BIVDA

Manifesto 2015

The British *In Vitro* Diagnostics Industry's Challenge to the next Government

Diagnostics; making a difference

Diagnostics are already providing information used to make 70% of clinical decisions by healthcare professionals. Better use of these tests could transform many patient pathways and release resource for utilisation elsewhere in the NHS.

Adoption of Innovation

The IVD sector has been well served by the addition of assessments by NICE, the creation of the NIHR Diagnostic Evidence Co-operatives and the plans for the Precision Medicine Catapult and MRC Pathology Nodes. However we still have a glass ceiling when it comes to uptake and diffusion of new tests and technology in the NHS.

The NHS Five Year Forward View has highlighted the need for new models of care that allow for greater access and uptake of diagnostics. The priority is, and must be, shifting healthcare out of hospitals and into the community. This will help to reduce emergency admissions, reduce demand and improve peoples' ability to self-manage their care.

There are, however, many examples of scenarios in which there is a complete 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.

Currently the budget for testing and general pathology in the NHS is separated from the rest of the budget for a medical pathway in an unhelpful way, which makes innovation and efficiency harder to achieve. BIVDA welcomes the steps being taken to roll-out capitated budgets and year-of-care tariffs, whereby a whole care pathway is integrated across a number of providers. However, when being commissioned the use of diagnostics is either misunderstood or, worse, not considered at all.

The future of healthcare is focused on personalising medicine and ensuring the right person gets the right treatment as early as possible. Innovations in diagnostics will be central in this drive, but the NHS is currently too inflexible when it comes to adopting such innovations. BIVDA believes that by working with industry, and with only limited upfront investment, considerable gains can be made.

We need the next Government to:

- **Amend the NHS Standard Contract so that commissioners always consider the role IVDs can play in a care pathway**
- **Provide guidance on the best IVD commissioning arrangements for different health economies**
- **Explore alternative models of reimbursement to incentivise adoption of innovation**

Fact

The adoption of screening tests for cervical cancer led to a 42% drop in incidence of the disease.

Doing Business with the NHS

IVDs are supplied under a range of contracting arrangements, which may have a considerable bearing on the price paid. These arrangements vary from simple 'one off' local orders, through to 'standing orders', and contracts worth tens of millions of pounds. These may be of varying duration - perhaps up to 10 years - and arrangements may be tailored to meet the requirements of a particular customer, including their patient population and clinical requirements.

The use of procurement intermediaries, including NHS Supply Chain, can also affect price, particularly given their requirement to generate revenue through supplier and NHS transactions.

There is currently little standardisation of process and documentation for large contracts, which can lead to the use of the large companies providing professional services to advise on what are essentially similar contractual arrangements. As such, the next Government should urgently look to improve the tender system for procurement.

BIVDA supports the ongoing commitment to ensure choice, competition and innovation in the NHS, and is keen to ensure that these principles are taken into account when diagnostics are procured.

Procurement policy throughout the NHS should focus on value enhancement and not just cost-cutting to ensure that IVDs bring benefits to both the NHS and to patients.

We need the next Government to:

- **Create regional procurement boards, which include industry, to give a platform for discussion and co-development of policy**
- **Ensure that information collected on the procurement of IVDs is accurate and fully considers the manner in which they have been acquired**

Fact

The IVD industry enables the NHS Pathology Service to manage its workload - approximately 900 million tests each year in the UK.

Safety & Quality

The regulatory system for the in vitro diagnostic industry is, in parallel with the medical device industry, going through regulatory change in the EU. BIVDA is supportive of the EU system and welcomes the development of the new Regulation which will provide a much better framework for our products as new tests and technologies are discovered and produced.

IVDs are inherently complex, biological products which need a lot of skill to develop; any test used in a clinical setting, whether commercial or by in-house manufacture by the NHS, should be made using quality systems and good manufacturing practice to ensure safe and reliable results are achieved routinely.

