

# Near Patient Testing The Value Story

Prevention · Patient Empowerment · Efficiency Savings



# NEAR PATIENT TESTING THE VALUE STORY

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# 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.

One of the main types of IVD is Near Patient Testing (NPT), also known as Point of Care Testing (POCT). 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.

Moving diagnostic tests to the point of care has the potential to alter substantially the delivery of care to patients, allowing timely diagnosis of patients at the bedside, in general practice, or in the community. NPT is an area of IVDs that has been gaining momentum over recent years and is now recognised as having a major role to play in redesigning services around the needs of the patient.

Despite this, industry still faces a glass ceiling when it comes to the uptake and diffusion of IVDs within the NHS. This is due to:

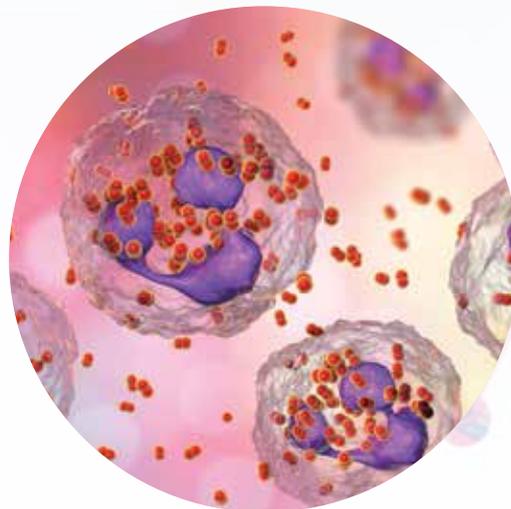
- **BUDGET SILOS** – At present, the budget for testing and general pathology in the NHS is separated from the rest of the budget for a medical pathway. This can often provide a disincentive to introduce cost-saving and potentially life-saving new tests because while the up-front and ongoing costs are 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.

Through this publication, we hope to encourage greater uptake of near patient testing by demonstrating the value of the IVD industry to patients, the NHS and the UK economy. While many of the accompanying examples and case studies are England focused, the wider issues concerning adoption of IVDs are applicable across the UK.

Pressure on the NHS's time and resources will continue to increase over the coming years. In order to ensure it has a sustainable future and to further improve patient outcomes, it is vital that steps are taken to increase the adoption of IVDs.



# THE ROLE OF NEAR PATIENT TESTING IN THE DIAGNOSIS OF SEXUALLY TRANSMITTED INFECTIONS



Key themes in this chapter:

- **PREVENTION** – Reducing the infectious period by diagnosing people more quickly
- **PATIENT EMPOWERMENT** – Patients are provided their results within hours, rather than days, arming them with vital knowledge about their sexual health
- **EFFICIENCY SAVINGS** – Fewer transmissions leading to reduced clinical costs

Despite numerous public health campaigns, the prevalence of sexually transmitted infections (STIs) is still an issue for the UK healthcare system. In 2017, there were approximately 420,000 diagnoses of STIs made in England<sup>1</sup>.

As many people with an STI do not display symptoms, *in vitro* diagnostics (IVDs) are key to diagnosing those who are infected. Typically, people attend a sexual health clinic where they may undergo a series of blood and urine tests. The results will then be communicated to the patient within a week or two.

Such clinics are vital for the diagnosis and treatment of STIs. However, there is now a new model of sexual health clinic, combined with rapid diagnostic testing, which is diagnosing and treating patients in a much shorter timeframe.

## *Case Study: The Dean Street Express Clinic*

The Chelsea and Westminster Hospital NHS Foundation Trust established the Dean Street Express Clinic in 2014. It was the first clinic in the world with an on-site, on-demand diagnostics solution – the GeneXpert® Infinity system.

### *How does it work?*

Dean Street Express is a London walk-in facility that offers sexual health screenings for people without symptoms wanting a check-up for STIs. Prior booking is not required and it uses the GeneXpert® Infinity system to provide rapid results for chlamydia and gonorrhoea.

The entire system is self-sampled and automated for gonorrhoea and chlamydia testing. Patients take a short survey and enter their details on a private touch screen. They then go into a booth, and with the help of a simple instructional video, complete the sampling process themselves. These samples are then transferred directly to the clinic laboratory via a specimen transport chute where staff load them for testing into the GeneXpert® Infinity system.

