TRANSFORMATION AND GROWTH: THE HEALTHTECH EFFECT

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EXECUTIVE SUMMARY

Transformation and Growth: The HealthTech Effect is intended as a resource for policy makers, and is published as the UK simultaneously devises a Life Sciences Sector Plan, a 10 Year Health Plan, and an NHS Innovation and Adoption Strategy. This document has three elements.

Firstly, <u>a series of recommendations</u> across five high level policy areas designed to ensure the continued growth of the sector and help the NHS make best use of HealthTech.

Next, <u>clinical speciality specific considerations</u> in some of the areas in which ABHI members are active.

Finally, there is a <u>set of case studies</u> illustrating how HealthTech that is available now can help the NHS achieve its three shifts from hospital to community, analogue to digital, and treatment to prevention. Alongside each technology are examples of some of the barriers preventing optimal adoption.

INTRODUCTION

ABHI is the UK's leading industry association for health technology (HealthTech).

Members, including large multinationals and small and medium sized enterprises (SMEs), supply products and services from syringes and wound dressings to in vitro diagnostics, surgical robots, and the delivery of remote care. The sector partners with the health and care system to save and enhance lives. The potential that HealthTech offers the UK is vast. Newer technologies such as AI, 3D printing and robotics underpin exciting and important developments in prevention, earlier and more accurate diagnosis and precision medicine. More traditional HealthTech continues to enable high-quality, cost-effective care for millions of NHS patients every day, and the use of these technologies needs to be optimised if we are to realise operational efficiencies and tackle some of the most pressing challenges facing the NHS, such as the elective backlog. HealthTech is also a significant contributor to the UK's economic growth. As the largest employer in the broader Life Sciences sector, HealthTech employs 154,000 people in 4,465 companies, with a combined turnover of £34bn.

The industry has enjoyed growth of around 5% in recent years. It is characterised by a very large number of small companies, start-ups, and spinouts, supporting the creation of high-quality jobs and sizeable manufacturing and R&D activity across the UK. However, data demonstrates that whilst there is significant positivity about the opportunity that HealthTech provides, the reality today is that significant barriers are limiting patient access. In 2024, <u>over a third of the sector</u> is prioritising regulatory approvals in other markets before the UK, half of companies are continuing to delay bringing innovation to the UK and a third of companies have removed existing products form the UK market. It also shows that for the third year in a row, the HealthTech sector is increasingly viewing the US as the most attractive market globally, and most notably in creating a regulatory environment that encourages investment and innovation. Increasingly, UK patients are receiving the benefits of HealthTech innovations later than those in other countries.

The UK has the opportunity to become a world leader in the evaluation, development and deployment of HealthTech, but we must do things differently to ensure it is our patients, clinicians and economy that benefit.

HEALTH WEALTH AND GROWTH:

A Sector Strategy to transform the economic and societal benefits of UK HealthTech

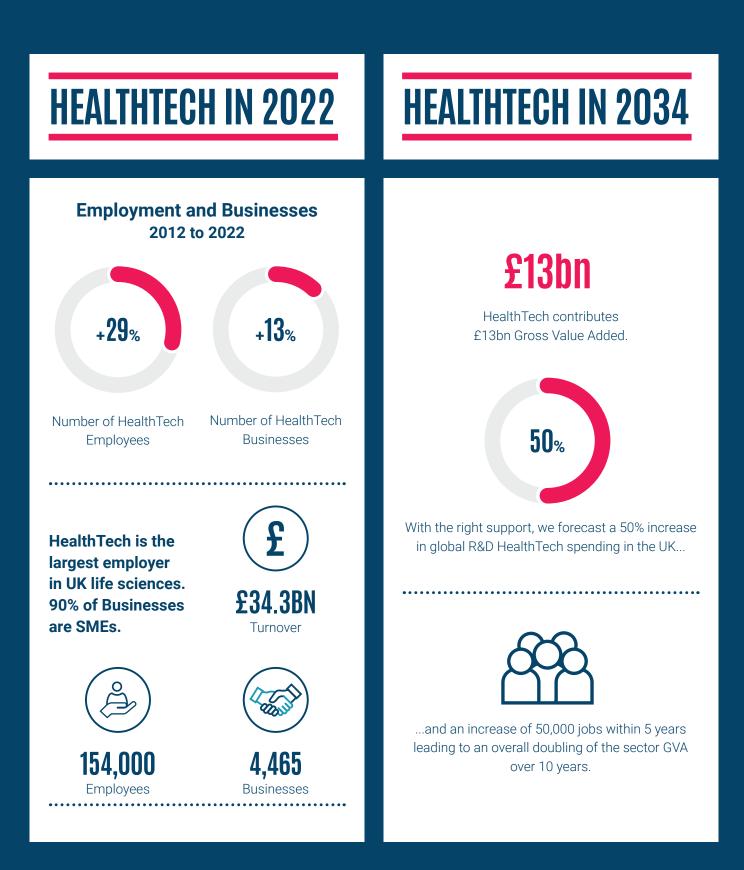
ABHI collaborated with the Imperial Centre for Sectoral Economic Performance to undertake an in-depth exploration of bold policies designed to unleash the potential of HealthTech as a pivotal driver of UK economic growth.

The report highlights HealthTech's substantial economic impact, equating its Gross Value Added (GVA) to that of the biopharmaceutical sector at £13bn. However, the growth potential of HealthTech is currently constrained by capital and skills shortages, compounded by uncertainties arising from Brexit. To address these challenges, the report proposes a series of targeted policy measures to bolster investment, including tax incentives, regulatory reforms, and fostering closer collaboration with the NHS to accelerate the adoption of innovations.

Key initiatives proposed include the recognition of product approvals from trusted international jurisdictions to streamline regulatory processes, tax reforms to enhance R&D investment, the establishment of a formal network of support to increase productivity, and the expansion of ABHI's <u>international</u> <u>accelerator</u> programme to boost exports. These measures are designed to enhance collaboration with the NHS, foster innovation, and drive economic growth within the UK HealthTech sector, and outline how industry itself can contribute to and drive an industrial strategy.

The report presents a clear vision for the future, outlining short, medium, and long-term policy recommendations that, if supported effectively, can significantly enhance efficiency and innovation in NHS healthcare delivery, while positioning the UK as a global leader in HealthTech. It projects a 50% increase in R&D spending, the creation of 50,000 new skilled jobs, and a potential doubling of the sector's GVA within the next decade.

The report not only sets out a robust industrial strategy for HealthTech but also presents a methodology for developing this strategy from the ground up, with industry leadership and government support.



THE HEALTHTECH EFFECT

In September 2024, Lord Darzi published his report on the performance of the NHS in England. It laid bare the challenges that are currently faced by the NHS but also made clear the opportunity, indeed the necessity, for the UKs health and care system to embrace technology. Subsequently the Prime Minister outlined the three shifts required within the NHS: hospital to community, analogue to digital and treatment to prevention. The Prime Minister has confirmed that the number one mission of this government is growth.

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As recognised by Lord Darzi, "The HealthTech industry will be pivotal to realising this potential. The Independent Investigation provided identified key themes on how the NHS can be resuscitated to bring health back into people's lives and the UK's economy. Shifting paradigms from management of disease to enable wellbeing will empower patients to fulfil their personal end economic potential. Moving care out of hospitals and into primary care will reduce inequality and improve access. Digitalisation will build health systems able to adapt to and overcome challenges as they arise. The HealthTech sector is uniquely positioned to be the convening force that draws full value out of these themes."

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The upcoming development and implementation of the <u>10 Year Health Plan</u>, the <u>Industrial Strategy and Trade Plan</u>, and associated Life Sciences Sector Plan all provide a once-in-a-generation opportunity to achieve this. Transformation and Growth: The HealthTech Effect collates ABHI's input into these initiatives, drawing on sector wide policy reform opportunities, and those in specific sub sector or clinical specialities, providing a complete blueprint for how to ensure HealthTech's potential is fully realised. If deployed effectively, the HealthTech effect can provide both the transformation that is required in the NHS, and drive the economic growth required to sustainably fund our public services.

POLICY REFORM OPPORTUNITIES

ABHI sees significant opportunities for policy reform in five areas.

Appointing a HealthTech Champion

Building a World-Leading Regulatory System

Professionalising Adoption

Delivering Secure and Competitive Data Infrastructure

V Growing UK-based HealthTech

Appointing a HealthTech Champion

Life science and engineering are the fundamental basis of HealthTech. The industry is characterised by rapid, often incremental, product design and development, dominated by SMEs. Therefore, any industrial strategy and long-term health plan should acknowledge the nuances that impact HealthTech. Current initiatives, such as the development of a Rules Based Pathway and the Late-Stage Assessment process, betray a lack of appreciation of how HealthTech differs from other parts of the life sciences sector.

The UK's tax and reporting burden on the HealthTech sector also continues to grow. Decisions such as increasing the employers' contribution to National Insurance have a compounding impact on HealthTech when happening simultaneously alongside a proposed Medicines and Healthcare products Regulatory Authority (MHRA) fee increase, reforms in Drug Tarriff Part IX, the delivery of Late-Stage Assessment, and the costs of Net Zero Transition. ABHI has identified 30 separate areas where costs to businesses are increasing, straddling employment, property and assets, energy and manufacturing, transport, and reporting. ABHI believes appointing a HealthTech Champion would

provide a clear and early signal of the Government's appreciation of the peculiarities of the sector. The individual should be supported by government officials and feed into the cross-government health and growth missions. A suitably experienced individual, and one with a good understanding of the machinery of government, could do much to join up policy and make a major contribution to the health and wealth of our country.

Building a World-Leading Regulatory System

The UK regulatory environment currently requires extensive and unnecessary duplication of effort. Post-Brexit modifications to the system have been slow, creating a high degree of uncertainty in the single most important process that improves healthcare for NHS patients and allows young HealthTech companies to start making revenues. This uncertainty deters investors and drives HealthTech companies away.

There are a series of measures Government can use to reduce this drag on growth quickly and with minimal expense. The report 'A sector strategy to transform the economic and societal benefits of UK HealthTech', which provides a methodology for how deliver a HealthTech industrial strategy, sets these out. They include:

- I. Accepting certain non-UK approvals of HealthTech products, including the US and EU, and advancing international data exchange agreements on vigilance and post-market surveillance in line with IMDRF principles.
- II. Developing a process for handling innovations, such as that outlined in the MHRA's Software as a Medical Device (SaMD) Roadmap, and determining the merits of the Innovative Devices Access Pathway (IDAP).
- **III.** Shifting the focus of UK regulatory resource towards post-market surveillance to support innovation, with a strengthened international approach to data sharing.
- IV. Developing innovative approaches to regulation, such as Outcomes Based Cooperative Regulation (OBCR).
- V. Training students in relevant disciplines in regulatory affairs.

