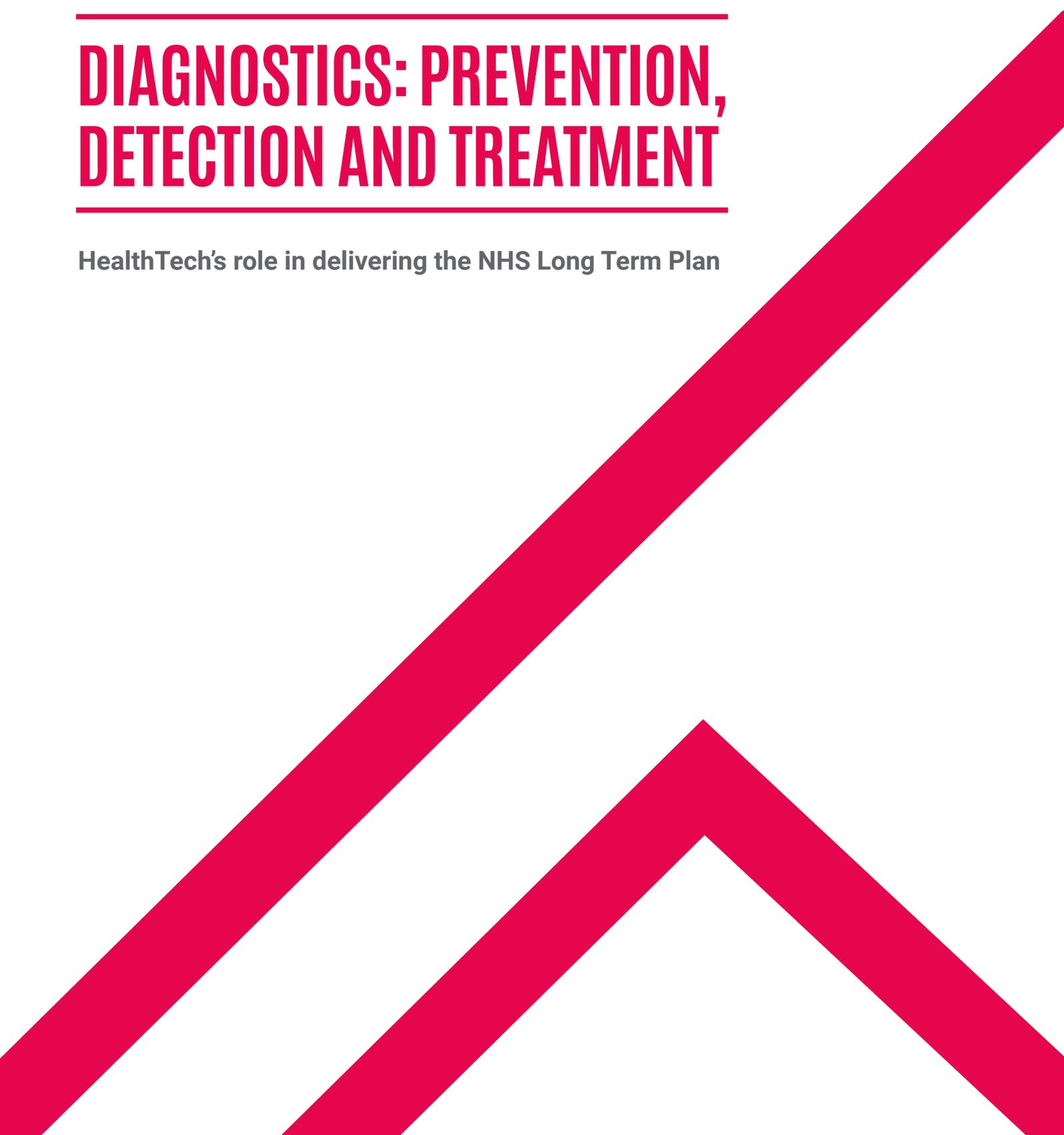


ABHI

DIAGNOSTICS: PREVENTION, DETECTION AND TREATMENT

HealthTech's role in delivering the NHS Long Term Plan



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EXECUTIVE SUMMARY

Diagnostics are integral to the delivery of modern healthcare. With the appropriate level of investment and support for the sector, the industry will continue to improve patient outcomes and NHS efficiency.

