



Working differently to  
provide early diagnosis  
Improving access to  
diagnostics



Deloitte Centre  
for Health Solutions

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## **The Deloitte Centre for Health Solutions**

The Deloitte Centre for Health Solutions, part of Deloitte UK, generates insights and thought leadership based on the key trends, challenges and opportunities within the healthcare and life sciences industry. Working closely with other centres in the Deloitte network, including the US centre in Washington, our team of researchers develop ideas, innovations and insights that encourage collaboration across the health value chain, connecting the public and private sectors, health providers and purchasers, and consumers and suppliers.

# Foreword

Early diagnosis of disease is better for patients and makes good economic sense. This Deloitte Centre for Health Solutions report examines how healthcare commissioners and providers can work differently with the diagnostic industry and other providers to increase early diagnosis and operate more efficiently in doing so.

While the report presents information for the United Kingdom, its focus is on healthcare services in England. The report's findings, however, have implications for healthcare services everywhere. It is the result of in-depth literature reviews and data analysis and draws on numerous discussions across healthcare and the life sciences industry.

The report's conclusions are predicated on three key themes:

- the need to improve access to early diagnosis in the face of rising demand and limited funding growth
- the financial, operational and cultural obstacles preventing early access to diagnostics
- how working differently could help.

We hope you find the research informative and insightful and welcome your feedback and comments.

**Karen Taylor**

Director, Centre for Health Solutions



# Executive summary

The relentless demand for healthcare services is set to continue for the foreseeable future, fuelled by population growth and increased longevity. However, since 2010, the National Health Service (NHS) has received flat rate funding and NHS organisations in England are required to deliver £20 billion of efficiency savings by 2014-15. If services continue unchanged, the predicted funding gap is expected to increase to £30 billion by 2020-21. A key policy driver, therefore, is the need to work differently to deliver more, better quality healthcare with fewer resources.

## **Early diagnosis makes clinical and economic sense**

Diagnostic testing is an integral part of the healthcare system, providing essential information to enable providers and patients to make the right clinical decisions. Indeed some 75 per cent of clinical decisions are based on a diagnostic test. Demand for access to quicker, more accurate diagnosis is rising at a rate of ten per cent per year, increasing costs and putting pressure on the capacity and capability of diagnostic providers. Improving the efficiency of testing, and the speed and accuracy of diagnosis, can provide a substantial contribution to the NHS's required savings.

From the patient point of view, early detection and diagnosis can prevent unnecessary pain and suffering. It can also reduce the scale and cost of treatment. A large body of research links early diagnosis to measurable health gains, such as improved survival rates and lower treatment costs. However, effective implementation of early diagnosis varies widely across the NHS and lags behind many European countries. For example, the United Kingdom (UK) is ranked 20th and 23rd respectively for the number of MRI and CT scanners per million people. Furthermore, the Department of Health estimated in 2010, that if cancer patients in the UK were diagnosed at the equivalent stage of their disease as in other European countries, up to 10,000 deaths could have been avoided.

Over the past four years the focus of policymakers, clinical leaders and managers has been on the financial challenges facing the healthcare sector, as well as the wide-scale reforms required by the Health and Social Care Act 2012. These developments have distracted attention away from considering how the NHS might harness technology and use existing NHS capacity more efficiently.

During the last decade the ability of the NHS to respond to year-on-year increases in demand for diagnostic tests was supported by significant government investment. However, the financial constraints over the past three years are putting increasing pressure on the resources available for purchasing new diagnostic equipment and plans to reconfigure pathology services and improve the efficiency and cost effectiveness of in-vitro diagnostic testing have been subject to long delays.

While the level of investment in diagnostic technology is relatively transparent (in 2012 the UK diagnostics industry was estimated to be worth around £2.37 billion), there are few measures of the impact of diagnostics on disease prevention, patient outcomes and overall healthcare expenditure. Evidence from the United States suggests higher expenditure on imaging can lead to a three-fold saving for every unit of currency invested. Similarly, investment in new, more sensitive, blood tests could save money and save lives.

## **Obstacles to access**

Widespread adoption of new diagnostic tests typically takes around ten years. Adoption is hampered by a lack of clarity about the research evidence required by those involved in approving the use of new diagnostic tests. At the same time, clinicians feel the technological advances do not always match their needs and there is poor evidence of clinical utility in peer reviewed literature, making it difficult to obtain commitment to change clinical practice.



NHS funding has been significantly reduced, with limited if any real-term growth in the face of predicted demand increases of around

**2.6%** per year



While the UK has been successful in developing new technologies, levels of uptake have been low compared to many other countries, such as Switzerland, Canada, Sweden and Norway. In 2011, the UK ranked **16th** in Europe in per capita spend on medical technology, below the European average



NHS organisations must deliver

**£20 billion**

in efficiency savings by 2014-15 and unless they adopt new ways of working, the funding gap will increase to **£30 billion** by 2020-2021



GP referrals for hospital diagnosis and treatment have increased year on year and, in 2012, numbered over **11 million.**

These referrals are a significant driver of NHS costs



Over the next ten years the ageing population and rising incidence of chronic disease will fuel a **10%** per annum increase in demand for blood and tissue tests



As a result of rising demand and national initiatives to improve access, between 2006 and 2012 MRI scans increased by **55%** and CT scans by almost **50%**



Despite rapid growth in numbers of scanning machines between 2002 and 2008, the UK still has fewer machines and does fewer scans per person than many other European countries, ranked **20th** and **23rd** respectively for number of MRI and CT scans per million people



**75%** of clinical decisions are based on a diagnostic test



In 2012 the diagnostic segment of the medical technology market in the UK was worth **£2.37 billion**, with diagnostic imaging worth around **£1 billion** and expected to grow at **9%** a year



In 2011 estimates suggested that the NHS would need to replace **50%** of its advanced diagnostic imaging machines within **three years** and **80%** within **six years**

The five main barriers to improving access to diagnostics and obtaining a diagnosis in an efficient and effective way are:

- **organisational** – poor communication between primary and secondary care, variable referral management practices, delays in reconfiguring pathology services and confusion over responsibility for technology assessments
- **financial** – perverse payment incentives and the lack of an effective activity based payment system, the short term nature of NHS budgeting and poor understanding of the cost benefits of diagnostic testing
- **operational** – capacity constraints, including variations in opening times, variable progress in automation, lack of trained staff and uncertainty over future demand
- **cultural** – failure to engage frontline staff, risk aversion at board level and inadequate collaboration with industry and other providers
- **regulatory** – new more exacting, European Union regulatory requirements for medical diagnostics.

#### Working differently to provide an earlier diagnosis

Improving diagnostics is dependent on more efficient use of existing capacity and quicker uptake of new, cost-effective technology. It also requires NHS staff to work differently. There are a number of initiatives aimed at improving diagnostics that are already having an impact in some parts of the NHS. If these were to be adopted more widely, they could help deliver more immediate improvements in early diagnosis.

These initiatives include:

- changing NHS commissioning practices to deliver improved outcomes and reduce unwarranted variation in practices and procedures including adopting effective approaches to referral management

- adopting new models of working with private and third sector providers
- increasing the scale and pace of the consolidation of pathology services
- developing new payment mechanisms to encourage more community diagnostics and point of care testing
- scaling up the adoption of new diagnostics that reduce the need for invasive procedures and companion diagnostics to support personalised treatments.

#### Innovation as a lever to improve early diagnosis

Technology and innovation are key drivers of improved productivity and have an important role to play in supporting early diagnosis. While the UK is recognised as a world leader in developing new diagnostic technologies, it has been less successful in adopting new diagnostic practice at scale. In 2011, the UK ranked 16th in Europe in per capita spend on medical technology, below the European average. In the past year or so, the Department of Health has launched a number of national policy initiatives to improve radically the adoption and diffusion of innovative practices and technologies across the NHS.

They include:

- the Department's December 2011 Innovation, Health and Wealth Strategy which reinforces the importance of developing effective patient pathways, including an early diagnosis pathway
- the establishment in May 2013 of 15 new Academic Health Science Networks (AHSNs) to help increase the uptake of innovation and improve communication and collaboration across the health value chain
- the National Institute of Health and Care Excellence's new compliance regime, including the new Diagnostics Assessment Programme and the Health Technologies Adoption Programme.



Two key drivers of variable provision of imaging are opening hours and availability of suitably trained staff. Indeed hospitals' standard opening times for services vary greatly; in the case of CT services, in 2010 these ranged from

**40 to 90 hours**

per week, with some 7-day and extended-hour services available.



There is a **10%** variation in prices paid for the same advanced imaging equipment, with limited means to examine variation due to lack of information and understanding of cost drivers and clinical outcomes. Consolidation of IVD pathology services would likely bring benefits, both in terms of services and costs. For example in London a 30 per cent saving could be made by shifting laboratories from their median volume to a volume of around 15 million tests.



Barriers to the adoption of new diagnostic tests mean widespread uptake in the NHS typically takes about

**10 years.**

Moreover, the benefits claimed, such as improved outcomes and associated disinvestment in old tests and practices, are not always achieved (or measured) in reality.



The absence of an effective activity-based payment system means lack of transparency around the costs of diagnostics and fails to incentivise adoption of new innovations.



Europe approves technology **43 months ahead** of the US and **60 months** ahead of Japan. Given the separate regulatory structures and different approval processes, manufacturers often apply for approval in Europe before the US.



◀ INPUT



These policy changes have the potential to provide a strong lever for improving early diagnosis, but will take time to embed. In the meantime there is a need for more specific action to improve the chances of an early diagnosis. This requires Academic Health Science Networks and the National Institute of Health and Care Excellence to work collaboratively within and across networks to develop a new diagnostic innovation pathway, with patients' interests as the unifying principle. It also requires policymakers, commissioners, providers and industry to work together more effectively, to deliver improved diagnostic services, specifically to:

- evaluate the benefits of a value-based payment system which rewards adoption of an effective diagnostic pathway
- reinvigorate the consolidation of pathology services and provide clarity on responsibilities for driving the consolidation
- develop a robust understanding of the value for money of existing diagnostic services and capture the real time impact of new diagnostics on downstream costs
- develop quality performance measures on diagnosis and referral activity and incentives for improving communication between GPs and specialists
- seek timely feedback on performance and outcomes from patients and patient groups
- agree outcome measures that support the development of a culture that rewards innovation

- seek to reduce unwarranted variations in provider performance in relation to referrals and diagnostic testing
- collaborate in providing training to staff
- develop new staffing models, including development of joint ventures
- identify a single contact for procurement of diagnostics with each hospital.

### Conclusion

Early diagnosis of disease is better medical practice and makes good economic sense. To continue delivering its essential services, the NHS needs to make changes to the way it deploys its staff, its methods and tools, and its contractual arrangements with providers. The central tenet of the NHS reforms is 'No decision about me, without me'. Unless this decision is based on an early and accurate diagnosis, it is likely to be flawed. By working differently, the NHS and medical diagnostics industry can provide access to smarter, faster diagnostics which reduce the poor health outcomes and higher downstream costs associated with late-stage diagnosis.