We must also not lose sight of the longer term. Currently, as planned, our regulatory system will be largely a UK version of a construct designed to manage the free flow of products within the single market and would maintain the peculiarities that exist in the roles and responsibilities of different organisations. As such, the regulator for medical devices, the MHRA, does not actually regulate, but rather is the guardian of a system which relies on the use of third-party, for-profit organisations (Approved Bodies) to certify conformity with regulations.

Current arrangements limit the ability of the UK Government to performance manage and improve the system, and instead they rely on competitive market forces to drive performance. However, in reality there is a supply shortage, as the capacity of Approved Bodies is heavily constrained by the skills availability of technical assessors, and the ability for companies to switch between providers if service is poor or overly expensive is heavily limited. In addition, transitioning between Approved Bodies can take two to three years, limiting the ability for an organisation to deliver innovation in the meantime. Consequently, competitive forces do not operate as intended and the costs of Approved Body services have skyrocketed, alongside a deterioration in the timelines for regulatory approvals. Recent ABHI data reported costs could be over 700% higher, and timelines 150% longer in the UK/EU when compared to the US, and there is little the regulator, MHRA, can do to intervene.

Simultaneously, the MHRA will proceed with increased costs on the sector for post marketing surveillance, in addition to the fees the sector already pays directly to Approved Bodies. Furthermore, the MHRA will go ahead with raising the fees that Approved Bodies pay to the Agency for designation, a cost that will inevitably be passed onto the sector. The current system is leading to ever-increasing costs, extended delays, and is drastically impacting the attractiveness of the UK market. There is an opportunity, post-Brexit, to think again about how we want our system to function.

VI. ABHI recommends that, the Regulatory Innovation Office (RIO), working alongside the Regulatory Horizon Council, MHRA, and the Competition and Markets Authority (CMA), urgently carries out a review that determines how our regulatory system might best be reformed, including the existing designation model for Approved Bodies.

Professionalise Adoption

Whilst the UK HealthTech ecosystem has tremendous strengths in innovation and early-stage research, supported by infrastructure such as the NIHR HealthTech Research Centres, <u>gaps are well recognised</u> in translation, adoption and spread.

Funding support specifically falls off in the translational research phase and is an area in which UK capability was rated behind the US and EU in ABHI/ CPI's recent survey. The certainty of adoption could help to pull technologies through this phase. However, it takes on average seventeen years for a new HealthTech device to go from successful clinical trial to adoption by the NHS. Given the pace of technological advances designed to improve patient health outcomes and, in many cases, improve NHS productivity, this has consequences on the quality of care that can be delivered by the NHS.

Additionally, there are capital funding issues within the NHS that are limiting its ability to sustainably invest in HealthTech. The capital backlog in the NHS should be addressed by reforming the Capital Departmental Expenditure Limit (CDEL) for the Department of Health and Social Care (DHSC) and providing a longer-term capital outlook to allow for planning. Many initiatives have aimed to overcome adoption challenges, with varying degrees of success. One however that the HealthTech sector remains optimistic for is the Innovation Ecosystem Programme (IEP). It particularly stands out from previous, similar, initiatives, in that it is being done by the NHS for the NHS. The stumbling block in almost all the previous exercises was the lack of engagement of the operational health service. This element, we believe, is particularly important for HealthTech versus the Life Sciences more broadly. HealthTech has traditionally been developed by close collaboration between industry and the clinical community, a relationship that remains vital for adoption and spread, especially where innovation leads to changes in clinical practice, location of care delivery, or diagnosis earlier in the patient pathway.

In the short term, the report 'A sector strategy to transform the economic and societal benefits of UK HealthTech' provides a methodology for how deliver a HealthTech industrial strategy, and recommends six immediate actions to professionalise adoption in the UK:

- I. Ensure there is a framework for the adoption of innovation by the NHS in partnership with the sector,
- **II.** Protect time for innovation within clinical timetables while enabling joint posts to allow NHS clinicians to work with industry,
- III. Appoint Board level Chief Innovation Officers in all NHS organisations and provide the resource and mechanisms to ensure innovation is managed and measured, in part through the Care Quality Commission (CQC) well-led framework,
- IV. Centralising some activities that currently lead to unnecessary duplication of work by both the NHS and HealthTech,
- V. Bring NHS savings targets in line with wider HMG productivity initiatives, i.e. moving from a one-year time horizon to five years,
- VI. Amend innovation adoption initiatives to encourage innovations that improve NHS productivity.

Deliver Secure and Competitive Data Infrastructure

To support the Invest 2035 Industrial Strategy, the UK government should leverage NHS data to drive innovation, improve patient outcomes, and boost economic growth. Establishing a national resource through a network of federated Sub-National Secure Data Environments (SNSDEs) would enable HealthTech researchers and companies to access vital healthcare data securely and ethically, fostering advancements in HealthTech solutions. The network must integrate NHS data systems across different departments, regions, and care providers to create a seamless, unified, multi-modal data landscape.

Unlocking NHS data would allow HealthTech firms to develop evidence-based products, services and AI tools that address pressing health challenges, aligning with government goals to enhance population health and stimulate the economy. For this approach to succeed, it is crucial that these data environments are designed with meaningful stakeholder engagement, ensuring they meet the needs of researchers and innovators.

Embedding user-centred design and robust security frameworks from the outset will protect patient privacy while promoting trust in data-sharing practices. This strategic use of data positions the UK as a leader in health innovation, accelerates R&D commercialisation, and maximises the economic impact of the HealthTech sector, ultimately supporting the UK's industrial strategy.

Orow UK-Based HealthTech

To fully capitalise on all available opportunities, the UK sector requires targeted support in three critical areas: access to finance, robust manufacturing capabilities, and export support. It is important that the industrial strategy enables HealthTech companies, particularly SMEs, to secure funding, scale production, and expand into international markets. By investing in these areas, the UK can empower HealthTech to deliver transformational health solutions, contribute to environmental goals, and foster sustainable economic growth.

First and foremost, innovative HealthTech SMEs need risk tolerant, long-term, patient capital to support them through the long process of product development and regulatory approval. Not surprisingly, many investors hesitate to take on that level of risk. As a result, young UK companies, whose products could save lives and improve NHS productivity, struggle, die, or move to places where capital is more plentiful, such as the US.

When small and scale-up companies do raise funding, they are incentivised to spend their development budgets outside the UK, where costs are lower, and markets are considered to be more receptive to new technologies. The NHS and the UK economy have suffered as a result. The UK has fallen from 4th to 10th globally in running the large clinical trials needed for regulatory approvals. These are the most expensive clinical trials to run, and their departure means a loss of high-value jobs, revenue to the NHS, and taxes to the Exchequer.

'A sector strategy to transform the economic and societal benefits of UK HealthTech' that provides a methodology for how to deliver a HealthTech industrial strategy, recommends:

- I. Incentivising capital inflows to the UK HealthTech sector from startup to post-IPO
- II. Using R&D Tax Credits to benefit the NHS and UK plc
- III. Increasing the attractiveness of the NHS as a place to research
- IV. Feeding the innovation pipeline with UK technologies.

HealthTech is also a major manufacturer in the UK and there is a significant opportunity to increase existing investment. Survey data showed 43% of the sector already manufactures in the UK, yet 69% showed some interested in an appropriate manufacturing grant. ABHI welcomes this Government's ongoing commitment to the £520m Life Sciences Innovative Manufacturing Fund (LSIMF). However, we do not currently believe existing schemes support the full breadth of the HealthTech sector, particularly because of the level at which the investment threshold has been set. Data demonstrate that only 19% of the HealthTech sector view a manufacturing grant of greater than £5m as most suitable.

Clean rooms and sterilisation services are also fundamental. Increasing the availability of these facilities across the UK would directly support the Industrial Strategy by enabling more HealthTech manufacturing and reducing reliance on international facilities. One small company is unlikely to be able to manufacture at the scale required to make a single clean room efficient, yet by acting as a catalyst for co-investment, the UK Government could reduce the risk of a joint initiative, stimulate further investment and provide companies with the confidence to scale up UK-based production.

ABHI recommends that UK Government;

- V. Either ensures the developing LSIMF is fit for purpose for HealthTech companies of all sizes, or urgently scopes a separate scheme that can accommodate support for companies that require a minimum investment of between £500k and £1m.
- **VI.** Provides support by creating initiatives that allow for the co-investment in manufacturing infrastructure (clean room and sterilisation facilities).

Finally, for any industrial strategy to appropriately support HealthTech, support for companies to export has to be considered, and, as the Life Sciences Plan identifies, the UK's share of global exports in the sector has plunged from nine percent to four percent between 2012 and 2020. There are two reasons for this:

- **a.** There has been a decline in financial support despite evidence that for every £1 invested by the government in the Tradeshow Access Programme (TAP), <u>an average of £40</u> was returned to the UK in taxable income.
- b. There is significant fragmentation in the support available. Companies report seeing wide variation in the level and quality of export support received. Some companies report being content, citing help from Embassies as being particularly strong, whilst others observe that the help they are able to access is limited in quality. Multiple organisations are currently engaged in supporting companies, and they should be seen as partners in a network with a common goal, utilising collective expertise. However, in practice, the process has been viewed as competitive by various government organisations, making collaboration unnecessarily difficult and confusing.

'A sector strategy to transform the economic and societal benefits of UK HealthTech' proposes;

VII. A Global Export Programme that prioritises the sector's needs and delivers a simplified framework of export services. Such an initiative could be led by industry, in partnership with government to drive economic growth.

SUBSECTOR AND CLINICAL Speciality opportunities

Whilst the first section of this report explored cross cutting policy reform opportunities, the HealthTech sector is incredibly heterogeneous, and this must be acknowledged if the industry is to be able to best contribute to both the NHS transformation and the drive for economic growth. HealthTech ranges from surgical gloves, to dialysis machines and in-vitro diagnostics, hospital beds and Al-enabled software. With such a range of products providing lifesaving and life enhancing care, companies producing them are also diverse. They do include large multinationals, but 90% of the sector is made up of SMEs. Therefore, any policy intending to support HealthTech requires both nuanced understanding and collaboration with industry.

