ABHI

MAKING IT HAPPEN: DELIVERING FUTURE INNOVATION IN HEALTHTECH

CONTENTS

FOREWORD

It is suffice to say that one year ago, none of us would have predicted what was about to happen, and none of us could have been adequately prepared. However, we have seen the best of how the NHS can adapt and operate in the face of adversity. The pandemic hit at an already challenging time at the end of the EU exit Transition Period, but through it all, we have seen a resilience and a determination that gives us hope. We see many key opportunities for collaboration between the government, the NHS, academia and industry to expedite the adoption of innovation.

What do we mean by "innovation" in patient care, and how do we describe it in the response to COVID-19? Is it individual technologies, such as those that deliver telemedicine, that were adopted at scale in response to lockdown? Or is it the innovation in the streamlining of systems and procedures in order to cope with the enormous strain on our healthcare system? Or is innovation actually best defined as the huge cultural shift that happened almost overnight as a result of the pandemic? Often, innovation fails, but we need to embrace this, learn from it quickly and be empowered to innovate again. This report aims to provide recommendations to help government do exactly that.

We have looked at the outcomes of innovation across many settings, including primary, secondary and social care, as well as from within industry, to study what has been successful, what has not, and to offer an insight into what the future may hold. But in doing so, we have raised questions that will need to be explored further. For example, in many instances what we have done was essentially solve a particular problem very quickly, but has there been the associated and necessary long-term, sustainable strategy developed alongside it to embed it into culture and practice? How do we sustain the changes we have embraced when it is in our very nature to go back to what is comfortable, to what is "normal"? We were able to switch quickly and effectively to text messaging services, remote triaging of patients and virtual consultations, but can this and will this work in the long-term? Can this type of technology support the democratisation of healthcare delivery, making it more accessible to the homeless or the young for example? Or, if this is a change that does not happen universally, will we merely create further, technology generated health inequalities?

We have seen the importance of timely and accurate diagnostic testing throughout the pandemic, and recognise that it will be key to managing the virus in the years to come. These lessons are applicable across other patient pathways and building an early diagnosis culture based on innovation must be a priority.

Innovation can also mean changes to the way our healthcare professionals deliver patient care. Longstanding NHS workforce challenges have been exacerbated by Brexit and COVID-19. Large numbers of staff are exhausted and there has been little time to think about even mandatory training, let alone the supplementary skills associated with new technologies. But we believe there is opportunity here too. The rapid adoption of technology and adaption to different ways of working has proven that change is in the DNA of the NHS, but we must continue to create a culture and environment that enables people and organisations to change. We must also look at the wider healthcare system and the patients it serves. One patient we spoke to told of how when booking for a GP appointment, she had to detail not only her medical details, but her ethnicity and salary bracket, causing her to question for precisely what purpose the information would be used. Public confidence, particularly in the collection and use of data, will be critical to realise the full benefits of technology. Collection of strong data allows healthcare systems to make informed decisions for patients. This is fundamental for understanding the burden of disease and unmet need, as well as researching and developing new innovative treatments and delivering quality healthcare services to patients. When applied effectively, data also supports value-based decision-making and sustainability of healthcare systems and can be used in effectively evidencing and evaluating innovation. This improves patient outcomes and safety, and helps the NHS to deliver the best possible care. Related to this is to what extend new, sovereign regulatory arrangements can work better to ensure patients have access to innovative, safe HealthTech.

This report also comes at a time when upcoming legislation will herald a fundamental change to the way in which care is organised through the creation of Integrated Care Systems across England. Intuitively, the move should break down siloed ways of working and budgets, a persistent and significant barrier to the adoption of new technologies. For patients, it ought to involve a more holistic approach, designing better care pathways to meet the entirety of their needs. As the new financial architecture of the NHS develops, appropriate payment mechanisms and incentives must be designed to facilitate the introduction of new technologies and the delivery of care remotely and / or in non-traditional settings.

The government is currently consulting on public procurement. Procurement cannot be simply about acquisition cost savings, it must provide the system with a true value-based offer, taking into account the full benefits of technology in the longer-term and the sustainability of supply. Too often initiatives have focussed on transactional arrangements that aim to reduce the number of suppliers to the NHS with no consideration of the implications for its supplier base or the impact on innovation, especially in niche and low volume clinical areas. This is a particular problem for SMEs who struggle to access appropriate finance, in part because the investors see the challenges they will inevitably face in the UK.

Perhaps, then, innovation is the ability for each part of the system to work together towards a common goal. During the pandemic, we have proven that when we need to, we can work together to create change and innovation. It is only by pushing forward do we find out what is possible and do the right thing for patients, science, the NHS and our economy. But what ultimately underpins all of this is people. We are all patients at one time or another and all of us will use the NHS in its various forms throughout our lifetime, so how do we protect it? By working together to continue to adapt to the world in which we live. Simply put, we must innovate.

INTRODUCTION

As the largest employer in the broader Life Sciences Sector, HealthTech (medical devices, diagnostics and digital health technologies) currently employs 131,800 people in 4,060 companies, with a combined turnover of £25.6bn, and has enjoyed annual growth of around 5% in recent years. The UK represents roughly 5% of the global industry, and HealthTech is set to remain a key driver of economic growth in our country, and is an industry government has committed to supporting.

Although the UK is seen as a key market, a recent survey of UK HealthTech companies (see appendix item 1) showed 70% have experienced rising costs of regulation, over a third see the NHS as an increasingly expensive customer to serve, and almost two thirds were negatively impacted by COVID-19. Despite this, there are significant opportunities. Whilst almost half of companies in the sector do not currently have either R&D or manufacturing facilities in the UK, a quarter are currently looking to expand here in the next year. There are also some signs that companies are beginning to view the UK market with increasing confidence, although for many this will depend on how quickly elective care returns consistently towards its pre-COVID-19 levels.

In the 1990s and 2000s, the NHS made large investments to reduce waiting times for planned surgery. Referral to treatment times remain low by historic standards, and GP referrals are flat, but in recent years treatment capacity has not grown fast enough to keep up with patient need, and the number of patients waiting longer than 18 weeks has been steadily increasing. The situation has been dramatically exacerbated by the COVID-19 pandemic. At the start of the pandemic around 1,600 people were waiting more than 52 weeks for treatment, that figure is now in excess of 300,000 and is set to grow as patients begin to re-enter the system, with the NHS Confederation estimating this number could be above 5 million[1].

It is 20 years since Sir Derek Wanless described the NHS as a late and slow adopter of technology and in the intervening years there have been many initiatives aimed at addressing this. The response to the pandemic has demonstrated that the NHS can be as agile and fleet-footed as any other healthcare system in the world, and now, we must not only build on the lessons learnt, we must also strive to overcome some of the more systemic challenges that still remain.

This report aims to provide recommendations for how the UK can work collaboratively to achieve both aims, and ensure innovation is encouraged for the benefit of patients, the NHS and the wider UK economy.

The recommendations (summarised on pages 6-10) focus on areas identified as critical to innovation, and are described as key drivers for the industry and the enablers required to achieve them.

Key drivers:

1. Sustaining positive pandemic response innovation
2. Building in an early diagnosis culture
3. Integration through remote care delivery

Key enablers:

1. A HealthTech champion
2. Research, development and manufacture of technologies
3. Developing our new regulatory system
4. Effectively evidencing and evaluating innovation
5. Encouraging the rapid adoption of technology
6. Supporting value-based decision making
7. Improving access to finance
8. Maintaining and expanding existing schemes

RECOMMENDATIONS SUMMARY

Key Driver #1 Sustaining positive pandemic response innovation

01.
- Take a whole pathway approach to ensure that patient flows are operating effectively, this includes:
  - 'Pre-hab' interventions to ensure patients are optimal for surgery, reducing cancellations and minimising length of stay.
  - Early-stage diagnosis and screening to identify and risk-stratify patients on waiting lists and to ensure clinically appropriate and timely referral pathways, via a multi-disciplinary team approach.
  - Discharge processes and facilities to maximise bed availability.

02.
- Acute capacity needs to be optimised through:
  - Appropriate use of independent sector.
  - Maximising alternative pathways to move to day case for the most clinically appropriate patients.
  - Rapid assessment and national roll out of changes to intervention protocols that support staff efficiency, reduce admissions and length of stay.
  - Target clinically appropriate high volume/low risk procedures for 'industrialisation' following GIRFT principles and restructuring service delivery.

03.
- A key national objective should be to increase the proportion of ambulatory or minimally invasive surgery vs general surgery. This needs investment in:
  - Infrastructure e.g. more efficient day surgery hubs.
  - Systems that support efficiency, such as those for list planning and staffing.

04.
- Provide incentive, funding, training and infrastructure for increased use of technology. This should include appropriate payment mechanisms and changing the funding regime to remove the need for in-year savings, publishing multi-year capital allocations and accelerating capital approval processes.

05.
- 'Technology' might usefully be defined as including:
  - Remote care and services including remote management/virtual wards and video and telephone appointments.
  - Infection prevention technology.
  - Self-care applications.
  - Data modelling and analytics
  - Diagnostics.

06.
- Adopt remote monitoring to support the urgent optimisation and prioritisation of the surgical waiting lists and backlogs nationally. Use of digital remote care can help identify deterioration, ensuring that those in need receive surgery at the right time, saving lives, improving patient outcomes, and reducing cancellations.

07.
- Remote monitoring should become the standard of care for patients post-operatively, supporting earlier discharge, enhanced recovery and minimising potential complications and avoidable readmissions.

08.
- Indications of undiagnosed chronic disease can be treated and monitored, rather than wait for acute secondary care admissions.

Key Driver #2 Building in an early diagnosis culture

09.
- Place early diagnosis at the centre of population health management through an expansion of the diagnostics workforce and the deployment of new service delivery models.

10.
- Increase investment in primary care, community and near patient diagnosis capacity. This should include the implementation of community diagnostic hubs.

11.
- Expand early access to diagnosis pathways.

