

Diagnostics in Healthcare

The British In Vitro Diagnostics Association Newsletter

BIVDA

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Introduction



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Chief Executive

I am pleased to welcome you to the 27th issue of *Diagnostics in Healthcare*, the quarterly update for parliamentarians on the *in vitro* diagnostics (IVD) industry brought to you by the British In Vitro Diagnostics Association (BIVDA).

In this issue we look at the demonstrable improvements in outcomes brought about by screening and early diagnosis, as well as recent developments in the work taking place between the Government, NHS, industry and the scientific community to encourage adoption of innovation in the NHS.

If you would like to find out more about any of these issues, or the role of diagnostics in the NHS more generally, then please do get in touch at doris-ann@bivda.co.uk.

BIVDA20

20 years of the British In Vitro Diagnostics Association

2012 marks 20 years of the British In Vitro Diagnostics Association (BIVDA). Since 1992 BIVDA and its members have been working to introduce new and innovative tests into the NHS. Advancements have been seen in tests to diagnose disease, as well as those to help patients manage their condition. In recent years there have been significant steps forward to develop tests that allow for treatments to be targeted to specific genes to increase effectiveness and efficiency.

During this time BIVDA has been pleased to work with Government and Parliament to ensure that tests are best used to improve outcomes for patients and their experience of care. We hope that this will still be the case 20 years for now, and that the collaborative nature of policy-making – through initiatives such as the Office for Life Sciences and the recent publication of *Innovation, Health and Wealth* – will continue to develop.

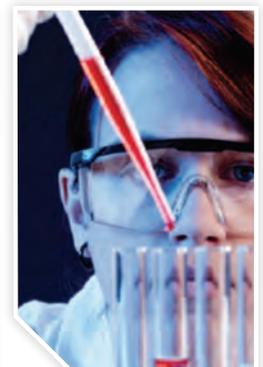
The publication of *Innovation, Health and Wealth* at the end of 2011 marked a major milestone for how innovation will deliver significant benefits for patients in the NHS and achieve real progress for the UK's life sciences sector. The report built upon a period of sustained engagement between the Government and industry – beginning with the creation of the Office for Life Sciences in 2009.



Working together to stimulate
innovation in the NHS

As a participant in the External Advisory Group for Innovation, Health and Wealth, which was instrumental in developing the proposals, BIVDA believes that the measures announced reinforce this genuine partnership between industry, the NHS and Government. This genuinely collaborative approach will deliver vital benefits to people's health and to the UK economy.

Innovation, Health and Wealth set out tangible and realistic proposals but it is crucial that the agreed steps are implemented quickly and across the board to ensure improvements in uptake of technologies that demonstrate value to the NHS. The *in vitro* diagnostics industry is already engaging with the Department of Health, the National Institute for Health and Clinical Excellence (NICE), clinicians, professionals across the NHS and the scientific community to invest time, expertise and knowledge to implement proposals, such as exploring options for a tariff for diagnostics. We look forward to seeing this partnership deliver improved patient outcomes.

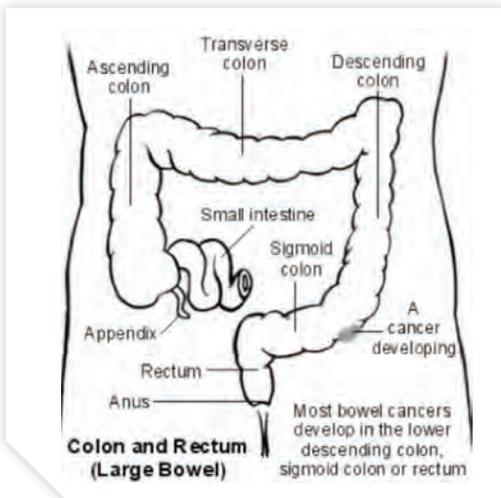


Diagnostics; making a difference

Improving screening to save lives

Early diagnosis can save lives. This is something that we have long known, but last year's study on the benefits of bowel cancer screening with flexible sigmoidoscopy (flexi-sig[®]) added to the evidence. The research shows that one off screening with flexi-sig between the ages of 55 and 64 can reduce the incidence of bowel cancer by a third and reduce deaths from the disease by up to 43%.