This section provides clinical speciality opportunities that support the NHS' three shifts, and the realisation of productivity gains.

Summary of Subsector and Clinical Speciality Opportunities

S	ABHI Cardiovascular	A National Cardiovascular Strategy as outlined in ABHI CVD: Health Check report focusing on inequalities of care, early diagnosis and remote monitoring.
	ABHI Diagnostics	An ICS-based Diagnostics strategy, greater funding for Diagnostics, better use of community-based diagnostics centres, and increased use of genomics for prevention.
	ABHI Diabetes	A National Diabetes Strategy unifying prevention, technology-based diabetes management and research into curative treatments.
9480 9 9 9 9 9	ABHI Digital Health	A national programme for the deployment of Digital Health technologies.
202	ABHI Orthopaedic	Increased roll out of specialist orthopaedic centres and surgical hubs.
	ABHI Robotic Assisted Surgery	A National Approach to the roll out of robotic technology including the use of Data and Real-World Evidence, focusing on equity of access through system deployment, increased education and training, and sustainable financing.
	ABHI Stroke	Increased roll out of 24/7 specialist stroke centres.
A THE	ABHI Vascular	A National Clinical Director for Vascular.
Sim	ABHI Advanced Wound Care	A National Approach to Wound Care including collaborative research, greater use of technology, policy incentives and funding, education and training, and monitoring and evaluation.

ABHI Cardiovascular

Cardiovascular disease affects roughly seven million people in the UK and is a significant cause of disability and death, with <u>175,000 deaths from heart and circulatory diseases</u> in the UK each year. Proportionate support both for and from the health system is necessary. Yet, as outlined in the <u>Darzi</u> <u>Report</u>, the outcomes for cardiovascular conditions in the UK are going in the wrong direction – the <u>mortality rate for people</u> <u>under the age of 75 began to increase</u> during the COVID-19 crisis, and rapid access to treatment has deteriorated.

ABHI is calling for a National Cardiovascular Strategy, as recommended in the <u>ABHI Cardiovascular Health Check</u> <u>Report</u>. Within this strategy, particular focus should be placed on highlighting the inequality of access and care for cardiovascular disease, an increased emphasis on early diagnosis, and increasing the use of remote monitoring. This strategy would also support the asks in the <u>British</u> <u>Heart Foundation's 'Hearts Need More' campaign</u>.

In a joint British Cardiovascular Societies consensus document, it is noted that whilst cardiovascular disease is still the leading cause of death for women globally, they are underdiagnosed, undertreated and under-represented in clinical trials. A report from the British Heart Foundation found that, in England, those living in the most deprived areas have the highest prevalence of smoking, physical inactivity and obesity, a lower likelihood of starting cardiac rehab, lower hospital admission rates for cardiovascular elective care but higher rates for emergency care, all of which lead to poorer health outcomes. It is further reported by the Kings Fund that rates of cardiovascular disease are higher among Black and South Asian groups than white groups, but despite this there is still under-representation of ethnic minority patients in trials. Inequalities in cardiovascular disease are multifaceted and as such need to be addressed urgently.

The longer a patient waits to be treated, the higher their risk is of becoming disabled or dying prematurely. Early diagnosis should be prioritised to ensure patients can have the best possible outcomes. For example, as outlined in the report Break free from CVD, a solution would be to proactively detect heart valve disease in community pharmacies. In addition, raising awareness can increase detection rates. For example, <u>The FAST campaign</u>, pioneered by <u>The Stroke</u> Association and NHS England, was transformative in its awareness raising for the general public to recognise the most common signs of a stroke, saving many lives. Similar support from the government should be given to the SLOW campaign (Shortness of breath, Light-headedness on exertion, Older than your years, or Weary). Heart valve disease (HVD) is a serious yet treatable condition, affecting more than 1.5 million people in the UK alone. Despite this, awareness of the symptoms in the general public is incredibly low.

Remote monitoring in cardiovascular disease also addresses many of the priorities in <u>Lord Darzi's report</u> and all the three NHS shifts as highlighted by the Prime Minister. It has benefits in overcoming inequality of access, by ensuring those in remote locations or with limited mobility can still be treated, and reducing the environmental impact of the healthcare delivery, through lessening the emissions produced when visiting a hospital.

ABHI recommends the development and delivery of a National Cardiovascular Strategy, co-created between the health system and industry, to build on the work already in place by the National Clinical Director for Heart Disease and the Cardiac Clinical Network. The need is apparent and should be a high priority.

ABHI Diagnostics

Access to timely and effective diagnostic information and services is critical to clinical decision making. The centrality of diagnostics to the NHS's ability to deliver patient services is <u>beyond doubt</u>. NHS England deliver approximately <u>26 million diagnostic tests</u> at a cost of £6 billion each year, with diagnostics playing a key part of more than 85 per cent of clinical pathways. Patients view diagnostics as <u>a fundamental</u> <u>part of the NHS</u> and the need for investment to modernise services and boost access is <u>universal in their feedback</u>. To maximise the value diagnostics offer and enable the three health shifts, the speed at which they are integrated and embedded into clinical pathways must be addressed.

Firstly, there must be an Integrated Care System (ICS)-based diagnostics leadership and strategy to complement national efforts. Early diagnosis offers the opportunity to treat diseases successfully rather than be detected at a late stage when treatment options are limited. No one test can achieve this, and workforce shortages, outdated processes, and inefficiencies are impacting the delivery of an integrated approach to how diseases are prevented, diagnosed, and treatment progression monitored. Networks, alliances and collaboration are, and will continue to be, the mainstay NHS delivery system to support population health management. Bringing together this distributed leadership into one cohesive effort will be key to successful reform. To do so, each ICS should develop a comprehensive diagnostics strategy to integrate services from separate diagnostic modalities and complement national effort. A foundation of this must be standardisation of protocols, workflows and systems as a critical first step in ensuring that diagnostic technologies can be effectively scaled across healthcare systems.

Secondly, new funding to the NHS must raise spending on diagnostics and technology infrastructure. The UK does not fund diagnostic technologies on comparable levels to other advanced economies. It is well below the OECD average for the number of CT, MRI and PET scanners available in hospitals. Industry analysis highlights that a third of endoscopy equipment is over 7 years old and that the UK, as compared to EU15

nations, sits at the bottom, on a per capita basis, of the in-vitro diagnostic market. The Times Health Commission noted that the NHS typically invests 1.5% of its budget in technology and data, as compared to 4 to 5 per cent in the US and 8 to 10 per cent by organisations undergoing major technology-based transformations. Further, the Commission highlighted that Trusts could achieve a return of £3 to £4 for every £1 of investment in technology. Therefore, funding of diagnostic technologies must rise, and should be focused on modernisation to ensure the latest generation of equipment, software, digital and data tools future-proof the delivery diagnostic services, streamline activity and improve efficiency. Further, health systems that lead the way as technology pioneers should be supported to develop as "centres of excellence" for trials and rollouts of advances in AI and digitalbased diagnostic technologies. This allows organisations to not only showcase to peers the potential of technology transformation, but also to attract industry investment in research and development.

Additionally, there has to be greater ambition for communitybased diagnostics. The 2021 Spending Review committed £2.3 billion of investment, over three years, to transform diagnostic services. Most of this funding has been used to increase the number of community diagnostic centres (CDCs) with 165 sites now operational having delivered over 9 million tests, checks and scans since 2021's inception. The gains in capacity provided by CDCs are welcome, but many are not actually fulfilling their original purpose of providing community-based services. To reduce pressures on hospital and GP services, the next phase of the CDC programme must have more ambitious targets, for increasing the number of centres based truly in the community, providing a greater range of tests, and partnering with private providers to build new facilities and provide capital investment. CDCs which are "ready now" should move to procure innovative diagnostic tests, because these not only enable more elective diagnostic activity, but also help to triage, assess, and treat patients to ease pressures on other health services, like A&E and general practice.

The NHS must also research and test the real-world delivery of new diagnostic models. Innovate UK Contracts for Innovation (formerly known as the Small Business Research Initiative, or SBRI) offers a mechanism to solve complex challenges by running competitive funding opportunities, to develop and adopt new solutions and technologies. They provide an opportunity to sustain economic growth. Since January 2024, under the Pharmacy First scheme, pharmacists in England can carry out consultations and issue antibiotics when appropriate for a limited range of common illnesses. From September 2026 all newly qualified pharmacists will be independent prescribers on the day of registration. And, under the Primary Care Network (PCNs) scheme, all PCNs are reimbursed towards the cost of clinical pharmacists who work across the PCN. These clinical roles are set to expand over the coming years and will require different models of diagnostic services to support that raised capability. Infection diagnostics is time critical. It ensures, for instance, the best outcomes for patients with sepsis, and provides the most effective antimicrobial stewardship programmes. Despite significant progress in the management of sepsis in England, there remains an urgent need to co-ordinate all the elements required to effectively manage patients with a severe infection in the rapidly changing environment of healthcare provision. With these circumstances in mind, a coordinated and cohesive series of Innovate UK Contracts for Innovation should be scoped and executed firstly to utilise the Pharmacy First programme and/or the PCN scheme to build more evidence to support scale-up of point-of-care testing based in these primary care facilities. Secondly, this series should model the wider health, societal and economic costs of antimicrobial resistance, so that an updated baseline is published from which AMR advancement initiatives can be benchmarked. Far too often, the use of diagnostic tests in infectious disease pathways is rejected on the grounds of not meeting cost-effectiveness, due to the narrow comparison with the prescribing of relatively inexpensive antimicrobials. This is at the expense of the wider health and societal determinants of antimicrobial stewardship.

Finally, the use of genomic testing should be widened to drive the transition to prevention. The UK has a unique opportunity to lead the global shift towards preventative healthcare by leveraging its strength in genomics research and clinical applications. The preventative health agenda requires a level of insight on disease development and progression which genomics is uniquely positioned to offer. Understanding the genetic drivers of disease and key risk factors allows for early behavioural actions and targeted medical interventions. The UK should expand genetic testing through the NHS Genomics Medicine Service to a broader range of cancers and other diseases. It should also develop linked datasets, so that clinical genomic outcomes are available for research purposes when unpicking disease progression. By expanding access to genomic testing, empowering patients and clinicians with genomic literacy, driving research and innovation, integrating pharmacogenomics into prescribing practices, and rolling out newborn genomic screening, healthcare can be transitioned from reactive to proactive. These efforts will address long-term public health challenges like cancer and cardiovascular disease, reduce health disparities, and foster a data-driven, sustainable model of care. A full plan, including detailed recommendations, can be accessed here.