12.	• Put in place strategic, co-ordinated system leaders with sufficient authority to drive holistic, early diagnosis in managing population health.
13.	• Deliver better coordinated care through appropriate data sharing.
14.	• Put in place necessary and appropriate payment, regulatory and assessment mechanisms to ensure that patients have access to innovative and lifesaving diagnosis solutions.
15.	• With NHS laboratories integral in delivering high quality tests, the process, timelines and outcomes of the pathology network consolidation in England needs to be urgently reviewed to take account of the proposed NHS reforms and lessons from setting-up the COVID-19 testing systems and infrastructure.
16.	• Build on lessons and opportunities, which have been established as part of the COVID-19 response, to further grow partnerships and collaboration between industry, NHS, academia and Government, that will support the development of the next wave of transformative diagnosis innovations.
17.	• Re-purpose the Testing Taskforce to focus on future planning for diagnostics. The taskforce should consider the key diagnostic competencies, capabilities and skills the UK requires to support the NHS in future pandemics or health emergencies, the current domestic supplier landscape and consider what incentives or interventions are needed to bridge the gaps.
18.	• Learning from the success of the UK Rapid Test Consortium (UK-RTC), further "consortia challenges" should be initiated to harness the UK's capability to research, develop and manufacture high-quality diagnosis technologies to aid early detection of disease. These could be delivered through an iteration of the existing "Sector Deals."
19.	• Appraise the success of the Medicines and Diagnostics Manufacturing Transformation Fund, in particular the capital grant regime, as a vehicle to attract foreign direct investment in the diagnostics sector. This will inform a Diagnostics Manufacturing Action Plan to address strategic weaknesses in the UK's diagnostics manufacturing base.
20.	• Develop an appropriately resourced industry / NHS /academia diagnostics translation accelerator to bridge the gap between early-stage science and the market. This could be modelled on the various Catapults that exist to coordinate and support the next wave of transformative diagnostics innovation.

Key Driver #3 Integration through remote care delivery

21.	• Create a cohesive system to gather evidence at scale. A greater understanding and evidence base are required for the benefit generated from digital components of virtual wards as opposed to more traditional telemedicine. Ensure the real time capture and aggregation of diagnostics data from these interactions.
22.	• Large scale trials should take place simultaneously across Trusts, geographies and patient groups, rather than in individual series. This way, evidence of enhanced patient outcomes and health system efficiency (e.g. reduced outpatients, admissions and A&E attendances and shorter length of stay and improved clinical capacity from saved time) can be demonstrated in multiple therapeutic areas, particularly across long-term conditions.
23.	• Ring-fence annual funding for digitally-enabled remote care. Annual funding and support must go beyond just the software to include devices and service transformation. Significant time is required by clinical teams to redesign pathways, operating procedures and to support implementation. Collaborate with industry to explore how they can best support the existing workforce. o Integrated Care Systems (ICSs) should be allocated funds to support the roll-out of remote patient monitoring across their footprints. o In-home vital signs devices should be procured centrally for use by ICSs to support adoption of remote care. o Payment mechanisms should be established to incentivise the use of remote monitoring technologies. o Increase patient awareness and use of remote monitoring.
24.	• The DPS Spark Framework should be used more widely and simplified to support rapid scaling.
25.	• Adopt national approval standards to speed up implementation. A national IG/Data Protection/Digital care standard, by which all remote monitoring providers need to be accredited, and which is accepted by all NHS providers, would drastically speed up implementation. The NHS Digital Technology Assessment Criteria process (supported by NHSX) could enable this.

Key Enabler #1 A HealthTech champion

26.	• Given both the size of the sector and the opportunity it holds, we recommend that government appoint a HealthTech Champion to sit alongside Professor Sir John Bell and ensure better representation of the sector.

Key Enabler #2 Research, development and manufacture of technologies

27.	• There should be a detailed mapping exercise to identify areas of HealthTech R&D and manufacturing excellence, including skills capability, in the UK along with a strategy to build on it, and the related sectors that could be developed alongside it.
28.	• A HealthTech specific catalyst should be developed to help crowd-fund finance for R&D.
29.	• Improve signposting to existing mechanisms and, where appropriate create new ones to bring NHS clinicians and managers together with the HealthTech industry to share issues and problems. (See also overarching challenge of HealthTech adoption).
30.	• Expand and increase the focus of demand signalling within the AAC.
31.	• For diagnostics specifically, a long term testing strategy will enable a stable environment for R&D and subsequent manufacture aligned with unmet needs.
32.	• Access to high quality, well curated data sets should be available to researchers and innovators to help them improve patient care and system efficiency.
33.	• International standards should be used to support a shared health dataspace, and facilitate secondary use of aggregated data for research, testing and the implementation of services.
34.	• Intellectual Property should accrue to those that are creating value.
35.	• Government should make funding available for a significant programme of data cleansing and curation, along with support for the delivery of health data infrastructure.
36.	• A public awareness campaign by the Government to highlight the benefits of data sharing to the individuals, peer groups, the NHS and wider society.

Key Enabler #3 Developing our new regulatory system

37.	• The UK should continue to advocate use of real-world evidence through registries, post-market surveillance and vigilance as a mechanism to stimulate innovation and the development and introduction of new products.
38.	• Capitalise on global interactions and maximise the global reputation of MHRA. Other jurisdictions could be considered as models for best practice.
39.	• Reduce the financial burden of regulation, particularly on SMEs, by ensuring alignment or recognition of global requirements and equivalents, particularly with auditing and Conformity Assessment.
40.	• Anticipate future trends in products (such as drug/device/digital/ diagnostic companions and combinations), thereby improving appropriateness, predictability and transparency of regulation.
41.	• Ensure the cost and time from invention to uptake is the minimum required to ensure patient safety and meet clinical needs.
42.	• Reconsider the UK standstill deadlines to include a more reasonable transition time to compulsory UKCA marking.

Key Enabler #4 Effectively evidencing and evaluating innovation

43.	• A more flexible approach to technology assessment, including the acceptance of real-world evidence and a wider definition of value, needs to be developed in conjunction with the HealthTech industry.
44.	• There needs to be flexible commercial arrangements, based on a value assessment of the wider UK economic benefits of HealthTech, and not solely on those enjoyed by the NHS.
45.	• Full implementation of the Health Technology Partnership (HTP) Access scheme that is currently in development.

Key Driver #5 Encouraging the rapid adoption of technology

46.	• Mandate through the upcoming NHS White paper that every NHS organisation must appoint a board level Chief Innovation Officer to share the success of technological innovation, drive clinical and patient enthusiasm, and support required transformational change.
47.	• As part of the CQC well-led framework, require an innovation reporting mechanism/scorecard.
48.	• Develop the Plagiarism Award, a prize for the timely and successful implementation of ideas borrowed from elsewhere.
49.	• Develop the Collaboration Award, a prize for innovative examples of collaboration between industry and NHS.
50.	• The Office for Life Sciences (OLS) should work with industry to develop an agreed set of metrics to measure progress of adoption.

Key Driver #6 Supporting value-based decision making

51.	• A value-based approach to procurement needs to be adopted through a multi-agency, cross-sector strategy with an objective to maximise rapid patient access to the latest, proven innovations. Methodologies should take into consideration system and relevant patient outcomes, clinical opinion, supply chain resilience, evidence, ethics and quality. Work should be completed to agree the metrics to which this is completed by linking evidence generation with a value-based approach.
52.	• New payment mechanisms should be explored to expedite the use of digital HealthTech. Considerations must also be given to broader based incentive schemes that can reward whole system performance and outcomes-based targets.
53	• The NHS needs to consider its impact on the supplier base and how it influences the cost to serve driven by its tendering and ordering behaviours.
54.	• There needs to be a fair, transparent and equitable mechanism for individual companies to raise concerns regarding the viability of pricing and consequent supply of any given product to the NHS.
55.	• Government and industry to re-engage on the Scan4Safety programme and support its full implementation by the NHS.

Key Driver #7 Improving access to finance

56.	• At the macro level, UK HealthTech needs to be perceived as a vibrant, entrepreneurial sector which is encouraging of innovators and thought leaders. All the initiatives mentioned elsewhere in this paper will help toward this goal but a concerted and sustained campaign to enhance the "invest in HealthTech" message could pay dividends. Government can play a major part in developing an improved HealthTech investment community.
57.	• The barrier presented by the NHS as a dominant buyer and a deterrent to adoption has to finally be broken. Fast-track, possibly pilot, innovation schemes which can bypass traditional procurement routes are essential. These would provide an early evidence base for further growth, or indeed kill off quickly those which are unlikely to succeed and avoid the "slow no" which is a drag on investment.
58.	• Expand and enhance the knowledge base of leaders through initiatives such as the Clinical Entrepreneur Programme. Several similar schemes exist on a regional basis and these should be encouraged and better coordinated.
59.	• An education and signposting scheme is required to help innovators through the maze of options through the whole spectrum from early stage and grant funding, right through to venture and corporate finance. Joining up national and regional initiatives would be beneficial. As an example, the Chamber of Commerce network has excellent resources for funding but not specifically targeted at HealthTech. Similarly, sector-specific resources from organisations such as Innovate UK EDGE, SBRI and the Knowledge Transfer network could be coordinated and developed.
60.	• At a time when cash flows have been seriously impacted, it is important that the NHS is a good payer, sticking to payment terms and, preferably, actually improving them. The failure of Trusts to pay on time is a persistent and significant issue for small companies. NHS organisations frequently work outside Government Prompt Payment Policy which can be crippling for SMEs.
61.	• HealthTech businesses must have the best possible access to existing schemes such as Coronavirus Business Interruption Loan Scheme (CBILS). Such schemes need to be fair and reasonable, without excessive interest rates or unfriendly terms. Cash flow issues could be abated if extensions cover off at least six months post a return to usual business. Government could helpfully extend guarantees to lenders and confirm the NHS as a blue-chip customer. HealthTech companies should be afforded 'special status' as suppliers to the NHS, allowing banks to extend credit without usual constraints (e.g. multiple of EBITDA increased).
62.	• An extension of time-to-pay schemes should be considered, covering VAT, PAYE, and Corporation tax.
63.	• The R&D tax credits scheme should be reviewed, and a two-tier system where companies with a less than £5m turnover receive a higher level benefit is recommended.
64.	• Advance Purchase Orders can be problematic in that they create a black hole for future sales, but in the current extraordinary circumstances they may be helpful to allow planning and stock build and provide extra security for lenders. A scheme should be considered to allow HealthTech companies to be paid in advance and stock called off as required.
65.	• NHS suppliers should be given an indication of future demand to facilitate the planning of manufacturing and distribution.