# Part 1. Diagnosing early makes good clinical and economic sense

Health services in most countries face unprecedented cost pressures and rising demand due to a complex range of factors, including population growth, higher life expectancy and increased public expectation. Diagnostics are an integral part of healthcare, with the results of tests critical to every stage of the patient journey. Rising demand for services is reflected in year-on-year increases in requests for diagnostic tests, but these tests are often accessed late in the disease progression. Clinical research suggests that diagnosing earlier would lead to better health outcomes and be cost effective.

## **Diagnostic tests provide a more precise diagnosis of the nature, cause and severity of disease**

Diagnosis is the process of identifying a disease or confirming its presence. It also enables administration of the right treatment and can reduce the need for invasive procedures. Medical diagnostics include physiological measurements, laboratory in-vitro diagnostic (IVD) tests, imaging tests and endoscopy. Diagnostics are integral to an effective healthcare system and inform a wide range of medical decision making, from personalised cancer treatment to identifying the right antibiotic to fight an infection.

Around 75 per cent of clinical decisions are based on medical diagnostic tests (diagnostics). Figure 1 illustrates a generic diagnostic pathway most patients are likely to follow. The role of the general practitioner (GP) is critical to the effectiveness of this pathway, because the majority of people first present with symptoms to their GP. For the most part, GPs access medical diagnostics either by sending the patient's blood or other tissue to a hospital pathology laboratory for IVD testing or referring the patient to a medical consultant in a hospital out-patient clinic for IVD, imaging and/or endoscopy tests. Around 20-25 per cent of patients first obtain their diagnosis following presentation at an Accident and Emergency Department.<sup>1</sup>

While delays in the patient presenting to a GP, and delays in GPs deciding to refer for tests, affect the chance of an earlier diagnosis, the focus of this Deloitte UK report is on the systems and processes that occur once the GP has decided to refer the patient for a diagnostic test. Given the wide range of diagnostics the report focuses specifically on IVDs, the most common diagnostic tests, and advanced imaging, the most accurate but costly tests.

## **Early diagnosis is important as it can improve a patient's prospects of recovery and is cost-effective**

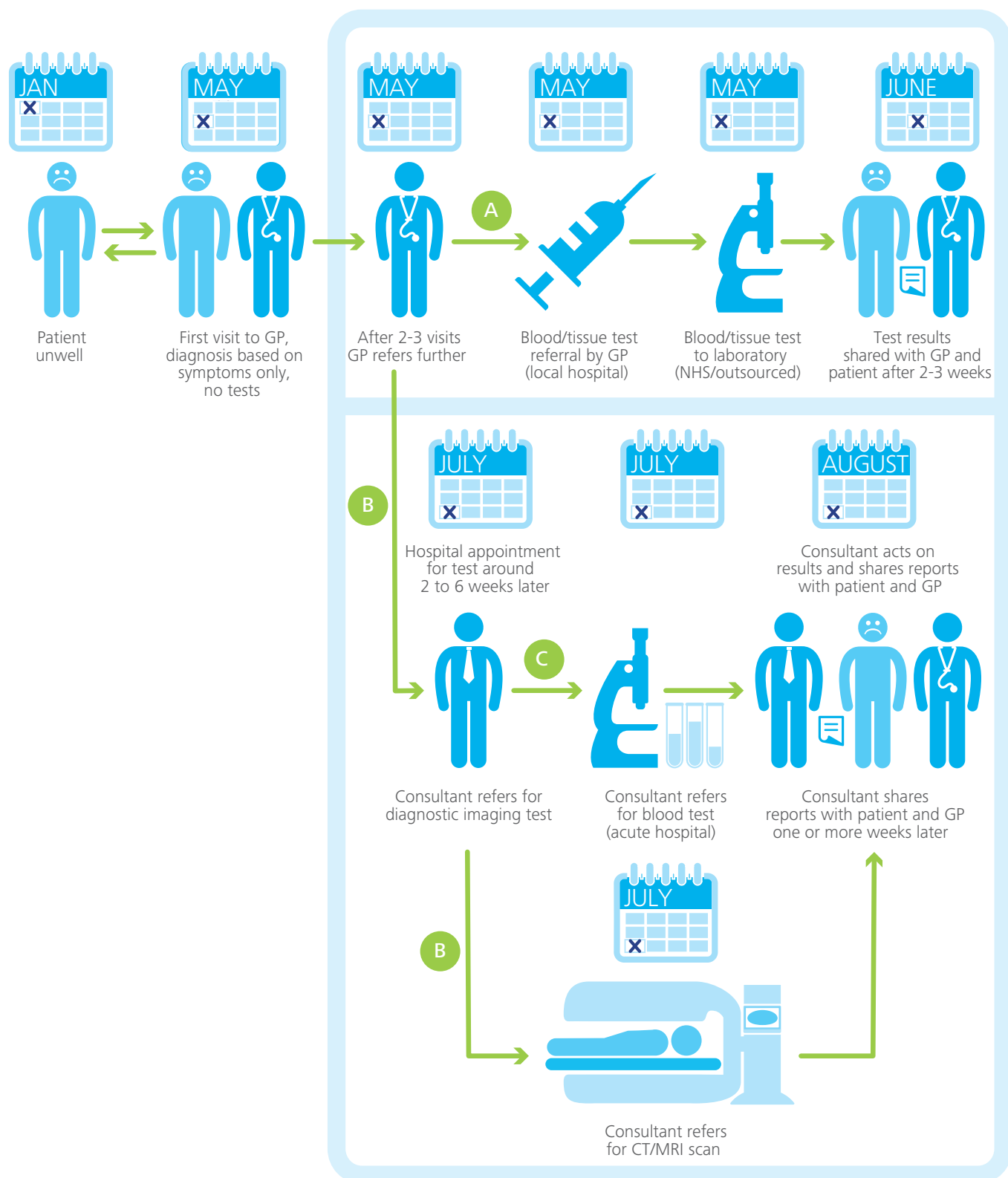
Traditionally, the NHS has been better at responding to ill health when it becomes serious rather than identifying and addressing problems earlier, when they are less expensive to treat.<sup>2</sup> Early detection and diagnosis prevents unnecessary pain, disability and in some cases death, by ensuring more targeted treatment and intervention. A key feature of many patient pathways is a requirement to detect disease early.<sup>3</sup>

An early diagnosis is also likely to reduce the scale and cost of medical intervention and hospital admission. Indeed, efficient and effective diagnostics can deliver improved outcomes and generate cost savings in several ways:

- reducing downstream treatment costs
- lowering hospitalisation rates
- cutting avoidable or inappropriate interventions
- enabling minimally invasive procedures that reduce operating-room time, length of stay and rehabilitation.<sup>4</sup>

Yet successive external reviews by independent organisations, such as the National Audit Office and the King's Fund, have shown that diagnosis is often too slow and can result in much higher financial and non-financial costs.<sup>5</sup>

Figure 1. The General Diagnostic Pathway: How most patients access a medical diagnosis



Early diagnosis may not always be a cost saving in the short term, as earlier detection is likely to mean earlier treatment. The benefits of earlier diagnosis have been demonstrated in research findings in a wide range of disease areas, and are supported in a number of NICE standards and guidelines.<sup>6</sup> Example 1 highlights some of the benefits of earlier diagnosis in three high prevalence disease areas.

A large body of cancer research indicates that early diagnosis is cost-effective, largely due to substantial improvements in health outcomes. Yet, diagnosis in the UK is often later than in many other European countries. Example 2 illustrates how earlier diagnosis of cancer is cost-effective and saves lives.

### National strategies and guidelines have helped improve mortality from major diseases in the United Kingdom but performance still lags behind other countries

During the past decade, the Department of Health has developed a number of national strategies to improve outcomes for major non-communicable diseases, which have highlighted the importance of widening access to diagnostics. The National Cancer strategy has been a particularly important driver of investment in new imaging technology. There are also national guidelines and standards on best practice, for example from the National Institute of Health and Care Excellence (NICE), which highlight the importance of early diagnosis.<sup>12</sup> Research shows that these strategies and guidelines have helped improve mortality from many diseases, including cancer and heart disease, although the mortality rates remain higher than in comparable European countries (Figures 2 and 3).

#### Example 1. The clinical, psychological, social and economic benefits of earlier diagnosis of diseases with high prevalence in the UK

- **Coronary Heart Disease (CHD):** Around 2.6 million people in the UK have CHD, including 700,000 with heart failure. CHD kills more than 110,000 people a year. It accounts for about three per cent of hospital admissions, incurring annual direct costs to the NHS of £3.3 billion and total costs of almost £9 billion. Investment in new technologies has seen significant improvements in diagnosis and treatment, and death rates have fallen by over 40 per cent as more people receive cholesterol and blood pressure lowering drugs. A reliable point-of-care test used in Accident and Emergency Departments prevents 500,000 hospital admissions annually. Advances in scanning technology now detect blockages before they do too much damage, enabling delivery of more targeted and cost-effective treatment.<sup>7</sup>
- **Stroke:** Every year more than 152,000 people have a stroke. Stroke is a medical emergency, one of the top three causes of death and the largest contributor to adult disability in the UK, costing over £3 billion annually in direct care costs and about £8 billion in wider economic costs. Significant improvements in stroke services over the past five years, particularly in terms of rapid access to brain imaging and early treatment with thrombolytic drugs, have delivered huge benefits in terms of outcomes. Similarly, early diagnosis and treatment of people with atrial fibrillation (a risk factor for stroke) could prevent around 4,500 strokes and 3,000 deaths per year. Detection and treatment of transient ischaemic disease (which significantly increases stroke risk) provides savings of around £600 per patient assessed and treated.<sup>8,9</sup>
- **Dementia:** Around 800,000 people in the UK are estimated to have some form of dementia, a number expected to double within 30 years. Estimated costs are expected to increase from £15.9 billion in 2009 (of which around £8.2 billion were direct health and social care costs) to £34.8 billion by 2026. Early diagnosis and intervention enables more to be done to slow disease progression, reduce hospital admissions and delay admission to care homes. Yet average time to diagnosis takes up to twice as long as in many other European countries. Economic modelling shows that the widespread adoption of good practice in diagnosis and treatment can lead to efficiency savings of at least £284 million per year and improve the social and psychological impact on the patient and the family.<sup>10,11</sup>