The sector is key to achieving the aims set out in the NHS Long Term Plan, and technology adoption must be based on whole-system benefits.

This report sets out eight diagnostic technology case studies, that illustrate the ability of the sector to improve patient outcomes and deliver cost-savings to the NHS.

To maximise this potential, ABHI makes the following recommendations:

1. The enhancement of diagnostic capabilities should be considered as a priority for NHS capital spending.
2. The development of a dataset to highlight variation in the use of diagnostic tests and the resulting impact on patient outcomes.
3. Training and upskilling of commissioners and system leaders in the scope and impact of diagnostics.
4. Whole systems savings identified as a result of investment in diagnostic services are re-invested in those service.

To support these recommendations, we encourage the establishment of a Diagnostics Working Party, including, but not limited to, industry, the NHS and appropriate Royal Colleges. The Working Party would drive the development of a holistic diagnostics strategy. Such a strategy should ensure that the use of diagnostic technology is considered across the entirety of patient pathways and supports the use of data to improve outcomes and system efficiency.

INTRODUCTION

The UK's health technology industry is now the largest employer in the broader Life Sciences sector, employing 127,400 people in 3,860 companies, with a combined turnover of £24bn¹. The industry has enjoyed growth of around 5% in recent years. A critical component of the sector is the field of diagnostics.

Incorporating technologies such as imaging, radiology, ultrasound, laboratory-based pathology sensors, specimen collection, near-patient biomarker testing and digital data systems, diagnostics are critical to the delivery of modern healthcare. The industry has significant impact, with pathology alone employing 25,000 staff, costing the NHS around £2.5 billion a year² and the UK performing over 45 million imaging procedures annually³.

By setting individuals on the correct treatment pathway, an early diagnosis can significantly increase the chances of a positive clinical outcome, as well avoiding inappropriate treatment and costs. The technologies also play an important role in a patient's ongoing care programme, enabling continuous monitoring and self-management.

An ageing population, lifestyle changes and a rise in obesity have all led to an increase in conditions such as cancer, stroke, heart disease and diabetes⁴, all areas which can be supported or

prevented through early and regular use of diagnostics. Despite widespread recognition of their value, diagnostic services have suffered from chronic underinvestment by the NHS⁵. The situation is exacerbated by traditional budgetary silos, making it difficult to justify investment in one part of the system if the benefits are realised elsewhere.

Lack of up-front investment has been a persistent and significant problem for the NHS, and has meant that potential savings and efficiencies have not been realised. A holistic approach must be considered when procuring products, with whole-system benefits and patient value the primary factors for consideration.

Technology continues to provide health care professionals with new ways of improving the quality of care a patient receives, and much of this stems from early and accurate diagnosis⁶. The Long Term Plan⁷ provides the NHS with the opportunity to recognise this through a coherent approach to investment and purchasing, and an appreciation that investment in diagnostics is also an investment in the health of our nation.

NHS LONG TERM PLAN

In January 2019, the NHS published its Long Term Plan (LTP), setting out exactly how the additional £20.5bn committed to the NHS over the next five years will be allocated. The LTP has a strong focus on evidence-based prevention, cemented through the publication of the Prevention Green paper, "Advancing our health; prevention in the 2020s"⁸.

Many of the changes recommended by the LTP and the Prevention Green Paper are underpinned by a need for faster, more accurate diagnosis delivered by the better use of technology. 2019 has seen a roll-out of new Rapid Diagnostic Centres⁹ across the country, presenting the possibility of significant investment in diagnostic hardware. Historically, long-term investment into high-cost equipment that produces savings over several years, has been side-lined in favour of a more short-term, transactional method¹⁰. The NHS now has the opportunity to fundamentally change this approach to technology procurement, with industry ready to work in collaboration.

The LTP also commits to improving the Bowel Cancer Screening Programme¹¹, detecting cancers earlier through lowering the screening age from 60 to 50. Actions are also in place to improve the detection of respiratory¹² and cardiovascular disease¹³, as well as diabetes¹⁴ and stroke¹⁵ services. All of the measures deliver significant benefits for patients, whether they are diagnosed with a disease or not. For those with a positive diagnosis, potentially life-saving treatment can begin, whilst those without can continue to lead a healthy life.