The first results, for chlamydia and gonorrhoea, are delivered within three hours and results for other tests are sent within six hours.

### The advantages for patients and the NHS

- It reduces worry and anxiety for patients as they do not have to wait for days to receive their test results.
- Patients also feel empowered as it is a quick, efficient and private process that gives them vital information about their sexual health.
- It helps to reduce the demands on staff – under the standard model for a sexual health clinic, staff are required to manually check-in patients and take their records. Under the Dean Street Express system, patients register themselves. This has also made the clinic significantly more cost efficient with benefits to the Trust.
- By providing test results within hours rather than days, the chances for an infected person to pass on their STI are reduced. In fact, “the Trust estimates that for every two people diagnosed with an infection, one partner was spared exposure”. This is obviously beneficial for patients but also reduces costs for the commissioners as further infections are prevented.
- The self-service element means that people who engage in ‘high risk’ behaviour are more likely to attend and get tested as there is less embarrassment. The service is also significantly quicker and more convenient for those with limited time.
- The service won a prestigious national Patient Safety Award in 2015, not only because of the public health benefit but because the automation has significantly reduced errors and improved linkage to care.

### Can it be replicated?

*“This model can definitely be replicated across other sexual health providers and this is a really exciting opportunity, not just for the UK but for sexual health globally, to improve diagnosis of STIs and to encourage people to screen regularly. There are definitely opportunities to use this point-of-care model across other healthcare settings.”*

James Beckett, General Manager Sexual Health, HIV and Dermatology at Chelsea and Westminster Hospital, NHS Foundation Trust, London, UK.

*Acknowledgement: Cepheid*

# ANTIMICROBIAL RESISTANCE: THE GROWING IMPORTANCE OF NEAR PATIENT TESTING



Key themes in this chapter:

- **IMPROVING PATIENT OUTCOMES** – Reducing the side effects and costs of inefficient treatment by being able to target the right therapy at the right time
- **EFFICIENCY SAVINGS** – Reducing bed days
- **TACKLING ANTIMICROBIAL RESISTANCE** – By reducing inappropriate antimicrobial prescribing
- **MOVING CARE FROM SECONDARY TO PRIMARY SETTINGS** – NPT increasingly allows testing to move from secondary to primary care settings

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:

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

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

Near patient 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) near patient testing can reduce antibiotic prescribing by 41%, which could result in an estimated saving of £56 million per year in the UK<sup>2</sup>.

### Case Study: Responsible Antibiotic Prescribing in Primary Care

Rationalisation of antibiotic use in the management of lower respiratory tract infection (LRTI) in primary care is a priority in the prevention of antimicrobial resistance (AMR). Despite repeated awareness campaigns, antibiotics are still prescribed for many patients with an acute uncomplicated LRTI<sup>3</sup>. Most of these infections are viral or self-limiting, and evidence from systematic reviews suggest only slight benefit is achieved from the prescription of antibiotics<sup>4</sup>.

#### How can this be improved?

A study was performed to see if the use of C-Reactive Protein (CRP) could reduce the prescribing rates for uncomplicated LRTI in line with NICE guidelines in a GP based Advanced Nurse Practitioner (ANP) clinic<sup>5</sup>.

#### Study design

- Over a 3-month period, patients presented to an ANP clinic were offered a Near Patient Testing (NPT) CRP test under the following conditions: aged 18-65, the patient has a suspected LRTI, duration of illness <3 weeks, patient requests antibiotics for their acute cough. Exclusion criteria - pregnant, immunocompromised, terminally ill, intubated in the past 12 months, acute pneumonia requiring hospital admission, under follow up for Chronic Obstructive Pulmonary Disease (COPD).
- The patients underwent a clinical examination by the ANP and NPT CRP testing was undertaken during the consultation. The decision to prescribe antibiotics was made based on NICE guideline CG1915 and clinical findings.
- Testing was done within the consultation using Alere Afinion™ CRP, a near-patient fingerstick blood test taking 4 minutes to deliver a quantitative CRP result.
- Patients not prescribed antibiotics, or offered a delayed script, were given written self-care advice.
- Patients notes were reviewed after 28 days for any unscheduled follow up/discharge letters due to respiratory infections.
- Results were compared with prescribing and follow up data from the same ANP clinic in the corresponding 3 months from the previous year applying the same inclusion/exclusion criteria.

