



PERSONALISING TREATMENT

IMPROVEMENT: PERSONALISING TREATMENT FOR PATIENTS –

An improved knowledge of the genetic and biochemical markers that sit behind diseases such as cancer means there is a growing number of medicines available that can be targeted at specific patient groups, to deliver the best possible outcomes.

Patient access to these treatments is reliant on the availability of appropriate molecular diagnostic tests. Diagnostic tests form an important and growing part of high quality care, helping to guide clinicians towards the right treatment option for a patient, as well as ensuring that NHS resources are used effectively.

An example of this can be found in breast cancer treatment. Around 20% of women with breast cancer are positive when tested for the HER2 gene, which is associated with aggressive cancer cell growth. Herceptin is a treatment designed specifically to target the HER2 protein.

Before beginning treatment, patients are required to be tested for their HER2 status. Clinical trials have shown that HER2 positive individuals receiving Herceptin as a treatment, experience substantial improvements in survival and quality of life compared to treatment, with conventional chemotherapy alone.

The highly targeted nature of the treatment means that response rates are good, and wastage is minimised. HER2 - negative tumours will not derive any benefit from Herceptin. It is therefore vitally important that patients who are positive for the protein are identified accurately to ensure that they will benefit from the treatment, and that those who are negative do not receive the treatment unnecessarily⁴.



SCREENING

IMPROVEMENT: THE IMPORTANCE OF SCREENING FOR PATIENTS –

Health screening is the process through which a patient can discover if they have a particular disease or condition even if they are not experiencing any symptoms and/or signs of disease.

Its main aim is to identify those individuals who have disease-causing pathogens in their system and thus initiate effective treatment as quickly as possible.

CERVICAL CANCER: A key area where screening has made a vital difference for patients is in cervical cancer. Cervical screening tests detect cancerous and precancerous changes in the cervix and the National Cervical Cancer Screening Programme was introduced in 1988.

The adoption of screening tests for cervical cancer has led to a 42% drop in incidence of the disease. It is also estimated to save 4,500 lives in England each year⁵.

It is hoped that a further 600 cervical cancers will be soon be prevented each year. Following a successful pilot programme and a recommendation by the UK National Screening Committee (UKNSC), the Government has announced that screening samples will be tested for human papilloma virus (HPV) first.

As the majority (99.7%) of cervical cancers are caused by persistent HPV infection, if HPV is found during screening it is a useful guide as to whether abnormal cells are present. Women can then be more closely monitored and, as a result, abnormal cells will be found sooner.

BOWEL CANCER: The Government has also approved the UKNSC's recommendation to replace the current test used in the Bowel Cancer Screening Programme (BSCP) in England with a new test – the faecal immunochemical test (FIT).

As a result of this decision, it is thought an extra 200,000 people could be tested at home each year as the new test is far simpler to use. It will be offered to all men and women aged 60-74 every two years in a bid to spot the early signs of bowel cancer⁶.

PREGNANCY: Screening also has an important role to play during pregnancy. For example, pregnant women are offered a screening test for Down's Syndrome to assess their chance of having a baby with this condition.

Typically, women undergo the combined test at 10-14 weeks. This involves a blood test and an ultrasound scan. If after the combined test a woman is found to be at higher risk, she will be offered a further diagnostic test, such as amniocentesis or chorionic villus sampling (CVS) which will determine whether the baby has Down's.

However, as approximately 0.5 to 1% result in a miscarriage, some women may choose not to take the test, even if they would welcome the certainty the result would bring.

Fortunately, there are non-invasive prenatal tests (NIPT) available, which can provide answers without the risk of miscarriage. A BIVDA member is leading the way through their partnership with St George's University Hospitals NHS Foundation Trust. They have successfully created a UK Centre of Excellence using the first regulated NIPT test⁷.

There is support for NIPT among clinicians. **Professor Basky Thilaganathan, Consultant Obstetrician at St George's, said:**

“ *NIPT has the potential to make a huge difference to the care and reassurance that clinicians can offer to pregnant women.* ”

NIPT is also welcomed by pregnant women.

A mother to be who chose NIPT over CVS said of her decision:

“ *It felt like there was no contest: one carries a risk of miscarriage, the other doesn't. We found out we could have the test done at St George's in South London; they were wonderful, it only took about 15 minutes from start to finish and we received the results five days later.* ”

Following a recommendation by the UK's National Screening Committee (NSC), NIPT will be offered on the NHS from 2018 for all high-risk women.