Key Enabler #8 Maintaining and expanding existing schemes

66.	• The extension and expansion of current initiatives which promote adoption of innovation. o The Academic Health Science Networks (AHSNs). o The Small Business Research Initiative (SBRI). o The Accelerated Access Collaborative (AAC) including the Med Tech funding mandate. o Regional Innovation Hubs. o Technology Transfer departments within academia. o Pathway transformation funds (PTF). o Made Smarter national funding rounds.

KEY DRIVER #1:
SUSTAINING POSITIVE PANDEMIC RESPONSE INNOVATION

On 30th January 2020, NHS leaders declared COVID-19 a serious, level 4, incident. This led to a five-pronged strategy to address the crisis, including postponing planned activity and stopping non-urgent care stopping during the initial surge of COVID-19 cases.

Following the peak of the pandemic in the UK in early April, NHS England (NHSE) announced, on 29th April, steps towards the reintroduction of planned care[3] opening up the possibility for a resumption in screening, referral pathways, diagnostics, non-urgent cancer care and elective interventions.

Up until September, when the number of COVID-19 cases began to quickly rise again, the NHS was broadly sustaining its recovery trajectory across all services[4], and was on track to deliver the targets set by NHS England as part of the phase 3 recovery plan[5].

This increase in performance was, however, derailed by a further rise in cases resulting in a second national lockdown. Whilst during this phase there was no blanket cessation of elective activity, the realities on the NHS frontline meant further non-urgent cases were cancelled.

It is difficult to estimate exactly the impact on waiting lists due to uncertainty about how many of the people who did not come forward for treatment during the COVID-19 period, will now do so in coming months and years[6]. Referrals remain well below pre-COVID-19 levels, which suggests that the hidden backlog of pent-up demand is continuing to grow[7].

It is generally accepted that waiting lists will increase by millions, this is on top of the existing list that for the past few years has consistently hovered around a 4.4million[8]. As of April 2021, there are around 4.7 million people waiting for routine operations, the most since 2007. Furthermore, there are nearly 388,000 people waiting greater than 12 months for non-urgent surgery compared with 1,600 pre-pandemic[9].

The waiting list could take up to two years to clear[10] depending on system capacity, whilst the Royal College of Surgeons has called for a 5-year strategy to tackle the waiting list situation[11].

Against this backdrop, the NHS is accelerating the delivery of operations and other non-urgent services as part of a £8.1 billion plan to help the health service recover all patient services following the intense winter wave of COVID-19[12]. NHS England has set out planning guidance[13] for the next 6 months (April – September).

This is a time for radical reform and a strategic view on how to re-shape health and care delivery by the NHS. This has been acknowledged by NHS England, with CEO Sir Simon Stevens saying they must look at it as an opportunity to think innovatively and radically about pathway redesign and that maximising elective capacity is vitally important[14].

Appropriate use of innovative technology to support fundamental changes in pathways design and place of care delivery, can enable effective triage, better patient flow through the system and release capacity. There are particular opportunities to increase ambulatory or minimally invasive surgery that will also deliver better patient experience and outcomes.

To deploy technologies effectively and at scale, there needs to be support from the financial system and we make recommendations on both capital and revenue budgets. Finally, ensuring patient care remains central to decision making as we look to embed the learnings of the pandemic, will be crucial. Building in mechanisms such as the patient activation measure should help ensure success in this area.

Case Study: Innovating delivery of treatment through the pandemic

After publication of the NICE COVID-19 Rapid Guidelines: Dialysis Service Delivery (NG160)[15] , Baxter Healthcare Ltd worked closely with the emergency Renal networks to operationalise the guidelines and to meet increasing demand for home therapies. This collaboration with the NHS enabled an additional 150 patients [by May 2020] to receive their treatment at home since the start of the pandemic. Capacity was increased for patient training through the Baxter Education Centres (BEC)[16] which opened seven days per week in Spring 2020 so more patients were able to stay at home. Home dialysis data from the Renal Registry showed a reduction in mortality compared to in centre hemodialysis, helping protect this vulnerable patient group.

Recommendations

- Take a whole pathway approach to ensure that patient flows are operating effectively, this includes:
  - 'Pre-hab' interventions to ensure patients are optimal for surgery, reducing cancellations and minimising length of stay.
  - Early-stage diagnosis and screening to identify and risk-stratify patients on waiting lists and to ensure clinically appropriate and timely referral pathways, via a multi-disciplinary team approach.
  - Discharge processes and facilities to maximise bed availability.
- Acute capacity needs to be optimised through:
  - Appropriate use of independent sector.
  - Maximising alternative pathways to move to day case for the most clinically appropriate patients.
  - Rapid assessment and national roll out of changes to intervention protocols that support staff efficiency, reduce admissions and length of stay.
  - Target clinically appropriate high volume/low risk procedures for 'industrialisation' following GIRFT principles and restructuring service delivery.
- A key national objective should be to increase the proportion of ambulatory or minimally invasive surgery vs general surgery. This needs investment in:
  - Infrastructure e.g. more efficient day surgery hubs.
  - Systems that support efficiency, such as those for list planning and staffing.
- Provide incentive, funding, training and infrastructure for increased use of technology. This should include appropriate payment mechanisms and changing the funding regime to remove the need for in-year savings, publishing multi-year capital allocations and accelerating capital approval processes.
- Technology' might usefully be defined as including:
  - Remote care and services including remote management/virtual wards and video and telephone appointments.
  - Infection prevention technology.
  - Self-care applications.
  - Data modelling and analytics.
  - Diagnostics.
- Adopt remote monitoring to support the urgent optimisation and prioritisation of the surgical waiting lists and backlogs nationally. Use of digital remote care can help identify deterioration, ensuring that those in need receive surgery at the right time, saving lives, improving patient outcomes, and reducing cancellations.
- Remote monitoring should become the standard of care for patients post-operatively, supporting earlier discharge, enhanced recovery and minimising potential complications and avoidable readmissions.
- Indications of undiagnosed chronic disease can be treated and monitored, rather than wait for acute secondary care admissions.

KEY DRIVER #2:
BUILDING IN AN EARLY DIAGNOSIS CULTURE

In the summer of 2020, ABHI produced a series of publications, under the title "Diagnostics: A Future Roadmap" [17], highlighting recommendations in areas of specific relevance to the HealthTech sector, so that the UK is both better prepared for future pandemics, and the sector is positioned as a key driver of economic growth.

The need to develop and strengthen UK diagnosis capability was identified as a strategic priority. Since the publication of our report, several others, including Professor Sir Mike Richards's for NHS England[18] and Cancer Research UK's "Early Detection and Diagnosis of Cancer: A Roadmap to the Future"[19], have stressed the requirement for investment and reform of diagnostic services.

NHS England/Improvement has a holistic diagnosis strategy (encompassing pathology, imaging, endoscopy, physiological, genomics) in its sights. The government must work with this, to align and deliver a holistic early diagnosis strategy with clear deliverables to achieve in a timely fashion. There are series of success measures we recommend the government aims for, including an increase in the per capita spend on diagnosis as compared to other European nations, guarantee of equity of access to tests, including scans, access across all regions of the UK and an increase in the level of investment in diagnosis, in both manufacturing and Research and Development.

The growth of a UK diagnostics industry would also be supported by a significant shortening of the technology adoption timeline, the full implementation of MedTech Funding mandate for all NICE approved diagnostics, and the recovery of waiting times for diagnostic testing to pre-COVID-19 levels and meeting the various targets laid out in the NHS Long Term Plan[20] related to early diagnosis.

The full benefits of diagnostics are realised when they are positioned as a key enabler for the delivery of population health management. Investment is key, and needed to address workforce shortages, upgrade equipment, adopt new technologies and service delivery models.

Expertise is crucial for the success of population health management. A wide range of health professionals is needed to provide a high-quality, efficient diagnosis service. However, over recent years expansion of these professional groups has not kept pace with increases in demand and activity. Staff shortages in radiology[21] and pathology[22] are well documented. There is an urgent need to develop and implement an NHS diagnostics workforce plan to boost expertise. As demand continues to rise over coming years, it will be vital to not only increase recruitment and training across all groups, but to also consider new roles and ways of working.

NHS laboratories are integral in delivering high quality tests, they conduct around 80% of in-vitro analysis[23]. They have high standards of accreditation, governance, and data connectivity to patient records. Yet, they have experienced serious under-investment.

New technologies and partnerships are changing how all diagnosis happens, for example through digitalisation and application of machine learning techniques. This modernisation drive provides an opportunity for new systems and processes to take hold and productivity to increase over the long-term.

Alternative diagnostic delivery models have emerged in recent years, the "place" where diagnosis occurs is moving ever closer to the patient.

Rapid diagnostics centres have been a success, yet most are centred on acute sites which are busy and not always easily accessible. By expanding community diagnosis provision, particularly for elective diagnosis or outpatient referrals, there is an opportunity to relieve pressure on hospitals and provide quicker access to tests and offer greater convenience to patients. Up-front investment is needed to build more capacity through the establishment of community diagnostic facilities. The exact number and how they should be configured needs to be agreed by each Integrated Care System.

This more distributed model can be complemented by the use of point of care testing (POCT), home testing and virtual consultations/digital tools to aid self-care. How we test for COVID-19 has brought POCT firmly into the public consciousness and provides a chance to look again at its application across a wider array of conditions.