#### Results and outcomes

- NPT CRP was easy to incorporate into the consultation and did not increase the work load of the clinic.
- Patients were more accepting and reassured when they were not prescribed antibiotics as demonstrated by reduced representation rates.
- 70% of patients presenting with suspected LRTI had low levels of CRP (CRP <20mg/L).
- 31% of patients were prescribed antibiotics on their initial presentation during winter 2014/15, compared with 8% the following year when NPT CRP was implemented.
- Unscheduled follow up within 28 days for patients who were not prescribed antibiotics reduced by >50%.

#### Conclusion and impact

- ANPs are well placed to drive this innovation forward and improve patient care.
- Implementing NPT CRP ensures responsible prescribing, reducing prescriptions by a third.
- The reduction in re-attendance rates infers a level of patient satisfaction and represents significant cost savings to GPs and wider urgent care services.
- Cost savings are made due to reduced antibiotic prescriptions and re-attendance rates.
- NPT CRP does not increase the work load in the clinic.

Acknowledgement: Abbott

### Case Study: Respiratory Tract Infections

Diagnostics have a vital role to play in diagnosing respiratory tract infections. However, as the current methods are complex and often performed in laboratories, this can result in a delayed diagnosis and lead to the inappropriate use of antivirals and antibiotics, and in some cases prolonged hospital stays.

#### How can this be improved?

Through greater application of the BioFire® FilmArray® Respiratory Panel (RP). It is a multiplexed nucleic acid test intended for use with BioFire® systems for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections.

The test is easy to perform by users without molecular expertise. It can be used in different settings closer to the point of patient impact, outside of the traditional molecular laboratory environment. Results are available in around an hour.

Currently, the BioFire® instrument is primarily used in laboratory settings. However, there are three UK publications describing its use in near patient settings (i.e. Medical Assessment Units<sup>6,7</sup> and Paediatric wards<sup>8</sup>). The option of introducing it into community use is also being explored in order to prevent the presentation of patients to hospital.

#### The advantages for patients and the NHS

A recent pragmatic, open-label, randomised controlled trial in a UK hospital<sup>6</sup> demonstrated:

- **EFFICIENCY SAVINGS** – Respiratory virus infection is a common cause of hospitalisation in adults – when used in a POCT setting use of the BioFire® FilmArray® Respiratory Panel was associated with a reduced length of hospital stay.
- **FASTER DE-ESCALATION OF INAPPROPRIATE ANTIBIOTIC USE** – More patients in the POCT group received single doses or brief courses of antibiotics than did patients in the control group.
- **MORE APPROPRIATE USE OF NEURAMINIDASE INHIBITOR** – with both faster de-escalation in influenza-negative patients and more use and reduced time to administration in influenza-positive patients in the POCT group.

*Acknowledgement: bioMérieux UK Limited*

## Case Study: Helping Wounds to Heal Faster

### What is the problem?

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 – 30 April 2013), only 43% of chronic wounds in the UK healed at a cost of ca. £3 billion<sup>9</sup>.

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.

### The solution – Near Patient Testing

A BIVDA member is leading the way in wound diagnostics by commercialising the world's first near patient tests for this field. WOUNDCHEK™ Protease Status 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<sup>10</sup>. WOUNDCHEK™ Bacterial Status 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 required<sup>11</sup>.

### How does it benefit patients and the NHS?

- The use of near patient 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*

## Case Study: Diagnosing Infectious Diseases

If a patient is presenting with symptoms of an infectious disease, it is vital that healthcare professionals are able to quickly and efficiently identify whether they are suffering from a bacterial, viral or fungal infection so that the appropriate treatment can be identified.

### Traditional methods

Typically, this has been done in the lab through traditional molecular diagnostic testing. However, this requires specialised skills and significant laboratory hands-on time to extract, amplify, and detect nucleic acid.

At a time when laboratory staff are facing increasing demands on their time, it is vital that the IVD industry leads the way in developing innovations that can reduce the workload and free up the time of our pathologists.

