ABHI
DIGITAL HEALTH

FROM POLICY TO PRACTICE: USING DIGITAL HEALTH TECHNOLOGIES TO ADDRESS CURRENT NHS CHALLENGES

CONTENTS

EXECUTIVE SUMMARY

Health and social care services are under extreme pressure. Non-pay cost inflation, seasonal illness, a waiting list backlog and people leaving the NHS workforce have created a resourcing gap that goes beyond funding. Both the NHS and the social care system need to make a step change in how they adopt and use innovation and technology, one that utilises existing staff and resources more effectively.

Whilst UK policymakers have recognised the importance of data driven technology through *Data Saves Lives*[1], *the Digital Health and Care Plan*[2], and *the National AI Action Plan*[3], practical barriers still exist which make it harder to put life-saving innovation into practice. The development of a UK sovereign HealthTech regulatory system offers an opportunity to support greater use of innovation. But beyond the regulatory system, ABHI, in consultation with its members, has identified further practical steps to support digital transformation, including developing payment pathways to support uptake of digital health technologies, allowing the system to recognise the value of early intervention on public health, and improving guidance on data use and data governance to support innovation.

The risk of inaction is clear. A recent ABHI survey[4] of HealthTech companies showed that three quarters of respondents currently believe that the UK risks no longer being seen as a priority market internationally, and only 17% of companies believe that the UK is taking an ambitious approach in the development of a sovereign regulatory system.

The UK is well placed to be a world leader with a distinct set of capabilities and globally leading academic and clinical assets, but there is a risk that we could lose our leading position as other countries continue to invest in infrastructure and develop processes to support and incentivise digital health care.

RECOMMENDATIONS

THE GOVERNMENT SHOULD:

1. Provide both the resource and political impetus to the MHRA to support the ambitious programme for Software as a Medical Device (SaMD) and ensure capacity to process digital health technologies.
2. NHS data should be curated and made accessible to innovators in a secure, agile and timely manner. Governance and commercial terms for access need to ensure the UK is a globally competitive location for innovation.
3. Develop an ambitious assessment programme for digital health solutions that supports clinical need, availability and choice.
4. Develop specific payment pathways that recognise the value that digital technologies can deliver in terms of early intervention, health prevention, and population level public health.

CHAPTER I: THE OPPORTUNITY

Digital technologies have radically reshaped modern life; but in healthcare we have yet to reach the level of implementation that would allow us to reap the full benefits of data driven technologies. Data and technology are continually opening up new areas of knowledge and have the potential to uncover new health interventions. To fully capitalise on this opportunity, we need to enable researchers and companies to explore patterns in disease progression that could help predict and prevent health conditions and improve people's quality of life.

> *"During the pandemic, within the UK there was a shift where you could do a lot very quickly regarding regulation and innovation, and that spanned from devices, to medicines, to vaccines and health data. We haven't capitalised on that opportunity."*
> *Professor Rebecca Shipley, Director of the UCL Institute of Healthcare Engineering*

The immense pressures of the pandemic accelerated adoption of new HealthTech, including remote consultations and remote monitoring. The pace and scale of adoption demonstrated what the NHS is capable of with the right leadership and resources. Our response to the pandemic made clear the promise of Digital Health Technology (DHT): a system where patients' conditions can be monitored with less disruption to their daily lives, where therapies and advice can be delivered clearly, predictably and promptly, and where treatments can respond more intelligently to an individual's circumstances.

But more than this, better health data, alongside our world-class research and clinical community, has the potential to inform early intervention, public health and prevention strategies in a way that has never before been possible. It is this aspect which has traditionally been hard to quantify, and even harder for policymakers to drive - but which is now the key to moving to more sustainable models of health and care delivery.

The right policy environment can help build on the UK's strength in Artificial Intelligence (AI) and digital health to help researchers develop new interventions. But if we want the benefits of innovation to get to the people who need it most, the seven million people on elective waiting lists and the NHS staff working through increasing demands, we need the processes and the leadership to put innovation into practice. The prize is huge. Better clinical outcomes for patients and better financial outcomes for the NHS, and a digital health technology industry that exports state-of-the-art technology to healthcare systems around the world. The growth of this industry helps patients, clinicians, the NHS, and the wider UK economy.

WHAT ARE DIGITAL HEALTH TECHNOLOGIES?

NICE defines Digital Health Technologies as digital products intended to benefit people or the wider health and social care system. This could include smartphone apps, standalone software, online tools for treating or diagnosing conditions, preventing ill health, or for improving system efficiencies, or programmes that can be used to analyse data from medical devices such as scanners, sensors or monitors[5]. Many DHTs will combine several different technologies, and some will be driven by AI or machine learning (ML) techniques.

The immediate opportunities for patients and their clinicians with better diagnosis

DHTs provide solutions that help patients and clinicians, saving time and financial resources, once adopted at scale. They may help monitor a patient's condition in a clinical setting, with clear parameters on when and how to flag any changes. Some support patients to monitor a condition without needing clinical supervision, cutting down on hospital appointments, and taking pressure off the NHS. Others may help in providing ongoing therapy to a patient, checking responses to treatment and giving important feedback to doctors. Some DHTs are designed to give extra information and education about managing a condition, or even to provide encouragement and get better levels of adherence to a programme of therapy.