By addressing these challenges and adopting a more cohesive approach, the UK can unlock the full potential of diagnostics to improve patient care, reduce long-term healthcare costs, and drive innovation. An ambitious, well-funded, and technologyfocused diagnostics strategy is not just essential for modernising NHS services—it is critical to achieving the broader goal of a more sustainable and efficient healthcare system.



ABHI Diabetes

Diabetes is a pressing health challenge, with an ever-increasing number of people <u>living with diabetes</u> and significant socio-economic impacts. By 2030, diabetes is projected to cost the UK's National Health Service (NHS) <u>over £16 billion annually</u>. However, through national leadership and policy co-ordination, the benefits of HealthTech can help to shift the focus of activity towards prevention, early intervention, and innovative care models. In doing so, the UK can not only improve health outcomes but also position itself as a world leader in diabetes management. The UK has an opportunity to lead the global fight against diabetes by utilising more technology, redesigning care services, and promoting a unified national approach. ABHI recommends that the UK Government should continue the focus by NHS England in creating a National Diabetes Strategy joining up prevention initiatives, technology-based diabetes management, and research into curative treatments. This strategy should include specific targets for reducing the incidence of diabetes, improving care outcomes, and ensuring equitable access to treatment and technology. By focusing on prevention and the use of technologies that mitigate these risks, the UK can dramatically reduce the financial burden on healthcare systems and society more widely.



ABHI Digital Health

The UK's Digital Health sector has seen remarkable growth over the last decade, driven by advances in technology, evolving healthcare demands, and strategic government initiatives. As the largest segment within the medical technology sector by employment, Digital Health has become central to addressing the challenges of an aging population, rising chronic diseases, and limited healthcare resources. The sector has benefited from initiatives like the <u>NHS Long</u> <u>Term Plan</u>, the <u>Digital Health and Care Plan</u>, and programmes such as the <u>NHS AI Lab</u>, leading to <u>a surge in venture capital</u> <u>investment</u> from £317 million in 2016 to £2.87 billion in 2021.

Digital Health presents substantial untapped opportunities for both economic growth and healthcare improvement. The sector is well-positioned for high-skilled job creation, export potential, and attracting investment, particularly in areas like AI diagnostics, telemedicine, and data analytics. Continued collaboration between the NHS, industry, and government can establish a strong home market and foster global competitiveness, intervention and personalised care plans, helping to prevent complications and reduce hospital admissions.

As such, ABHI recommends a national programme for the development and deployment of Digital Health, a proposal of which can be found <u>here</u>. The programme should involve several key elements. First, enhancing digital infrastructure is essential. This includes investing in high-speed connectivity, robust health data platforms, and secure cloud computing

systems. These investments will enable better access, sharing, and analysis of health data across the NHS, supporting the development of innovative digital tools and services. Secondly, maximising the value of NHS data is crucial. By improving data integration, governance, and access through initiatives like the Secure Data Environment (SDE) network, the NHS can leverage its vast data resources for research and development, driving innovation in areas like AI and predictive analytics.

The programme should also emphasise workforce development, focusing on training healthcare professionals in digital skills and creating new specialist roles to support digital transformation. Additionally, policy support is critical to streamline regulatory processes and incentivise the adoption of Digital Health innovations within the NHS. Cybersecurity measures will be required to safeguard patient data and maintain operational stability, particularly as the use of connected HealthTech expands.

The ABHI-recommended national programme for Digital Health outlines a pathway for leveraging the UK's strengths in technology and healthcare to drive innovation, improve patient care, and support economic growth. Through targeted investment, enhanced infrastructure, and strategic partnerships, the UK can position itself as a global leader in Digital Health, benefiting both the NHS and the broader economy.



ABHI Orthopaedics

Orthopaedics is an area that has seen <u>significant increases</u> in <u>waiting times</u> in recent years. As the upcoming UK population demographics shifts occur, the burden on this clinical area is only set to increase and so things must be done differently to ensure effective care can be delivered within the resources available. Joint working between industry and the NHS can help address the elective backlog and ease the pressure on the NHS workforce.

ABHI recommends supporting specialist orthopaedic centres and surgical hubs to engage with industry in joint working to harness the benefits of innovative medical devices. Industry solutions for pathway management, preoperative planning, robotics assisted surgery, operating theatre efficiencies and regenerative medicine approaches for joint healing offer huge benefits to patients and clinicians Joint working with industry can ensure the benefits of these innovations are utilised right across the NHS.

The UK has an opportunity to become a global leader in the uptake and use of innovative medical devices in orthopaedics. This can support improved patient outcomes, system efficiencies and a thriving HealthTech industry.



ABHI Robotic Assisted Surgery

Robotic-assisted surgery (RAS) has made significant advancements in the UK since its introduction in the late 1990s. Despite the global uptake, including over <u>1.8 million</u> <u>procedures</u> in 2022, RAS adoption in the UK has been inconsistent. Whilst <u>over 100 UK hospitals</u> have integrated RAS systems, its implementation often depends on local availability, rather than patient need, due to inconsistent capital funding, and a lack of a unified national strategy, unlike in Wales and Scotland. This inconsistent adoption limits the full potential of RAS, which offers notable benefits like reduced recovery time, minimised physical strain on surgeons, and increased access to minimally invasive procedures.

The potential of RAS is substantial. It has shown significant growth, particularly in urology, colorectal, and gynaecological surgeries, where nearly half of pelvic cancer operations now utilise robotic systems. The technology underpinning RAS integrates advanced robotics, Al-driven decision-making, highdefinition imaging, sensors for real-time feedback, and augmented reality for enhanced surgical precision. These technologies require strong R&D capabilities, robust clinical support, and extensive workforce training to be effectively implemented.

To maximise the benefits of RAS across the UK, ABHI recommends a national programme focusing on four core areas: real-world evidence, equitable access, education and training, and sustainable financing. More detail on the proposed programme can be found <u>here</u>.

Collecting standardised real-world evidence is crucial to validating the clinical and economic value of RAS, facilitating its broader integration into NHS services. This data will help identify areas of high demand and guide system deployment to optimise capacity. Ensuring equitable access to RAS is essential; access should not be influenced by geography, socioeconomic status, or gender. National incentives and benchmarks can help standardise access and support the utilisation of surgical hubs, particularly in high-demand specialties like orthopaedics.

Education and training are critical for successful RAS implementation. A standardised curriculum for surgical staff at all levels, including non-surgical support roles, is recommended to build a skilled workforce capable of handling the complexities of RAS. Additionally, patient pathways must be adapted to accommodate RAS, enhancing efficiency and reducing hospital stays. Sustainable financing is needed to overcome the high costs associated with RAS. Flexible funding models, including value-based procurement and central financing, can support strategic investments in RAS technology, allowing healthcare providers to realize long-term benefits. Continued collaboration between the NHS and industry partners is essential to provide the necessary training, technical support, and infrastructure for effective RAS deployment.

The proposed national programme aims to address these needs, supported by strategic funding and industry engagement. By embracing a unified approach, the UK can harness the full potential of robotic-assisted surgery, improving patient outcomes, reducing hospital stays, and positioning itself as a leader in surgical innovation.



ABHI Stroke

As noted by the <u>Stroke Association</u>, stroke is a leading cause of disability and the fourth biggest killer in the UK. It is forecasted that over the next 10 years the number of stroke survivors will increase by 60%, potentially adding a cost to the NHS of <u>£75 billion</u>. Whilst there are technologies that provide cost effective diagnosis and treatment for stroke, speed of access remains unequal across the UK. It is critical that patients get seen imminently to prevent life-altering changes.

Evidence shows that to maximise patient outcomes following an ischemic stroke, accessing thrombectomy services fast is essential. However, point-of-care diagnosis, timely referral, and access to 24/7 specialist stroke centres providing such treatment remains a challenge across the UK. <u>Only 3.3% of</u> <u>patients receive</u> this routine treatment, leaving the UK lagging lag behind many other countries, with treatment rates varying hugely between London and regions like the East and North East. As outlined in the Lord Darzi report, there is vast disparity in the number of patients with a suspected stroke who have the necessary imaging within an hour of being in hospital, with some hospitals being as low as 40%.

ABHI recommends the increased roll out of 24-hour, 7 day-a-week specialist stroke centres, inclusive of thrombectomy capabilities, across the UK to ensure patients have the treatments to ensure the best possible outcomes. To support the centres, a programme of skills and training will need to be provided to ensure relevant resources are available to deliver, including initial education to increase understanding of all staff involved in stroke treatment, and critical resources such as additional angiography suites.



ABHI Vascular

Chronic limb-threatening ischaemia (CLTI) and the associated high rates of lower limb amputation place a significant burden on the UK health and care system, <u>3,068 of 11,426 procedures</u> <u>in the UK in 2021</u> were primary major lower limb amputations. In addition, currently <u>1 in 500 people in the UK live with a leg</u> <u>ulcer</u> placing a significant burden on NHS services and over 120,000 patients are waiting to access care for their venous disease. The estimated associated healthcare costs of venous Wound Care are <u>£3.1 billion per year</u>.

Evidence from a <u>recent study</u> demonstrates that enhancing limbsalvage strategies can lead to substantial economic benefits for the NHS, with potential annual savings exceeding €9 million (£7.5 million) if amputation rates are reduced from 10% to 3%. However, the national leadership of vascular conditions remains unclear within NHSE. A National Clinical Director for Vascular, akin to that seen for heart disease and others, could oversee this initiative and others including solutions for Vascular wounds, and enable the establishment of protocols for early identification and referral of patients at risk, which is critical for resource allocation and effective intervention. ABHI recommends that a National Clinical Director for Vascular could lead a national transformation programme that prioritises collaboration with the full ecosystem including the relevant clinical societies, clinical registries and industry partners to significantly enhance the effectiveness of vascular care. By leveraging innovations in technology and treatment methodologies, such a strategy can facilitate the adoption of evidence-based practices that promote limb salvage over amputation.