### A new way forward

A BIVDA member is able to offer multiplex ePlex® assays for infectious disease diagnostic testing in patients. The Blood Culture Identification (BCID) Panel enables physicians to quickly and effectively identify bacterial, viral or fungal infections and the Respiratory Pathogen Panel (RPP) identifies 20 viral and 4 bacterial targets to aid in determining the appropriate treatment with the goal to improve patient care.

The ePlex System can be integrated into the entire infectious disease diagnostic workflow such that physicians/clinicians, laboratory staff and nurses use the test.

Physicians will order the test which will be transmitted directly to the ePlex system via a bi-directional laboratory information system (LIS) interface. The laboratory staff or nurses will receive the test order, which can be confirmed with the Pending Test Order list on the ePlex system. The laboratory staff or nurses will then run the test with less than two minutes hands-on time and rapid time to result of 90 minutes. Upon test completion, the results will automatically be sent back to the physician via the bi-directional LIS interface.

### How does it benefit patients and the NHS?

- **ANTIMICROBIAL RESISTANCE** – The ePlex RPP assays identify a wide range of potential viruses responsible for respiratory tract infections. A positive result can reduce the improper use of antimicrobials. The ePlex BCID assays identify the causative agent for bloodstream infections and the associated resistance marker in <2 hours from blood culture bottle positivity. By providing these results 12-72 hours earlier than standard of care, the correct antibiotic can be chosen, and appropriate escalation/de-escalation decisions can be made.
- **BRINGING CARE CLOSER TO HOME** – The ePlex ease-of-use allows testing to be done by a wide range of staff, from laboratory technicians to nurses in Near Patient Testing. The ease-of-use and error proofing supports: testing near patient in the admissions and emergency ward, testing 24 hours a day, 7 days a week, testing at remote hospitals with no molecular experience required.
- **MOVING CARE FROM SECONDARY TO PRIMARY SETTINGS** – The simplicity of workflow, built-in error proofing and novel LIS integration capabilities support testing in primary care settings.
- **PATIENT EMPOWERMENT** – ePlex RPP and BCID assays have comprehensive coverage. The BCID panels are separated out into a Gram-negative, Gram-positive and fungal panels ensuring they are the most comprehensive panels on the market today and which also give resistance gene information. Providing patients with an answer has been shown to positively impact patient satisfaction. By ePlex providing a definitive result this can also improve patient compliance in regard to use of antimicrobials or antivirals.

- **EFFICIENCY SAVINGS** – The ePlex ease-of-use, rapid workflow, quick time-to-result, complete IT integration and comprehensive results all deliver significant IVD testing efficiency which leads to the following key benefits:
  - Improved use of patient isolation rooms
  - Enhanced bed management to reduce nosocomial infections
  - Improved antimicrobial stewardship
  - Reduced hospital length of stay
  - Reduced patient morbidity and mortality
  - Improve patient satisfaction
- **PREVENTION** – The comprehensive, near-patient, rapid result of ePlex can prevent inefficient use of isolation rooms, prevent nosocomial infections, and prevent improper use of antimicrobials.

*Acknowledgement: GenMark Diagnostics*

# PREVENTING UNNECESSARY HOSPITAL ADMISSIONS: HOW NEAR PATIENT TESTING DIAGNOSTICS IS PLAYING ITS PART



Key themes in this chapter:

- **BRINGING CARE CLOSER TO HOME** – Preventing unnecessary hospital admissions
- **EFFICIENCY SAVINGS** – In cases where admission is necessary, reducing length of stay
- **PATIENT EMPOWERMENT** – Helping elderly patients to maintain their independence

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 also help to reduce costs by preventing hospital admissions and moving care out of expensive acute settings.

## *Case Study: Oxford Emergency Multidisciplinary Unit*

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

### *Why was it established?*

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 frailer 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.

### *How is near patient testing involved?*

Within the doors of the EMU is a near patient 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.

### *What are the benefits for patients and the NHS?*

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 month<sup>12</sup>.

### *Can it be replicated?*

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. Near patient testing has been reported as being integral to the operation and success of the unit.

## Case Study: Enabling Clinical Access to Time-Sensitive Diagnostic Information

### What does the test do?

A BIVDA member has created a panel for use in the in vitro quantification of analytes in arterial, venous, or capillary whole blood.

The i-STAT System offers a comprehensive range of clinical tests in a single near patient testing platform, allowing clinicians to access the time-sensitive diagnostic information they need, when and where they need it.