Highlighted in the LTP¹⁶, and frequently referenced by NHS leaders¹⁷, are issues surrounding workforce. It remains, the single biggest challenge for the NHS, with a reported 100,000 staff vacancies¹⁸ exacerbated by increased demand on the service. Technologies that diagnose early, when used appropriately, can alleviate such strain.

The LTP has been warmly received by industry, with the commitment to diagnostic technologies a welcome move. The Prevention Green Paper goes into further detail about how improved diagnostics, supported by data can help deliver the ambitions laid out. It is vitally important then, that money committed to the Plan is carried through into action, and not diverted to correct longstanding problems within other parts of the service. Industry remains committed to supporting the LTP's implementation through the provision of high-quality diagnostic technologies aimed at prevention and accurate diagnosis.

The following case studies have been provided by ABHI members, with each example supporting the aim of the LTP, i.e. to further improve the delivery of the screening programmes, increase uptake and learn the lessons from the recent issues around breast and cervical screening, and modernise and expand diagnostic capacity. For each case study, the current situation is detailed and suggestions are made as to how technology can help.

CASE STUDY 1

TRANSNASAL ENDOSCOPY

NHS Long Term Plan Aim



The LTP has laid-out a strong commitment to the improvement of cancer services, with ambitious targets in place to increase survival rates. The government has also reaffirmed its pledge to lower the bowel cancer screening age by ten years, from 60 to 50 in England, alongside the adoption of the much-awaited faecal immunochemical test (FIT)¹⁹. In order to turn this vision into a reality, however, an overhaul of diagnostic services is required.

The Current Situation



The current demand for upper and lower gastro-intestinal endoscopy services alongside pathology, which provides key diagnostic tests for cancer, is incredibly high and continues to increase²⁰. This is also coupled with a serious lack of capacity to match the need both in infrastructure and staffing, leading to a knock-on effect on waiting times. Many patients are currently waiting too long between being referred and undergoing diagnostic testing – a situation unlikely to improve without adequate capacity. Scotland currently screens bowel cancer from the age of 50 to 74 using the FIT which improves the chances of an early diagnosis²¹. Imminent adoption of the FIT test in England has the potential to detect more early stage cancers than the current screening test and will likely place additional demands on endoscopy services when introduced throughout the rest of the UK.

Technology Overview



One way to help ease the burden on endoscopy services, and meet this LTP aim, is through the introduction of a Transnasal endoscopy service. An alternative to conventional oral gastroscopy, Transnasal endoscopy utilises a super slim scope which can be inserted through the nose, avoiding the gag reflex and making the procedure more comfortable for patients²².

How Technology Can Help



A Transnasal procedure requires minimal, or in the majority of cases, no sedation, enabling quicker patient recovery and reducing personal inconvenience. This also leads to an increase in throughput, allowing the hospital to carry out more gastroscopies per session, reducing cancer waiting lists and freeing-up procedural time and resource for more complex procedures. Transnasal service can also be delivered in an outpatient setting; this presents an opportunity to free-up vital clinical space within the dedicated endoscopy unit. As a result of changing the clinical setting, a trust can prioritise more urgent cases, which could also ease waiting times. A further benefit associated with outpatient Transnasal services is the potential to upskill and champion the role of Nurse Endoscopists. With the challenge to maintain staffing levels, Nurse-Led Transnasal services could have a positive impact on the cancer outcomes laid-out in the LTP. Setting up a Transnasal service is quick and involves no significant infrastructural changes, allowing redistribution of resources to not only help meet waiting times but make significant savings for individual trusts.

CASE STUDY 2

FLOW CYTOMETRY

NHS Long Term Plan Aim



The LTP states that by 2021, pathology networks will deliver quicker test turnaround times, improved access to more complex tests and better career opportunities for healthcare scientists at less overall cost²³. A collaborative approach, facilitated through the adoption of diagnostic technologies, will be critical to supporting this objective.