We must consider how POCT can play a role to empower patients to accurately and proactively diagnose, and subsequently manage, their own health. The infrastructure and processes for ordering and distribution of lateral flow home testing kits, an effective channel to reach citizens, can be retained and leveraged to expand POCT.

Patient pathway transformation will be needed to realise system value, as well as improve patient experience, from this distributed, early/proactive diagnosis approach. NHS England/Improvement should identify three or four high impact diagnosis technologies/ service delivery models with a goal of embedding them into pathways, completing the transformation within two years, both demonstrating the system value of earlier access to diagnosis and delivering material improvements in the patient experience.

Recommendations

- **Place early diagnosis at the centre of population health management through an expansion of the diagnostics workforce and the deployment of new service delivery models.**
- **Increase investment in primary/community diagnosis capacity as well as closer to the patient. This should include but not be limited to the implementation of community diagnostic hubs.**
- **Expand early access to diagnosis pathways.**

The opportunity that diagnosis presents in supporting health improvement and management is now strongly recognised by the public. However, the system in which diagnosis operates is complicated and disjointed, with decision making markedly slower and more disparate than in other countries[24].

Though activity levels are now increasing, diagnosis procedures remain well below pre-pandemic levels[25] and a plan is needed by NHSE/I on the recovery of waiting times for diagnostic testing to pre-COVID-19 levels, and to restate the various targets laid out in the Long Term Plan related to early diagnosis.

To deliver our earlier recommendation, leadership and resourcing is much needed to ensure alignment and strong co-ordination of strategy implementation. A new 'National Diagnosis Strategy' should be set out by the NHS addressing how the backlog of diagnostic activity will be cleared and the transformation of diagnosis to facilitate earlier detection and prevention across national clinical priorities such as cancer, and self-care for chronic conditions.

The plan should also focus on expanding the provision of qualified individuals to support the boosted role for diagnostics in patient pathways, as well as developing the technical and professional capacity to support the shift to earlier detection and diagnosis, particularly those with the technical proficiency to lead the step change to digital diagnosis and remote monitoring.

We would also suggest the appointment of a 'National Diagnosis Director' operating jointly from the Department of Health and Social Care and NHS England/Improvement, and clear guidance on the intended roles and responsibilities between different governmental departments and NHS Authorities. There should also be close working between devolved nations on a national diagnosis strategy so lessons can be shared.

Recommendation

- **Put in place strategic, co-ordinated system leaders with sufficient authority to enable the role of holistic, early diagnosis in managing population health.**

The move to conducting more diagnosis in primary care and community settings, and closer to the patient, must dynamically embrace the adoption of digital innovations.

The COVID-19 response has shown that sharing data and acting on that information quickly, have been strategies enblers in managing the impact of the pandemic. Digital apps (in particular the NHS App and the NHS COVID-19 App), as well as text messaging, have been important tools to engage citizens. Data links (e.g. connecting test and genomic sequencing results to patient records) and sharing amongst partners has helped to identify coronavirus variant hotspots and deploy surge testing and enhanced contact tracing.

The value of quick access to accurate information and the utility of digital tools has fundamentally shifted public perception of data sharing and integration for the better. To test this, two high priority disease pathways should be selected for digitalisation to the fullest possible extent, ensuring data flows seamlessly through care settings in a secure, compliant and accessible fashion.

The NHS is data rich[26], its patient records cover the entire UK population from birth to death . However, at present health data is collected by an extensive range of organisations and processes, meaning researchers, commissioners and innovators are not always able to access the NHS data they need due to the fragmented nature of the datasets, the lack of interoperability and the burdensome and diverse information governance requirements.

Information governance requirements should be standardised through a Centre for Data Collaboration. The NHS and industry are already working towards greater interoperability of technology systems and this will continue in a targeted fashion. There is a need to invest in data quality through building-out Health Data Research UK structures so that we can embrace the UK's unique global position to become a global leader in AI, machine learning and automated technologies.

Recommendation

- **Deliver better coordinated care through appropriate data sharing.**

A combination of central interventions and local initiatives need to come together to drive-up the adoption of diagnostics technologies. To bring through innovative diagnostics tools will require new or enhanced funding and access mechanisms. The Accelerated Access Collaborative (AAC) and the MedTech Funding Mandate for devices and diagnostics must be supported by the necessary funding and infrastructure to expand the adoption and diffusion of a significantly greater number of diagnostic technologies than the few it currently allows.

The feasibility of an early access scheme for diagnostics, equivalent to that for medicines, should be explored to ensure that promising, innovative diagnostic technologies that do not meet each of the Funding Mandate eligibility criteria, but have a sound clinical and economic proposition, are able to be commissioned through central funding.

As the NHS moves to Integrated Care Systems, and away from activity-based payments, the new payment system should look to remove financial silos so that the value and benefits of diagnosis, as with other technoilogies, are recognised across the entirety of a patient pathway. NHS procurement of diagnostics needs to better prioritise reliability, sustainability, and value, learning the lessons from COVID-19 and NHS England/Improvement and the Department of Health and Social Care should state their intention to move more diagnostic commercial awards onto longer term strategic partnerships based on genuine risk-share, value and population health, rather than procurement on unit cost for short-term savings. Routes to market and procurement approaches must provide greater flexibility, to help smaller businesses gain commercial traction with the NHS. A UK-wide national, standard set of contractual requirements for Pathology Managed Services, based on clinical need that represents an equitable balance of risk between NHS organisations and suppliers, must be negotiated. Focus then needs to be given to ensure the standards are fully utilised.

The new UK regulatory framework for medical devices and in vitro diagnostic medical devices should act as enablers of new technology allowing patients and clinicians access to innovative diagnostics technologies that meet high unmet clinical need as early as possible through the use of innovative regulatory mechanisms such as target product profiles, common specifications, MHRA premarket role and post market clinical evidence drawn from real world clinical experience and enhanced surveillance methodologies.

NICE's stated intent to increase the use of different types of evidence, with an emphasis on real world evidence sources, will be particularly important for the development of guidance for diagnostics. Assessors of diagnostic technologies need to have diagnostics expertise in order to mitigate concerns that a conservative approach to evaluation may be taken when what is considered to be gold standard evidence is not always available.

Recommendation

- **Put in place necessary and appropriate payment, regulatory and assessment mechanisms to ensure that patients have access to innovative and lifesaving diagnosis solutions.**

The reform of NHS pathology services has been underway for a number of years, and the strategic purpose of this reform must now be reviewed.

The reform agenda needs to be more than a simple consolidation or networking of existing NHS sites. It should consider how citizens access diagnosis services, where best to conduct and process tests and scans, and how data and results are disseminated. The diagnosis workforce plan recommended above needs to be part of this review.

The goal should be to move the service to wherever it makes most sense for the citizen, and move the test processing to wherever the best quality and productivity can be guaranteed. This will mean an audit and assessment of the diagnosis asset base (that built for the COVID-19 response and that which existed previously). A role for the high-throughput Lighthouse Labs must be identified as they have the potential to perform the bulk of the non-urgent NHS workload. They would, of course, need to retain necessary agility and responsiveness to changes in demand for particular diagnostic services, e.g. as an outsourced provider of private testing.

Recommendation

- **With NHS laboratories integral in delivering high quality tests, the process, timelines and outcomes of the pathology network consolidation in England needs to be urgently reviewed to take account of the proposed NHS reforms and lessons from setting-up the COVID-19 testing systems and infrastructure.**

Central to the UK's COVID-19 testing response, has been collaboration between different organisations within the diagnostics ecosystem, public and private laboratories, NHS England, Department of Health and Social Care, Public Health England, academia, and industry, small and large. Whilst national leadership will help with alignment and co-ordination, a broader forum to ensure the different groups continue to co-ordinate, share learning and work collaboratively will be crucial to ensure the achievements and progress made are not lost. Trust is key to facilitating partnership working and a broader forum will continue to help in this regard.

We have formed a diagnostics group under the auspices of the HTP, to bring together the different organisations in the system and build supporting resource and capability within the OLS and broader government as necessary. New partnerships should be forged to improve analytics and information sharing so that the utilisation of diagnostic technologies informs population health management, screening and surveillance.

Recommendations

- **Build on lessons and opportunities, which have been established as part of the COVID-19 response, to further grow partnerships and collaboration, between industry, NHS, academia and government, that will support the development of the next wave of transformative diagnosis innovations.**
- **Re-purpose the Testing Taskforce to focus on future planning for diagnostics. The taskforce should consider the key diagnostic competencies, capabilities and skills the UK requires to support the NHS in future pandemics or health emergencies, the current domestic supplier landscape and consider what incentives or interventions are needed to bridge the gaps.**
- **Learning from the success of the UK Rapid Test Consortium (UK-RTC), further "consortia challenges" should be initiated to harness the UK's capability to research, develop and manufacture high-quality diagnosis technologies to aid early detection of disease. These could be delivered through an iteration of the existing "Sector Deals."**
- **Appraise the success of the Medicines and Diagnostics Manufacturing Transformation Fund, in particular the capital grant regime, as a vehicle to attract foreign direct investment in the diagnostics sector. This will inform a Diagnostics Manufacturing Action Plan to address strategic weaknesses in the UK's diagnostics manufacturing base.**
- **Develop an appropriately resourced industry / NHS /academia diagnostics translation accelerator to bridge the gap between early-stage science and the market. This could be modelled on the various Catapults that exist to coordinate and support the next wave of transformative diagnostics innovation.**

KEY DRIVER #3:
INTEGRATION THROUGH REMOTE CARE DELIVERY

The NHS Long Term Plan called for improved remote care so patients could "better manage their own health" and "avoid up to a third of outpatient appointments, saving patients 30 million trips to hospital and saving the NHS over £1 billion a year". The plan also called for clinicians to "access and interact with patient records and care plans wherever they are, with ready access to decision support and AI".

The pandemic accelerated the need for remote care and helped to move services online[27] with the NHS launching 'Health at Home' on April 10th 2020 to support remote care[28].

The benefits have been clear with improved patient safety and outcomes, increased patient reassurance, early identification of health deterioration, reduced pressure on hospital services through reduced admissions and readmissions, and clinical efficiency, capacity and cost savings.