> *"Within five to ten years, most patients with chronic conditions will have some form of diagnostic device at home that they can use to make sure their condition is much more routinely tracked and measured."*
> *Dr Mike Burrows, National Academic Health Science Networks Coordination Director*

Some use cases may be direct replacements of traditional interventions, delivered in more effective or efficient ways, relieving NHS backlogs and workforce pressures. Making better use of limited clinical staff and ensuring patients are being seen by the right people at the right time is essential in supporting the NHS through future delivery challenges. But other use cases offer an altogether different approach, supporting more nuanced interventions which can empower patients to take control of long-term conditions, or help patients (and their healthcare professionals) understand more about their individual responses to interventions.

> *"There is a real opportunity to see how people are prepared to interact with making healthcare decisions by themselves and self-managing health or chronic disease."*
> *Professor Rebecca Shipley, Director of the UCL Institute of Healthcare Engineering*

One of the biggest untapped opportunities for DHTs, however, is in public health and prevention strategies. Risk monitoring can inform screening programmes for at-risk groups or help monitor conditions to avoid over-medicalisation of treatment. DHTs are also well placed to encourage and embed positive behaviours, for example rehabilitation or appropriate levels of physical exercise after surgery. These wider benefits, better public health, better quality of life, and better use of health and care services, are vital to the long-term future of the NHS. Securing this will need an approach from policymakers that enables smart, personalised treatments and prevention plans to be delivered at scale, and it is essential that the regulatory environment and payment pathways to support this transformation.

WHAT DOES CLINICAL EFFECTIVENESS MEAN FOR A DIGITAL HEALTH TECHNOLOGY?

When generating evidence of clinical effectiveness, developers are encouraged to think about the people their intervention is designed for, how the product will be used in clinical practice against the current standard of care, and how it compares to other forms of treatment that might be available. When measuring benefits, they are encouraged to think about benefits to patients in terms of clinical outcomes and safety. Finally, NHS resources also have to be considered: for example a reduction in follow-up appointments, the ability for patients and clinicians to monitor a condition safely at home without visiting hospital, or a reduction in further clinical interventions.

Individual developers are by necessity primarily concerned with benefits to the NHS. But there may be much wider social and economic benefits that, whilst difficult to quantify with as much certainty, should be taken into account by policymakers when considering how to accelerate the adoption of DHTs. A Social Return on Investment (SROI) model might look at broader factors. Does a DHT help prevent long term co-morbidities that put pressure on the NHS? Does it improve a patient's broader quality of life, their mental health, or their ability to be productive at work or remain active, could a DHT improve a carer's quality of life?

HOW DIFFERENT HEALTH SYSTEMS MEASURE WIDER BENEFITS – GERMANY

As well as positive medical benefits, the German Federal Institute for Drugs and Medical Devices asks developers to show improvements in things that are relevant to the life of the patient[6], including:

- **Coordination of treatment procedures**
- **Alignment of treatment with guidelines and recognised standards**
- **Adherence to treatment**
- **Facilitating access to care**
- **Patient safety**
- **Health literacy**
- **Patient autonomy**
- **Coping with illness-related difficulties in everyday life**
- **Reduction of therapy-related efforts and strains for patients and their relatives**

Wider opportunities for the UK

The digital health technology sector contributes to the ecosystem of UK innovation, most clearly in the field of AI which is central to the UK's ambitions to become a science super-power. The sector supports a pipeline of STEM talent from the UK's world-leading universities into rewarding AI careers and attracts inward investment to the UK: healthcare-related AI start-ups attracted a record £683m in 2021[7].

The UK's strength in AI is underpinned by an internationally respected approach to data security and privacy standards. The UK Government has led the world in creating a framework of institutions committed to ethical data stewardship, including the Centre for Data Ethics and Innovation and the NHS AI Ethics Initiative.

The UK's comparative advantage in digital health technology is not just a function of government's historic commitment to the sector and the strengths of our higher education system. The NHS has one of the world's biggest and most diverse longitudinal health datasets. NHS patient data is a national asset with a potential value estimated by EY at nearly £5bn per annum through operational savings for the NHS, better patient outcomes and the generation of wider economic benefits to the UK[8]. Making use of this data has the potential to help inform drug discovery and gene therapies, and to support researchers and clinicians understand complex conditions and comorbidities – but this value is not being fully realised. Making this data accessible to innovators in an agile and timely way will ultimately unlock new treatments that can improve patients' lives both here in the UK, and around the world.

The risk of inaction

Patients, the NHS and the UK taxpayer should have a stake in the value of the scientific insights that their data can generate. Policy needs to take a broad view of how this value is allocated, not just in terms of return for the NHS, but also in the economic impact of employment, productivity and tax returns that a thriving UK DHT sector could deliver for the economy. The risk of inaction is that value, jobs and clinical breakthroughs will be commercialised outside the UK. We need a strategy that takes account of the international regulatory environment, the specific challenges and opportunities of data driven technologies, and the need to maintain ethical standards, efficacy and public trust.