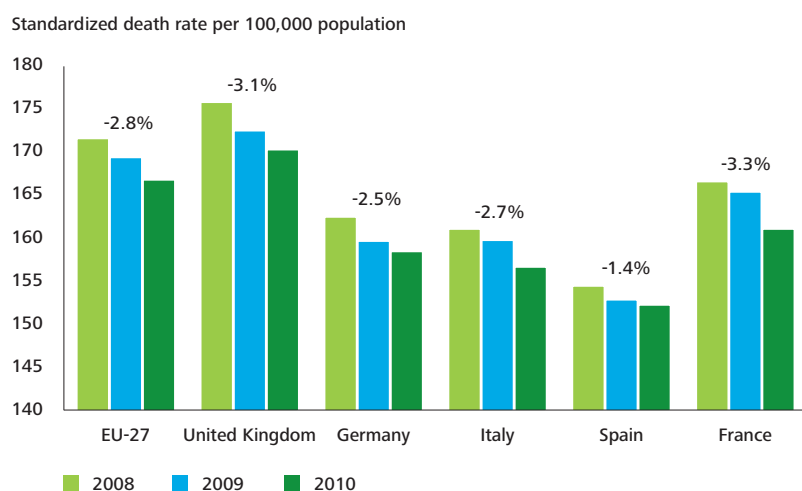
#### Example 2. Earlier diagnosis of cancer is cost-effective and saves lives

Cancer survival in England is poor compared with many other European countries, due to a combination of late presentation, delays in GP referral and variable access to diagnostic tests. Every year, more than 330,000 people are diagnosed with cancer and around 130,000 die from the disease. The Department of Health estimates that if patients in England were diagnosed at the equivalent stage as in other comparable countries up to 10,000 deaths a year could be avoided. Research to determine the impact of earlier detection and diagnosis on costs and benefits in breast, colorectal and lung cancer found this to be generally cost-effective but not necessarily cost-saving, the main benefit being a substantial improvement in health outcomes. The methodology used by the National Institute of Health and Care Excellence to determine whether a product or treatment is cost-effective is based on a quality adjusted life year (QALY) calculation. Products with a QALY below £20,000 are considered to be cost-effective. For example:

- **Breast cancer** – improving one-year survival from 93.8 per cent to the best European rates of 95.2 per cent. Additional diagnosis costs of around £85 million would be offset by modest savings in treatment costs of £9 million. However, 319,000 life-years would be gained with average cost per life gained of £2,329, therefore seen as cost-effective.
- **Colorectal cancer** – achieving the one-year best-practice survival rate in Europe of 79.0 per cent. Initial diagnosis costs of £272 million would reduce over time and would be offset by a modest saving in treatment costs of £14 million. Altogether, 41,000 life-years would be gained with average cost per life saved of £6,241, judged to be cost-effective.
- **Lung cancer** – an improvement could be achieved in the one-year survival rate from current 28.0 per cent to 33.3 per cent (the best European rates are 37 per cent). Initial costs of diagnosis would be £95 million, reducing over time, and additional treatment costs would be £9 million, but with 42,000 life-years gained and an average cost per life saved of £2,376, again cost-effective.

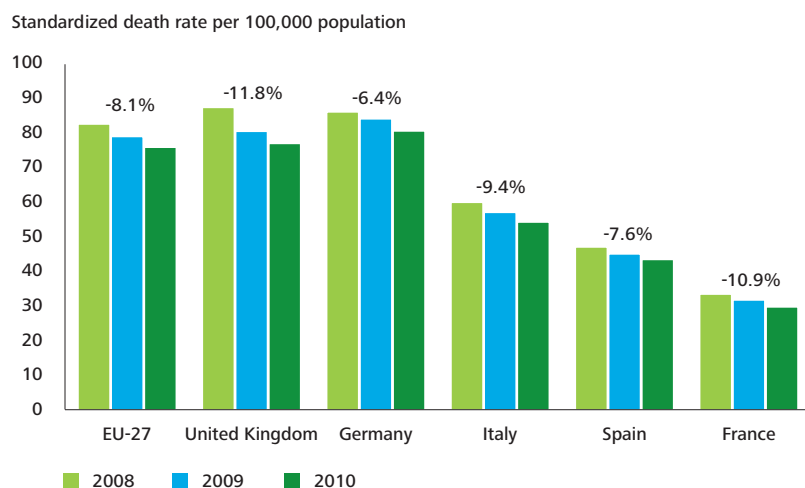
Source: All figures derived from Department of Health analysis for the November 2010 National Awareness and Early Diagnosis Initiative (NAEDI).

**Figure 2. The UK death rate due to cancer has declined steadily, however, it is still higher than the European average and the rates in comparable European countries**



Percentage figures above bars show extent of change during the period 2008-2010  
Source: Eurostat 2012, accessed, August 2013

**Figure 3. The UK death rate due to heart disease has steadily declined but is now slightly better than the European average and remains higher than Italy Spain and France.**



Percentage figures above bars show extent of change during the period 2008-2010  
Source: Eurostat 2012, accessed, August 2013

### Diagnostic tests have increased year-on-year

The total diagnostic market in the UK in 2012 was worth around £2.37 billion. The IVD market accounted for £1.16 billion and is estimated to grow at around 2.2 per cent a year to reach 1.53 billion by 2017.<sup>13</sup> The diagnostic imaging market in 2012 was worth around £1 billion and is expected to grow at around nine per cent per annum to £1.4 billion by 2017.<sup>14</sup>

The main developments that have increased spending on diagnostics are:

- increased availability and expanded indications for monitoring of chronic diseases and targeting of treatment
- year-on-year increases in the number of NHS attendances, including GP consultations, Accident and Emergency attendances, outpatient appointments, elective and emergency admissions
- growing pressure from patients, clinicians and healthcare commissioners, who expect more rapid and more accurate diagnoses
- recent technological advances in tests and electronic devices, with tests which were previously only available in laboratory or hospital settings now available as bedside 'point-of-care' tests.

### The past decade has seen a ten per cent per annum increase in IVD tests

More than 700 million IVD tests, such as blood and tissue tests, are carried out each year. IVDs are used to monitor disease progression, efficacy of therapy and to target patients for specific drugs and therapies. Indeed, laboratory and point-of-care tests using IVDs underpin around 70 per cent of clinical decisions.<sup>15</sup> A wide range of IVD testing is used routinely by pathologists to detect cancers, based mainly on histopathology (biopsies examined for the presence of tumour cells). Better application of IVDs using biomarkers is starting to improve the accuracy of tests and consequently patient outcomes.<sup>16</sup>

The total cost of pathology services in England is around £2.8 billion per annum. The number of IVD market tests has been growing at a rate of around ten per cent a year over the past decade and is projected to grow at an average annual rate of 10-20 per cent in the future.<sup>17</sup>

Much of this growth is being driven by increases in GP requests, fuelled by the rising incidence of chronic illnesses, with chronic diseases accounting for around 50 per cent of all pathology activity. The shift towards personalised medicine will create demand for more molecular-based investigations, and is likely to increase IVD activity and service costs. Further innovation and demographic pressures are likely to lead to demand accelerating over the next decade.<sup>18</sup>

#### The use of advanced imaging has also increased year on year but still lags behind many countries

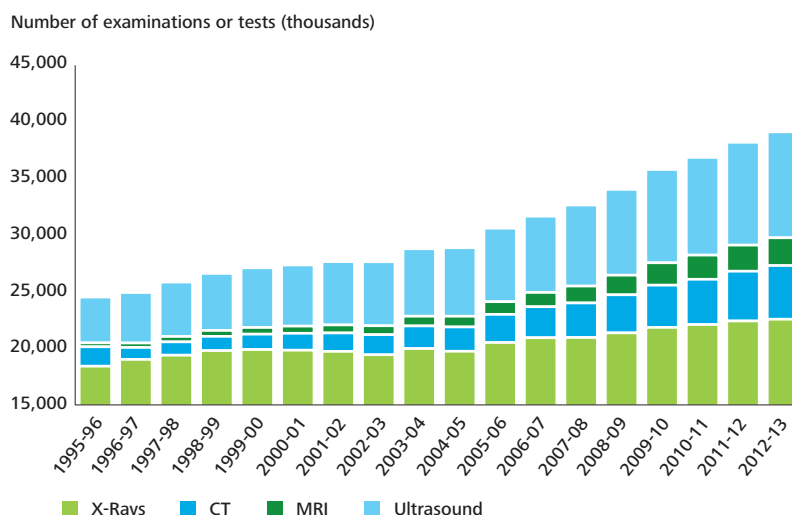
The increasing prevalence of long-term conditions and complex comorbidities has resulted in a steady increase in the number of requests for diagnostic imaging. These include X-rays, ultrasound tests and large increases in more advanced imaging technology, such as Magnetic Resonance Imaging (MRI) or computerised tomography (CT) scanning. MRI and CT scanning have a higher cost than X-ray but enable much more accurate diagnosis.<sup>19</sup>

Advanced imaging can help detect disease at its most curable and least costly stage. While X-ray and ultrasound can increasingly be ordered directly by the GP, more advanced imaging tests are normally accessed following referral to a hospital outpatient clinic or as part of an emergency or elective hospital admission. Indeed, direct access to tests via primary care remains extremely variable and limited.<sup>20</sup>

During the 1990s, the number of CT and MRI machines per head of population was much lower in the United Kingdom than in other developed countries. In 2000, as part of its efforts to improve cancer services, the Department of Health introduced the Cancer Equipment Programme, spending over £400 million on new CT, MRI and Linear Accelerator machines. As a result all hospitals now have access to some form of scanner and most acute care hospitals have access to CT and MRI scanners.<sup>21</sup>

Due to rising demand and national initiatives to improve access, the last 15 years have seen year-on-year increases in all imaging tests, particularly the top four (Figure 4). Between 2006-07 and 2012-13, X-rays increased by 7 per cent, MRI scans by 44 per cent, CT scans by 55 per cent and ultrasound by 5 per cent. The total number of these tests in 2012-13 was 39 million.<sup>22</sup>

**Figure 4. Total number of imaging and radio-diagnostic examinations or tests, by imaging modality, England, 1995-96 to 2012-13**



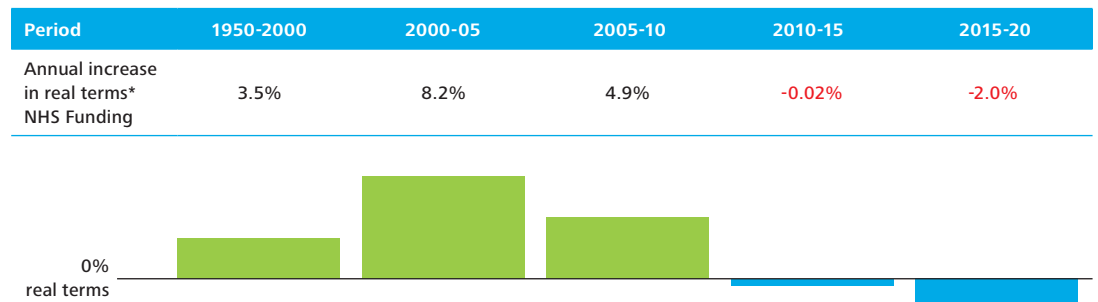
Source: NHS England, Annual Imaging and Radiodiagnostic dataset, August 2013.