### Where is the test used?

In a variety of settings including Intensive Care Unit (ICU), Cardiovascular Intensive Care Unit (CVICU), Operating Room (OR), Cardiovascular Operating Room (CVOR), Emergency Department (ED) and Ambulatory Emergency Care (AEC).

### What are the benefits for patients and the NHS?

The use of i-STAT CHEM8+ cartridge in an ambulatory setting can help to faster identify those patients who do not need to be admitted to hospital and thus streamline the care of this patient group. It facilitates rapid clinical decision making and enhances the clinical pathway.

The i-STAT CHEM 8+ test, together with other i-STAT tests (CG4+ and PT/INR) were used for redesigning the ambulatory emergency services at James Paget University Hospital, resulting in:

- A reduction in the average length of stay (LoS)
- An increase in the number of 0-day LoS
- A reduction in the number of 1,2 & 3-day LoS
- Considerable cost benefits

*Acknowledgement: Abbott*

### Case Study: Preventing Unnecessary Admissions for Patients Suffering from Peritonitis

Peritonitis is an infection of the inner lining of the stomach. If left untreated, it can become life-threatening.

#### How is the condition managed?

Currently, peritoneal dialysis patients check their waste dialysate bag for cloudiness as an indicator of possible infection. If a cloudy bag is seen, or other symptoms such as abdominal pain or fever occur, the patient will attend their local renal clinic or A&E department where testing of the dialysate for white cell count and microbiology culture will take place. As it can take up to 4 hours before the white cell count result is available, and 2-3 days before the culture result is known, the patient is usually put onto a broad-spectrum antibiotic immediately.

A waste dialysate bag can be cloudy for reasons other than infection i.e. if the patient has had a 'rest' day from dialysis, and for some patients it is difficult to tell whether a bag is actually cloudy or not. In a significant number of instances where patients make these unscheduled visits, they will not have an infection, but there is currently no alternative choice of action available to them.

#### How are things changing?

A BIVDA member has developed PERiPLEX, a lateral flow device, designed for self-testing, which detects two recognised markers of infection in peritoneal dialysate taken from the waste bag of a patient on peritoneal dialysis. Detection of either, or both, of these markers indicates the potential presence of peritonitis, prompting the patient to seek urgent medical assistance.

The answer is provided in a simple visual manner, similar to a pregnancy test. If a negative result is obtained, the patient does not need to travel to a clinic and will also not be put onto unnecessary antibiotic treatment. This is particularly helpful for patients living some distance from their medical centre. A positive result means that that patient needs to seek medical advice urgently.

In a clinic setting, a negative result from a test performed when the patient first arrives can help to reduce unnecessary antibiotic prescriptions and can also save patient waiting time.

#### How does this benefit patients and the NHS?

- Use of the test will help to reduce unnecessary antibiotic prescribing.
- It will also reduce the number of times a patient needs to attend a renal clinic or A&E department unnecessarily.
- A larger clinical study is planned to demonstrate the ability of the test to detect infection earlier than the current cloudy bag observation; this would allow earlier detection of peritonitis, leading to earlier treatment which would minimise possible damage to the peritoneal lining, and thereby increase the length of time a patient can remain on peritoneal dialysis.

*Acknowledgement: Mologic*

# THE IMPORTANCE OF SELF-MANAGEMENT AFTER DIAGNOSIS



Key themes in this chapter:

- **PATIENT EMPOWERMENT** – Enabling and helping patients to manage their own conditions after diagnosis
- **EFFICIENCY SAVINGS** – By meeting demand more appropriately

With people living longer and a rise in the number of those suffering from multiple, chronic conditions, demands on the NHS are increasing. Therefore, to ensure the long-term sustainability of the NHS, it is vital that wherever possible and appropriate, patients are empowered to help manage their own conditions after diagnosis.

## *Case Study: Littlewick Medical Centre*

The Littlewick Anticoagulation Service in Derbyshire has been operating since 2008. Patients can have their anticoagulation therapy monitored locally, in primary care clinics or even at home, resulting in good compliance, improved internal normalised ratio (INR) control and greater patient satisfaction.

