHING A NEW RELATIONSHIP WITH THE EU

The UK's membership of the EU affects many of the regulations that shape the environment in which the IVD sector operates. As the UK negotiates a new relationship with the EU, it is vital to ensure that the UK environment for IVDs and life sciences as a whole remains as attractive as possible, for the benefit of the NHS, UK economy and most importantly, patients.

We strongly urge the Government to align with the EU IVD Regulation and, if possible, retain Notified Body and Competent Authority status to allow the EU or UK authorities to mutually accept devices lawfully marketed in other territories, and ensure the UK market is open for business for countries that conform to regulations other than CE marking.

It is also important that UK IVD companies are able to continue recruiting skilled students and professionals from across the globe.

REFERENCES

- 1 BIVDA, Robust, Fair and Sustainable: Our Vision for the Future Access and Provision of Molecular Diagnostics in England, 2016
- 2 Department of Health, Changes to cervical cancer screening, 2016
- 3 Department of Health, New bowel screening test to save hundreds of lives, 2016
- 4 Premaitha, St George's University Hospitals NHS Foundation Trust and the SAFE test laboratory – powered by the IONA® test
- 5 Alere International, Straight to the Point: Ensuring the Rational Use of Antibiotics in Primary Care using C-Reactive Protein Testing, 2015
- 6 ThermoFisher Scientific, Safely Reduce Antibiotic Exposure B-R-A-H-M-S Procalcitonin (PCT): An Effective Tool for Antibiotic Stewardship, 2016
- 7 Pathology in Practice, February 2017
- 8 Guest JF, et al. Health economic burden that wounds impose on the NHS in the UK BMJ Open 2015; Dec 7; 5(12):e009283. doi: 10.1136/bmjopen-2015-009283
- 9 Lauchli S, et al. The use of a point of care test for bacterial protease activity in chronic wounds. Wounds Int. 2015;6(4):22-28
- 10 BIVDA, Manifesto: Challenge to the Next Government, 2015
- 11 Roche Diagnostics, Benefits of High Sensitivity Cardiac Troponin Testing, 2014
- 12 British Journal of Healthcare Management 2014 Vol 20 No 7
- 13 BIVDA, Making Britain Healthy: Unlocking the potential of in vitro diagnostics in the NHS, 2011
- 14 BIVDA, Diagnostics in Healthcare, Summer 2015
- 15 BIVDA, Membership Data, 2016
- 16 MedTech Europe, European In Vitro Diagnostics Industry - Facts and Figures
- 17 Office for Life Sciences, Strength and Opportunity – Annual Update, 2015
- 18 Office for Life Sciences, Strength and Opportunity – Annual Update, 2015
- 19 NHS England, Pathology Quality Assurance Review, 2014
- 20 PwC, The Economic Contribution of the UK Life Sciences Industry, 2017
- 21 Office for Life Sciences, Strength and Opportunity – Annual Update, 2015
- 22 Evaluate, MedTech World Preview 2016, Outlook to 2022
- 23 Grand View Research, Europe In Vitro Diagnostics (IVD) Market Size Report – 2024, 2016
- 24 Monitor, Deloitte, Medical Technology An industry study for the Office for Life Sciences, 2015
- 25 BIVDA, Manifesto: Challenge to the Next Government, 2015
- 26 Office for Life Sciences, Department for International Trade, In Vitro Diagnostics Campaign
- 27 MedTech Europe, European In Vitro Diagnostics Industry - Facts and Figures

ABOUT BIVDA

BIVDA (The IVD technologies industry body) is the go-to organisation supporting members and key stakeholders to provide cost-effective patient outcomes using IVD technologies and innovation to transform patient pathways. It has been leading the industry for 25 years since its establishment in 1992 and represents over 150 members. Our industry plays a critical role in the NHS; 70% of clinical decisions are made using some form of IVD test.

What does BIVDA do?

- Leads the IVD industry by informing and influencing on regulatory and legislative matters, both at a national and European level
- Raises awareness of the clinical and cost utility of innovative diagnostics in the provision of effective healthcare
- Engages with the NHS and Department of Health to ensure effective public procurement of IVD products
- Provides the voice for the UK IVD industry

Engaging with BIVDA

Stakeholders are invited to engage with BIVDA in a number of ways:



bivda.co.uk



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[linkedin.com/company/
british-in-vitro-diagnostics-association](https://linkedin.com/company/british-in-vitro-diagnostics-association)

Newsletter: If you would like to receive a copy of our quarterly newsletter for stakeholders, Diagnostics in Healthcare, please email enquiries@bivda.co.uk.

We would be happy to discuss any of the issues raised in this report in more detail. To take forward the arrangements, please contact us via the details below.

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