The Current Situation



Pathology in the UK is facing considerable challenges – from rising demand, to delivering near-term national savings of over £200 million²⁴. Consolidating the provision of services into a 'hub-and-spoke' model is expected to deliver sustainable savings and greater flexibility to meet future needs. In this model, the 'hub' laboratories serve as centres for handling specialised and non-specialised analyses across providers and the 'spoke' labs afford the necessary on-site services and capability for the turnaround of essential point-of-care tests.

With an ageing population and new diagnostic tests, volumes are expected to rise year-on-year when there are already significant stresses on laboratory capacity, processes and staff. It is unlikely that incremental improvements in current processes will be sufficient to cope with the future system needs.

Technology Overview



The laboratory team at Addenbrooke's Hospital, Cambridge has demonstrated how a collaborative approach to meeting future needs can help. As a regional specialist centre for the analysis of haematological cancer, samples would arrive from a wide geography at unpredictable times. Complicated multi-step sample preparation procedures and running multiple batches requiring time critical attention could all lead to risk of error.

Working closely with industry, the team, scoped-out the use of new technologies to improve their processes. One such test programme trialled flow cytometry equipment, which is

comprised of a sample preparation unit linked to a sample analysis unit. During the trial, the equipment reduced the number of manual processing tasks by 67% (from 49 to 16) and reduced the number of critical error prone steps (errors that could affect the patient) per run by 100% (from 25 to 0)²⁵. The sample processing time and in particular the variability in time to results was reduced, alongside significant improvements in sample, reagent and process traceability with a shift from paper to electronic records helping meet KPI and ISO compliance. The solution proposed also freed staff time to focus on more patient-centric care – diagnostics not paperwork.

How Technology Can Help



Technology and automation are essential to deliver the improved laboratory capacity, productivity and flexibility that healthcare providers need. With diagnostic services underpinning the treatment choices for the vast majority of patients, getting the future design of services right will be key to ensuring the safe, efficient and sustainable delivery of healthcare. Ongoing collaboration and joint development between diagnostic service providers, healthcare professionals and industry will be essential.

CASE STUDY 3

INTEGRATED POINT OF CARE TESTING

NHS Long Term Plan Aim



The LTP outlines several important changes to the way the NHS should work to support patients and their carers. Improving care for older people living with frailty or multiple long-term conditions is one of its priorities.²⁶

It also includes that there should be reforms to hospital emergency care – or Same Day Emergency Care with new diagnostic and treatment practices allowing patients to spend just hours in hospital, rather than being admitted to a ward.²⁶

Integrated point-of-care testing devices are well suited to increasing patient involvement and reducing the patient's perceived sense of waiting.²⁸ The use of point-of-care testing can expedite care, relieve burden on emergency services and reduce hospital admissions.

The Current Situation



Between 5% and 10% of all people attending the Accident and Emergency Department (A&E) and 30% of patients in acute medical units (AMU) are older people with frailty.²⁹

Rising patient demand across urgent and emergency care services means increasing admissions impact on patient flow in A&E, increased bed occupancy and outlying patients across the hospital with an inevitable negative impact on patient outcomes and experience and increased length of stay. Trusts need support to improve quality, effectiveness and productivity across acute frailty care pathways.³⁰



Technology Overview

Point-of-care diagnostics gives rapid results, enabling frailty patients to be treated within 30 minutes of arriving at hospital.³¹ Advanced, easy-to-use blood analysers provide a broad range of real-time, lab quality results within minutes. Accelerating the patient care decision-making process, these systems make patient testing fast, easy and accurate. They operate with the advanced technology of single-use test cartridges allowing rapid treatment decisions, which lead to enhanced quality of care and improved system efficiency.

Oxford University Hospitals NHS Trust established an Emergency Multidisciplinary Unit (EMU) in 2012. Supported by point-of-care testing, over 60% of patients are managed in the EMU on a purely ambulatory path, eliminating the need for a hospital bed. The care process in the EMU is personalised – tailored to risk, patient and carer preference. With the average patient age of 80, point-of-care diagnostics fulfils these requirements.³²

How Technology Can Help



The introduction of rapid diagnostic testing, facilitated by point of care testing, reduces admissions and length of stay for patients. It also supports early discharge, decreases emotional distress and risk of infection and lessens disruption with care package delays.