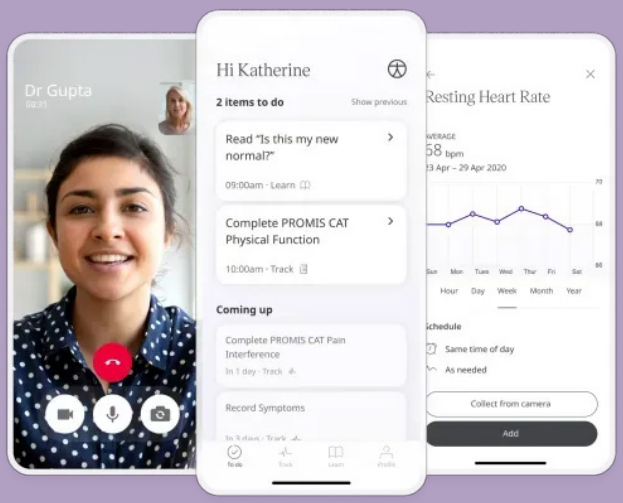
CASE STUDIES

Case Study: Accel-Heal

The number of patients living with wounds including hard to heal ulcers rose **by 71% between 2013 and 2018.** These conditions cause pain for patients, can reduce mobility and quality of life, and can require long term intervention - for instance regular visits from a district nurse to apply traditional treatments like dressings and gels. Patient management costs for the NHS increased by 48% over a five-year period.

Scientists have known for decades that electrical stimulation can help to help heal wounds, but the treatment has not been standardised, and was only available in specialist clinics, if at all.

A small portable device developed by Accel-Heal enables nurses to use the product in front-line health care - for example in a patient's home - and can accelerate the healing process and help with pain management.



Case Study: Huma

London based HealthTech company Huma is behind the Hospital at Home platform which collects real-world patient data remotely and connects it to clinical teams. The platform supports clinical decision-making by providing features like threshold-based flagging systems, trend visualisation and telemedicine for direct communication.

A trial[9] of virtual Covid wards in Germany during the pandemic showed reduced hospital stays and lower mortality rates. Benefits to patients included increased levels of reassurance and targeted education content, empowering patients to better track and manage their health.

CHAPTER II: THE BARRIERS

Regulatory

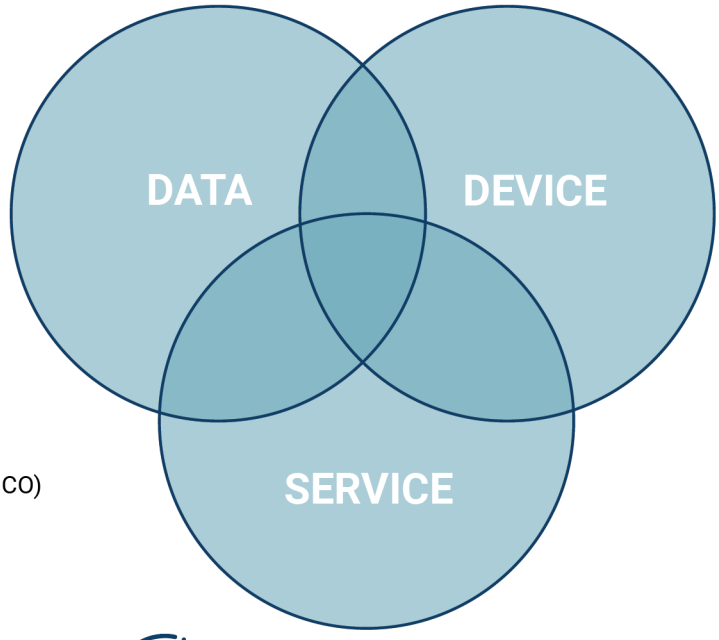
Effective regulation of DHTs is essential in ensuring clinical efficacy and patient safety. It also builds clinician and patient confidence in using new technologies and techniques in identifying and treating disease. But regulatory architecture also needs to support innovation and novel forms of interventions. In our Digital Health Regulatory Concepts[10] report we set out some of the underlying features of the regulatory system which are currently creating barriers to innovation.

Lack of regulatory coordination

DHTs often combine a variety of techniques to get the best results for patients. A product might look like a device, using sensors to gather data on vital signs. It might use machine learning to understand and interpret vital signs, and to decide when to flag clinicians, or inform clinical decision-making. AI might also be used to iteratively improve processes. A device or treatment could also provide a service to patients, for instance giving health and care advice in their own homes. Responsibility for regulating these different aspects could fall across different bodies:

Innovation outpacing regulation

Technologies like machine learning and AI can involve rapid iteration of algorithmic models. A diagnostic tool might respond to a huge amount of data and update the way it makes recommendations about appropriate care in real time. Whilst some developers have given extensive thought to oversight of unsupervised learning models and, for instance, perpetuating bias in data or bias in how patients are treated, there is a lack of clarity over how the regulatory regime should approach this. Despite work being done by the MHRA and NICE - which updated its evidence standard framework on DHTs in 2022 to reflect continuously learning algorithms – regulation on the whole still lags behind technology. Further guidance for DHTs would help innovators, and an approach that takes account of the international regulatory environment would support the UK industry.