The current system funds a succession of isolated pilot programmes which dilutes the data and slows down transformation.

Case Study: Rapid implementation of digital virtual wards during the COVID-19 pandemic

COVID-19 deaths in England increased from 21 (March 12th 2020) to 1,568 two weeks later[29]. Facing unprecedented pressure, the NHS revised guidance to control infection during in-person visits, prioritise high-risk patients and adopt remote triage[30]. Remote care achieved even more. North-West London (NWL) CCGs and Watford General Hospital (of West Hertfordshire Hospitals NHS Trust, WHHT) worked with NHSX and industry partner Huma, to design and rapidly scale a digital virtual ward for patients with mild-to-moderate COVID-19 who had been discharged from hospital (WHHT) or identified from general practice (NWL), but needed monitoring from home to avoid readmission or speed up hospitalisation. Compared to standard telephone-only virtual wards, the app-based digital one almost doubled clinical capacity, saved significant clinical time and reduced readmission rate by over one-third[31]. Silent hypoxia cases were automatically flagged and patients were reassured when the app informed them their data had been reviewed. The programme, which helped change thresholds of concern for silent hypoxia, has expanded to 13 sites across London and the South East, and supported over 3,400 symptomatic patients.

The model could be used to support long term conditions including hypertension, asthma, COPD, heart failure and diabetes, and patients on heart and musculoskeletal surgery waiting lists, improving efficiency by reducing illness or anxiety-driven last minute cancellations and prioritising those most in need. Digital transformation can also help tackle the health inequalities which have been exposed during COVID-19 by improving access to care, hard to reach communities and rural geographies.

Recommendations

- **Create a cohesive system to gather evidence at scale. A greater understanding and evidence base are required for the benefit generated from digital components of virtual wards as opposed to more traditional telemedicine. Ensure the real time capture and aggregation of diagnostics data from these interactions.**
- **Large scale trials should take place simultaneously across Trusts, geographies and patient groups, rather than in individual series. This way, evidence of enhanced patient outcomes and health system efficiency (e.g. reduced outpatients, admissions and A&E attendances and shorter length of stay and improved clinical capacity from saved time) can be demonstrated in multiple therapeutic areas, particularly across long-term conditions.**
- **Ring-fence annual funding for digitally-enabled remote care. Annual funding and support must go beyond just the software to include devices and service transformation. Significant time is required by clinical teams to redesign pathways, operating procedures and to support implementation. Collaborate with industry to explore how they can best support the existing workforce.**
    - **Integrated Care Systems (ICSs) should be allocated funds to support the roll-out of remote patient monitoring across their footprints.**
    - **In-home vital signs devices should be procured centrally for use by ICSs to support adoption of remote care.**
    - **Payment mechanisms should be established to incentivise the use of remote monitoring technologies.**
    - **Increase patient awareness and use of remote monitoring.**
- **The DPS Spark Framework should be used more widely and simplified to support rapid scaling.**
- **Adopt national approval standards to speed up implementation. A national IG/Data Protection/Digital care standard, by which all remote monitoring providers need to be accredited, and which is accepted by all NHS providers, would drastically speed up implementation. The NHS Digital Technology Assessment Criteria process (supported by NHSX) could enable this.**

KEY ENABLER #1:
A HEALTHTECH CHAMPION

There is a tendency to view life sciences almost exclusively through a biopharmaceutical lens. This has created policy anomalies that hamper progress for the HealthTech sector. HealthTech operates fundamentally differently, and the way technology is regulated, appraised and funded must be considered accordingly. HealthTech is far less homogeneous with over 500,000 different types of medical devices produced globally, compared with only 20,000 medicinal products[32].

The pace of iteration is more rapid, months rather than years, and the development of devices is often done in very close collaboration with clinicians, who continue to rely on industry for support and training whilst simultaneously informing product development.

Recommendation

- **Given both the size of the sector and the opportunity it holds, we recommend that government appoint a HealthTech Champion to sit alongside Professor Sir John Bell and ensure better representation of the sector.**

We believe that a sector Champion would be able to contribute to defining the future role of medical devices, diagnostics and digital health technologies, including leveraging the potential of data connectivity, and ensure the role of the sector is fully engaged in the next Life Sciences Strategy as part of the Plan for Growth.

The role would also encourage the NHS to work more closely with the sector on the restoration and recovery of elective procedures, provide a focussed response to consultation on the secondary legislation emanating from the Medicines and Medical Devices Bill, ensuring the many opportunities that lie therein are fully grasped.

KEY ENABLER #2:
RESEARCH, DEVLEOPMENT AND MANUFACTURE OF TECHNOLOGIES

Policy on Research and Development and manufacturing of HealthTech needs to be further refined if the UK is set to meet its own ambitions of being a global life sciences hub and deliver secure and resilient product supply to the NHS.
There now needs to be a concerted effort to improve UK manufacturing capacity as part of a broader strategy to build supply chain diversification and resilience, and embed the many positive aspects seen in the reaction to the pandemic. There has been a significant response from UK industry to the supply chain challenges presented by COVID-19. Combining skills, knowledge and expertise from the HealthTech sector with wider manufacturing capacity, prevented collapse of the supply chain in some critical areas and rapidly brought on increased product volumes.

The UK has long had the opportunity to be a global leader in health research through leveraging the data opportunities that exist within the NHS. Fundamental to realising the full potential of HealthTech is access to high quality, well curated data sets. Anonymised aggregated datasets should be available to benefit patient care and system efficiency and generate economic growth. International standards should be used to support a shared health dataspace, and facilitate secondary use of aggregated data for research, testing and the implementation of services. Data is reusable and cannot, therefore, be traded on a simple transactional basis, so there needs to be flexible commercial arrangements.

Recommendations

- **There should be a detailed mapping exercise to identify areas of HealthTech R&D and manufacturing excellence in the UK along with a strategy to build on it, and the related sectors that could be developed alongside it.**
- **A HealthTech specific catalyst should be developed to help crowd-fund finance for R&D.**
- **Improve signposting to existing mechanisms and, where appropriate create new ones to bring NHS clinicians and managers together with the HealthTech industry to share issues and problems. (See also Overarching challenge of HealthTech adoption).**
- **Expand and increase the focus of demand signalling within the AAC.**
- **For diagnostics specifically, a long-term testing strategy will enable a stable environment for R&D and subsequent manufacture aligned with unmet needs.**
- **Access to high quality, well curated data sets should be available to researchers and innovators to help them improve patient care and system efficiency.**
- **International standards should be used to support a shared health dataspace, and facilitate secondary use of aggregated data for research, testing and the implementation of services.**
- **Intellectual Property should accrue to those that are creating value.**
- **Government should make funding available for a significant programme of data cleansing and curation, along with support for the delivery of health data infrastructure.**
- **A public awareness campaign by the government to highlight the benefits of data sharing to the individuals, peer groups, the NHS and wider society.**

KEY ENABLER #3:
DEVELOPING OUR NEW REGULATORY SYSTEM

Maximising the global opportunities of the UK regulatory process, will ensure that there will be a greater acceptance of data derived in the UK and allow for future regulatory recognition across jurisdictions. Likewise, future-proofing the new UKCA Marking requirements will produce a more predictable regulatory platform, especially if that platform is supported by appropriate, proportionate and timely guidelines for new and emerging technologies.

Furthermore, the combining of globalisation and future-proofing principles, will also have the effect of reducing the financial burden for UK manufacturers and developers, as data commonality will allow for greater global market access.

Developing a regulatory platform that allows for enhanced product availability will not, however, be beneficial to UK manufacturers, without faster innovation uptake within the NHS. The use and monitoring of products post-market, using real-world data as a mechanism to enhance overall post-marketing surveillance programmes, could potentially be used to supplement clinical performance data and thereby allow earlier product introductions.

Such ambitions are essential to meeting the regulatory challenges of the Medicines and Medical Devices Act, which highlights the needs of making the UK a favourable environment for research, development, manufacture and supply of medical technologies.

Case Study: How the right regulation can support innovation

At the start of the pandemic, with only approximately 8,500 ICU ventilators available in the UK for clinical procedures, together with the expectation of a high number of serious COVID-19 cases, there was huge demand for more invasive mechanical ventilators.

In March 2020, Penlon answered the government's 'call to arms' in an innovative way of developing a hybrid emergency ventilator with the combination of three x CE marked anaesthesia devices to meet the MHRA's Rapid Manufactured Ventilator Specification. Having a strong heritage of robust medical devices in more than 90 countries, an integrated QMS and no vigilance issues, engaging with the MHRA and the Notified Body from the outset was imperative in strategising a route for Emergency Use Authorisation under UK MDR 2002 derogation.

With a single compelling purpose of saving lives; the MHRA and Notified Body committed dedicated resources to independently assess the technical, risk, material safety and clinical documentation for patient safety. Bringing all parties together, including the Cabinet Office, we had open, transparent and regular dialogues, whereby we developed a step by step program towards Emergency Use Authorisation using a pathway of UK MDR 2002 derogation, which was achieved within 30 days. A special COVID-19 reportability scheme was also set up on the MHRA Yellow Card system.

The UK Regulatory process permitting Emergency Use Authorisation (EUA) under UK MDR derogation was instrumental in helping Penlon deliver these vital ESO 2 ventilators to the NHS, well ahead of any vaccination program commencing. A pre-requisite of EUA was to ensure a pathway to achieving formal CE certification, and, as this was prior to the complexities of Brexit, this was achieved in 3.5 months. The achieving of the CE mark allowed the UK Cabinet office to ship a quantity of the ventilators to British overseas territories and keep the devices.