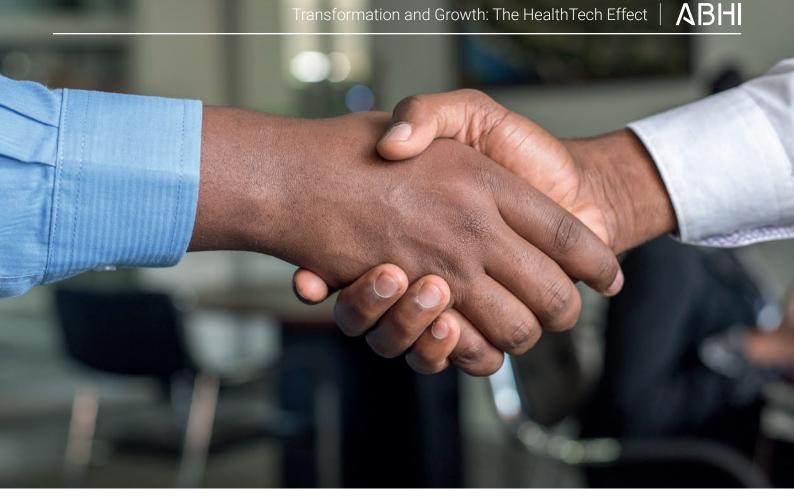
ABHI Advanced Wound Care

The Advanced Wound Care sector is a critical component of the UK's HealthTech industry, comprising nearly 100 companies and employing over 4,000 individuals. The UK sector maintains a strong global standing, hosting the headquarters of two of the top three international Wound Care companies. Its success is bolstered by the NHS's expertise in tissue viability services and extensive academic support for research and development. Wound Care in the UK also represents a significant healthcare burden, driven by factors such as an aging population, rising rates of diabetes, and obesity. This area of care ranks among the highest expenditures for the NHS, with estimated annual costs nearing £10 billion, 80% of which is incurred in community-based care. The bulk of these expenses are linked to the time and labour of healthcare professionals rather than the cost of Wound Care products, highlighting the need for a systemic overhaul. The sector faces additional challenges due to a shortage in the workforce, particularly among district nurses and specialist tissue viability roles. Despite recent increases in the number of community nurses, the UK remains one of the lowest-ranked countries in the OECD for non-hospital-based nursing staff, limiting the effectiveness of Wound Care management and contributing to unwarranted variations in care quality.

ABHI recommends a comprehensive national approach to enhance the Wound Care sector's role in improving healthcare efficiency and supporting economic growth, and we have developed a proposal of <u>what this should entail</u>. It focuses on five key areas.

Firstly, it recommends the establishment of collaborative research hubs that integrate expertise from NHS clinicians, industry leaders, and academic institutions. These hubs would drive the development of innovative Wound Care products, including advanced dressings and integrated monitoring sensors, while utilizing clinical data insights to refine product designs and support evidence-based practices. Digital Health solutions form another cornerstone of the approach, emphasising the need for smart Wound Care devices that facilitate remote monitoring and patient self-management. Such technologies aim to reduce hospital admissions by allowing patients to be monitored at home, with integration into NHS frameworks through structured clinical trials ensuring adaptability and high standards of care. Policy support is another crucial aspect, advocating for clearer accountability within NHS leadership for Wound Care delivery and streamlined approval processes for new products. We propose adopting a value-based reimbursement model to enhance patient access to advanced Wound Care technologies and to encourage further investment from the industry. Workforce training and education are central to the plan's success, with a focus on expanding the roles of district nurses and specialist healthcare professionals in alignment with the NHS Workforce Plan. This would include cross-sector training programmes utilising Al and VR-enhanced tools to improve wound assessment capabilities. Finally, the strategy emphasises the importance of robust monitoring and evaluation frameworks. It proposes the establishment of performance benchmarks and long-term studies to assess the outcomes of Wound Care innovations, leveraging real-world data gathered collaboratively by NHS, academia, and industry partners.

This strategic approach seeks to streamline the development and implementation of new Wound Care technologies, ultimately reducing the financial burden on the healthcare system and improving patient outcomes. Initial investments in research hubs, Digital Health infrastructure, and workforce training are expected to yield significant long-term savings by minimising hospital admissions and complications. Additionally, the initiative aims to stimulate R&D and manufacturing growth, positioning the UK as a global leader in Wound Care innovation. By harnessing the combined strengths of its industrial, clinical, and academic sectors, the UK has the opportunity to create a robust and thriving Wound Care ecosystem that delivers both improved patient care and significant economic benefits. Transformation and Growth: The HealthTech Effect



CONCLUSION

This report outlines a transformative reform agenda to support the UK's HealthTech sector, emphasising its potential to drive significant improvements in patient care and stimulate economic growth. By leveraging the latest technological advances across sub-sectors like Digital Health, Robotics, and Advanced Wound Care, the UK stands poised to become a global leader in HealthTech innovation. However, achieving this vision requires a unified national strategy, targeted investments, and robust collaboration between the NHS, industry, and academia.

Central to this strategy is the need to address existing barriers, including regulatory complexities, funding challenges, and workforce constraints. The proposed recommendations call for streamlining regulatory processes, enhancing the integration and access of NHS data, and providing sustainable financing models that incentivise the adoption of new technologies. By creating a supportive environment for innovation and prioritising real-world evidence collection, the sector can effectively demonstrate the value of its solutions, driving faster and more consistent adoption across the healthcare system.

A key theme throughout this report is the importance of equitable access. HealthTech solutions must be deployed across the NHS in a way that benefits all patients, regardless of geography, socioeconomic status, or clinical specialty. National strategies for each sub-sector, such as robotics and advanced Wound Care, aim to standardise access and ensure that innovations are implemented where they are most needed, addressing disparities in care and improving outcomes for patients.

The potential economic impact of a thriving HealthTech sector is profound. By fostering a robust environment for R&D, manufacturing, and export, the UK can attract significant investment, create high-skilled jobs, and boost its position in the global market. The strategies outlined in this report not only support the industrial growth of HealthTech but also align with broader national priorities, including improving NHS efficiency, reducing healthcare costs, and advancing the UK's Net Zero targets.

TECHNOLOGY CASE STUDIES

The following case studies all provide examples of technologies that support the three key shifts within the NHS: from hospital to community, from analogue to digital, and from treatment to prevention.

AI-ENABLED STETHOSCOPES

What is an AI-Enabled Stethoscope?

An Al-Enabled Stethoscope is the integration of a traditional stethoscope with Artificial Intelligence (AI) to improve its diagnostic abilities. These devices incorporate sensors, software, and AI algorithms to analyse sounds in real time. The use of this technology can make abnormalities easier to detect, identify patterns, such as <u>heart murmurs that might otherwise be missed</u>, and, with the right supporting technology, the technology can be monitored remotely by a specialist.

How does it contribute to the 'Three Shifts'?

Hospital to Community



The use of AI-enabled stethoscopes in community pharmacies specifically reduces pressure on hospitals and GP surgeries. This is partly because they demonstrate <u>higher referral rates for non-trivial HVD cases</u> (70% more compared to GPs), which itself is the result of diagnostic capability being brought closer, and therefore made more accessible, to the patient. Some devices with this technology require little training to use, and so can more easily be translated into a community setting where highly qualified healthcare professionals may be scarce.



Analogue to Digital

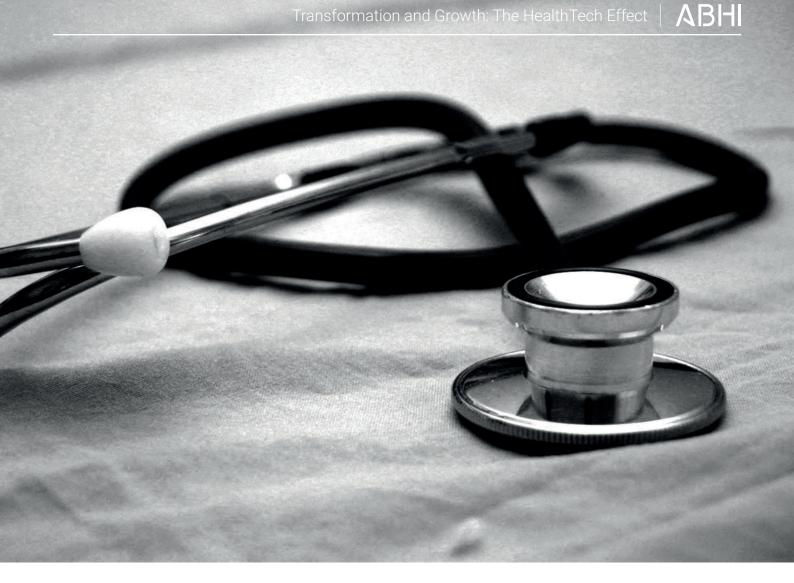
Al-enabled stethoscopes contribute to the digitisation of the NHS by replacing traditional stethoscopes and allowing integration with electronic health records. They can also be remotely monitored by specialists.



Treatment to Prevention

Al-enabled stethoscopes in community settings allow early identification of HVD, including aortic stenosis, which often remains undiagnosed until it progresses to severe stages. Early detection prevents complications such as heart failure, reducing costly and invasive interventions downstream.

Transformation and Growth: The HealthTech Effect



Potential Financial Impact on the NHS

Given a 'model ICB' with a population of 100,000 patients above the age of 65, estimates on file from eMurmur suggest that, with AI-enabled stethoscopes being used to detect HVD in community pharmacies, annual savings of up to £520,274 for that ICB are possible. This is because fewer patients with HVD will go undetected and untreated, resulting in a lower number developing heart failure as a consequence. Investigators from Imperial College London and its associated NHS Trust said that implementation of this technology could 'save the health payer system £2,400 per patient'.

Barriers to Adoption

Pilot projects in the UK have been run involving Al-enabled Stethoscopes, and a large-scale trial is taking place in 200 GP practices across England and Wales. Additionally, the technology is <u>already being adopted</u> in healthcare systems in the US. However, adoption is being delayed with the inconsistent levels of digitisation present across pharmacies, as the Stethoscopes would only be most effective if integrated into the correct IT systems. One expert group during the above study remarked that some existing systems were 'cumbersome' and 'risky'. Capacity challenges also play a part in stopping adoption, as only some pharmacies have the facilities and time needed to properly implement these devices.

ROBOT-ASSISTED SURGERY SYSTEM

What is a Robot-Assisted Surgery System?

A Robot-Assisted Surgery System is a minimally invasive surgical platform that combines robotic technology with HD imaging to assist surgeons in performing complex procedures. This system can collect data on usage metrics during surgery and can be used for a variety of operations such as urology, general surgery, gynaecology, and thoracoscopic procedures.