Regulation and other informal oversight from:
- UK GDPR
- Network and information systems regulations
- National Data Guardian
- Information Commissioner's Office (ICO)
- Opt Out

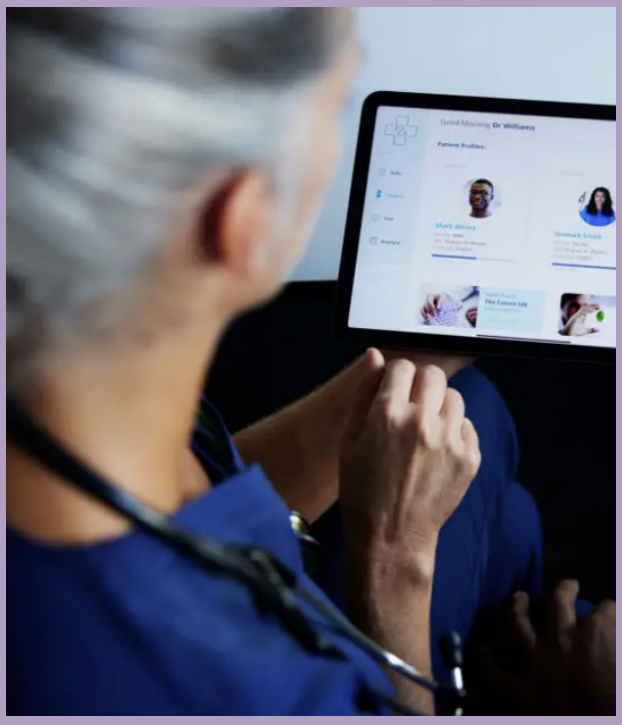
Devices regulated by:
- Medical Device Regulation
- Software as Medical Device
- NICE Evidence Standards framework
- Digital Technology Assessment Criteria

Services regulated by:
- Care Quality Commission (CQC)

CASE STUDIES

Skin Analytics

There are more urgent suspected cancer referrals for skin than any other speciality but the Dermatology workforce has nearly one in four Consultant posts unfilled. As cancer incidence and referral rates continue to rise, performance against nationally agreed cancer pathway targets is falling. Skin Analytics AI medical device, DERM, can support these pathways by helping identify benign (non-cancerous) lesions without using trust dermatologist capacity while maintaining a high sensitivity. DERM has been shown to support improved cancer waiting time performance with around one in five cases not requiring Trust dermatologist input. Skin Analytics has received NHS recognition as a winner of the AI in Health and Care Award and their technology has been used for more than 37,000 skin cancer assessments within NHS partnerships across the UK.



Secure Data Environment: Canon

The Innovate UK funded Industrial Centre for Artificial Intelligence Research in Digital Diagnostics (iCAIRD) has pioneered the concept of is pioneering AI training across individual sites with federated learning. The project has leveraged the existing investment in Scotland in regional safe havens (or SDEs) through a triple helix consortium (of the NHS, industry and academia) to create and validate novel AI in both radiology and pathology imaging. Core to iCAIRD's success has been the development of Canon Medical's Safe Haven AI training Platform (SHAIP) which has allowed UK SME Bering Research to produce a UKCA marked solution for Chest X-Ray classification (BraveCX)[11] as well as advancing Canon Medical's own AI algorithm developments in Stroke and other areas.

A new approach to regulation

The UK has an opportunity to become a world leader in health data use and medical discovery. We want to see policymakers help create a trusted data community between patients, clinicians, healthcare providers and life sciences companies that is secure, transparent, fair and effective. As with many new technologies, there are legitimate questions over whether DHTs could have unintended consequences for patients, particularly for under-represented groups or for those who have poor access to digital connectivity. Impacts on clinicians' time, and the financial resources of hospitals and other healthcare environments should also be considered as this is developed.

The government has started to make the case for data sharing for public benefit in the Health Data Strategy, Data Saves Lives, but demonstrating the positive contribution of data to global health is a long-term project which requires long-term commitment. Industry and commercial partnerships are key to unlocking innovation in a responsible and ethical way that can make the UK a world-leader in health innovation. The Multi-agency Advisory Service being established by NHS England, which is designed to be a cross-regulatory advisory service for developers and adopters of data driven technologies in healthcare, will be an important part of delivering clear and joined up advice on regulation. However, further changes may be needed to streamline the system itself.