Recommendations

- **The UK should continue to advocate use of real-world evidence through registries, post-market surveillance and vigilance as a mechanism to stimulate innovation and the development and introduction of new products.**
- **Capitalise on global interactions and maximise the global reputation of MHRA. Other jurisdictions could be considered as models for best practice.**
- **Reduce the financial burden of regulation, particularly on SMEs, by ensuring alignment or recognition of global requirements and equivalents, particularly with auditing and Conformity Assessment.**
- **Anticipate future trends in products (such as drug/device/digital/ diagnostic companions and combinations), thereby improving appropriateness, predictability and transparency of regulation.**
- **Ensure the cost and time from invention to uptake is the minimum required to ensure patient safety and meet clinical needs.**
- **Reconsider the UK standstill deadlines to include a more reasonable transition time to compulsory UKCA marking.**

KEY ENABLER #4:
EFFECTIVELY EVIDENCING AND EVALUATING INNOVATION

Policy makers tend to be familiar with the pharmaceutical route to market and associated evidence generation. HealthTech faces a very different pathway to market from a regulatory, assessment and adoption perspective.

The Independent Medicines and Medical Devices Safety Review[33] recommended increased post market surveillance to monitor of how medical devices and pharmaceuticals perform in "real world" patients. Importantly, the government, through the Medicines and Medical Devices Act now has the power to establish a UK-wide medical devices information system. This system will mean in future, subject to regulation, medical device procedure and outcome data can be routinely collected from all NHS and private provider organisations across the UK, "ensuring that no patient in the UK falls through the gaps". The system will need to ensure that it engages with patients and raises awareness of its public protection role.

This data could also be used to demonstrate the benefits that products and associated services bring to patients. NICE is currently consulting on their methods and processes for health technology appraisals. Guidance is required for medical device manufacturers on the recognised methods of assessing treatment for conditions to assist companies and researchers in their evidence gathering. Unlike for pharmaceuticals, where randomised control trials (RCT) are considered as the gold standard, the same is not the case for medical devices where there are challenges such as patient recruitment, retention and follow-up and ethical considerations in the use of a double blind RCT in gauging the clinical effectiveness of, for example, an interventional procedure. Instead, studies of medical devices tend to be small and observational. There is therefore the need for flexibility in the assessment and evaluation of medical devices, particularly for the more innovative, first-in-class technologies. Recognition from medical research bodies is needed that a dogmatic approach to the hierarchy of evidence is not always appropriate.

There then needs to be substantive linkages between the output of formal assessment programmes and the commissioning processes, accompanied by a clear implementation strategy.

Rather than cumbersome innovation pull initiatives that aim to pick winners centrally, we recommend systems that would support local investment in new commercial models such as risk share, outcomes-based payments and managed access arrangements. Evidence collected during these types of initiatives could be used in later technology evaluations, which would also provide the "real world" perspective.

Medical devices deliver significant benefits not just to individual patients, but also wider society and these benefits should be reflected in their evaluation. The use of databases and the development of patient registries, outcome measures and real-world data are a promising development and should be supported by the health system. An area which is currently lacking in the evaluation of evidence is how the use of medical devices changes medical or clinical practice and/or NHS service delivery. In the case of services, medical device manufacturers provide a range of additional care packages such as telehealth/nursing support and patient/healthcare professional education and training. Companies are required to produce regular reports to Trusts and CCGs on the quality and impact of these services, including cost savings, and it would be useful to look at these impacts in the consideration of the supporting evidence needed on the efficacy of the medical devices involved.

Health economic modelling needs to reflect the wider benefits of a medical device to the individual patient and society. In particular, aside from clinical data, there should be greater emphasis placed on relevant Quality of Life (QoL) measures and social impact indicators in the consideration of evidence, since there is a link to the outcomes of product use with good care which include better mental health and wellbeing, more personal independence, the ability for the patient to self-manage their care, the return to work/future productivity and reduction in health inequalities.

Likewise, indicators that point to better public or population health and the preventive agenda should be included. There are some validated generic QoL instruments such as EQ-5D and SF-36 but, research in medical devices is dynamic and requires flexibility. For this reason, there may be the need to adapt some of these tools to the specific disease areas/conditions, in line with the medical device used.

A managed access scheme for medical devices will help manufacturers and researchers to build the required evidence for technology appraisals.

Technology assessment can be dogmatic in its consideration of a hierarchy of evidence. Randomised controlled trials (RCTs) may be the gold standard for head-to-head mega trials of pharmaceuticals, but are not always appropriate for HealthTech.

Recommendations

- **A more flexible approach to technology assessment, including the acceptance of real-world evidence and a wider definition of value, needs to be developed in conjunction with the HealthTech industry.**
- **There needs to be flexible commercial arrangements, based on a value assessment of the wider UK economic benefits of HealthTech, and not solely on those enjoyed by the NHS.**
- **Full implementation of the HTP Access scheme that is currently in development.**

KEY ENABLER #5:
ENCOURAGING THE RAPID ADOPTION OF TECHNOLOGY

The ability of the NHS to rapidly introduce innovation has been a long-standing issue, with the perceived wisdom that the UK is a late and slow adopter. The response to COVID-19, however, has shown that with the necessary set of conditions, the NHS can rapidly implement new technologies and ways of working.

This progress notwithstanding, there have been many initiatives in the NHS to support the adoption and spread of innovation, but, an agile and innovation-led culture has never been at the centre of the NHS. Whilst locking in the benefits of the positive change resulting from the response to COVID-19 is a good first step, there is a need to seize the opportunity to re-engineer the way the NHS works to deliver the innovative operating models that the government's COVID-19 recovery strategy sets out. This should build on the positive trajectory, in place prior to the pandemic, that we have seen accelerate in the response. Collaborative working has been paramount in the pandemic response.

The HealthTech industry fully supports the move towards Integrated Care Systems (ICSs). A persistent and significant barrier to the adoption of innovation has been that investments in one part of a local system may yield benefits in another with no financial linkages between the two. We believe that ICSs could remove these barriers between organisations and care settings, enabling a focus on patient pathways and facilitating interventions and technologies that can improve whole system efficiency and patient outcomes.

Funding mechanisms that support the introduction of innovation and incentivise collaboration between organisations, will be vital to realise the full potential of HealthTech. Current funding mechanisms are not agile enough to support the introduction of new innovations, leading to cumbersome processes that aim to centrally pick winners, rather than create systems that would support local investment in new ways of working. The move towards new payment models should encompass initiatives that support co-working between the NHS and industry through risk share, outcomes-based payments and managed access arrangements. This will require an accurate and timely costing process. Our work with the Nuffield Trust in 2017[34] taught us that a significant barrier to the adoption of innovation is the fact that it is nobody's job. NHS Trust Boards see regular metrics on finance and performance, quality and safety, and workforce, with Executive Directors responsible for these important areas. As part of their "Well Led" inspection framework, NHS organisations are required to have robust systems and processes in place for learning, continuous improvement and innovation. But, with few exceptions, nobody at a Board level holds this portfolio. ABHI believes that every NHS Trust should appoint a Board level Chief Innovation Officer. Collaboration with outside organisations such as Industry and Academia should also be actively encouraged.

As technology and service delivery become intertwined and ever more reliant on data, it is important that that current, separate regulatory processes and organisations are aligned. This will require an increase in the pace of co-working across the Medicines and Healthcare Products Regulatory Agency (MHRA), Care Quality Commission (CQC) and the Information Commissioner's Office.

Case Study: How collaboration can support adoption

As part of a unique national programme, Abbott has worked collaboratively with the NHS England and NHS Improvement Diabetes Prevention Programme to improve access to the FreeStyle Libre Flash Glucose Monitoring System which is designed to replace routine self-monitoring of blood glucose ' finger-prick' testing, for people aged four or over[35]. The intention to provide Flash glucose monitoring, to all people with diabetes meeting the defined criteria, was announced in November 2018 and this commitment was further endorsed in the NHS Long Term Plan. The digital tools available support remote monitoring enabling HCPs to effectively monitor multiple people with diabetes under their care. In March 2019, just 8%[36]. of the estimated quarter of a million people in England with type 1 diabetes used FreeStyle Libre. Following implementation of the programme, which involved the support of key stakeholders like Diabetes UK and NHS Clinical Commissioners, as of February 2021, national uptake has increased dramatically to 37%[37] of all people with type 1 diabetes.

Recommendations

- **Mandate through upcoming legislation that every NHS organisation must appoint a board level Chief Innovation Officer to share the success of technological innovation, drive clinical and patient enthusiasm, and support required transformational change.**
- **As part of the CQC well-led framework, require an innovation reporting mechanism/scorecard.**
- **Develop the Plagiarism Award, a prize for the timely and successful implementation of ideas borrowed from elsewhere.**
- **Develop the Collaboration Award, a prize for innovative examples of collaboration between industry and NHS.**
- **The OLS should work with industry to develop an agreed set of metrics to measure progress of adoption.**

KEY ENABLER #6:
SUPPORTING VALUE-BASED DECISION MAKING

The Carter Review (2016) on productivity and performance in English hospitals[38] revealed the fragmented nature of procurement practices in the NHS which led to wide variation and inconsistencies in clinical care. It made the case that the NHS could achieve better cost efficiencies in its purchasing of goods and services. Following the report, the Procurement Transformation Programme (PTP) was implemented and began to consolidate the supply chain process by centralising the sourcing, supply and delivery of healthcare products and services through NHS Supply Chain (NHS SC).

This has brought about much change in the procurement landscape, delivered cost-savings to the NHS and has resulted in more joined-up working with manufacturers and service providers. Over the last two years, it has been pivotal in ensuring continuity of supply of medicines and medical devices during the Brexit transition period and COVID-19 pandemic.

While there is much to commend its success, there have been issues with the way in which the management and administrative functions of NHS SC have grown over this period and the wide range of bodies, working groups and pilots formed to support NHS SC. Questions remain over the openness and transparency of some of these bodies and how they work with other suppliers such as social enterprises and private sector contractors.

At the level of product and service procurement, the Category Towers were formed by NHS SC to ensure cost efficiencies in the bulk purchasing and distribution of what are sometimes considered commoditised items. A far greater challenge has been in the procurement of highly personalised medical devices which require a complex set of clinical and benchmark criteria to enable procurement decision-making.

Value-based healthcare (VBH) models found in the US such as the patient centred medical home (PCMH) and accountable care organisations (ACO) evolved from the desire to have in place a more equitable, evidence-based, quality focused system of health provision[39].