CASE STUDY 4

SINGLE OPERATOR CHOLANGIOSCOPES

NHS Long Term Plan Aim



Within the LTP, cancer care and a quicker diagnosis are highlighted as a clinical priority³³. To achieve this a new faster diagnosis standard will be introduced from 2020 to ensure most patients receive a definitive diagnosis within 28 days of referral. Technologies with improved diagnostic capabilities will help achieve this aspiration.

The Current Situation



There are currently around 2,400 bile duct³⁴ and 10,000 pancreatic cancers³⁵ diagnosed in the UK each year. Both forms of cancer are typically difficult to diagnose and treat due to lack of symptoms in the early stages of disease. These particular diseases often require multiple investigations to deliver an accurate diagnosis.

An endoscopic procedure called endoscopic retrograde cholangiopancreatography (ERCP) is an important component of this diagnostic pathway. ERCP is frequently used to evaluate suspected cancers of the bile or pancreatic duct and a specific technique called brush cytology is used during the procedure to obtain small tissue samples for testing. Only 46% of patients receive a definitive diagnosis using these techniques³⁶ and require repeat procedures to confirm a diagnosis, placing additional burden on endoscopy services and hospital waiting lists. This uncertainty may also increase patient anxiety and delay treatment, which could compromise outcomes.

Technology Overview



Single operator cholangioscopes can be inserted directly into the bile or pancreatic ducts during any ERCP procedure. They have an integrated digital camera that enables the clinician to directly visualise and assess suspicious lesions and perform a targeted biopsy using specific forceps; which collectively deliver high diagnostic accuracy ranging from 85% to 94%³⁷.

How Technology Can Help



As demand for hospital services increase, technologies that enable clinicians to manage their patients in a more efficient manner will help providers meet these growing needs and improve patient care.

The use of single operator cholangioscopes in suspected pancreas or bile duct cancers may reduce the need for additional testing and repeat procedures compared to traditional ERCP, thus lessening the burden on endoscopy services and reducing associated costs. Single operator cholangioscopes may also enable faster, more definitive cancer diagnosis enabling patients to receive treatment sooner.

CASE STUDY 5

HEART FAILURE BIOMARKERS

NHS Long Term Plan Aim



Improved heart failure management is key to better patient outcomes and quality of life. The LTP has identified this through focussing on better supporting multi-disciplinary teams and improved early assessment³⁸. However, fulfilling these goals is challenging when considering current resources, staffing levels, required system changes and the increasing prevalence of heart failure. Diagnosis and management of the condition through the measurement of natriuretic peptides can play an important role in delivering a high quality and cost-effective service.

The Current Situation



Heart failure affects more than 580,000 people in the UK, with many thousands more remaining undiagnosed estimated to be 920,000 in total.³⁹ The condition incurs high costs to the NHS, accounting for approximately two per cent of the total NHS budget – estimated at £2 billion and one million patient bed days, annually.^{40,41}

Heart failure was the cause of over 73,000 emergency hospital admissions in 2017/2018⁴² and acute heart failure is the most common cause of admissions in people over 65.⁴³ With an ageing UK population, the number of admissions for heart failure is predicted to rise.⁴⁴ However, tests already exist which could play a significant part in the early diagnosis of people with suspected heart failure and also to the costs incurred by the NHS.

Technology Overview



Heart failure biomarkers are an important aid in the diagnosis of individuals suspected of having congestive heart failure. They support clinical decision making at every stage of care, with gold standard heart failure biomarkers noted for their powerful prognosticator ability, regardless of therapy.

How Technology Can Help



Heart failure biomarkers can accurately provide objective information to support clinical decision making from diagnosis to monitoring, delivering improved care for every heart failure patient. Testing in secondary care alleviates pressures on consultants by reducing the amount of echocardiograms⁴⁵. Cardiology teams are stretched and there are not enough echocardiographers to meet patient demand, but advanced heart failure biomarker testing reduces the need for unnecessary and inappropriate echocardiograms.

The laboratory and point-of-care test equipment to run natriuretic peptide testing is widely available in labs in the UK but not yet optimally utilised.