How does it contribute to the 'Three Shifts'?



Hospital to Community

With the technology <u>shortening the patient's length of stay</u> in a hospital, more patients can be transferred to community care for recovery and monitoring, as long as there is capacity. This will be much more effective if RAS is properly integrated with other technologies such as remote monitoring, so that the transition of a patient from hospital to a community setting can be smooth.



Analogue to Digital

Because of its added advantages in <u>data collection and the ability to integrate</u> with other hardware and software, RAS systems can contribute to the elimination of paper-based records and provide healthcare professionals with a more integrated database. Additionally, these systems can be used to <u>digitise</u> <u>surgical training</u>, providing surgeons with realistic and immersive simulations which replicate chosen scenarios. The adoption of this technology could therefore train higher-skilled surgeons for the NHS.

Potential Financial Impact on the NHS

Estimates of the financial impact of RAS Systems suggest savings of more than £1,000 per patient through the avoidance of complications which are more common with traditional methods of surgery. Also, the potential for uptake is substantial. Analysis of the 2021/2022 <u>NHS Hospital Episode Statistics</u> (<u>HES</u>) data suggests that converting just 25% of open surgeries to RAS could save the NHS approximately £57 million through shorter hospital stays.

Barriers to Adoption

Repeated raids on capital technology budgets to cover day-today spending have left the technology underfunded, with <u>nearly</u> <u>£876 million</u> diverted in the 2024-25 financial year alone. In addition, procurement rules, such as those in <u>IRF16</u>, limit the NHS's ability to use flexible financing options like pay-per-use or leasing agreements. Clearer government guidance on what qualifies as capital expenditure is also needed to encourage greater investment and address the funding shortfall.

INTERVENTIONAL RADIOLOGY THROUGH HISTOTRIPSY

What is Histotripsy?

Histotripsy is a non-invasive therapeutic technology that uses controlled, high-intensity ultrasound pulses to target and destroy tissue, without relying on heat or ionising radiation. By generating localised "bubble clouds" through acoustic cavitation, histotripsy enables the destruction of specific tissues, such as liver tumours, while minimising damage to surrounding tissue. The approach offers precision comparable to cutting-edge radiation therapy, but with reduced costs and without the risks of radiation.

How does it contribute to the 'Three Shifts'?

Hospital to Community



Histotripsy's accessibility to other specialities means that it can be easily operated outside of the hospital and in the community. Any trained clinician, such as a radiographer or nurse, rather than solely a doctor, can perform treatment successfully if the tumour is located. The technology is already <u>being safely</u> <u>implemented</u> in the community in the US, in locations that are a long distance from tertiary care centres. Further, histotripsy shifts patients out of hospitals quicker than traditional methods, as patients recover faster from the treatment they receive. They can therefore be transitioned to community care at an earlier stage in their recovery.



Analogue to Digital

The platform utilises software and robotics to ensure the treatment is delivered with millimetric precision and with uniformity every time. This is a shift from the current, analogue method of treatment, which depends on the surgeon's hands, to a new, digital one.



Treatment to Prevention

Though not a directly preventative treatment, the use of histotripsy to increase existing treatment capacity would <u>reduce the delays</u> currently experienced by many cancer patients, and therefore would decrease their risk of mortality. This would prevent more people being treated using traditional methods at a later stage. Indeed, histotripsy is suited to early-stage treatment because it is non-invasive and therefore doesn't disrupt patients' lives nearly as much as other treatments.

Potential Financial Impact on the NHS

The potential for NHS savings with histotripsy is significant. Estimates on file from HistoSonics showed local Trust savings of several million pounds, depending on how many surgical procedures are replaced with this method. A histotripsy unit does not need a surgical theatre nor physical radiation protection, both of which <u>decrease its cost</u> relative to current cancer treatments. Further, it can take only <u>up to ninety minutes</u> to be administered to a patient, dramatically increasing the efficiency with which cancer patients can be treated.

Barriers to Adoption

The adoption of histotripsy in the UK offers the opportunity for a "<u>leading role globally</u>" in the development of the treatment. Histotripsy has already undergone <u>pre-clinical trials</u> and international <u>clinical trials</u>, securing <u>FDA approval</u> in February 2024. In the UK, however, more trials are ongoing, and the technology has been selected for the <u>Innovative Devices Access</u> <u>Pathway (IDAP)</u>. Given the pace of development in the US, it is important that further approval and adoption is not stalled in the UK, especially because of the treatment's potential to greatly improve the cancer patient pathway.

VIDEO RHINOLARYNGOSCOPE

What is a Video Rhinolaryngoscope?

A Video Rhinolaryngoscope is an advanced diagnostic tool designed for the early detection and precise diagnosis of conditions affecting the throat and upper airway. Its imaging capabilities, including Narrow Band Imaging (NBI), allow for the identification of subtle tissue changes that may indicate early-stage cancer or precancerous lesions. By providing high-resolution images while remaining minimally invasive for patients, it transforms care pathways and enhances patient outcomes.

How does it contribute to the 'Three Shifts'?



Treatment to Prevention

The Video Rhinolaryngoscope's ability to detect early-stage cancerous or precancerous lesions allows for earlier intervention, preventing disease progression and reducing the need for later and more expensive treatments.



Analogue to Digital

As a fully digital device, the Video Rhinolaryngoscope provides high-quality images that can be stored, shared, and analysed for telemedicine and remote consultations. When integrated with tools like connected medical recorders, it supports digital workflows that modernise diagnostic and care processes.



Hospital to Community

This technology makes it possible to <u>perform biopsies</u> with the patient under local anaesthesia, allowing them to be conducted in an outpatient setting in the community, rather than in a hospital.

Potential Financial Impact on the NHS

The Video Rhinolaryngoscope offers significant potential for cost savings and productivity improvements within the NHS. By enabling outpatient biopsies under local anaesthesia, it shortens the time from consultation to diagnosis, enhancing productivity by allowing more patients to be diagnosed in less time. The <u>Scottish Health Technologies Group</u> (SHTG) documents that 'a reduction in the number of patients requiring inpatient biopsy procedures will lead to <u>substantial resource</u> <u>savings</u> for NHS Scotland'

Barriers to Adoption

Video Laryngoscopy (VL) is relatively available within UK hospitals but sees a significant lack of use disproportionate to this availability. In a 2017 national survey conducted on the treatment, <u>50% of respondents</u> said that VL had been introduced without any formal teaching, limiting the amount of healthcare professionals who might use it as a first-choice treatment. This is particularly concerning given VL's necessity in treating patients who experience complications with primary airway techniques. One study calls for a "shift in mindset" among healthcare staff to a point at which VL is regarded as a "basic standard of care for airway management". The treatment has faced cultural barriers, with other methods such as Direct Laryngoscopy (DL) often preferred and used instead.

DIGITAL CARE PLATFORM

What is a Digital Care Platform?

Digital care platforms are designed for patients undergoing treatment, such as hip, knee, and shoulder replacements, as well as for the healthcare professionals treating them. The platform uses digital devices to optimise patient engagement, adherence, and recovery outcomes through the monitoring and collection of Patient-Reported Outcome Measures (PROMs). They can feature self-directed video exercises, real-time messaging with picture-sharing, and recovery curves to monitor progress. The platforms can integrate seamlessly with healthcare systems, enabling a data-driven approach to care.

How does it contribute to the 'Three Shifts'?



Hospital to Community

Because it allows the use of remote monitoring, the digital care platform reduces the need for in-person physiotherapy and post-operative consultations. This allows patients to recover independently at home, which lowers the strain on hospital resources and quickens their transition from tertiary care to community.

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Treatment to Prevention

The platform's reporting and intervention capabilities mean that complications during recovery are reduced. By allowing healthcare professionals to address these potential issues early, it enhances patient outcomes and prevents the escalation of post-operative challenges.

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Analogue to Digital

The platforms can integrate with Electronic Health Records (EHR) and automate enrolment processes from surgical scheduling, eliminating the need for paper-based work.

Potential Financial Impact on the NHS

Digital care platforms have demonstrated significant cost-saving potential. Research indicates that their use reduces physiotherapy visits while delivering comparable recovery outcomes to traditional care. One study found <u>reduced</u> <u>re-admission rates</u> (2.5% vs. 6.7%) and emergency department visits (2.5% vs. 8.2%) among patients using the platforms. By lowering hospital stay length and improving surgical preparation, the technology can also free up hospital beds, further decreasing costs for the NHS.

Barriers to Adoption

Barriers to adoption include information governance challenges, such as the lack of a standardised Data Protection Impact Assessment (DPIA) template for NHS hospitals, limited IT resources, delays in integrating the platform with hospital EHR systems, and workforce constraints. Resistance to change, including assumptions that older patients cannot engage with digital tools, also delays adoption.

BLOOD-BASED BIOMARKER TESTS

What is a Blood-Based Biomarker Test?

A blood-based biomarker test is a diagnostic or monitoring tool that measures specific biological molecules ("biomarkers") in the blood to provide information about a person's health. These biomarkers can include proteins, metabolites, DNA, RNA, or other molecules that indicate biological processes.

How does it contribute to the 'Three Shifts'?



Hospital to Community

The blood-based biomarker test requires only a simple blood draw, eliminating the need for specialised equipment and technicians required for the current method, the echocardiogram. As a result, it can be conducted more easily in a community setting, bringing diagnosis closer to patients.



Treatment to Prevention

The biomarker test detects CVD at an earlier stage than echocardiograms, often before structural abnormalities are visible on an echocardiogram. This allows for timely intervention which reduces the risk of costly complications like heart attacks or strokes and supports the shift from treatment to prevention.



Analogue to Digital

Some blood-based biomarkers are being developed as <u>digital biomarkers</u>, leveraging advanced technologies and data analytics to measure the health of a patient remotely. This can be done in real-time and can also be integrated into NHS's digital infrastructure, making these biomarkers valuable in the NHS's shift from analogue to digital.

Potential Financial Impact on the NHS

Blood-based biomarker tests are generally less expensive than <u>echocardiograms</u> because they do not require the equipment nor the highly trained staff to be administered, meaning they are also <u>more accessible and scalable</u>. In being able to detect CVD earlier, the tests also reduce the chance that more costly interventions for the patient will be needed at a later stage. Cost-savings potential is also large because, at present, echocardiography is one of the <u>most used and highly requested</u> diagnostics procedures in the UK health system.