BIVDA welcomed the commitment by the Department of Health to invest £60 million over the subsequent four years from 2011/12 to support the incorporation of flexi-sig into the current bowel cancer screening programme. Effective implementation of the screening could help to contribute to the commitment within Improving Outcomes: A Strategy for Cancer that 5,000 lives a year would be saved by 2015.



Increasing awareness and early diagnosis

Improvements in outcomes brought about by screening can only be achieved if people are aware of the signs and symptoms of diseases. Raising awareness of the signs and symptoms of bowel cancer will therefore be vital to ensuring that people are screened and any issues are identified. There is work to be done here, and the National Cancer Intelligence Network has shown that 25% of bowel cancer patients present as emergency cases – suggesting that they have not been diagnosed at an early stage of the disease.

Regional early diagnosis bowel cancer pilots have proved to be highly effective, with results showing a 48% increase in the number of people who visited their GP with symptoms, and a 32% increase in referrals for testing to hospitals, and a 75% recognition of the advertising among the public. This led to a national awareness campaign, Be Clear on Cancer, with funding of £8.5 million attached.

This campaign has the potential to significantly improve outcomes for people with bowel cancer, and, if successful, should be extended to other disease areas. The recent commitment to launch a national lung cancer awareness scheme is therefore welcome news. The lung cancer awareness scheme is again based on local pilots which demonstrated clear value – both in terms of improved awareness of the symptoms of lung cancer and increased confidence in recognising the symptoms. There was a 23% increase in attendance to primary care, and the campaign was agreed to be important with support from 94% of the public and 87% of GPs surveyed.



Ensuring quality and equity in *in vitro* diagnostic testing

***In vitro* diagnostic tests have a significant role identifying and screening for disease as well as monitoring and managing treatment. They are therefore critical to providing quality care for patients and a vital part of care pathways. Ensuring that all tests are carried out at the highest possible quality is essential.**

In the early 1990s it was agreed that there should be a pan European Union regulatory system for IVDs. Regulations were developed under the umbrella of the Medical Device Directives with the In Vitro Diagnostics Medical Device Directive (IVDD 98/79/EU) coming fully into force across the EU on 8 December 2003. While commercial tests are covered by the Directive, tests developed in NHS laboratories are exempt.

'In house' tests have the potential to promote innovation and efficiency in the NHS. Indeed, many of the tests manufactured by BIVDA members have their origins in 'in house' testing, and the commercialisation of 'in house' tests can provide a potential income stream to the NHS. However, to ensure that all diagnostic use is of the highest quality and does not threaten the commitment to patient safety, BIVDA believes that there should be increased regulation of 'in house' diagnostic tests. We believe that it is important that quality is consistent among all tests, wherever they are developed, as a matter of patient safety and clinical accuracy.

The Directive is currently under review, and while the updated version will maintain the exemption for 'in house' testing, it is likely that there will be additional conditions:

- The 'in house' tests must be produced and used under the same quality management system within the healthcare institution
- All 'in house' tests will be subject to vigilance reporting so that any incidents which could cause harm to patients are notified to the Medicines and Healthcare products Regulatory Agency (MHRA)
- The exemption will not include tests at the highest risk level. These are tests whose results affect both individuals and the populations (eg tests to screen the blood supply for infectious disease)



BIVDA supports moves to ensure that 'in house' testing meets minimum standards of quality and safety. We believe that the Department of Health should collect a database of 'in house' testing information so that there is a clear record of which tests are being developed and for what clinical purpose they are being used. We hope to work with the Department of Health and the MHRA to ensure that all of these vital *in vitro* diagnostic tests are being carried out to the highest standards across the country.