Acknowledgements: Premaitha



PROTECTING PATIENTS FROM AMR CONSEQUENCES

IMPROVEMENT: PROTECTING PATIENTS FROM THE CONSEQUENCES OF ANTIMICROBIAL RESISTANCE (AMR) –

Widespread use of broad-spectrum antibiotics has helped to create multi-drug resistant strains of infectious disease. AMR is a concern as resistance can spread globally, rendering some infections untreatable and increasing the risks associated with other procedures where antibiotics are employed such as surgery and cancer treatment.

At present, prescribing broad-spectrum antibiotics is often necessary because it can take days to culture a sample of bacteria and understand what it is and what drugs will treat it. The use of modern diagnostic testing, whether in the lab or at the point of care, to direct antibiotic prescribing has several benefits:

- Reduce time to appropriate treatment decision
- Reduce the use of broad-spectrum antibiotics
- Reduce possible side effects of unnecessarily aggressive antibiotics

Modern diagnostics are incorporating the latest technology advances and, in so doing, are reducing the time needed to identify infectious agents and determine their resistance traits from days to hours.

Point of care testing can play a vital role in aiding the decision about whether to prescribe antibiotics or not. These tests are quick and easy to perform, and can be used during a patient consultation or be completed while the patient waits, allowing immediate diagnosis and treatment choice. This prevents the need for prescribing 'just in case' and ensures patients receive the most appropriate treatment in a timely manner.

Studies have found that C-reactive protein (CRP) point of care testing can reduce antibiotic prescribing by 41%, which could result in an estimated saving of £56 million per year in the UK⁸.

Additionally, Procalcitonin (PCT) is also key in supporting the responsible use of antibiotics. It allows for both a rapid and reliable diagnosis of systemic bacterial infections and a potential reduction of 9% in treatment costs⁹.

REDUCING UNNECESSARY ANTIBIOTIC PRESCRIPTIONS – Birmingham Children's Hospital have effectively demonstrated that IVDs can play a vital role in reducing unnecessary antibiotic prescriptions.

The Accident and Emergency Department have piloted a rapid point of care test produced by a BIVDA member company, to determine whether patients presenting with sore throats had a bacterial infection (Strep sore throat) and required antibiotic treatment.

Between 23 August and 16 November 2015, all children presenting to the A&E department with pharyngitis were assessed for inclusion in the study. **In total, 214 children participated and the results showed that during the pilot, 51/214 (24%) of children were prescribed an antibiotic – a 70% reduction in antibiotic prescriptions for tonsillitis in the A&E department¹⁰.**

Acknowledgements: Alere, Thermofisher, bioMérieux



WOUND CARE

IMPROVEMENT: INCREASING THE RATE OF HEALING – Wound care has historically been limited to the use of dressings in an attempt to prevent infection and give the wound time to heal. While dressings have become more sophisticated over time, some of the local underlying causes of chronic wounds – previously defined as wounds that remain unhealed after 4 weeks – have been largely ignored.

Chronic wounds impose a significant health economic burden in the UK. Lack of understanding of the cause of non-healing leads to inefficient treatment and poor outcomes. **In a 12-month period (1 May 2012 to 30 April 2013), only 43% of chronic wounds in the UK healed at a cost of ca. £3 billion¹¹.**

New advanced therapies are available but they usually have a specific mode of action and are often not cost effective unless targeted. More precise treatment that addresses the specific underlying cause of non-healing is required. This has led to the advent of wound diagnostics that are able to help identify the cause of non-healing.

A BIVDA member is leading the way in wound diagnostics by commercialising the world's first point of care tests for this field. Their test detects EPA (elevated human protease activity), a marker of chronic wound inflammation. A wound with EPA has a very low chance of healing without appropriate intervention.

Another test detects BPA (bacterial protease activity), which is indicative of pathogenic behaviour of bacteria in the wound. BPA presents itself not only in observable infections, but also prior to clinically observable infection, at a point where antimicrobial treatment is typically required¹².

The use of point of care wound diagnostic tests could reduce the cost of inefficient treatment and delayed healing by being able to target the right therapy, on the right patient, at the right time and for the right length of time. The tests also promote the prudent use of advanced therapies and antimicrobials by reducing the use of treatments based only on empirical evidence in an era where clinical efficiency and antimicrobial stewardship are global imperatives.

Acknowledgement: Woundchek Laboratories



THE BENEFITS OF EARLY DIAGNOSIS

IMPACT: THE BENEFITS OF EARLY DIAGNOSIS – Myeloma is a cancer arising from plasma cells, a type of white blood cell, which is made in the bone marrow.