A new approach to regulating DHTs

The new UK Conformity Assessment (UKCA) is an opportunity to demonstrate leadership in regulation of DHTs, particularly as part of the government's objective for the UK to be a science and technology superpower. The process of initial and ongoing approval, and of post-market surveillance, needs to reflect the rapid pace of iteration in AI supported technology. We welcome the international approach being taken in this area with joint work with other key jurisdictions and the proposals to adopt a classification system based on International Medical Device Regulators Forum principles.

The work programme[12] proposed for Software as a Medical Device (SaMD) and AI as a Medical Device (AIaMd) offers the opportunity for the UK to be a leader in this area. Standards can have a strategic role in providing a faster and more agile route to addressing gaps in the regulatory regime. Utilising international, harmonised standards (IEC, ISO) that can evolve over time, and quickly respond to changes in technology should be the default approach rather than utilising legislation.

A new approach to data regulation for DHT post market surveillance

For any new health technology, assessment and ongoing monitoring is essential. Not only do clinicians and developers want to make sure that a technology is delivering for patients, but an effective monitoring process allows them to continue learning about how to improve the intervention. This could unlock insights about a health condition, or how it interacts with other conditions.

For clinical trial data, this wider benefit is recognised under the Data Protection Act 2018 which takes account of health data for research, but there is no equivalent for datasets created during post-market surveillance for DHTs. Whilst the traditional healthcare regulatory framework includes confidentiality and the regulation of medical devices, General Data Protection Regulation (GDPR) concepts like data controllers and data processors do not have a clear read-across to healthcare, where other actors like healthcare providers and researchers also have a role in understanding and using data for public benefit. This disconnect has been recognised by the National Data Guardian as one reason that NHS organisations can be cautious about sharing data[13].

There is an opportunity to clarify regulatory guidance in this space. Although such a change would not require legislation, it would require collaboration between the National Data Guardian, ICO, NHS, the MHRA and the Health Research Authority.

GDPR and the common law duty of confidentiality also differ when it comes to thresholds for anonymisation. Often clinicians and developers may be unaware that consent is one of several possible grounds for data sharing under GDPR that may be available to innovators in the life sciences industry. This lack of clarity can constrain the ability to share datasets which might help monitor, evaluate and improve how technology contributes to patient health and wider public health.

Government and the NHS should explore ways to clarify the overlapping regulatory regime, including, for instance, guidance on the legal basis for processing data that is available under the GDPR. Policy makers should consider changes to legislation to recognise scientific data sharing as a public interest. Further encouragement is needed, are example from the ICO, MHRA and NHS governance teams - for the NHS to get the full benefit. A streamlined authorisation scheme to enable access to de-identified personal information for clearly defined secondary use would also support research and interventions that could inform public health advice and improve patient care.

Data sharing

A complex and overlapping regulatory environment can make NHS organisations wary of data sharing. NHS data is subject to the common law duty of confidentiality and to UK GDPR, but different Integrated Care Boards Trusts may have different interpretations of information governance rules. This can impede the flow and analysis of health data, particularly for DHTs which generate large datasets with the potential to open up entirely new avenues of clinical research.

Unblocking these information flows creates a huge opportunity for UK health innovation. Not only can AI models help monitor massive volumes of data and real time information, supporting clinical decision-making, but datasets created by DHTs could be used as a novel form of health information to help researchers understand how to improve treatments.

A new approach to data governance

To make full use of these opportunities we need a regulatory environment that recognises how AI processes work and allows developers to show that their models are able to be tested and monitored, that software can be rolled back to previous states when required, and that bias and anomalies can be detected and rectified in the system.

NICE has recently issued updated guidance that takes these kinds of technologies into account, but we recommend that regulators consider further steps, including greater use of, and access to, regulatory sandboxes, and using risk-based mechanisms that enable pre-qualification of algorithms or platforms to speed up regulatory approvals. Alignment between NHS, Health Research Authority and MHRA on data governance and data sharing would also support adoption of technologies that improve patient outcomes.

In general, the government should continue its stated objective of seeking a global approach to regulation, data privacy and data exchange with countries where there is no trade deal or adequacy arrangement in place, whilst remaining committed to data adequacy with major trading blocks such as the EU.

We also recommend that the proposals in the government's *Data: a new direction* consultation to enable private companies, organisations and individuals processing personal data for a public body to be permitted to rely on that body's lawful ground for processing the data. Any list of legitimate interests for which no balancing test would be required within UK GDPR, as proposed in Data: a new direction, should remain dynamic so as not to limit future applications. We believe there is an opportunity to provide sector specific, legitimate interests in areas with particular public interest benefits.