CASE STUDY 6

MRI COMPRESSED SENSING

NHS Long Term Plan Aim



The LTP states that “capacity in diagnostic services has not kept pace with the growth in demand. We (the UK) have fewer MRI and CT scanners per capita than most OECD countries.”⁴⁶ Yet, the number of patients referred for diagnostic testing continues to rise. Technological advances and the appropriate investment that provides high-quality results more quickly will underpin the new model of diagnostic provision.

The Current Situation



The number of MRI scans performed annually in England continues to grow⁴⁷, which is compounding pressures on radiologists. Figures suggest that their workload has increased by 30% in recent years⁴⁸. There is also an ongoing nationally recognised shortage of diagnostic radiographers, particularly those specialising in MRI and CT^{49,50}. This increased workload is having detrimental impacts on the radiology workforce, with radiologists and radiographers showing signs of stress and burnout in part due to longer working hours, a factor in taking an early retirement or a change in career.⁵¹ The use of MRI is predicted to increase further, due to an increase in chronic conditions.

This underlines a need for increased efficiencies in imaging services in the UK.

Technology Overview



Since its introduction, magnetic resonance (MR) has been challenged by the time needed to reach a diagnosis. Today, the imperative to shorten MR examinations without reducing image quality has become even more urgent due to the increase in chronic conditions and an increase in productivity is therefore critical.

Compressed sensing is a signal processing technique built on the fact that signals contain redundant information. In magnetic resonance this technique is used to reconstruct a full image from severely under-sampled data) more quickly, whilst maintaining high image quality.

How Technology Can Help



The latest advanced systems deliver better image quality, even for challenging patients, and perform MRI examinations up to 50%⁵² faster with acceleration for all anatomies in both 2D and 3D scanning. Furthermore, immersive audio-visual experience is delivered to calm patients and guide them through the scan.

Through advanced compressing sensing, radiographers and radiologists can accelerate their imaging examinations while maintaining image quality. This approach increases productivity, precision and diagnostic confidence, whilst delivering an enhanced patient experience.

CASE STUDY 7

BLOOD CULTURE INCUBATOR

NHS Long Term Plan Aim



Through the LTP, the NHS will accelerate action to achieve 50% reductions in neonatal mortality by 2025.⁵³ Technologies that support the timely availability of results for neonates are therefore critical in both identifying potential issues and enabling patients to be appropriately discharged, freeing-up bed space.

The Current Situation



At present, early onset neonatal sepsis is a significant cause of neonatal mortality and morbidity⁵⁴. The early initiation of antibiotics in babies suspected of having the condition is critical. Once 36-hour blood culture results are available, and provided that the neonate remains well with reassuring C-reactive protein levels, antibiotics can be stopped. Delays in the availability of 36-hour blood culture results can lead to prolonged and unnecessary hospital stay of clinically well neonates and their mothers who have been started on antibiotics because of risk factors and have reassuring CRP levels. These delays have been put down to two main reasons:

- > **Delayed transportation** (Non-specific and variable collection times dependant on availability of hospital porters)
- > **Blood cultures not placed in incubators out of hours** (Lack of on-site microbiology staff out of hours to place samples in the incubator).

Technology Overview



Blood culture incubators can be utilised to eliminate these delays. The system enables a vial-activated workflow that helps reduce hands-on time, identifies anonymous vials and utilises an interface with a LCD touch screen, status indicators and a barcode scanner at each module. The system allows blood cultures to be placed immediately into the incubator by clinicians taking the samples from the neonates. It provides data management with enhanced blood culture observation, in and out of the laboratory, helping reduce workflow interruptions and communicate preliminary or final results to caregivers.

How Technology Can Help



The introduction of the blood culture incubator within a neonatal unit enables the timely availability of results for neonates who are clinically well and awaiting results prior to stopping antibiotics and being discharged. This improves patient care through quick discharges from hospital, improved hospital bed turnover and antibiotic stewardship by preventing unnecessary prolonged antibiotic treatment. When introduced into a clinical setting, the use of a blood culture incubator has been proven to significantly reduce the median time of hospital stay by 20.4 hours.