The purported benefits for the healthcare system include better outcomes for patients, higher patient satisfaction for hospital providers, stronger cost control and risk management for payers and, in the case of suppliers, the ability to align prices with outcomes. The end goals are to enable better health in populations and reduce healthcare spending.

This shift in focus towards a VBH model complements the NHS RightCare ethos and the Getting It Right First Time (GIRFT) programme which place value at the centre of care provision with the intention to reduce unwarranted variation in local populations. In fact, the RightCare model prescribes 'personalised value' in addition to the two perspectives described above[40]. This approach relates to the value that each patient deems important to them in their care and their desired outcomes.

At the core of RightCare is availability of evidence and data to recommend a care pathway, presided over by strong clinical leadership. One of the criticisms has been that NHS Supply Chain with its various working groups and the Clinical and Product Assurance (CaPA) unit have often worked in silos. The focus was on delivering value at the level of cost, based on measures such as product features that did not take into consideration quality of life impacts and patient choice. In essence, despite the nod towards VBH, health variation continued to exist due to the stringent following of the standards and commissioning advice set by these groups. It would be useful for commissioning bodies and those setting procurement guidelines to pay heed to the personal value described above to ensure that patient views and needs are met.

NHS procurement frameworks agreements have typically been focused solely on price with the cheapest costs/bids being put on the list. For instance, in the case of medical devices, there have been several initiatives developed by contracting authorities including threshold and reference pricing, mini competitions and electronic reverse auctions (e-auctions) which have, in fact, stifled competition and innovation. These approaches turn the NHS-supplier relationship into a purely transactional one and, more importantly, result in the adversarial nature of procurement marked by distrust and a lack of transparency between procurement and commissioning managers and manufacturers. Medical devices are seen as commodities and lower price points from other economies are used as a crude comparator. This has the effect of pricing some manufacturers, particularly indigenous SMEs out of the market. Apart from resulting in the use of lower quality medical devices in the NHS, in the medium to longer-term, such procurement procedures can lead to the UK being regarded as a low-innovation country which is counter to the government's objective to make the UK a global leader in the life sciences.

NHS SC started to examine embedding value-based procurement (VBP) into its procurement model in 2019 as a means to enable better purchasing and sustainability. This approach to examining financial benefit to the health system above a reduction in purchase price[41] is welcomed by medical device manufacturers. There is much to recommend the development of VBP as a method of procurement for the NHS. It signals a shift in the traditional payer-supplier relationship since payers will need to look at longer-term benefits based on patient outcomes.

Similarly, manufacturers must rethink their way of working beyond selling to individuals. Proposals to the NHS must include the tangible and value-added benefits of product use and all products claims must be supported by robust evidence, thereby representing a change in the way research, audit and reporting are conducted in medical devices. This impetus to generate good quality evidence on unmet need, patient experience and quality of life is in line with the current NICE reviews into health technology appraisal topic selection, methods and processes and the preference for HealthTech Connect as the channel to introduce new promising technologies into the market.

In their report[42] on the VBP pilots published in February this year, the VBP project team at NHS SC observed that commitment is needed from trust finance teams, at the executive level, to get buy-in for VBP programmes. In cases where senior executives were engaged in the concept of VBP, they were more willing to unlock the resources and cooperation needed to make it a success. The report also noted that deliverables are needed from suppliers on the forecasted outcomes and promised efficiencies to incentivise the NHS to adopt VBP solutions. To this end, the project team have created a VBP assurance framework to help the NHS and suppliers. It is hoped that as the NHS transitions into Integrated Care Systems, the benefits of VBP can be maximised when delivered at scale across a system, taking into consideration whole life costing in patient pathways and the removal of silo budgeting.

Case Study: How value based healthcare can support enhanced patient outcomes

An example from Hospital Universitari Bellvitge: Value Based Healthcare services contractto improve post stroke patient management

The scope of this project related to patients, who suffered a stroke and are discharged from the hospital, for follow-up and monitoring during the first year of the acute episode.

Project fundamentals were as follows:
Patient Journey Co-Creation **– Utilising external Healthcare Consulting experts to shape the reorganisation of patient care pathways. This enabled a new pathway plan definition.**

Personalised Monitoring **–involved use of new digital technologies to monitor risk factors in an integrated approach to tailor each patient's disease management.**

Digital Solution **– A digital solution deployed for integral patient management. Deployment of the diagnostic and technological infrastructure.**

Commitment to performance **– Collaboration model based on the final value obtained. Variable budget based on performance.**

In summary, the services contract is developed on the deep understanding of the patient journey and how healthcare pathway optimisation could enhance patient outcomes through an outcome based performance for the hospital. (See appendix 2).

Recommendation

- **A value-based approach to procurement needs to be adopted through a multi-agency, cross-sector strategy with an objective to maximise rapid patient access to the latest, proven innovations. Methodologies should take into consideration system and relevant patient outcomes, clinical opinion, supply chain resilience, evidence, ethics and quality. Work should be completed to agree the metrics to which this is completed by linking evidence generation with a value-based approach.**

A significant barrier to adoption for digital health products and solutions is that they are not routinely funded as part of existing payment practices (e.g. coding criteria do not exist). Payment and financing schemes need to be modernised to support digital transformation. Digital health solutions encompass a wide range of technologies at different stages of technical maturity and evidence base. To help the development of a digital health ecosystem a broad spectrum of payment mechanisms should be available to enable commissioners/providers to access the technologies through appropriate funding routes that manage risk for both parties.

A clear pathway for assessment and payment decisions is needed (i.e. step by step schemes including defined organisational responsibilities and criteria for obtaining decisions).

Flexible processes and payment criteria should be developed for assessing the value of digital health products and solutions, taking account of the fast-paced nature of digital product innovation. This should utilise the NICE Evidence Standards Framework as its foundation and provide a process link to appropriate payment mechanisms. Consideration is also required on how the Digital Technology Assessment Criteria (DTAC) can be used as part of an assessment process leading to payment decisions.

This can build on the work to date through programmes such as the Innovation and Technology Payment /Innovation and Technology Tariff, the Rapid Uptake Products programme, Accelerated Access Collaborative and MedTech Funding Mandate. However, its end goal should not be 'picking winners," but development of de-risked systems open to all technologies.

For "App" type products that are likely to be used directly by patients in a home setting, the prescription mechanisms should be considered if GP oversight is required, or, if not, direct download via sign posting on the NHS App library.
The national payment system is currently focused on activity and does not provide an effective route for many digital health technologies. Consideration should also be given to development of pathway budgets that can incorporate the use of these technologies.

In addition to direct payment and contracting mechanisms, considerations should also be given to broader based incentive schemes that can reward whole system change and outcomes. For example, incentives could be paid for the use of technologies to reduce, for example, A&E attendances, outpatients visits, re-admissions or falls, via an innovation fund.

For highly complex and ground-breaking technologies a payment with evidence development scheme should be considered.

Recommendation

- **New payment mechanisms should be explored to expedite the use of digital HealthTech. Considerations must also be given to broader based incentive schemes that can reward whole system performance and outcomes-based targets.**

The cost and operational implications of EU exit have been of a higher magnitude than was anticipated. Shipping costs, exacerbated by the pandemic, have increased exponentially and, whilst some elements may be expected to reduce in time, others, such as those associated with new customs procedures will remain. ABHIs' survey showed that two thirds of companies have experienced an increase in their cost to serve the NHS. These costs come at a time when companies are facing other pressures such as new regulatory requirements in Europe and uncertainty over evolving sovereign arrangements in the UK.

Yet despite the increases in costs that all of us are experiencing in our everyday lives, the NHS has a adopted a zero-inflation policy, believing itself to be immune from inflationary pressures.

The NHS clearly has to obtain best possible value for the UK taxpayer, but if it becomes an unattractive market, patients will lose access to new, innovative technologies. SMEs are particularly vulnerable to aggressive pricing strategies and the explicit policy of reducing supplier numbers. Theses strategies are not consistent with the aim, enshrined in the Medicines and Medical Devices Act, to ensure that the UK is seen as a favourable place to supply HealthTech. Furthermore, a reduction in the supplier base is counter productive in the long term and a cost reduction strategy and reducing the number of SMEs also reduces innovation, especially in niche and low volume clinical areas, often the domain of smaller companies.

Recommendations

- **The NHS needs to consider its impact on the supplier base and how it influences the cost to serve driven by its tendering and ordering behaviours.**
- **There needs to be a fair, transparent and equitable mechanism for individual companies to raise concerns regarding the viability of pricing and consequent supply of any given product to the NHS.**

The Scan4Safety programme (originally the "eProcurement Strategy") was launched in 2014 by the Department of Health and Social Care (DHSC) to improve patient safety and supply chain efficiencies via the introduction of barcoding standards across NHS in England. The programme mandated the adoption of GS1 coding standards for product identification and the implementation of Pan European Public Procurement Online (PEPPOL) standards for interoperability.

Clear milestones were set out for suppliers to the NHS. These milestones have required costly logistical, packaging and IT changes for all suppliers, whilst tender documents have required suppliers to confirm their adherence to the programme. Milestones were also created for NHS Trusts to guide them towards compliance, but without target dates.

Suppliers made significant investments in recognition of the benefits to the NHS, along with tangible benefits to themselves, such as savings in manual order, invoice, and credit handling.

At the launch of the programme, six demonstrator Trusts were announced and received funding to become compliant with the programme. This has been accomplished to varying degrees and, since then, it appears that only a limited number of additional Trust have followed suite. In early 2019 the DHSC announced that with the 'pilot' complete, the programme was transitioning to NHSX. Suppliers understand that NHSX is now working on the next phase of the programme, including future funding.

As only a small number of Trusts are PEPPOL ready, or even working towards becoming so, the investment that suppliers and Trusts have made so far is not realisng the anticipated benefits. The limited uptake of the programme means that the cost of exchanging standardised documents in the supply chain is higher than before. We believe that cost savings for the NHS are still achievable, if the widespread adoption of the PEPPOL standard, as originally planned, is adhered to. Unchanged, there is the inevitably risk that these higher costs to serve are passed onto the NHS.