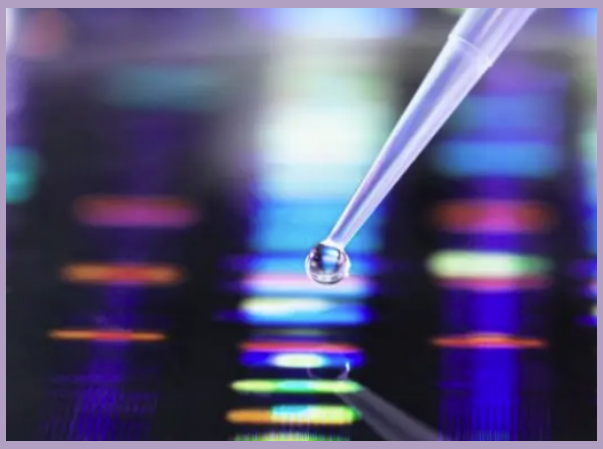
CASE STUDIES

Eating Disorders in Cornwall

Tunstall Healthcare use remote monitoring to support children with eating disorders in Cornwall. Patients are able to monitor their physical recovery without the need for face to face contact, maximising the effective use of resources within clinical teams. Early identification of stalling or falling physical recovery and response, reduces the risk of escalation to an urgent case and avoids secondary care admission.

A total of £81,000 cost was avoided in 2021/22 with reduced inpatient and Emergency Department stays. Patients save on average 64.5 hours of travel time, totalling 978 miles not travelled and £890 in petrol costs.

"The children we support are extremely vulnerable, and any delay or interruption to the treatment they receive could have serious implications for their recovery."
"Being able to deploy a solution so rapidly enabling us to continue helping them has been a real relief."
Michele Boyce, Service Lead Nurse, Kernow Health.



Open Medical: Digital Transformation at a London Trust

A London Trust faced a 20% skin cancer referral increase, high Consultant vacancy rates, and substantial locum costs. Open Medical provided the Trust with a digital tool to help meet demand, cut costs, and support the healthcare professionals.

Pathpoint eDerma is a cloud-based, clinically-coded, customisable platform, developed alongside clinicians for optimised dermatology service coordination. It enables healthcare providers to manage multiple aspects of a patient pathway via a single centralised platform. It provides visibility of the end-to-end patient journey, bridging primary and secondary care and, transcending geographical boundaries.

The Trust's distinctive service workflow involves nurses conducting initial skin lesion triage with a dermatoscope and a camera. With eDerma, the Trust triaged 97% of urgent skin cancer referrals within 48 hours and reduced evaluation time to six minutes. It generated cost savings of £132,000, and obtained 100% user satisfaction. eDerma empowers clinicians to save lives by enabling rapid access to care.

Data infrastructure

The NHS dataset is a unique national asset. Combined with AI and ML processes, it could help unlock discoveries that not only help UK patients and the NHS, but also improve lives around the world. But the cost of preparing and curating patient data for data driven research and innovation is estimated at £2-3 billion[14]. The quality of NHS datasets, the range of electronic patient record (EPR) platforms used, the time it takes to get access to data and the cost are all barriers to innovation.

In a system containing as many sovereign, free-standing organiations as the NHS, it is difficult to mandate a national EPR system, but some of the value and innovation potential of NHS datasets could be unlocked via national standards of inter-operability, data access and data portability for EPR platforms. Updating procurement processes would ensure these standards are reflected in EPR contracts over time. These standards and Application Programming Interfaces (APIs) would benefit from being open and non-proprietary.

Proposals for a number of sub-national Secure Data Environments (SDEs) are an important step forward. To maximise their value for research and innovation it will be important that commercial use cases are considered in the development of the SDEs, such as the ability for companies to be able to import and link their own datasets and utilise proprietary analytical tools.

The transition from data sharing to data access within a federated model as the default way to access NHS health and social care data for research and analysis is a significant step in the data infrastructure. Central to this approach should be clarity on terms and conditions for commercial access to data, and a focus on streamlined governance, and globally competitive commercial terms and fair recognition of value and Intellectual Property assignment.

Despite current challenges, the government must protect funding for the development and on-going running of this vital element of data infrastructure.

Commercial partnerships

The private sector has an important role to play in generating innovation, and the way that commercial partnerships are structured are key to ensuring that innovation creates public value for patients, clinicians and the NHS as a whole. We believe that partnership models can take account not only of these forms of public value, but the contribution to making the UK a globally competitive location for investment and growth.

To create the policy environment for innovation of public value to thrive, we recommend that policymakers address the IP assignment and protection regime, ensuring that it is transparent and aligned with value creation. In general, the system should support data sharing partnerships between NHS and commercial entities and consider commercial models that support innovation, collaboration and, crucially, risk-sharing.

Funding pathways

The potential of DHTs to support health prevention, treatment and monitoring is well recognised, yet some may not easily fit into existing funding pathways, which can create challenges for wider adoption. Central government spending traditionally breaks down into capital (for instance hardware or building) and revenue, or day-to-day spend (on, instance workforce). Yet these binary categories do not reflect the cost structure of running complex services which are likely to include, software as a service, consultancy, data analytics, licenses and revenues. A more flexible approach, with transparent criteria, assessment processes and reimbursement pathways that recognise the benefits to patients, clinicians and to public health, would help incentivise digital transformation and demonstrate the UK's world-leading position on HealthTech innovation.