We need the next Government to:

- **Ensure there is balance between the cost burden of complying with regulation and the risk to patient safety**
- **Support the regulatory framework in the EU**
- **Support access to patient samples to enable development of new tests and process control during manufacturing**

> *The increasing reliance on diagnostic tests in clinical decision making, combined with the dramatic shift in the number and complexity of [in-house tests] being offered, are posing increasing risks to patients" US Food and Drug Administration.*
>
> *US Food and Drug Administration, Paving the Way for Personalized Medicine, 2013

Fact

Each year, about 2 million units of donated blood are screened for infectious disease using diagnostic tests to enable safe transfusion into patients.

About

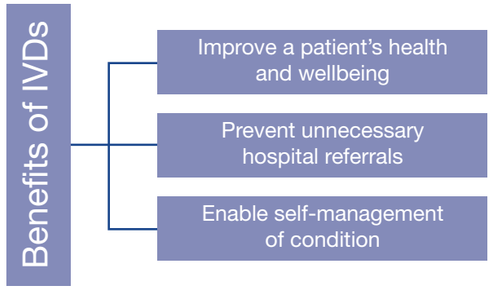
IVDs are an essential part of the NHS. They are used to both enable diagnosis and to rule out causes of ill health. They are also used to monitor, screen and assess people for any potential health problems they might have. Increasingly they allow people with chronic disease to manage their own conditions. It is estimated that 70% of clinical decisions are made using some form of IVD[1]. As such, their contribution to healthcare systems around the world and to the health of our nation should not be underestimated. Effectively used IVDs help to reduce hospital stays, support patients to look after their own health, resulting in a healthier population and economic growth in the long run.

[1]NHS Choices, Pathology services explained, available at:
http://www.nhs.uk/nhsengland/aboutnhsservices/pathology/pages/pathology-services-explained.aspx

BIVDA represents over 100 companies operating throughout the UK and internationally, from micro companies to large multinationals. The IVD industry has been a leader in healthcare innovation in recent years and strives to develop more efficient, effective and accurate diagnostic tests that deliver significantly improved patient outcomes.

In addition to the supply of products into the NHS, BIVDA member companies employ more than 8,000 people in the UK and play a significant role in UK exports; UKTI estimate the IVD sector is the single largest sector in medical technology exports.

The Value of IVDs



In vitro diagnostics 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 about £700 million annually on our products – less than 1% of the total NHS budget yet around 70% of clinical decisions are made using IVDs.

Case study – Identifying heart attacks

Chest pain accounts for approximately 10 per cent of A&E attendance in the NHS. It can be a signifier of myocardial infarction (heart attack) as well as other heart conditions. Traditional testing can take 12 hours to confirm or rule out a heart attack. However, a new generation of high sensitive diagnostic tests can either confirm or rule out a diagnosis in as little as 2-3 hours – a significant difference. If these tests were used on 10 patients a day in a single A&E department, it is estimated that it could save up to 28,000 hours of staff time per year.

In order to ensure that the recent innovations in the sector lead to improvements in patient care, this BIVDA manifesto has described the three major policy areas for our sector and offers suggestions on what the next Government should achieve to ensure that the UK healthcare system gets the best benefit from our industry's technologies.

Fact

By 2025, it is expected that 5 million people in the UK will have diabetes. Diagnostics are essential to diagnose this at risk population rapidly and then help them to manage their disease and enjoy quality of life.

Please do get in touch to ask for any more information or if you would like to arrange a meeting with BIVDA

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The role for IVDs in Antimicrobial Resistance (AMR)

Widespread use of broad-spectrum antibiotics has helped to create multi-drug resistant strains of infectious disease. Bacteria in the body unaffected by antibiotics not only gain resistance to them, but also find themselves competitor-free as other strains are killed off, giving them more space and resources to multiply.

At the moment the prescribing of broad-spectrum antibiotics is necessary because it can often take days to culture a sample of bacteria and understand what it is, and precisely what drugs will treat it.

Cutting-edge diagnostics, incorporating the latest genetic advancements, are reducing the time needed to identify thousands of bacterial strains to mere hours, preventing the need for overprescribing and giving patients access to the right drugs at the right time.