Although the number of CT and MRI machines and scanners increased rapidly across the UK, particularly between 2002 and 2008, they also increased in all other European countries. As a result, the UK still has fewer scanners and is:

- ranked 20th in the number of MRI scanners per million people (5.9, compared with 12.2 in the Netherlands, 10.7 in Spain, 10.3 in Germany and 7.0 in France)
- ranked 23rd in the number of CT scanners (8.2 per million, compared with 17.7 in Germany, 15 in Spain, 12.3 in the Netherlands and 11.8 in France).

Furthermore, the number of tests performed per 1,000 people also lags behind most European countries. There is no general guideline or benchmark regarding the ideal number of CT scanners or MRI units per head of population. However, too few units may lead to access problems in terms of geographic proximity and increased waiting times. Too many may result in an overuse of costly diagnostic procedures, with limited benefit to patients.<sup>23</sup> As shown earlier, in Figures 2 and 3, the UK's higher mortality rate suggests that there may be a case for more scanners, or at least for using existing equipment more efficiently, to increase access and improve the chances of earlier diagnosis.

Figure 5. Changes in real term funding across key periods in the NHS



'Real-term' funding is defined as the increase in cash funding adjusted for general inflation in the UK.

The Government's flat funding growth for the NHS does not include any allowances for:

- population increase
- demographic pressures (obesity, ageing populations)
- service provision improvements (new drugs, treatments etc.)
- increases in healthcare cost inflation above general inflation
- increases in what is counted within the remit of this spend

In total these are estimated to increase demand by between 2.6 and 4.0 per cent per year.

Requiring savings of up to

**20%**

The 'Nicholson' Challenge  
£20 billion by 2014-15

And without changes in service delivery

**30%**

by 2020-21 and £30 billion by 2020-21

Source: Deloitte Healthcare Consulting review of Department of Health data

### Reduced funding in the face of increased demand requires the NHS to improve efficiency and productivity

Over the last decade, the ability of the NHS to respond to increasing demand for diagnostic tests was supported in part by the UK government's significant investment (Figure 5). Since 2010-11, however, NHS funding across the whole of the UK has been flat, and is expected to remain flat for the foreseeable future. This lack of real-term growth in the face of increasing demand of around 2.6 per cent per year will place unprecedented financial pressures on healthcare and require the NHS to deliver more high quality services, including diagnostics for the same or less.<sup>24</sup>

In order to maintain quality and meet demand the Department of Health has required the NHS to deliver around £20 billion of efficiency savings by 2014-15 (Figure 5).<sup>25</sup>

In July 2013, NHS England detailed the challenges facing the NHS and expressed the expectation that if services continue to be delivered in the same way, the £20 billion efficiency savings required by 2015 are unlikely to be sufficient to meet future challenges. Furthermore, without making significant changes to the way services are delivered the funding gap from 2013-14 to 2020-21 is likely to be £30 billion. It emphasised the importance of the NHS working differently, including making the most of new medicines and new technology.<sup>26</sup>

A key policy driver for healthcare, therefore, is the need to improve efficiency, productivity and cost-effectiveness and deliver more, better quality care for less. This was behind the Department's 2010 Quality Innovation Productivity and Procurement (QIPP) challenge, subsequently adopted in 2012 by the NHS Commissioning Board (now NHS England).<sup>27</sup> The UK Government and NHS England have been unequivocal in calling for improved adoption of innovative technology as a key contributor to addressing this challenge. Alongside this is the need for changes to clinical and staff practices, including new ways of working.<sup>28</sup>

### Improving access to early diagnosis can help deliver improved productivity

NHS England's July 2013 consultation document titled "The NHS belongs to the people: A call to action", reiterates the need for the NHS to work differently. The consultation is aimed at identifying solutions to tackle failures in care and raise performance. It highlights the need to harness technology and use capacity more efficiently. Early diagnosis and appropriate treatment of disease are identified as being fundamental to this agenda.<sup>29</sup>

Industry groups have demonstrated how the NHS could reduce costs, transform patient care and deliver tangible improvements in operational performance through investment in imaging and other diagnostic technology. However, while the level of investment in diagnostics is transparent, there are few measures of the impact on disease prevention, disease outcomes and overall healthcare expenditure.

A growing body of evidence demonstrates that increased use of advanced imaging technologies has benefited patients by enabling more convenient and less invasive diagnosis and treatment. Research from the United States shows that imaging can mean fewer complications, fewer misdiagnoses and shorter lengths of stay (image-based procedures are estimated to be three to seven times more cost-effective than surgical biopsies). Higher expenditure on imaging is a predictor of reduced length of stay and correlates with increased life expectancy and a three-fold saving for every unit of currency invested. This is in spite of some new diagnostic procedures being initially more costly.<sup>30</sup>

The continuing pressure on funding will inevitably have an impact on the budget available for diagnostics, creating an environment where the need to deliver more effective diagnostic services with fewer resources will be an even greater imperative.

Part 2 of this report examines some of the main obstacles to accessing efficient and effective diagnostics. Part 3 evaluates examples of initiatives already in place in some parts of the NHS but which need to be more widely adopted. Part 4 identifies some of the new organisational changes intended to facilitate new ways of working and details some of the further actions needed to improve early diagnosis.





# Part 2. Obstacles to accessing an early diagnosis

Widespread adoption of new diagnostic technology in the NHS typically takes around ten years. Moreover, claimed innovation and benefits, such as improved outcomes and associated disinvestment in old tests and practices are not always achieved (or measured). Additionally, there is poor evidence of their clinical utility in peer-reviewed literature, limiting the potential to recommend new tests in clinical practice guidelines. The business case for new tests is therefore difficult to make and often fails to convince clinicians of the benefits of changing their clinical practice.<sup>31</sup>

The five main barriers to delivering more efficient and effective diagnostics are:

- **organisational** – including poor communication between primary and secondary care and variable referral management practices, delays in reconfiguring pathology services and confusion over responsibility for technology assessments
- **financial** – perverse payment incentives, short termism and a lack of understanding of the cost benefits of diagnostic testing
- **operational** – such as variations in opening times, lack of trained staff and uncertainty over future demand
- **cultural** – failure to engage frontline staff and risk aversion at board level
- **regulatory** – introduction of new, more exacting European Union legislation for medical devices and IVDs.

## Organisational barriers impede access to early diagnosis

### Poor communication and variable referral management practices can delay diagnosis

For the majority of patients in the United Kingdom, general practice is the primary access point to health care, with the GP acting as the gatekeeper to elective specialist and secondary care. In fulfilling this role effectively GPs need to balance several competing concerns and sources of information, including patient expectations.

Many GPs feel that organisational changes to the way the NHS operates have made it harder for them and hospital specialists to forge close relationships. For example the Choose and Book system which means GPs are often unable to refer to a named clinician. Inadequate communication creates barriers between GPs and specialists and undermines the development of effective information exchange and GPs' ability to seek informal advice.<sup>32</sup>

In 2012 there were around 332 million GP consultations,<sup>33</sup> and over 11 million referrals to secondary care for diagnosis and elective care triggering an annual spend of more than £15 billion. The total number of GP referrals for diagnosis has increased year-on-year and is an important NHS cost-driver.<sup>34</sup>

The NHS has developed a number of approaches to referral management – for example, educational interventions, referral guidelines, organisational interventions, financial incentives, and the use of measures and metrics and in last few years has introduced Referral Management Centres (RMCs). Indeed, the past decade has seen a rapid growth in the number of published clinical guidelines to support referral from primary to secondary care with NICE publishing over 100 evidence based guidelines including clear patient referral criteria and timeframes. In addition the Map of Medicine provides GPs with an interactive web-based tool, comprising hundreds of evidence-based care pathways, to support GP referral. Despite this, the diagnostic process in primary care is challenging with ten-fold variations in referral rates between practices.<sup>35</sup>

The King's Fund report Referral management: lessons for success, concluded that peer review among GPs and feedback from consultants appeared to be particularly effective. It also suggested that full-scale RMCs are unlikely to present value for money and some of the new clinical triage and assessment services might add to rather than reduce costs. It recommended a referral management strategy built around peer review and audit, supported by consultant feedback, with clear referral criteria and evidence-based guidelines as likely to be both cost- and clinically-effective.<sup>36</sup>

### **Delays in reconfiguring pathology services have meant a missed opportunity for improving value for money of IVD testing**

An independent review of NHS pathology services, chaired by Lord Carter of Coles, was set up in 2005 to “advise Ministers on the timeliness, reliability, capacity and efficiency of pathology services in England”. The first report, in 2006, made a number of recommendations aimed at improving the delivery of NHS pathology services, but noted the absence of robust data on the cost of providing these services.

The second report, in 2008, was based on an in-depth analysis of activity and cost data from a representative sample of NHS pathology pilot sites. It found wide variations between sites due to the extent of automation and size and complexity of the workload. The report confirmed that service consolidation would enhance quality by creating economies of scale. Consolidation would also enable pathology services to respond to the challenges presented by innovation (for example genetic testing), system and workforce reforms. It identified potential savings of some 10-20 per cent (£250 million to £500 million) from consolidating pathology services into reconfigured networks and said these savings should be reinvested in improving quality and patient safety.<sup>37</sup> The Department of Health welcomed the review and established teams in the ten Strategic Health Authorities (SHAs) to implement its recommendations.<sup>38</sup>

Progress to date, however, has been variable. While there has been some local, bottom-up reorganisation, broader reconfiguration has been subject to long delays, due in part to vested interests, concerns about patient safety and a lack of available capital. This has been compounded by the NHS reforms, specifically the abolition of SHAs, changes to the commissioning environment and concerns in some regions that the reconfiguration may not deliver the projected cost savings. Market uncertainty, which tends to slow progress, has been exacerbated by suggestions that reconfigurations could face challenges by the Office of Fair Trading.<sup>39</sup>

### **Duplication of technology assessments delays adoption of new diagnostics**

Health Technology Assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology and involves multiple stakeholders.<sup>40</sup> While formal HTAs typically occur at national level, they are also performed incrementally at regional and local levels, including by individual hospitals. This duplication increases the risk of conflicting HTA results.

HTA agencies, including NICE, follow the pharmaceutical sector’s approval process, which mandates evidence from randomised controlled trials. In many cases, such evidence is often unavailable at the time of launch. The gap between information required and information available also presents a block to local adoption of innovative technologies, including new diagnostic technology.<sup>41</sup>

### **Financial barriers impede access to more effective diagnostics**

#### **Lack of a diagnostic tariff and pervasiveness of silo budgeting**

The NHS’s Payment by Results system, introduced in 2003, records and remunerates around 60 per cent of hospital activity and has had a significant impact on reducing waiting times and lengths of stay. There is no evidence that it has reduced quality of care.<sup>42</sup> However, payment for diagnostic activity is complex. Historically, outpatient testing is included in the outpatient attendance tariff while inpatient diagnostics are generally based on block contracts. The absence of an effective activity-based payment system has meant a lack of transparency around costs and has undermined adoption of new innovations which could improve access to earlier diagnosis.