> *"The greatest threat to roll out and rapid adoption for us is information governance which takes up so much resource. A standardised approach across the NHS could significantly accelerate deployment of data driven innovations."*
> *CEO, UK Digital Start-up*

A new approach to funding pathways

A well-designed funding system would recognise and reward not just the value that technology provides to patients and clinicians, but the value it provides to the NHS and beyond. Do they empower patients to manage their conditions themselves, reducing pressure on the NHS and improving quality of life? Do they provide an alternative to drug treatment? Do they support education and public health? And do they contribute to broader disease prevention?

The move from activity-related payments towards population-level funding with outcomes-based payment is a welcome step that helps the system focus on these wider public policy objectives. In the longer term, some DHTs, for example apps that help support rehabilitation, may not be regulated products under

CASE STUDIES

Helicon Health / Adherium Hailie® Smart inhaler

This technology supports self-management of children with asthma.

Smart inhalers can transform how children and their families live with asthma. These devices improve adherence to medication and reduce asthma attacks in the hospital setting (Morton R 2017 Thorax).

Families managed in the Leicester paediatric asthma service tell us that smart inhalers help them with asthma self-management at home and reduce the need for face-to-face hospital visits. Data from smart inhalers can be shared with GPs and/or practice asthma nurses and can be used in remote consultation.

Helicon Health, the UK partner for Adherium, supplies the Hailie® solution as the world's most clinically supported asthma medication adherence solution. Comprised of Hailie® secure cloud-based platform which captures medication use data from Class I, Bluetooth® enabled sensors which wrap around patient inhalers and provide real-time feedback to patients via the Hailie® app; and to their physicians via the web-based portal.

Monitoring medication adherence with timely intervention helps reduce hospital admissions, improving outcomes and quality of life while taking pressure from the NHS. For a select and increasing range of Hailie® sensors, physiologic parameters are also monitored.

Having physiological parameters, such as peak inspiratory flow, and inspired volume etc. allows clinicians to confirm that the medication was taken, and taken correctly.

MediMusic – Case Study

MediMusic is a business-to-business service that uses artificial intelligence and machine learning to create audio fingerprints which mimic the human brain's response to music and then scientifically dispense it as an efficacy-driven medicine for the benefit of clinical pain and anxiety. The company applies 40 years of academic research, proving music will reduce pain, anxiety, cognitive impairment and associated medication costs.

MediMusic auto-creates personalised, smart playlists that use predictive analysis to reduce heart rate, increase heart rate variability and positive endocrine secretions. Monitoring via a heart rate wearable creates a bio feedback loop, that refines the service and provides evidence based key performance indicators for healthcare services.

A validation trial with Lancashire Teaching Hospital NHS Foundation Trust demonstrated a heart rate reduction of 23-25% in dementia patients, with further trials in planning to investigate chronic pain, opioid tapering and dementia, including cost benefit analysis.

the UKCA regime, but they could still play a major part in prevention and should not be excluded from funding frameworks. Existing funding mechanisms may struggle to recognise the more esoteric benefits of a particular intervention, like patient empowerment – but we recommend adaptations to create a system that supports prevention and digital transformation.

This would involve developing a range of payment mechanisms that reflect different risk, different technological maturity, and different settings. Uncapping reimbursement mechanisms for market ready products would enable greater competition and allow local systems to choose the most appropriate solution.

Initiatives like the MedTech Funding Mandate are helpful but are limited to technologies that have had NICE guidance, presenting an extremely high bar to access, exacerbated by limited assessment capacity and long time frames. Funding at a category level would enable tariffs to reflect different use cases: for instance, a remote monitoring intervention could have a tariff for cardiovascular, diabetes and respiratory, which would help the system as a whole assess the cost-effectiveness of a new DHT solution in different clinical contexts. The recently introduced Early Value Access scheme will address some issues and has been piloted with DHTs. This will provide a more rapid assesment process, however there is no linkage to reimbursement to support early adoption.

A national payment system designed to take account of data infrastructure and future innovation would be extremely welcome. An appropriate coding methodology could be introduced for digitally enabled pathways to ensure accurate capture of cost and value. This change would make it easier to identify where an activity or service can be delivered more effectively or efficiently through a new technology. This would also allow the system to monitor effectiveness and level up care across regions.

Where there is a high level of unmet need, but uncertainties about clinical or cost-effectiveness exist, we would recommend a payment mechanism to test effectiveness on a time limited basis.

Some DHTs have the potential to predict disease risk, supporting screening programmes, or to help broader disease prevention efforts. In these cases, per capita payments could offer a way to build prevention into the funding system and take pressure from NHS waiting lists. In a decentralised system, these reimbursement mechanisms are one of the most important levers available for policymakers to achieve real change and address resource challenges through prevention.

Assessment

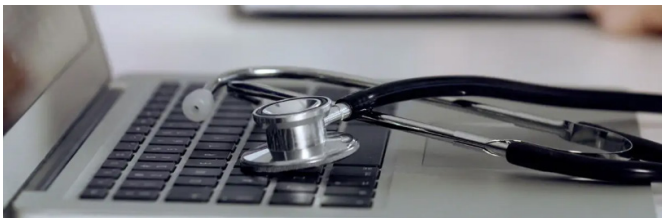
For many treatment options, NICE assessments can offer a clear signal about the value and effectiveness of a product. NICE has completed its first assessments of DHTs under a pilot programme, and this paves the way for an assessment process for DHTs with the highest clinical, financial or operational risk. Currently, assessment regimes are less focused on wider benefits like public health or prevention, and there are some changes that could make assessment more innovation-friendly.