Diagnosics in action

BIVDA member company, Xpert® *C.difficile*, from BIVDA member company Cepheid, is a new molecular test – essentially a mini-laboratory in a cartridge. The assay's intended use is to help diagnose, confirm and exclude CDI in less than 1 hour. It is very easy to use and needs only 1 minute of preparation time.

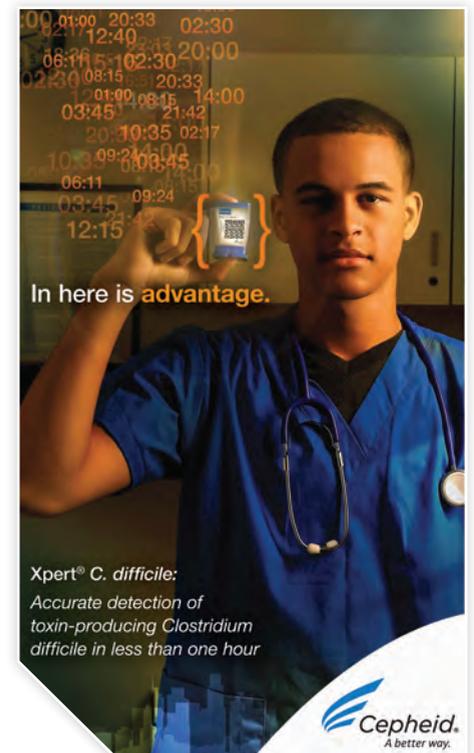
Clostridium difficile infection (CDI) is the most significant cause of hospital-acquired diarrhoea. *Clostridium difficile* (*C. diff*) rarely causes problems in children or healthy adults, as it is kept in check by the normal intestinal population of bacteria. Antibiotic therapy can disturb the balance of bacteria in the gut allowing *C. diff* to multiply rapidly and produce toxins which cause illness in vulnerable patients. More than 80% of *C. diff* infections reported are in people over 65 years old. The effects of *C. diff* infection range from mild to severe diarrhoea and even can result in life-threatening inflammation of the bowel. (Source: HPA)

Currently clinicians are forced to choose between solutions that deliver either speed or accuracy. Doctors often use these tests in combination, the disadvantage being that it takes 2 to 3 days to obtain a definite result. Meanwhile patients are suffering. By using the Xpert *C. difficile*, a new, fast and reliable test (in combination

with other clinical information) the time to reach optimal treatment is significantly shortened. Earlier access to appropriate treatment reduces patients' symptoms and infectivity, avoiding the spread of disease to other patients. It also means reducing overuse of unnecessary and ineffective antibiotic treatment.

In addition to further suffering by patients, healthcare acquired infections are very costly to the NHS. As pointed out in a recent DH study, the key to reducing the total burden of CDIs lies in disrupting transmission. Investing in early diagnosis and prevention is highly cost-efficient. Diagnosing hospital acquired infections up to 3 days earlier reduces hospital stays, unnecessary transmissions and, in the long run, the total burden of disease.

Respective health-economic studies have been performed and are in the process of being published.



About BIVDA

The British In Vitro Diagnostics Association (BIVDA) represents the *in vitro* diagnostics (IVDs) industry in the UK, representing about 90% of the industry active in the UK. BIVDA member companies employ more than 8,000 people directly in the UK and provide the tests and equipment to the NHS to allow rapid diagnosis. IVDs also enable screening for disease, identifying, monitoring and managing treatment and are vital to ensure the safety of the blood supply for transfusion. Information from IVD tests accounts for about 70% of the information on a patient's record. Increasingly diagnostics are available for use in a primary care setting and to enable people to manage their own diseases from home including as part of telehealth systems. This reduces the need for hospitalised care and will improve quality of life for much of the population. IVDs will also play an important part in determining correct drug therapies for individuals and patient cohorts enabling targeted medication.

www.bivda.co.uk

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Please don't hesitate to contact the Chief Executive, Doris-Ann Williams if you would like any further information about any of the aspects of this issue or about *in vitro* diagnostics in general. She is always more than willing to visit you in Westminster.

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