Within hospitals, budgets also tend to be allocated to individual departments, causing difficulties in determining the benefits of a technology which operates across the whole patient pathway. These challenges are compounded by silo-budgeting, because the potential savings may be realised in a different place from where the cost is incurred. In response to concerns about lack of funding incentives, the Department of Health announced that from April 2013 there would be a separate “unbundled” tariff for diagnostic imaging in the outpatient setting.<sup>43</sup>

Another development that is likely to influence the funding of diagnostics is a national consultation on the development of the tariff and other possible payment mechanisms.<sup>44</sup>

#### **Limited robust, reliable data on the rate of return on investment in diagnostic technology**

While the level of investment in medical technology is known, measurement of patient outcomes is relatively under-developed. Historically, the NHS has also been poor at capturing running costs of diagnostic services. For example, in focusing on service line reporting, hospitals are not always aware whether highcost imaging machines, used across service lines, are a source of revenue or a driver of costs. This lack of data prevents providers assessing the efficiency and cost-effectiveness of services.<sup>45</sup> The need for more advanced ways of measuring return on capital investment, including the impact on downstream costs, would benefit from closer cooperation between hospitals and industry suppliers.

There is also a lack of clarity about the level of research evidence required by stakeholders involved in the approval, adoption and reimbursement of new tests. This creates a financial disincentive among industry and research funders to invest in generating research evidence for new diagnostic tests, including demonstrating their cost-effectiveness. For the diagnostic technology industry, return on investment in diagnostics is lower and the rapidity of change in technology higher than in industries such as pharmaceuticals. As a result industry tends to generate the minimum level of research evidence necessary for regulatory approval, with less focus on clinical outcomes.<sup>46</sup>

For NHS procurement teams and decision makers, assessing the cost-effectiveness of new tests is confusing, especially for clinicians, who may often feel that the technological advance is not necessarily something they need. Improving this situation requires more effective communication between clinicians, procurement teams and the diagnostics industry to develop robust economic modelling.

#### **Investment decisions in IVD testing are focused on cost**

Some 35-45 per cent of laboratory tests are referrals from primary care. The tests are usually provided by pathology departments in NHS hospitals, although some hospitals now provide testing facilities in the community. A few commissioners have entered into contracts with the independent sector, either for an agreed range and volume of tests or a managed service. Independent sector penetration of the market is, however, still relatively limited. Historically it has been difficult to determine the costs of pathology tests. A number of pilots conducted as part of the second Independent review of pathology services found wide variations both within and between regions.<sup>47</sup> Proposals for tariffs for IVD testing, contained in the Independent Review of NHS Pathology Services, have yet to be implemented.

Regional variations in IVD costs have been attributed to differences in the extent of automation and economies of scale. Most laboratory services are run as separate ‘financial and management silos’. Reports from the Department of Trade and Industry, the Health Select Committee and the Healthcare Industries Task Force have concluded that the NHS is too focused on cost, rather than on benefit, when making investment decisions. A small investment in pathology services can disproportionately improve the quality and lower the total cost of a healthcare encounter.<sup>48</sup> Increasing laboratory automation enables shorter turnaround time and increased testing volume for IVDs, and can increase capacity by between five and seven per cent a year.

As reimbursement for IVD pathology services within hospitals remains part of the out-patient tariff, this perversely incentivises hospitals to carry out invasive procedures even when these could be avoided by using new IVD tests. As a result, uptake of new tests remains very low. Adoption of disruptive innovative diagnostics often requires a time-consuming business case which can be difficult to identify.

## **Operational barriers undermine effective delivery of diagnostics**

### **Variations in opening times and non-availability of trained staff undermine the efficient and effective operation of diagnostic imaging**

In 2010 and 2011, diagnostic imaging accounted for around six per cent of all medical procedures performed in the UK (Yorkshire and the Humber was lowest at 5.9 per cent and London highest at 7.5 per cent).<sup>49</sup> Waiting times are variable, with patients accessing an MRI scan within two weeks of referral in 2009-10 ranging from less than 20 per cent to 93 per cent.<sup>50</sup> The NHS Operating Framework 2012-13 introduced an expectation that less than one per cent of patients should wait six weeks or longer for a diagnostic test.

Two key drivers of variable provision of imaging are opening hours and supply of trained workforce. While emergency provision of imaging diagnosis is mandated across all Trusts, standard opening times for services vary greatly. For example, opening hours for CT services in 2010 ranged from 40 to 90 hours per week. Further, working patterns can leave high-value equipment idle for comparatively long periods. In response to the QIPP challenge, many more NHS organisations are increasing opening times and exploring options for shared solutions.<sup>51</sup>

The availability of a suitably qualified diagnostic imaging workforce is a major challenge. NHS organisations are struggling with persistently high vacancy rates (approximately 7 per cent for consultant radiologists) and attrition from training programmes for diagnostic staff. Training more radiologists takes time. For example, it takes more than five years for a physician to become a consultant radiologist.<sup>52</sup> Training technicians to do more is a possibility given the increased reliability of technology. However, the absence of agreed governance and quality standards undermines the wider adoption of new ways of working.

### **Increasing the capacity of imaging capability is challenging due to high costs and uncertainty over future demand**

Decisions in hospitals about the technical functionality of new machines are largely influenced by the ability of Trusts to 'future proof' against emerging trends, such as clinical and technological developments and an ageing population. They also seek a balance between buying functionality needed now or in the future, with the risk of it being redundant and never, or only partially used. More immediately, the NHS is challenged to make better use of existing capacity to meet a recent mandate for 24/7 radiology cover.<sup>53</sup>

Hospitals are responsible for obtaining and maintaining diagnostic equipment (whether bought, leased or managed equipment services). Costs must be recovered through revenue from commissioners. Funding for equipment comes from the following primary sources: income from service provision, Department of Health loans, private sector loans or charitable funding. There is currently a ten per cent variation in prices paid for the same equipment, with limited information and understanding of cost drivers and clinical outcomes from different imaging technology.<sup>54</sup>

The significant investments made between 2002 and 2008 in purchasing replacement and additional diagnostic scanning machines is now presenting a challenge for the NHS. Most of these scanners have a ten year life and hospitals are facing difficult decisions in deciding how to meet the costs of replacing these machines. In 2011, the National Audit Office estimated that around half of all machines across the NHS were due for replacement within three years, and 80 per cent within six years.<sup>55</sup>

### **NHS procurement processes are difficult for the diagnostics industry to navigate**

NHS decision making on procurement for diagnostics is confusing. The medical diagnostic industry often lacks clarity as to whom they should be pitching across all stages of the process. Procurement is complicated by an ever-changing NHS landscape, including a higher number of procurement providers and advisers. NHS Trusts can use regional procurement hubs, the NHS supply chain or buy directly from suppliers. New contracts frequently overlap and incur high administrative costs.<sup>56</sup> Procurement of innovative products is especially poorly understood because of the lack of comparable products against which to benchmark their added value.<sup>57</sup>

### **Use of private sector provision to increase capacity is declining**

Over the past decade, the requirement to meet national waiting time targets led to an increase in private sector provision of imaging tests. However the challenging financial climate means hospitals are now cutting back on outsourcing, even if it leads to longer waiting times. Trusts are increasingly considering whether purchasing, leasing or managed equipment services will provide the best value in the face of rising demand for CT and MRI scans. In 2012, the Department of Health announced a £300 million fund for capital equipment purchases.<sup>58</sup>

### **Cultural barriers arise as a result of failure to engage clinicians**

Most technology innovations will have service implications and many service innovations will need the support of an enabling technology. There is therefore a need to engage frontline staff responsible for implementation. Many of the smaller diagnostics companies find it difficult to engage staff in hospitals as they are often resistant to change and fear the technology could undermine or even eliminate their role. There is also a general aversion to risk in adopting new technology at board level.<sup>59</sup>

The development of new tests is often driven by industry identifying technological possibilities rather than responding to an identified clinical need. There is also a resistance to adopting best practice that might have been developed in another organisation, even where there is evidence of effectiveness.<sup>60</sup>

### **The regulatory landscape is complex and subject to change**

Diagnostic technology has to meet regulatory standards, which can delay availability of new diagnostics. The regulation of medical devices is managed by the Medicines and Healthcare Products Regulatory Agency (MHRA) and subject to European Union (EU) legislation. Devices are typically designed and engineered for a specific use and new versions are often improved incrementally within 12-18 months of a product being on the market. Repeat trials to prove evidence of quality and effectiveness of these upgrades is generally not always needed.<sup>61</sup>

The European approval process for medical devices was established more than 20 years ago and is soon to be overhauled. Safety and performance requirements are set by individual countries which then select legally and technically independent, competent bodies called Notified Bodies (NBs) to check conformation with the EU Directives. There are currently 76 NBs in 25 countries, including the MHRA. NBs issue certificates of conformity, known as the Conformité Européenne or CE marking. A CE mark means a product can be used in the EU. Changes to approved design must also receive NB approval. This approach provides assurance on safety while guaranteeing relatively fast access to innovation. Indeed, Europe approves technology 43 months ahead of the United States and five years ahead of Japan. However, wide variability in NB standards means manufacturers frequently seek out the NB they expect to be most favourable.<sup>62</sup>

For the majority of diagnostic tests, the only formal evidence required is the CE marking. This is about to change. In September 2012, the EC published proposals for two new regulations on medical devices and IVDs which will replace the existing directives.<sup>63,64,65</sup> The changes include greater transparency, better traceability in the supply chain, additional pre-market scrutiny and enhanced clinical evidence requirements for higher-risk devices.<sup>66</sup>

These revisions are expected to encourage a single, safer EU market for IVDs.<sup>67</sup> As 92 per cent of IVDs are developed and manufactured in Europe, these changes have significant implications for manufacturers. For example, the increase in time-intensive assessments could lead to reduced investment in research and development in the sector.<sup>68</sup> Greater clinical requirements may also act as a barrier to market entry, though they may make decisions on clinical practice easier.<sup>69</sup>

# Part 3. Working differently to improve access to diagnostics

Improving diagnostics is dependent on more efficient diagnosis and referral practices and on utilising diagnostic capacity more effectively. It also requires quicker uptake of new, more cost-effective technology. Given the significant financial challenges, it relies on NHS staff, who account for 70 per cent of the NHS budget, to work differently. There are a number of initiatives specifically aimed at improving diagnostics that are already having an impact in some parts of the NHS. If these were to be adopted more widely, they could help deliver more immediate improvements in early diagnosis. This part highlights solutions that could help deliver more immediate improvements in earlier diagnosis.

## **Changes to NHS commissioning practices can be used to improve access to diagnostics**

The Health and Social Care Act 2012 established around 220 Clinical Commissioning Groups (CCGs) to commission healthcare services for their local populations and has necessitated the development of new relationships and adaptations of systems and processes to suit changing customer needs.