Ensuring that assessment looks at cost effectiveness and wider health benefits would allow NHS systems to use solutions that address the most pressing problems they face. This would also reflect developments in other jurisdictions such as Germany. Assessment criteria should be transparent and specific, and financial criteria should be based on cost effectiveness and value to patients, clinicians and the NHS. Within NICE, it is important that internal capacity is developed so that DHTs can be assessed and approved at scale.

> *"The lack of reimbursement pathways for digital health technologies presents a barrier to adoption that other countries are starting to address. There is a risk that the UK will start to lag behind European and US health systems if changes are not implemented."*
> *Peter Ellingworth, CEO, ABHI*

Pricing and procurement

Procurement processes are one way for policymakers to support innovation and digital transformation within the NHS. Dynamic Purchasing Systems (DPS) have been used effectively by the NHS for example the Spark DDPS allowed health and social care organisations a fast, easy and secure way to access remote monitoring technologies to provide more care to people within their own home during the pandemic. For this reason we would support further use of dynamic systems which do not duplicate other regulatory or assessment processes.



NEXT STEPS

This paper sets out the features of a system which uses innovation and technology to address the NHS's most pressing challenges. Many of the system changes we describe do not require legislation. What is needed is leadership from the centre of the system to put these practical changes into practice. We suggest the following immediate steps to prioritise digital innovation that delivers for patients, clinicians, for the NHS, and for the wider UK economy:

1. Provide both the resource and political impetus to the MHRA to support the ambitious programme for Software as a Medical Device (SaMD) and ensure capacity to process digital health technologies.

2. NHS data should be curated and made accessible to innovators in a secure, agile and timely manner. Governance and commercial terms for access need to ensure the UK is a globally competitive location for innovation.

3. Develop an ambitious assessment programme for digital health solutions that supports clinical need, availability and choice.

4. Develop specific payment pathways that recognise the value that digital technologies can deliver in terms of early intervention, health prevention, and population level public health.

The UK is well placed to be a world leader with a distinct set of capabilities and globally leading academic and clinical assets. This report outlines some of the practical steps that need to be taken to ensure the UK capitalises on these assets and continues to be one of the leading countries in digital health. There is a risk that we could lose our leading position as other countries continue to invest in infrastructure and develop process to support and incentivise digital health care.

To realise the benefits of DHTs for patients, clinicians, health system and economy we need to ensure the positive policy environment is actively pursued and results in practical steps that delivers meaningful change for innovators seeking to develop and deploy in the UK.

ABOUT ABHI:

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

ABHI supports the HealthTech community to save and enhance lives. Members, including both multinationals and small and medium sized enterprises (SMEs), supply products from syringes and wound dressings to surgical robots and digitally enhanced technologies. We represent the industry to stakeholders, such as the government, NHS and regulators. HealthTech plays a key role in supporting delivery of healthcare and is a significant contributor to the UK's economic growth. HealthTech is the largest employer in the broader Life Sciences sector, employing 145,700 people in 4,300 companies, with a combined turnover of £30bn. The industry has enjoyed growth of around 5% in recent years. ABHI's 330 members account for approximately 80% of the sector by value.

ABHI DIGITAL HEALTH:

ABHI Digital Health works with national organisations to ensure the UK maximises opportunities for citizen health and economic wealth by investment in data driven healthcare and creates a strong infrastructure and commercial environment to support development of the best HealthTech solutions.

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13 NHS staff 'tremendously anxious' over data sharing, says new national leader

14 Realising the value of health care data: a framework for the future

GLOSSARY

ABHI	Association of British HealthTech Industries
AI	Artificial Intelligence
AIaMd	AI as a Medical Device
API	Application Programming Interface
CQC	Care Quality Commission
DERM	Deep Ensemble for the Recognition of Malignancy
DHT	Digital Health Technology
DPS	Dynamic Purchasing System
EPR	Electronic Patient Record
EY	Ernst & Young Global Limited
iCAIRD	Industrial Centre for Artificial Intelligence Research in Digital Diagnostics
SDE	Secure Data Environment
ICO	Information Commissioner's Office
IEC	International Electrotechnical Commission
IMDRF	International Medical Device Regulators Forum
IP	Intellectual Property
ISO	International Organization for Standardization
MHRA	Medicines and Healthcare products Regulatory Agency
ML	Machine Learning
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
SaMD	Software as a Medical Device
SHAIP	Safe Haven AI training Platform
SME	Small and medium-sized enterprises
SROI model	Social Return On Investment
STEM	Science, Technology, Engineering and Mathematics
UK GDPR	UK General Data Protection Regulation
UKCA	UK Conformity Assessment

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