Barriers to Adoption

The adoption of blood-based biomarker tests in the UK health system is slowed by data integration challenges, which complicate the adoption of the tests because there are difficulties incorporating their results into existing NHS systems like electronic health records. One report identifies that the UK has a <u>shortage of staff</u> trained in the field of genomics and biomarker testing, leading to slowed adoption and use of these tests.

DIGITISED DIAGNOSTIC Blood tests

What is a Digitised Diagnostic Blood Test?

A digitised diagnostic blood test is a genomic test which runs on interpretive software. It can rule out infection and sepsis in the patient within three hours, thereby providing clinicians the confidence to withhold, delay, or reduce antibiotics if given a low-risk score. It can also run on existing NHS technology, requiring no upfront capital cost.

How does it contribute to the 'Three Shifts'?



Hospital to Community

The test can identify patients at low risk of sepsis who do not require admission to a hospital and may therefore be treated within the community instead.



Treatment to Prevention

The test empowers clinicians to withhold or reduce antimicrobial use. This in itself prevents the unintended side effects of antimicrobial treatment, which can affect 35% of patients. Overall this avoids the 6% of patients which end up needing additional care because of these side effects.



Analogue to Digital

These tests can integrate with electronic health records to improve the accessibility of patient data, and some can <u>utilise advanced machine learning</u> to generate their infection scores. This ability eliminates paper-based records and automates the data analysis process for healthcare professionals.

Potential Financial Impact on the NHS

The "Adverse Events" associated with the prescription of antibiotics for suspected respiratory infection, such as the unintended side effects mentioned above, incur <u>an NHS cost</u> <u>of £326m</u>. Yet, up to 70% of these prescriptions are inappropriate. Further, evidence from the U.S. establishes that sepsis has the <u>second-highest hospital readmission rate</u> out of all conditions, costing hospitals \$41 billion (£33.6 billion). The adoption of Infection Detection Systems could tackle the same problem in the U.K. by ensuring sepsis survivors have the early access to primary care needed to follow up on their treatment and avoid later expensive escalation.

Barriers to Adoption

The principal barriers to the adoption of this technology arise from challenges with the NHS's digital infrastructure. A recent report into Community Diagnostic Centres (CDCs) in England found that digital advancements <u>are implemented inconsistently</u> and that data sharing between CDCs is fragmented. These problems inhibit the adoption of digitised diagnostics such as the blood tests discussed in this case study.

IN VITRO DIAGNOSTIC Multivariate index assay for Hepatocellular carcinoma

What is an In Vitro Diagnostic Multivariate Index Assay for HCC?

An in vitro diagnostic multivariate index assay (IVD-MIA) is a diagnostic test that combines multiple clinical factors (or 'biomarkers') to assess a patient's risk of a specific condition or disease, in this case for hepatocellular carcinoma (HCC). HCC is the most common cancer affecting the liver, and is the third-most common cause of death by cancer overall. In its early stages, HCC often has non-alerting symptoms, so it is important that everyone with cirrhosis (a type of late-stage liver disease) is tested twice yearly. An IVD-MIA for HCC is a regulated, accurate test which combines two blood tests with gender and age, and can be used to find HCC at an early stage.

How does it contribute to the 'Three Shifts'?



Treatment to Prevention

The primary advantage of IVD-MIA technology is its ability to identify high-risk individuals with chronic liver disease who are at an increased risk of developing liver cancer, allowing for targeted prevention and intervention at an earlier stage. In doing so, these devices shift the focus from reactive treatment to proactive prevention.



Analogue to Digital

IVD-MIA technologies often rely on digital platforms for processing and interpreting biomarker data. These digital tools improve diagnostic accuracy and supports decision-making, transitioning the NHS from analogue to digital.

Potential Financial Impact on the NHS

IVD-MIA for HCC does offer significant cost savings. For 100,000 patients over a lifetime of the twice-yearly surveillance, the standard method of testing for HCC would result in 132,000 false positives, which would then require follow-up testing with MRI or CT scans. This number could be reduced to 79,000 with the use of IVD-MIA for HCC, resulting in imaging-associated cost savings of £7,301,492, coupled with a reduction in waiting lists. This number, according to data on file from Roche Diagnostics, could be reduced

Barriers to Adoption

The scaling of IVD-MIA technologies is being slowed down due to the duplicative nature of the adoption pathway in the UK. For example, each individual Trust is required to produce their own Digital Technology Assessment Criteria (DTAC) assessment, which adds unnecessary delay. There has also been a lack of awareness of the technology from healthcare professionals, which has further slowed adoption. NHS procurement and commissioning teams have required guidance on how to procure the relevant Al solutions which best complement the technology.

DIGITAL PATHOLOGY

What is Digital Pathology?

Digital Pathology (DP) involves the analysis of digitised microscope slides containing tissue samples, which can then be viewed and shared using specialised software. Through this it assists in the diagnostic and treatment stratification of cancer patients and enables the following use of AI algorithms to complement pathologists' diagnostic capabilities.

How does it contribute to the 'Three Shifts'?



Treatment to Prevention

Digital pathology allows for faster and more accurate analysis of tissue samples, reducing the time to diagnosis for conditions like cancer, cardiovascular diseases, and inflammatory disorders. The Al algorithms that can be used in DP can detect subtle changes in tissue samples, thereby identifying disease markers earlier than conventional methods. These factors mean that healthcare professionals can conduct earlier interventions in patient conditions, avoiding costly late-stage interventions.

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Analogue to Digital

DP substitutes traditional pathology methods, which are made up of physical slides and microscopes. These are labour-intensive and are prone to logistical challenges. Digital pathology replaces these with high-resolution digital images (via whole-slide imaging), eliminating the need for physical slide handling and enabling instant access to samples.



Hospital to Community

As mentioned, DP can also allow remote access, which disperses care from hospitals because community centres can access specialist staff without the need for them to be there physically.

Potential Financial Impact on the NHS

DP can deliver significant cost-savings. One study states that digital pathology can improve workforce-related efficiencies by <u>approximately 15%</u>, coming from better productivity and remote working capabilities. On top of this, the use of digital slides eliminates the need for physical storage, reducing space, maintenance, and transportation expenses. Finally, DP increases diagnostic accuracy, reducing the risk of errors that can lead to unnecessary treatments or extended hospital stays.

Barriers to Adoption

The main barrier which is slowing the adoption of digital pathology is its integration into NHS software and a lack of infrastructure. DP requires a range of interconnected technologies to enable efficient data storage and retrieval. Also necessary are slide scanners capable of producing high-quality and high-volume whole slide images of glass slides, as well as an effective Image Management System. Without these in place, a Trust cannot benefit fully from the adoption of digital pathology.

LEFT ATRIAL APPENDAGE CLOSURE DEVICES

What is an LAAC Device?

An LAAC Device is an implantable device designed for left atrial appendage closure (LAAC), a procedure that reduces the risk of stroke caused by blood clots in the left atrial appendage (LAA) of the heart. It is particularly beneficial for patients with non-valvular atrial fibrillation (AF) who cannot take oral anticoagulants (OAC), due to bleeding risks or other concerns. The device is implanted using a minimally invasive catheter-based technique, providing a safe and effective alternative to long-term OAC therapy.

How does it contribute to the 'Three Shifts'?



Treatment to Prevention

LAAC devices play a crucial role in the prevention agenda by reducing the risk of stroke in patients with AF who are unable to tolerate long-term OAC therapy. This prevents complications and costly interventions downstream.



Hospital to Community

By decreasing the incidence of strokes and major bleeds in high-risk patients, an LAAC device can reduce lengthy hospital stays, enabling more patients to be managed in community settings.

Potential Financial Impact on the NHS

LAAC devices have proven to be cost-effective, especially or patients with contraindications to OAC. Although the initial procedure costs may be higher, long-term savings are achieved through a reduction in stroke incidence and the associated care expenses. Furthermore, fewer complications and hospitalisations related to stroke alleviate the strain on healthcare facilities and support more efficient resource allocation.

Barriers to Adoption

Commissioning challenges mean that access to LAAC procedures is limited to a small number of centres in England, creating geographic disparities. Specialised cardiac centres have been attempting to gain commissioning status for LAAC, but complex and inconsistent approval pathways are hindering these efforts. Additionally, a lack of awareness among healthcare professionals about LAAC procedures results in delayed patient referrals. These challenges are exacerbated both by the limited physician time for education, and by unreliable internal hospital communications, meaning that LAAC devices are only being adopted very slowly by the NHS.

PREDICTIVE REMOTE HEART Monitoring device

What is a Predictive Remote Heart Monitoring Device?

A Predictive Remote Heart Monitoring Device is an advanced, remote heart failure diagnostic and monitoring solution designed for patients with implanted cardiac devices such as cardiac resynchronisation therapy and implantable cardioverter defibrillators. This alert-based technology provides early warnings of worsening heart failure which enables medical teams to intervene before symptoms escalate. Already recommended by the National Institute for Health and Care Excellence (NICE) as part of diagnostic guidance (DG61), this device allows proactive patient management, reducing the need for unnecessary hospital visits which

How does it contribute to the 'Three Shifts'?



Hospital to Community

A predictive remote heart monitoring device detects early signs of worsening heart failure, often before symptoms appear. This allows patients to be managed in their homes or community settings, reducing hospital admissions.



Analogue to Digital

This device uses digital technology and integrates data from cardiac devices into actionable alerts which can then guide clinical decisions and enable timely interventions. In doing so, it avoids a paper-based workstream in favour of a faster, digital one.



Treatment to Prevention

By identifying potential heart failure events early, a remote heart monitoring device helps prevents hospitalisations and complications, thereby supporting a proactive rather than reactive care model.

Potential Financial Impact on the NHS

According to recent NICE diagnostics guidance (DG61), heart monitoring devices are <u>cost-saving</u> compared to standard remote monitoring for heart failure patients with cardiac devices. The technology reduces heart failure-related hospitalisations, better using hospital resources and freeing up capacity in an overburdened system.

Barriers to Adoption

There are several barriers to adoption for this device. Effective use of a predictive remote heart monitoring device requires regional clinical pathway redesigns to ensure there are clear protocols for responding to heart failure alerts. There are also funding challenges that prevent the device's adoption. While the underlying cardiac devices are funded through specialised services, the monitoring aspect of the device is commissioned locally by Integrated Care Boards, which limits adoption because of a lack of dedicated funding or incentives.