Since April 2013, NHS England has been responsible for holding CCGs to account for delivering value for money and quality outcomes. The NHS Outcomes Framework and NHS Constitution set out new goals and responsibilities, recognising that approaches to delivery will vary. Earlier diagnosis is identified as a key component in the delivery of the “outcomes” domain.<sup>70</sup>

The NHS Operating Framework for 2011-12 and 2012-13 includes actions to deliver improved access to diagnostics, with CCGs responsible for commissioning the additional direct access tests. However, they are free to choose other approaches to delivering early diagnosis, for example increased use of the urgent referral pathway or commissioning access to independent diagnostic companies.

NHS England's *Everyone Counts: Planning for Patients 2013/14* consultation outlines the incentives and levers which it proposes should be used to improve services. A priority is to move to routine services, including diagnostics, being available seven days a week. As a first step the focus is on improving access to hospital diagnostics, all alongside improving urgent and emergency care.

Some commissioners are starting to use their contracts to specify improved access and referral practice, along with requiring feedback on key performance indicators on outcomes. These contracts should require providers such as GPs and hospitals radiology departments and pathology laboratories to provide data on numbers and cost of diagnostic testing. There remains a need for better quality measures on diagnosis and referral. While referral rates are an important example of this, commissioners should use referral rates as an indicator for further investigation rather than as a blunt instrument in evaluating performance. Commissioners need to develop incentives for improving communication between GPs and specialists as good clinical relationships can help improve the quality of diagnosis and referral; they can also make it easier for GPs to seek informal advice, thereby reducing the need for referrals and avoiding duplication of tests.<sup>71</sup>

## **Building on the greater involvement of private and third sector providers**

Provision for an Any Qualified Provider (AQP) regime has led to a number of private-public partnerships offering specific diagnostic procedures. From April 2012 the Department committed to extending AQP for certain diagnostic tests accessed directly by patients in the community, such as imaging, cardiac and respiratory tests. At the time the estimated costs of patients accessing diagnostic tests in the community was over £140m a year. As a range of NHS and independent sector imaging providers were already in existence, along with some nationally agreed tariffs for imaging, this was seen as a strong base upon which to build an AQP. To date the provision of CT and MRI scanning by AQP has been limited with wide geographical differences.<sup>72</sup>

In addition, with a large amount of diagnostic equipment requiring replacement in the coming years many hospitals are turning to outsourced solutions to provide:

- access to capital given the current constraints on NHS capital expenditure
- provision of services with improved clinical outcomes
- trained and skilled staffing and standard operating procedures.<sup>73</sup>



### **Example 3. The London NHS Diagnostic Service: A collaboration between NHS London and InHealth**

The London Diagnostic Service offers GPs and other healthcare professionals direct access to high-quality diagnostic and imaging scans and tests. An award-winning collaboration between InHealth, a privately-owned UK-based company, and NHS London, the service guarantees patients are seen within 13 working days of referral, with an electronic diagnostic report provided by email or post. The centre delivers diagnostic services from 60 locations across London to 100,000 patients per year. Additionally, InHealth provides 10,000 scans yearly for the NHS PET/CT South contract, from 18 locations on behalf of the Department of Health. It has 70 MRI scanners (many operating 98 hours a week), 12 CT and six PET scans and audiology and endoscopy assets, in total providing over 600,000 radiology episodes per year.

InHealth has invested some £18 million in IT systems and capital equipment to develop their services in London and the NHS PET/CT South scheme, with the aim of providing additional capacity, including five new MRI scanners, effectively making the partnership the UK's largest radiology department.

The London Diagnostic service has been available in London for more than six years and has involved detailed local engagement with GPs to ensure that referral mechanisms and pathways are effective.

Feedback from patients has been consistently positive with 98 per cent reporting their experience as very good or excellent. A survey of the clinical management outcome for 800 patients referred direct by a GP for a diagnostic test, MRI, ultrasound scan or echocardiogram found that direct access to a diagnostic test, following clear guidance provided to GPs, resulted in 71 per cent of patients being managed in primary care.<sup>74,75</sup>

### **Example 4. Radiology Reporting Online (RRO): A joint venture between University College London Hospitals (UCLH) Foundation Trust and Imaging Partners Online, a private company in Sydney, Australia**

UCLH needed 24-hour radiology reporting but was concerned about potential costs, the ongoing need to improve quality, efficiency and productivity, and impact of the European Working Time Directive. Radiology trainees were on duty overnight at a cost to the NHS and reported only a few urgent scans. To comply with the Directive, they had to take the following day off. Audits also identified a poor reporting standard. At the same time, the radiology landscape was experiencing an explosion in demand (CT activity rose from around 7,000 in 2001-02 to 21,500 in 2010-11) and an IT revolution.

In 2009, UCLH entered into a joint venture with Imaging Partners Online to provide out-of-hours services for urgent diagnostic scans. UCLH staff were given a single access number to obtain a consultant-led, fully audited service for diagnostic scanning. After 12 months, the service was expanded to include daytime imaging work. Radiologists in the UK report scans until 11pm, when UK-qualified consultant radiologists in Sydney and Melbourne take over until 8am, giving a 24/7 service, 365 days per year.

As a result, working practices have been transformed. Junior doctors have much richer training and the imaging department can harness the skills and experience of the private sector and deliver a radical change in reporting. As a joint-venture partner, UCLH can reinvest any profits from RRO. Outpatient CT scans that previously took an average of 26 days from exam to report now take around 2.5 days. The waiting time for reporting routine GP scans has reduced from up to two weeks to 24 hours. RRO provides daytime, after hours, urgent and locum reporting of diagnostic images and creates potential for NHS trusts to access radiology expertise in specialties where they have none.

The financial gain from greater productivity is significant. For example, a reporting centre delivering 15 reports per hour rather than ten would deliver a productivity saving of around 30 per cent, either through reporting more examinations or reducing the cost base. The gains from overnight reporting are high because the cost of keeping junior doctors in the hospital to report overnight is up to three times more expensive than using RRO, where the reporting is done by consultant radiologists. Improved productivity and efficiency in turn enhances the patient experience. UCLH has been able to dispense with locums and stop outsourcing some of its MRI reporting.<sup>76</sup>

To sustain the ability of CCGs to use AQP to stimulate competition in a local health economy, private-sector diagnostics providers are looking to create a differentiated offering that is responsive to customer needs. These include: faster turnaround times for reporting, access to advanced technology and equipment, up-skilled radiographers, robust and timely repairs and effective maintenance and IT solutions. Examples 3 and 4 illustrate how private providers are working with the diagnostic industry to improve access to diagnostics.

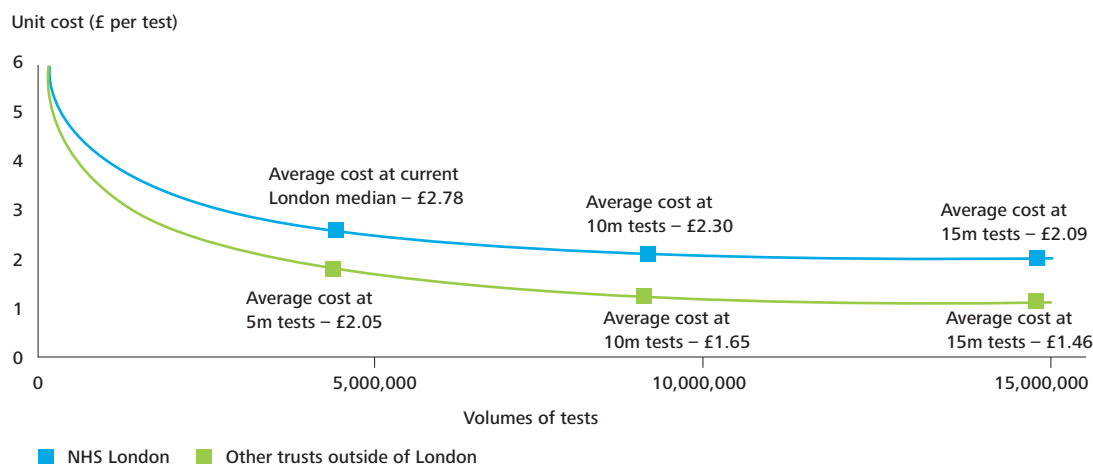
To support timely access to promising technologies, the private sector needs to identify and develop alternative business cases, including methods of funding and mechanisms for evidence-based development.<sup>77</sup> Increased focus on innovation without upfront costs could be affected by rental and leasing systems.<sup>78</sup>

### **Increasing the scale and pace of pathology services consolidation**

A key solution for controlling pathology expenditure, given increasing activity levels, is the development of hub and spoke laboratory networks, as initially identified by the Carter review.<sup>79</sup> Implementation of the review's recommendations has been significantly delayed, but consolidation would likely bring benefits, both in terms of services and costs.<sup>80</sup> Figure 6 illustrates the potential estimated economies of scale, that could be achieved based on an analysis of the relationship between activity volumes and unit costs across 40 laboratories. For example, a 30 per cent saving could be made by shifting laboratories in London from their median volume to a volume of around 15 million tests. However, barriers to achieving this include the need for networked IT solutions, for hospitals to work more collaboratively, concerns over contractual relationships and the potential challenge by competition authorities.



**Figure 6. Economies of scale which can be achieved through consolidation of pathology laboratories**



Source: Deloitte Economic Consulting analysis of relationship between activity volumes and unit costs across 40 laboratories

### Development of new payment mechanisms to encourage more community diagnostics

Changes in the current funding system are required if the NHS is to move care from the expensive hospital setting to the community. One option is fixed, all-inclusive payments for hospitalisation to ensure a more transparent association between effective uses of diagnostic tests, especially the high cost of advanced imaging technologies, and overall healthcare costs.