The Government has already identified the need to move diagnostic technology from research laboratories as a key area of its antimicrobial resistance strategy and BIVDA strongly supports continued efforts to improve data collection, antimicrobial stewardship and health education at a time when the sustainability of the current crop of antibiotics is absolutely vital to the UK's health.

However, currently the annual budget for laboratory medicine is £2 billion. This is less than 7% of the economic cost of infectious disease (£30 billion per year). At a time when the CMO recommends the inclusion of antimicrobial resistance on Tier 1 of the National Security Risk Register, the next Government should ensure the NHS is making the most of IVDs, particularly in primary care.

We need the next Government to:

- **Improve access to vital diagnostics in primary and secondary care to combat AMR**
- **Launch a campaign to raise awareness of the importance of IVDs to tackling AMR in primary and secondary care**
- **Ensure that support is given to IVD companies for research and development and not just to focus on drugs**

Fact

Colds and flu are caused by viruses – using antibiotics to treat these contributes to antimicrobial resistance.

> If we don't take action [to tackle AMR], in 20 years' time we could be back in the 19th century where infections kill us as a result of routine operations.
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> *Professor Dame Sally Davies, Chief Medical Officer*
>
> Department of Health, UK calls for international action on antimicrobial resistance, 20 May 2013.
> Available at: https://www.gov.uk/government/news/uk-calls-for-international-action-on-antimicrobial-resistance

The Use of In-House tests by the NHS

The IVD industry recognises the need for the NHS to use in-house tests where there are no commercial alternatives or where the patient would otherwise be unable to get a diagnosis and treatment. However we do not agree that the NHS should act as a manufacturer for routine tests as we would argue this is not the best use of NHS resources.

The use of in-house tests raises obvious questions about quality assurance and patient safety in a world absent of the usual oversight of regulatory agencies.

While there are thousands of commercially manufactured diagnostic tests available, BIVDA research has shown that around 50% of NHS providers use in-house diagnostic tests to aid their work. The definition of an 'in-house' test varies from using a commercial CE-marked test in a novel way, through to the development of wholly new markers, assays and algorithms*.

[*In guidance concerning forthcoming changes to European IVD regulation, the MHRA considers that 'important changes which modify [the] original performance' of an IVD may bring a product into the scope of regulation; otherwise the in-house exemptions will remain in line with current policy]

The level of regulation of commercial versus in-house test development varies enormously. At present in-house tests and off-label uses are largely unregulated. Hospitals will have their own methods by which effectiveness and risk are judged, however there is no centralised register of the types of test used, the populations on which they are used, and why an in-house method rather than a commercial test was chosen.

Accuracy, reliability and safety are the critical components of a diagnostic test from a public safety perspective. Therefore BIVDA would like the new Government to ensure that the Medicines and Healthcare products Regulatory Agency (MHRA) has new responsibilities to regulate in-house tests to guarantee they are both safe and consistent.

For more information on in-house testing please see BIVDA's *Safe and consistent?* report which is available at: http://www.bivda.co.uk/Portals/0/Documents/Bivda_in-house_testing_audit.pdf

We need the next Government to:

- **Understand the circumstances in which in-house tests are used**
- **Ensure guidelines for newly developed in-house tests are in place**
- **Regularly audit internal processes to ensure the safety and performance of in-house tests is up to standard**

BIVDA, Safe and Consistent? The regulation of pathology testing, 2013

Fact

50% of NHS providers use in-house diagnostics tools to aid their work – we need to ensure this is done safely and reliably.

What is in-house testing?

- A test which has been designed and developed in a public health or NHS laboratory, and with reagents produced in the laboratory
- A test which is used off-label – i.e. a commercial test which complies with the IVD MD Directive 98/79/EU and, as such is CE-marked – but where the user does not comply with the manufacturer's instructions for use in some significant way
- The use of a commercial test for a clinical purpose for which it has not been designated by the manufacturer
- The use of a commercial test which is not CE-marked but is sold for Research Use Only where the results are used to support clinical decisions or disease management