Traditionally, patients suspected of having myeloma were investigated in the laboratory using a combination of serum electrophoresis (SPE) and urine analysis. A positive result in either or both tests resulted in referral to a Haematologist for further investigation and confirmation of diagnosis. However, this investigation panel is flawed, as very few patients supply the necessary urine and/or the urine analysis is insensitive, often resulting in a missed or delayed diagnosis.

Urine analysis has traditionally been used in this panel as, until recently, it was the most sensitive method to detect free light chains, often the only indicator of this disease. However, if free light chains are present, they are also always found in the serum (even in some patients when not found in the urine).

As a result, NICE NG35 (2016) recently recommended urine analysis was replaced by a serum test to detect these light chains, serum free light chain analysis (sFLC).

Implementation of this test can therefore reduce delays in diagnosis. This is important as a missed/delayed diagnosis in myeloma can result in the development of several, often life threatening, complications such as spinal cord collapse and renal failure.

Preventing complications can also reduce financial costs for the NHS.

For example, in cases where delayed diagnosis has resulted in renal insufficiency, the patient may require dialysis at a cost of £35,000 each year to the NHS.

Acknowledgement: The Binding Site



INCREASING NHS EFFICIENCY

IMPACT: INCREASING STAFF EFFICIENCY ON THE FRONT LINE – Chest pain accounts for approximately 10% of A&E attendance in the NHS. It can be a signifier of myocardial infarction (heart attack) as well as other heart conditions.

This means that patients need to be monitored and extensive tests need to be carried out. Traditional tests can take 12 hours to confirm or rule out a heart attack. However, a new generation of highly sensitive tests (High Sensitivity Cardiac Troponin Testing) can either confirm or rule out a diagnosis in as little as 2-3 hours.

If this test was used on 10 patients a day in A&E, it is estimated that it could free up to 28,000 hours per year in one A&E department alone¹³.

Health economic analysis from one of BIVDA's members also suggests that use of their high sensitivity Troponin test may be cost-effective compared to standard troponin testing for adults presenting with acute chest pain, in particular for the early (within four hours of presentation) rule-out of non-ST-segment elevation myocardial infarction (NSTEMI).

Estimated savings of approximately £200 per person with suspected NSTEMI, resulting in potential savings of up to £37 million to the NHS in England per year¹⁴:

- **Reducing hospital time**
- **Reduced use of hospital resources**
- **Reduced the need for empirical treatments**

Acknowledgement: Roche Diagnostics



NEW MODELS OF CARE

IMPACT: NEW MODELS OF CARE: PREVENTING HOSPITAL ADMISSIONS –

Shifting care into the community is an ambition of healthcare systems around the world. There are many reasons for this, but importantly for the NHS it can help to reduce costs by preventing hospital admissions and moving care out of expensive acute settings.

An award-winning service in Oxford is leading the way in innovative community care, making a real difference to improving patient health and wellbeing.

The Oxford Emergency Multidisciplinary Unit (EMU) in Abingdon, was set up to meet the urgent assessment and treatment needs of patients with multiple, often complex problems. Led by Dr Dan Lasserson, this unit focuses on older and more frail patients in the community, and is open seven days a week. Patients can be referred by either their own GP, a community nurse, or ambulance paramedic.

Within the doors of the EMU is a point of care blood testing service that gives rapid results as well as X-Ray facilities, both enabling a speedy diagnosis.

Dr Lasserson has said that patients can have their test results back within 61 minutes of picking up the phone to emergency services. This rapid diagnosis enables quicker decision-making, leading to faster treatment as appropriate. There are a number of beds available to those who need to stay in longer, as well as follow up services for care at home, if necessary.

The EMU model boasts huge cost savings to the NHS. Indeed, recent figures show that 85% of patients assessed by the unit go home the same day having received the appropriate attention. This compares to 75% of 85 year olds who stayed for a period of at least 10 days in the John Radcliffe Hospital – with 10% staying for one month¹⁵.

The model of care set out by the EMU has led to duplicate units not only in the Oxford region, but also across the UK. Point of care testing has been reported as being integral to the operation and success of the unit.



NHS FINANCIAL SAVINGS

IMPACT: NHS FINANCIAL SAVINGS – Many patients present with symptoms of possible bowel disease and further examination to obtain a diagnosis usually involves an invasive and unpleasant test such as a colonoscopy or small bowel radiology.

Calprotectin is a quick and simple diagnostic test that is performed on a stool sample to differentiate between organic intestinal disease such as Inflammatory Bowel Disease (IBD) and functional bowel diseases such as Irritable Bowel Syndrome (IBS), enabling a swift diagnosis and allowing the correct treatment to be initiated. This means many individuals can avoid having to undergo unnecessary testing such as colonoscopies.