The Association of British Healthcare Industries has proposed a new tariff supporting the incorporation of innovations. It also suggests that the Commissioning for Quality and Innovation (CQUIN) system could be used as a powerful lever to reward innovation.<sup>81</sup>

As noted in Part 2, the current payment system for diagnostics lacks flexibility and fails to encourage out-of-hospital activity.<sup>82</sup> As part of 'Improving Outcomes: A Strategy for Cancer', in 2011 the Department committed to funding GPs for direct access to selected diagnostic tests.<sup>83</sup> It used a payment by results tariff to incentivise quick, direct access to outpatient diagnostics. Usage data, which enables GPs to benchmark their referrals, is now published alongside GPs use of the two-week urgent referral pathway.<sup>84</sup> The second year report on progress in December 2012 concluded that reporting of the direct access tariff has helped increase direct access referrals. NHS England is currently considering proposals to publish tariffs for diagnostic imaging in outpatients departments separately from outpatient attendance tariffs.<sup>85</sup>

### Scaling up the adoption of new diagnostics in non-hospital settings

A range of diagnostic equipment and tests is employed in mobile units, clinics, primary care settings and the home. For example, ultrasounds typically designed for hospitals are now used in a variety of primary care settings. This is partly due to the collapse in the price of diagnostic technology (between 2000 and 2007 the average price of an ultrasound machine fell from £57,000 to £31,000 and soon there will be ultrasounds costing £10,000 or less). Being able to access low-cost, hand-held devices in the surgery, for example, allows GPs to refer patients to hospital for a CT or MRI scan when more granularity is required. This could help reduce the increasing burden on traditional diagnostics, alleviate patient concerns and lower the incidence of late-stage presentations.<sup>86</sup>

Increased use of point-of-care diagnostics in primary care or urgent care centres is also facilitating quicker and more accurate treatment, as well as reducing hospital costs. This can reduce the number of patients in hospital beds waiting to access or obtain the results of a diagnostic test. The default position of the expensive hospital setting is often used despite evidence of cost-savings and convenience of testing in the community.<sup>87</sup>

There is strong support for patients to choose their diagnostic provider at the time of referral, especially if hospital admission can be avoided. However, the provision of choice must be managed carefully to avoid delays to patient care or unnecessary repetition of diagnosis. Preventing duplication of tests requires both behavioural and logistical solutions.<sup>88</sup>

**Example 5. Improving efficiency using a simple point of care diagnostic test**  
Calprotectin is a simple diagnostic test allowing GPs to differentiate between organic intestinal disease, for example inflammatory bowel disease, and functional bowel diseases such as irritable bowel syndrome. The results are quickly produced from a stool sample, preventing the need for more invasive procedures such as colonoscopy. The test also can be used to identify treatment success or failure, increasing the quality of patient care. Financial modelling from one primary care trust serving 350,000 people identified potential annual savings of £750,000. The NHS could save tens of millions of pounds if this were to be replicated across the country. However, despite the advantages to both patients and the NHS, many laboratories struggle to obtain funding to introduce the test.<sup>90</sup>

**Example 6. Use of a biomarker diagnostic test during surgery to reduce recalls for follow-up surgery**

A biomarker, developed for use during surgery for primary breast cancer (PBC), can significantly reduce recalls for follow-up surgery. By enabling a biomedical scientist to carry out the diagnostic test during the operation, it eliminates the need to send removed sentinel lymph nodes to pathology labs for post-operative investigation. Typically, around 20-30 per cent of operations for PBC result in the need for secondary surgery. The test reduces this need to five per cent or less and also allows chemotherapy to commence up to two to four weeks earlier. Although of high quality, innovative and efficient, it is not currently in widespread use in the UK. An NHS Technology Adoption Centre case study suggests the test could potentially eliminate around 11,000 second surgeries per year, save 24,000 bed days (or five bed days per patient costing £4 million), reduce length of stay and improve efficiency.<sup>92</sup>

**Example 7. An innovation developed in the United States to detect and treat Alzheimer's disease**

Some 5.3 million Americans have Alzheimer's, cases of which are expected to triple by the 2050s. The cost of treating Alzheimer's in America is approximately \$172 billion per year and is expected to rise to \$1 trillion by 2050. GE Healthcare is collaborating with Merck on an experimental therapy to diagnose and treat Alzheimer's using GE's PET amyloid-imaging agent, flutemetamol, along with Merck's MK-8931 which targets beta-amyloid (proteins commonly found in the brains of Alzheimer's patients, thought to affect the lead-up of neuron degeneration in the disease). Flutemetamol, a tracer molecule associated with the isotope fluorine-18, binds to beta-amyloid and can be used as an imaging agent to detect beta-amyloid deposits, which in turn should help identify patients who might benefit from MK-8931.<sup>94</sup>

Preliminary results from two Phase II trials with flutemetamol have met their primary endpoints to confirm its potential application as an imaging agent to detect beta-amyloid plaque, improving the possibility of more effective diagnosis.

Under the current healthcare model, GPs are expected to see and treat a wide range of conditions with only limited access to effective diagnostics. Delivering a greater proportion of care in the community requires enhanced diagnostic capability or access to mobile diagnostics for GP practices. Care needs to be more accessible and provide patients with choice. It also requires treatment to be simpler and more convenient. Therefore, existing healthcare structures, financial incentives and the roles of healthcare professionals need to change. Ultimately, hospitals will need to give ground to new models of care and new players, using technologies that enable less expensive, but appropriately trained, professionals to do progressively more sophisticated work in less expensive settings.

**Increasing uptake of new developments in diagnostics**

Cancer research has been instrumental in driving innovation in diagnostics and many new simple IVD tests can accurately diagnose and eliminate the need for invasive procedures. However, uptake of these tests is still very low.<sup>89</sup> Example 5 illustrates how the use of point-of-care diagnostics in primary care can reduce hospital costs and save time and worry for patients.

This is a fast-moving field of technological development and innovation, with recent product launches and a wide number of tests in development that improve existing diagnostics. For example, the new specific sub-type of the marker prostate specific antigen (PSA) that improves the of detection prostate cancer.<sup>91</sup> Example 6 improves the direction of prostate cancer illustrates how a new biomarker in primary breast cancer surgery can reduce recalls for further operations.

Most, if not all, cancer drugs now in research and development will require a companion diagnostic by the time they are launched (they will be diagnostic-dependent drugs). Their use will be limited to a defined sub-group of patients where the drugs are known to be effective, leading to more personalised medicine.<sup>93</sup>

Nuclear medicine, which uses small amounts of radioactive isotopes to diagnose and/or treat diseases such as cancer and heart disease while providing information about structure and function within the body, is the next new diagnostic tool. Using radioisotope diagnostics, a doctor can gather medical information that would otherwise be unavailable, or require surgery or more expensive diagnostic tests. These imaging procedures are revolutionising the understanding and treatment of a range of conditions, often identifying abnormalities early on (Example 7).

Other developments that are expected to transform diagnostics in the medium term include:

- **Improved MRI imaging speed:** The introduction of MRI scans over 30 years ago revolutionised diagnostic medicine; the challenge now is improving imaging speed. MRI images in general (and dynamic MRI images in particular) can be highly compressible and provide flexibility in sampling patterns. MRI scans can therefore be accelerated by obtaining fewer samples and exploiting the compressibility of the underlying images for reconstruction. This offers a quicker way to take pictures of soft tissues by recording data randomly, drawing a sparse image and filling in the incomplete picture using algorithms. While still being perfected, it is already in use in a handful of clinics.
- **New tests for lung cancer:** Low-dose chest CT scans can detect lung cancers in high-risk populations (over 50s, heavy smokers) and lower cancer mortality. However, most 'positive' findings are benign (>95 per cent) necessitating expensive follow-up testing to identify who has a cancer. Several new, non-invasive and cheaper tests are being developed to help differentiate cancers from benign lung nodules. These include a new type of sputum analysis, a breath analysis, a blood test measuring certain tumour markers, a blood test looking for auto-antibodies and a standard PET/CT scan. Each of these tests has different sensitivity and specificity rates and it is not yet clear which is most effective.
- **Biomarkers:** Together with investigations of molecular indicators of a specific biological state, biomarkers are increasingly the focus of health research. Advances in molecular biology and progress in genomics and proteomics are driving new medical tests. Biomarkers can enable earlier or more definitive diagnosis, identify at-risk people, provide more precise prognosis, fine-tune treatment selection and deliver personalised medicine.
- **Systems biology:** This is considered promising for the future of science and medicine but currently has limited practical solutions. Ten years after the successful completion of the Human Genome Project, biologists and chemists are working together to create a comprehensive model of biological systems. This project is at the limits of analytical science and computational resources. Identifying new uses for microfluidics and nanotechnology is increasingly important, as is extending computational techniques to enable computer modelling to achieve unique insights and understanding.



# Part 4. Innovation as a lever to improve early diagnosis

Technology and innovation are two of the main drivers of improved productivity.<sup>95</sup> While the UK has been successful in developing new technologies, levels of uptake have been low compared with countries such as Switzerland, Canada, Sweden and Norway.<sup>96,97</sup> In 2011, the UK ranked 16th in Europe in per capita spend on medical technology, below the European average.<sup>98</sup> While improving diagnostics is dependent on more efficient and effective use of existing equipment (Part 3), it also requires more rapid uptake of new and more cost-effective technology.

This part of the report highlights the policy initiatives and structural and operational changes that, if adopted, could help improve access to diagnostics in the longer term. It also identifies further actions that could lead to improvements in the shorter term.

## **New policy initiatives to promote the uptake of innovation at scale**

In December 2011 the Department of Health launched 'Innovation, Health and Wealth: Accelerating adoption and diffusion in the NHS' (IHW), in recognition of the need to address the UK's poor record in adopting, commercialising and implementing innovative practices at scale. This strategy aims to address concerns over lack of transparency and accountability in the innovation landscape, variable compliance with NICE technology appraisals and confusing layers of organisations acting as gateways between the NHS, academia and industry.<sup>99</sup>

The Department of Health expects the IHW strategy to provide impetus to increase the adoption of innovation at pace and scale throughout the NHS, including equitable access to valued state-of-the-art medical innovations in all parts of the country.<sup>100</sup> Launched alongside the government's ten-year 'Strategy for UK Life Sciences', its goal is to strengthen the UK's health and life sciences sector based on collaboration between academia, the NHS and industry.<sup>101</sup> Indeed, the Department of Health suggested that innovative medical products should be able to fulfil the goal of NHS productivity savings of £20 billion by 2014-15 on their own. Also, the sooner life-limiting and chronic conditions are detected, the easier (and in principle cheaper) they are to treat.<sup>102</sup>

One year on, the Department of Health's December 2012 progress report highlighted a number of actions underway. The two actions likely to provide the biggest organisational changes in support of the adoption of innovative diagnostics are:

- engaging with the 15 Academic Health Science Networks to align education, clinical research, informatics, innovation, training and healthcare delivery
- streamlining the NICE compliance regime to reduce variation and strengthen compliance with technology assessments.<sup>103</sup>