### *Anticoagulation service – the traditional model*

In the past, patients on anticoagulation therapy, such as warfarin, had to attend a hospital outpatient clinic every month to have a blood sample taken from their arm. The blood would then be sent to a local laboratory and the result would be communicated to the patient's GP within a day or two. The GP would make a decision regarding any required change in warfarin dose and the patient would be advised. This process was time consuming and costly for the patient, in terms of travel and time off work; in some cases, this could lead to non-attendance. In addition, there would be a long delay between taking the blood sample and receiving dosing advice, with several points at which communication could potentially break down.

### *A new model of care*

For patients on anticoagulation therapy for the treatment of atrial fibrillation (AF), deep vein thrombosis (DVT) or pulmonary embolism (PE), or for the management of a mechanical heart valve, an important part of their care is regular blood testing to monitor their INR. Near patient testing technology, such as the CoaguChek® XS Plus system, now enables INR monitoring to be performed by healthcare professionals closer to the patient, in primary care. Requiring just a finger prick of blood, the sample can be taken, INR obtained, and dosing advice given during a single consultation. As this eliminates the journey to hospital and the delay in results, it is much more convenient and acceptable for patients. In certain situations, near patient testing technology also enables patients to test their own blood, whether they are at home, on holiday or travelling due to work, using a handheld meter such as the CoaguChek XS system. With patient self-testing (PST), the patient telephones the anticoagulation team with their INR measurement and receives any required dose adjustments straight away. If the patient has hearing difficulties or is travelling abroad, this can also be done by email or text, making it easier for the patients to comply with regular INR monitoring.

### How does it benefit patients and the NHS?

- Patients can achieve improved time in therapeutic range (TTR) for PST and enhanced independence, providing a safe and convenient alternative for suitable individuals on warfarin therapy.

*“This is a patient-centred service, which reflects and reinforces the aims of the Littlewick Medical Centre to provide high quality, patient-focussed care. It allows them to live near-normal lives, particularly for self-testing patients, as they can now go on holiday for long periods more easily. Providing this service has strengthened our links with the local hospitals and other GP practices in the area.”*

Dr Naveed Abbasi, GP partner, Littlewick Medical Centre

*Acknowledgement: Roche Diagnostics*

# 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 all across the UK.

While the IVD sector is already making a significant difference in these areas, we have identified five priorities 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 Near Patient Testing and other IVD tests within the NHS is still taking too long. Typically, widespread adoption of new diagnostic tests takes approximately 10 years.

We expect that the Government will implement the recommendations of the Accelerated Access Review (AAR) and will continue progress on the Life Sciences Industrial Strategy. This would 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

From reading this report, the importance of IVDs in overcoming the challenge of antimicrobial resistance (AMR) is clear. 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.

The understanding of the beneficial role of IVDs in this area is increasing among both clinicians and policymakers. To build on this progress, BIVDA calls for 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. This could result in reduced levels of 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 costs are borne by the innovators, the savings accrue further down the patient pathway.

BIVDA calls for Government to introduce a funding mechanism, which does not disincentivise the uptake of IVDs, thereby encouraging the NHS to increase the adoption of IVDs and enabling better patient access to diagnostics.

### Why have we chosen the term Near Patient Testing?

There have been a number of terms used for tests performed outside of a laboratory setting, whether these are inside a hospital or in the community. The main two terms used in this report are Near Patient Testing (NPT) or Point of Care Testing (POC or POCT). It could be argued that these refer to slightly different uses but, in the UK, we have typically used POC. However, the IVD Regulation in the EU now mandates NPT by using the term in the official text. For that reason, BIVDA has decided to use NPT for this publication and more widely. NPT refers to tests performed by a healthcare professional and not by the patient (or a carer) which is termed self-testing.

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# 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. We currently represent over 150 member companies, ranging from British start-up companies to UK subsidiaries of multinational corporations. Our members' activities within the NHS include the supply and maintenance of pathology equipment and reagents (both laboratory-based and near patient testing), training, clinical evaluation work, and engagement with both procurement and clinical personnel.

## 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



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To contact BIVDA:

Telephone: +44 (0)8456 188 224

E-mail: [enquiries@bivda.org.uk](mailto:enquiries@bivda.org.uk)

British In Vitro Diagnostics Association  
299 Oxford Street (5<sup>th</sup> floor) · London · W1C 2DZ