The benefits of Calprotectin to the NHS are that it is simple, non-invasive and low cost – it could save the NHS £162 million¹⁶. It is ideal for serial monitoring of disease activity and treatment success. It also allows disclosure of treatment failure, allowing patients to avoid prolonged courses of steroid drugs when these are not proving effective.

Despite the benefits of the test, use of it is far from widespread – the estimated rate of use for Calprotectin tests ordered by GPs ranged from 0.01 to 5.1 per 1000 practice population.



CONTRIBUTION TO THE UK ECONOMY

INVESTMENT – 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.

EMPLOYMENT AND PRODUCTIVITY

- The IVD industry directly employs more than 8,000 people in the UK
- This includes more than 1000 people in R&D and 2,500 in manufacturing¹⁸
- The IVD industry provides direct employment for 75,000 people in Europe¹⁹
- IVD companies include subsidiaries of multi-nationals, UK SMEs and also start-up companies²⁰
- SMEs with fewer than 250 employees make up 98% of medtech companies
- Two thirds of employment in the life sciences sector is found outside London and the South-East²¹
- Regarding indirect employment, around 33,000 people employed are in over 150 NHS England organisations responding to approximately 200 million pathology services requests a year²²

PRODUCTIVITY

- The average productivity of UK Life Sciences employees, expressed as Gross Value Added (GVA), is £104,000 compared to the UK GVA average of £49,000 – more than double the UK average

TURNOVER AND GROWTH

- IVDs are the second largest sector by turnover within the UK medical technology sector
- The UK IVD sector was worth £730 million in 2014
- The *in vitro* diagnostics global market is set to grow at 5.1% per year, reaching \$67.3bn in 2020
- The Europe IVD market is expected to reach over USD 15.5 billion by 2024 – the UK is expected to be the fastest growing region during the forecast period²⁶

TRADE

- The UK is a net exporter of IVD products, with £1.1 billion exported in 2013²⁷
- UKTI estimate the IVD sector is the single largest sector in medical technology exports
- A strong R&D base and lead in genomics sequencing and digital health pathology is continuing to create cutting edge technologies ripe for export²⁹

R&D

- The IVD industry reinvests between 12%-15% of its revenue into R&D, making it one of the most R&D intensive sectors on par with the pharmaceutical industry in Europe. By comparison, Europe's software and computer services industry reinvests only 9.6% of sales³⁰

IVDs: TRANSFORMING PATIENT PATHWAYS

In vitro diagnostics (IVDs) can be found in almost every clinical area.

It is estimated that around 70% of clinical decisions are made using an IVD test.



TISSUE DIAGNOSTICS



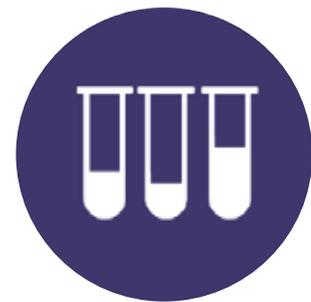
CARDIOVASCULAR DISEASE



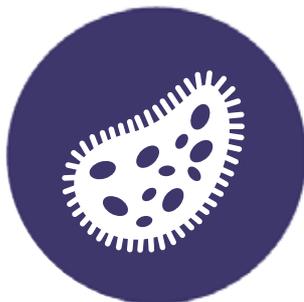
GENETIC TESTING



DIABETES



CANCER



INFECTIOUS DISEASE



PREGNANCY AND NEONATAL TESTING



DEMENTIA

THE IVD INDUSTRY IN NUMBERS



70%

of clinical decisions are based on IVD tests

In vitro diagnostics is the largest category in the global medical technology market with an annual sales of

£49.9 billion
in 2015

2 million
units of donated blood

are screened for infectious disease using diagnostics tests to enable safe transfusion into patients

The UK is the

fifth largest
IVD market

in Europe



The UK spends only

£10 per capita on IVD products,

less than half of spend per capita in **France, Germany and Italy**



The UK IVD sector was worth

816 million in 2016



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**



900 million
tests are carried out each year in the uk

The UK is a net exporter of IVD products, with

£1.1 billion exported

IVDs IN ACTION - CALPROTECTIN

The below diagram highlights just one example of how an IVD (Calprotectin) can improve outcomes by potentially reducing the number of tests a patient undertakes in the pathway, enabling faster diagnosis and preventing admissions, delivering benefits for both the patient and NHS.