CASE STUDY 8

RIGHT FIRST TIME URINE SAMPLE COLLECTION

NHS Long Term Plan Aim



At the heart of the LTP is the need to modernise and expand diagnostic capacity⁵⁵. From high-cost, capital equipment, through to the perceived 'simple' tests such as urine sample collection, the NHS must look at diagnostic capabilities right across the patient pathway.

The Current Situation



65 million urine samples are collected in the UK each year, with over 22% providing unreliable specimens⁵⁶. The cost of retesting failed specimens equates to over £113m, which rises significantly when taking account of staff time, administration and repeat resources⁵⁷. Yet unlike blood, there is no protocol around the urine collection process.

Global guidelines around the collection of urine for routine medicine specify that midstream is required⁵⁸. Because midstream is difficult to collect it is rarely requested or provided, leading to high urine specimen contamination rates and false positives - in turn, perpetuating failed analysis, diagnosis and treatment. Repeat testing and testing of false-positive specimens is a costly diversion for an already stretched NHS, leading to delayed treatment, repeat appointments and tests, unnecessary antibiotic prescribing and the development of more chronic and serious conditions. Siloed budgeting within the NHS also means that the buyer budget does not benefit from the savings, as these lie within microbiology.

Technology Overview



Right first-time urine collection systems guarantee the correct part of the urine stream for accurate analysis, diagnosis and treatment of routine conditions and antenatal screening. A device's funnel rejects the first 20ml of urine, causing a compressed cellulose sponge to expand and block the outlet. Midstream is then diverted into the specimen collection tube. When this is full a one-way valve prevents "bladder urine" from diluting the specimen.

How Technology Can Help



Right first-time urine analysis means that diagnosis and treatment is swift. Accuracy avoids the prescription of unnecessary antibiotics, costly repeat patient appointments and tests, UTI-related conditions and unplanned hospital admissions. With urine specimen contamination rates varying nationally, adoption can help in the reduction of national health inequalities and enable workforce efficiencies through right first-time results.

CONCLUSION

The examples provided in this paper detail just eight diagnostic technologies that, if widely adopted, could have a significant impact on patient outcomes and NHS efficiency. When we consider the wider HealthTech industry, and the thousands of diagnostic technologies within it, such products and services have the ability to revolutionise the way that care is delivered and equip the NHS with the tools that will ensure its sustainability.

There has, arguably, never been a more important time for the NHS to refocus its attention and reallocate its resources accordingly. The demographic changes in our population demand a radical shift in how we approach healthcare. Diagnostic solutions must be seen as a key enabler, rather than simply being perceived as an overhead cost. The NHS has outlined its commitment to prevention, and diagnostic technologies will be key to realising the aims set out in the LTP. Industry is committed to supporting this transformation.

In order to support the implementation of the NHS Long Term Plan and address the issues outlined in this report, we recommend that:

1. The enhancement of diagnostic capabilities should be considered as a priority for NHS capital spending.
2. The development of a dataset to highlight variation in the use of diagnostic tests and the resulting impact on patient outcomes.
3. Training and upskilling of commissioners and system leaders in the scope and impact of diagnostics.
4. Whole systems savings identified as a result of investment in diagnostic services are re-invested in those services.

To support these recommendations, we encourage the establishment of a Diagnostics Working Party, including, but not limited to, industry, the NHS and appropriate Royal Colleges. The Working Party would drive the development of a holistic diagnostics strategy. Such a strategy should ensure that the use of diagnostic technology is considered across the entirety of patient pathways and supports the use of data to improve outcomes and system efficiency.

HOW WE DEFINE DIAGNOSTICS

Example products categories are:

- › Imaging
- › In-vitro Diagnostics (e.g. blood and urine biomarker tests)
- › Endoscopy
- › Diagnostic radiation devices
- › Digital health technologies
- › Genomics

Adapted from: The Office of Health Economics (2019). *The Value of Knowing and Knowing the Value*.



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Association of British HealthTech Industries
Suite 2, 4th Floor, 1 Duchess St,
London, W1W 6AN

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+44 (0)20 7960 4360
enquiries@abhi.org.uk

www.abhi.org.uk

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