CLOUD-BASED ENDOSCOPY Platforms

What is a Cloud-Based Endoscopy Platform?

A Cloud-Based Endoscopy Platform is a software which uses cloud computing to store and analyse data related to endoscopic procedures. It enables healthcare professionals to better access and share information, providing a secure and centralised online environment instead of relying on local servers or analogue procedures. Since the platform is cloud-based, healthcare staff would be able to access information remotely and from separate hospitals if it were implemented. These platforms come with AI and data analysis abilities integrated, allowing for more efficient and accurate operations.

How does it contribute to the 'Three Shifts'?



Hospital to Community

As mentioned, the fact that the platform is cloud-based makes possible remote and decentralised access to data and AI tools, dispersing access to health information away from tertiary care centres and into community settings.

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Analogue to Digital

Cloud-based endoscopy platforms act either as replacements to existing analogue processes or as improvements upon digital infrastructure. In both cases, their main advantage is the further digitisation of data storage and analysis in endoscopy through the inclusion of the cloud.



Treatment to Prevention

By enabling real-time data analysis and Al-assistance, the platform supports earlier detection of disease and therefore supports earlier prevention. This proactive approach helps shift focus from treating advanced conditions to identifying and managing them at earlier stages, improving long-term health outcomes.

Potential Financial Impact on the NHS

The Cloud-Based Endoscopy Platform has the potential to deliver substantial cost savings for the NHS. For one, the software used in endoscopy data storage <u>no longer needs to be housed</u> by expensive hardware, lowering costs. The cloud platform, in supporting innovative and community-centred endoscopy initiatives <u>such as this one</u> by the Royal United Hospitals Bath NHS Foundation Trust (RUH), can contribute to savings in treatment costs. In RUH's case, there was a £30 reduction in the cost of treatment per procedure.

Barriers to Adoption

A significant barrier to the adoption of these platforms is the administrative workload of the Digital Technology Assessment Criteria (DTAC). A HealthTech company must complete a separate DTAC for each Trust they are looking to sell their device to. The NHS's own ongoing provisional review of DTAC has acknowledged that change to the process could <u>substantially reduce the burden on industry</u>". Another barrier to adoption for this technology is a lack of understanding of AI, which is utilised by some of these platforms, within the NHS. Using targeted education to raise awareness of AI's potential benefits and limitations, as well as building trust in AI generally, remains a critical step in encouraging its integration into the healthcare sector.

DIGITAL LEAKAGE NOTIFICATION System for stoma

What is a Digital Leakage Notification System for Stoma?

A digital leakage notification system for stoma is a sensor layer that detects leaks under a stoma baseplate and notifies the user via a smartphone app. For the over 200,000 individuals living with a stoma in the UK, this innovation offers reduced leakage onto clothing, decreased anxiety about leaks, improved quality of life, and minimised unnecessary baseplate changes.

How does it contribute to the 'Three Shifts'?



Hospital to Community

The system empowers patients to manage their care at home. The app records and tracks leakage events, and in doing so provides data that can be shared with healthcare professionals for remote consultations, meaning patients no longer need to visit hospitals as much and can receive care in their communities and homes.



Analogue to Digital

There is no analogue equivalent to the use of these systems. Previously, patients have relied on manual checks, which can disrupt their daily life or sleep. Digital leakage notification systems offer a seamless digital solution, leveraging sensors and app-based reporting to simplify leakage management.

Sickness to Prevention

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In giving patients a digital and automated system which notifies them of leakages, this technology addresses the root causes of patient anxiety and social isolation stemming from stoma leakage. This prevents the escalation of these mental health problems and therefore lessens the burden on later-stage psychological care. Additionally, by <u>alerting users to leakage issues early</u>, it reduces skin irritation and unnecessary product changes, preventing chronic problems which may otherwise require a hospital visit or an escalation of care.

Potential Financial Impact on the NHS

These systems, through <u>significantly reducing</u> the number of leakage incidents that patients suffer (an 82% reduction), mean less stoma bags need to be used by patients. A clinical study is forthcoming from Coloplast in January 2025 that will highlight the significant cost savings associated with decreased baseplate consumption. Further, notification systems alleviate demand on stoma care nurses through enabling patients to self-manage their care, which will allow those nurses to increase their productivity in other areas.

Barriers to Adoption

Firstly, whilst these systems are <u>not an expensive product</u>, cost pressures are such that even relatively inexpensive products are not being offered to NHS patients. Secondly, the technology does require additional training, since it does require a new set of skills to manage patients.

HOME HAEMODIALYSIS

What is Home Haemodialysis?

Home haemodialysis is shifting of dialysis treatment for kidney failure, traditionally done in a hospital, to a patient's home. This can be transformative for patients, since treatment demands several hours on a dialysis machine three times a week. In offering flexibility in scheduling, for example the option for shorter, more frequent dialysis sessions, this program improves quality of life and improves clinical outcomes for patients. In the <u>NHS Grampian Home Haemodialysis initiative</u>, four patients successfully completed haemodialysis in their homes in a pilot phase, and one reported that it had "changed their life". There are plans to include twenty more patients in this program in 2025.

How does it contribute to the 'Three Shifts'?



Hospital to Community

By empowering patients to administer dialysis at home, home haemodialysis shifts care from hospitals to the community. Regular nursing visits are conducted for oversight, ensuring safety and support without the need for frequent hospital visits by the patient.

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Analogue to Digital

The program uses digital monitoring tools to allow healthcare professionals to track patient outcomes remotely. This reduces the reliance on traditional in-hospital monitoring methods and supports the NHS's digital transformation goals.



Sickness to Prevention

Home dialysis empowers patients to take control of their treatment, encouraging adherence to prescribed regimens. The flexibility to schedule treatments at convenient times for the patient also reduces their stress, preventing the escalation of mental illnesses.

Potential Financial Impact on the NHS

By reducing the need for hospital-based dialysis, the initiative lowers operational costs for healthcare facilities. Research suggests home dialysis <u>costs between £16,000 and £23,000</u> per year; hospital dialysis costs more, between £20,000 and £24,000. The use of home-based dialysis also reduces transportation expenses, financial and environmental, for both patients and healthcare providers.

Barriers to Adoption

Despite the bold initiative by NHS Grampian and the significant research supporting home haemodialysis, practical barriers are limiting its adoption and use in the health system. For example, less than 0.5 % of houses are deemed adequate for home haemodialysis, opening questions about whether the NHS should seek to rehouse patients who would benefit most from the treatment. Further, patients need to be actively supported in their transition to greater self-management of their treatment. Many patients misunderstand how to deliver their own treatment, and displayed apathy due to factors such as denial of their condition, social circumstances and pressures, and their lived experiences with the health system.

IN SITU HYBRIDISATION ASSAY For light chain mrna

What is In Situ Hybridisation Assay for Light Chain mRNA?

In Situ Hybridisation (ISH) is a diagnostic tool which analyses a biopsy sample to find a specified type of RNA within a cell. In the case of light chain mRNA, ISH can be used to find its presence and type in tissue samples. This information is crucial for the diagnosis of B-cell lymphomas and plasma cell neoplasms, as it helps determine the clonality of the B-cells involved.

How does it contribute to the 'Three Shifts'?



Hospital to Community

Though not contributing directly to this shift, ISH Assays for light chain mRNA detection indirectly support it by improving diagnostic capabilities more generally. The Assay provides <u>more accurate diagnostic results</u> than traditional methods, leading to faster treatment decisions which reduce the need for prolonged hospital stays or multiple visits.



Analogue to Digital

These assays offer the possibility of being integrated with automated immunohistochemistry platforms. This automation can potentially reduce processing times and improve efficiency in pathology laboratories, contributing to the NHS's shift from analogue to digital work processes.



Sickness to Prevention

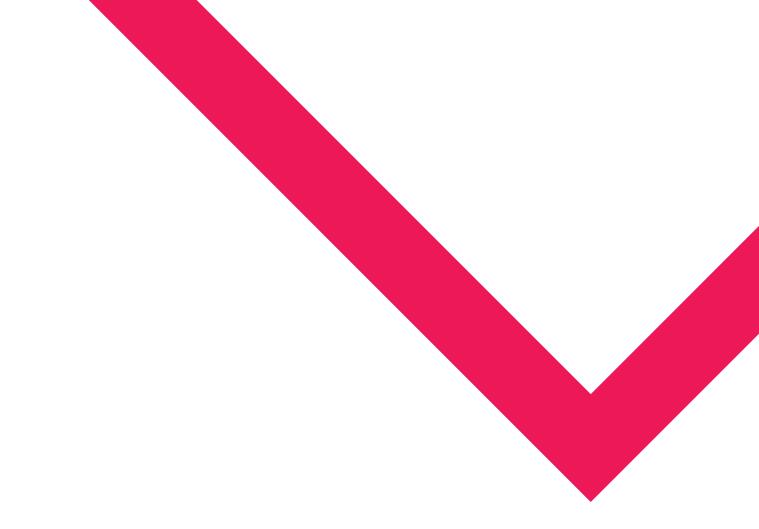
This technology can detect B-cell lymphomas and related disorders with <u>improved sensitivity</u> upon current methods used in the UK. This capability would lead to earlier diagnosis for patients, allowing for earlier intervention from healthcare professionals and avoiding the need for later-stage treatment which is often costlier.

Potential Financial Impact on the NHS

While direct cost savings for ISH assays for light chain mRNA are not immediately apparent, there are potential economic benefits for the NHS in the long run. The improved sensitivity and specificity of ISH assays could lead to more accurate diagnoses, potentially reducing the need for repeat testing or additional diagnostic procedures. This efficiency could translate into significant cost savings over time, especially considering a standard biopsy analysis using routine diagnostic panels costs £2,257. Further, the multiplexing capability of some ISH techniques, such as ExFISH, allows for the detection of multiple RNAs simultaneously. This could reduce the number of separate tests required, leading to further cost efficiencies.

Barriers to Adoption

ISH assays for light chain mRNA are not currently being used in clinical practice in the UK, but are used in other European countries such as Belgium and Germany. This is because the technology lacks a UK-specific evidence base, despite having a suitable evidence base in other sources. Another barrier has been a lack of awareness and experience of the technology within the NHS. Many clinicians and pathologists are not yet familiar with the technology and its advantages, while flow cytometry and other methods are well-established for detecting light chain mRNA.





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