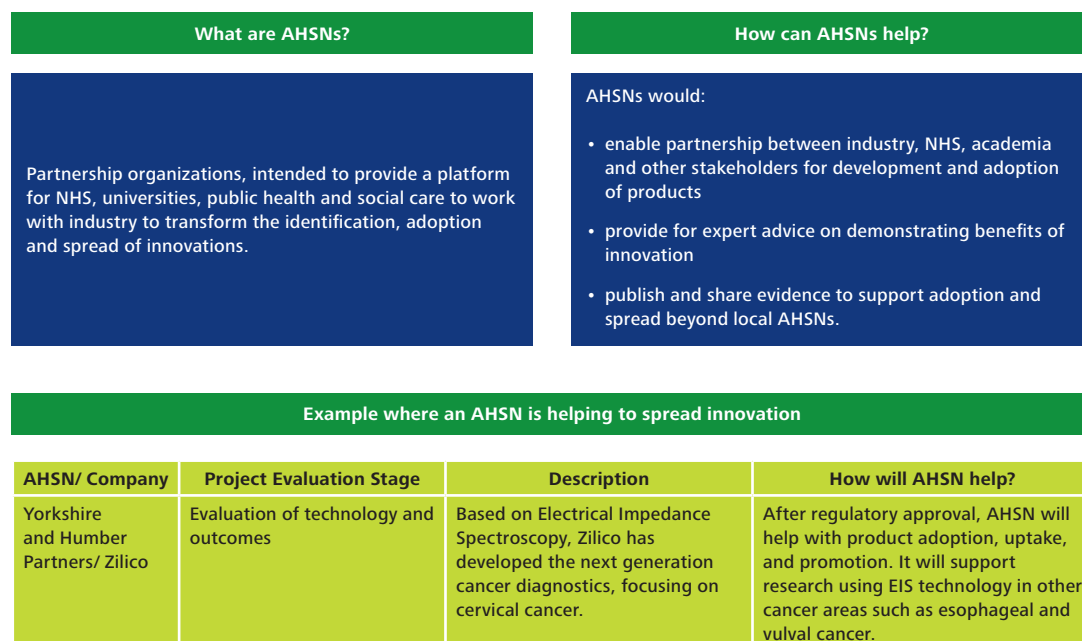
In addition, the Health and Social Care Act 2012 established a new statutory duty for CCGs and NHS England to promote innovation. Local initiatives to encourage uptake of innovation, including innovative diagnostics, are also being introduced. The resulting infrastructure to support the wider adoption and implementation of innovation is expected to be transparent with clear roles, responsibilities and accountabilities.<sup>104</sup>

## **Academic Health Science Networks could be a key driver of uptake of new diagnostics**

IHW identified the need to develop strong, cross-boundary networks, proposing the establishment of AHSNs aimed at providing the bridge between industry, the NHS, relevant arm's-length bodies and academia, especially with regard to innovation (Figure 7).<sup>105</sup> The expectation is that AHSNs will focus on different types of innovation (biomedical, information, service and business) at all stages of the process and support the spread of high-impact innovations, especially nationally-designated technologies.<sup>106</sup>

AHSNs have been established under a five-year licence as locally-owned, partnership organisations based on an incorporated model (such as companies limited by guarantee or community interest companies). They are led by a corporate board with an independent chair and accountable officer. The NHS and the medical technology industry have welcomed this as an opportunity to identify new, innovative ways of working. For the industry, a key attraction is the single point of access into the NHS. AHSNs are expected to be familiar with the medical technology development processes and to maximise the potential of partnering with medical technology companies to understand emerging innovations.<sup>107</sup>

**Figure 7. The role of Academic Health Science Networks**



Source: Deloitte review of NHS England's announcement of decision to designate 15 AHSNs, May 2013 and Yorkshire and Humber Academic Health Science Network case studies.

The 15 designated networks were announced by NHS England in May 2013. A total of £70 million has been set aside to support AHSNs in the first year, with individual networks receiving between £2 million and £7 million depending on their business case, local population size and costs associated with their areas of focus. Business cases are wide ranging and target areas such as alcohol-related conditions, cancer, dementia, genetics, information management and patient safety.<sup>108</sup>

The lack of consistent evaluation is currently a key barrier to entry for the industry, especially for smaller companies. The AHSNs will be expected to be a gatekeeper for this process, possibly by providing a certificate of approval for use by the NHS to avoid individual hospitals undertaking separate tests.

### Streamlining the compliance regime for technology evaluation to improve adoption

Response to the consultation IHW identified the multiple evaluations of the same technology occurring across the NHS as inefficient, time-consuming and draining on industry resources. A small comparative study also revealed poor compliance with guidelines in NHS Trusts.<sup>109</sup> The IHW strategy confirmed that the innovation landscape lacked transparency and accountability, with variable compliance with NICE Technology Appraisals (TAs), and confused and cluttered layers of organisations seeking to serve as gateways for interaction between the NHS, academia and industry partners. Value for money and innovation were not a central priority throughout the system. IHW committed the NHS to establish a NICE compliance regime to ensure rapid and consistent implementation of NICE TAs throughout the NHS. That regime was introduced in January 2012, including a new requirement, set out in the Operating Framework, binding the NHS to comply with NICE TAs.<sup>110</sup>

Given the difficulties in proving impact, NICE has established the Diagnostics Assessment Programme (DAP). This is designed to assess innovative diagnostic tests and techniques where evaluation is complex and can only be made on the basis of clinical utility and cost-effectiveness, and where improving health outcomes is likely to be associated with increased overall costs. When diagnostic technologies offer similar health outcomes but at lower costs, or improved outcomes at similar costs, they are evaluated by the NICE Medical Technology Evaluation Programme. Although still early days, DAP is expected to encourage the NHS to adopt cost-effective technologies more rapidly and consistently.<sup>111</sup>

NICE has also been commissioned by NHS England to take over the work of the NHS Technology Adoption Centre (established in 2007). The Health Technologies Adoption Programme will develop 'adoption packs' for introducing specific technologies into routine clinical use in a sustainable manner. NICE will also produce around 40 medical technology innovation briefings per year to boost adoption throughout the health service. These will outline new products and summarise evidence of clinical impact and cost-effectiveness.<sup>112</sup>

### Better use of new technology will improve early diagnosis

Radically altering the way the NHS operates and overcomes barriers to innovation will require the transformation of structures, processes, cultures and behaviours. It will also take time, and time is a luxury that neither patients nor the NHS can afford.

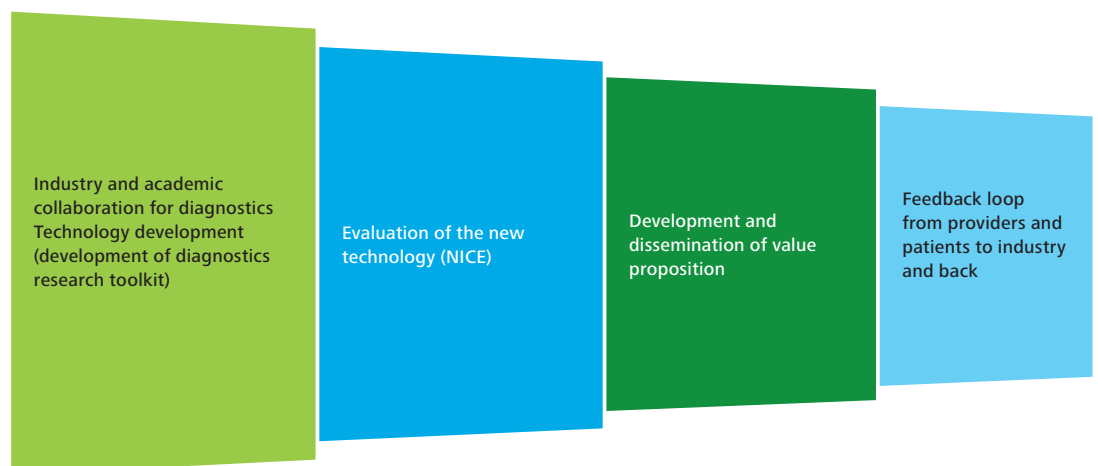
As highlighted in Part 3, many technological advances in tests and devices that were previously only accessible in laboratory or hospital settings are now available as point-of-care tests or even for self-testing by patients. In addition, clinicians and patients now expect to receive an accurate diagnosis more quickly. Getting more for less is not about finding the cheapest solution, but entails matching the right treatment to the right patient at the right time while reducing the need for cost-intensive services. It means diagnosing early and providing treatment at the earliest opportunity.

There is a danger that in response to financial austerity, spending on medical technologies becomes an easy target for cost cutting but, as the evidence in this report shows, this would be a retrograde step. A better strategy would be to encourage use of new diagnostic technology to help staff, who account for 70 per cent of health spending, to work differently. This would not only represent better value for money, but would also be advantageous for patients.

### Further actions to help deliver an earlier diagnosis

NHS commissioners and providers need to work differently with each other, with industry and other private and third sector providers to develop a new diagnostic innovation pathway that has the patient's interest as the unifying principle (Figure 8).

**Figure 8. The diagnostics innovation pathway**  
The use of a diagnostics innovation pathway can help improve early diagnosis of disease



Source: Deloitte research



Within this diagnostic pathway there are a number of specific actions which participants might prioritise:

**Policy makers should develop new approaches to funding diagnostic services to support the adoption of new diagnostic pathways.** Innovation is undermined by the NHS's silo-based funding structure. Consideration of the development of tariffs for imaging and IVD testing should be expedited and the benefits or otherwise of introducing a value-based pricing system, similar to that proposed for the pharmaceuticals industry, should be considered.

**Providers and commissioners should collate evidence on the financial and operational performance of diagnostic services in order to deliver efficiency and productivity savings.** There is a need to develop a robust understanding of the value for money of existing imaging and IVD services including working together to collect and collate data on running costs, utilisation rates, waiting times and benchmark the performance data. Commissioners should also look at ways of improving communication between GPs and specialists.

**Commissioners should identify effective ways of reducing the barriers preventing new players entering the market.** Contracting should support the development of a culture that respects and rewards innovative methods of delivering high quality diagnostics.

**Commissioners should collect and collate information on patient outcomes and user experience in obtaining a diagnosis to inform evaluations of GP referral practices and provider performance.** In particular they should investigate and seek to reduce variations in referral practice and patient outcomes.

**Commissioners and providers should see patients as the ultimate judge of what works best in terms of access to diagnostics and the timeliness of diagnosis.** They should encourage patients and patient groups to provide timely feedback on their diagnostic experience, using social media, NHS websites and patient-led forums.

**Providers need to work with the diagnostic industry to help tackle the lack of availability of suitably trained diagnostic staff.** Providers need to adopt new staffing models, including partnership working with industry to tackle this challenge. Further developments could include training more technicians to do the testing, supported by agreed governance and quality standards.

**NHS procurement organisations need to help the diagnostic industry to improve their understanding of NHS procurement processes.** They should help healthcare providers identify a single point of contact for industry, and develop a register of procurement officials for each hospital.

**The diagnostic industry should work with providers to develop research evidence on the performance of new diagnostic technology.** Industry should work with providers to capture the real time impact of new diagnostics on downstream costs. Industry groups should support the development of business cases and help providers understand how they might use new technology to work differently, including providing staff and patient education programmes.

**Policy makers should expedite the implementation of the Carter recommendations on the reorganisation of pathology services.** Now that the NHS reforms have had time to bed down, NHS England should consider how to ensure the implementation of the report recommendations so as to realise the savings identified. It should also help clarify the position with regard to the potential challenge by the Office of Fair Trading.

**ASHNs need to work collaboratively to help spread innovation and enhance patient experience.**

ASHNs need to become change agents and adopt effective communication and engagement strategies and engage the diversity of the whole network. If AHSNs are to serve as an effective gateway to the life sciences industry they should provide a single point of entry for the industry and co-operate rather than compete with each other to encourage the adoption of evidence based innovation. ASHNS should also work collaboratively with NICE and lend support to NICE's new compliance regime for technology innovation.



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