Recommendation

- **Government and industry to re-engage on the programme and support its full implementation by the NHS.**

KEY ENABLER #7:
IMPROVING ACCESS TO FINANCE

Securing appropriate finance is an essential link in the chain of translating an idea into a commercial success. In general, The HealthTech sector has not been seen historically as an attractive proposition for the investment community. While there is little doubt that our universities and clinicians produce world class research and innovation, translating this into successful products and companies lags behind comparable jurisdictions. There have been some outstanding success stories, but these tend to be the exception rather than the rule. In effect our HealthTech entrepreneurs and leaders have been badly served by the availability of finance and in the worst cases look elsewhere for their growth.

Companies describe multifarious issues, including a perceived resistance to change and inertia in our structures which act as a brake on innovation, and the fragmented nature and complexity of the sources of finance and the failure to adequately join up providers with innovators. The existence of the NHS as a dominant buyer, perceived to be a late and slow adopter of innovation, is frequently cited as discouraging investors. There is also a gap between grant/early-stage funding and finance for growth, a period referred to as the "Valley of Death" for small companies. Finally there is a failure to distinguish between companies and products, which discriminates against the development of some technologies. Not every innovation can create a company on its own, but many can thrive if they are subsequently developed by established players.

Recommendations

- **At the macro level, UK HealthTech needs to be perceived as a vibrant, entrepreneurial sector which is encouraging of innovators and thought leaders. All the initiatives mentioned elsewhere in this paper will help toward this goal but a concerted and sustained campaign to enhance the "invest in HealthTech" message could pay dividends. Government can play a major part in developing an improved HealthTech investment community.**
- **The barrier presented by the NHS as a dominant buyer and a deterrent to adoption has to finally be broken. Fast-track, possibly pilot, innovation schemes which can bypass traditional procurement routes are essential. These would provide an early evidence base for further growth, or indeed kill off quickly those which are unlikely to succeed and avoid the "slow no" which is a drag on investment.**
- **Expand and enhance the knowledge base of leaders through initiatives such as the Clinical Entrepreneur Programme. Several similar schemes exist on a regional basis and these should be encouraged and better coordinated.**
- **An education and signposting scheme is required to help innovators through the maze of options through the whole spectrum from early stage and grant funding, right through to venture and corporate finance. Joining up national and regional initiatives would be beneficial. As an example, the Chamber of Commerce network has excellent resources for funding but not specifically targeted at HealthTech. Similarly, sector-specific resources from organisations such as Innovate UK EDGE, SBRI and the Knowledge Transfer network could be coordinated and developed.**
- **At a time when cash flows have been seriously impacted, it is important that the NHS is a good payer, sticking to payment terms and, preferably, actually improving them. The failure of Trusts to pay on time is a persistent and significant issue for small companies. NHS organisations frequently work outside government Prompt Payment Policy which can be crippling for SMEs.**

- **HealthTech businesses must have the best possible access to existing schemes such as Coronavirus Business Interruption Loan Scheme (CBILS). Such schemes need to be fair and reasonable, without excessive interest rates or unfriendly terms. Cash flow issues could be abated if extensions cover off at least six months post a return to usual business. Government could helpfully extend guarantees to lenders and confirm the NHS as a blue-chip customer. HealthTech companies should be afforded 'special status' as suppliers to the NHS, allowing banks to extend credit without usual constraints (e.g. multiple of EBITDA increased).**
- **An extension of time-to-pay schemes should be considered, covering VAT, PAYE, and Corporation tax.**
- **The R&D tax credits scheme should be reviewed, and a two-tier system where companies with a less than £5m turnover receive a higher level benefit is recommended.**
- **Advance Purchase Orders can be problematic in that they create a black hole for future sales, but in the current extraordinary circumstances they may be helpful to allow planning and stock build and provide extra security for lenders. A scheme should be considered to allow HealthTech companies to be paid in advance and stock called off as required.**
- **NHS suppliers should be given an indication of future demand to facilitate the planning of manufacturing and distribution.**

KEY ENABLER #8:
MAINTAINING AND EXPANDING EXISTING SCHEMES

Innovators and potential entrepeneurs face a daunting task to navigate their way through the myriad of processes and organisations offering help. There is no criticism of the amount of support available or indeed the desire to promote and accelerate worthwhile innovations. The challenge is to make sure the system as a whole presents a clear pathway better to identify the most appropriate route from idea to commercial success.

A simple Google search for "NHS Innovation" will reveal pages of possibilities and a novice innovator may be deterred by the apparent complexity. While a rigid, formulaic, approach to innovation is unlikely to succeed, a clear signposting process to find the relevant help as quickly as possible and navigate through the maze would be beneficial.

Where should an innovative clinician start when trying to take an idea to market foe the first time? Their trust? NICE? the AAC? AHSN? Health Tech Connect? Industry? or any other of the support organisations offering help? The answer is unlikely to be a one-size-fits-all solution but highlighting and enabling key individuals who can steer through the process would be invaluable. Recommendation 46 would support this objective.

A number of clinical entrepreneurship programmes have produced good results but are not available in sufficient numbers. Similarly, the variety of funding schemes available have achieved successes but are not sufficiently accessible or supportive. (The refusal to provide feedback to unsuccessful applicants is a good example).

Quickly identifying possible successes from time-consuming failures is equally important and again needs experienced guidance.

The 2018 King's Fund paper *Adoption and spread of innovation in the NHS*[43] expands on this theme well.

Lord Darzi's views on innovation are well known and the AAC will undoubtedly make an impact but its processes must be easy to access for all potential innovators throughout the NHS system.

Case Study: Accelerating adoption and spread through AHSN support

Pando is a communications platform for healthcare professionals, created by NHS doctors which helps NHS workers exchange patient information, make clinical decisions and manage their workload securely.

The AHSN conducted an assessment of the economic, health and social outcomes of its solution and qualitative review. A cost-benefit analysis measured impact in terms of real monetary cost, headcount, material reduction and productivity improvement standards relative to other current options of communication.

The AHSN is now supporting with adoption and spread, with engagement in over 200 organisations, Pando has now onboarded over 30,000 NHS healthcare professionals, processing more than 8 million clinical messages across 5,000 clinical teams. It is the only app listed in the COVID-19 section in the NHS Apps Library that is made solely for health and social care professionals. It is also has NHS Digital approval and has been widely used as part of the COVID-19 response.

Recommendation

- **The extension and expansion of current initiatives which promote adoption of innovation:**
  - **The Academic Health Science Networks (AHSNs)**
  - **The Small Business Research Initiative (SBRI)**
  - **The Accelerated Access Collaborative (AAC), including the Med Tech funding mandate**
  - **Regional Innovation Hubs**
  - **Technology Transfer departments within academia**
  - **Pathway transformation funds (PTF)**
  - **Made Smarter national funding rounds.**

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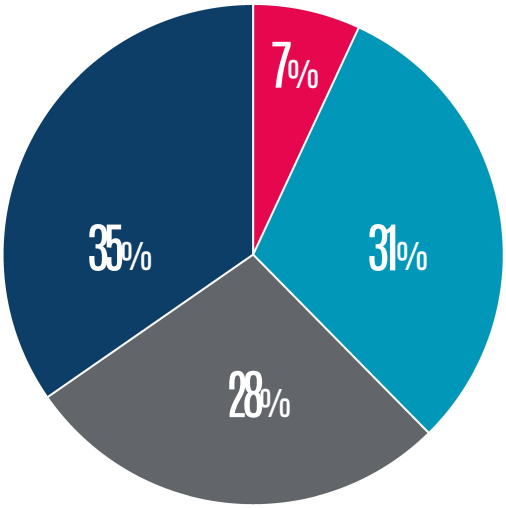
APPENDIX 1:
ABHI SURVEY ANALYSIS

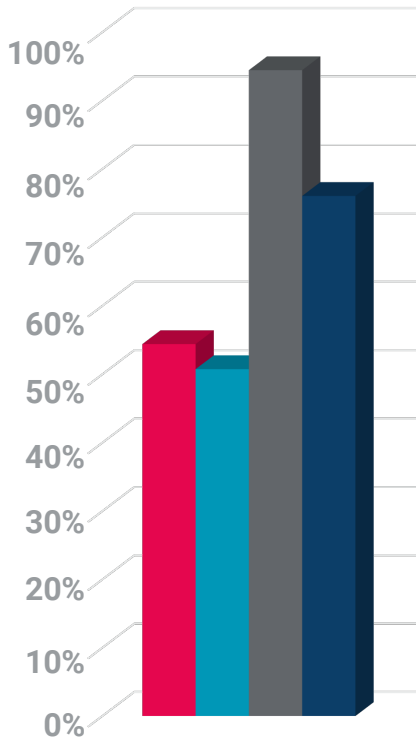


72 Responses

Company Size: Large **35%** SME **65%**

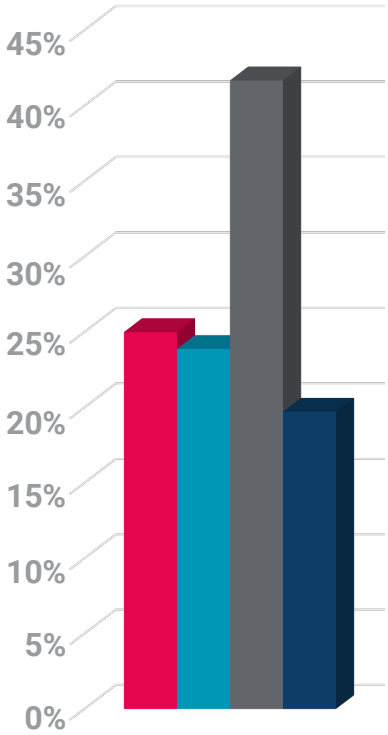
1 - 10 employees
10 - 50 employees
50 - 250 employees
250+ employees

HealthTech Functions in the UK



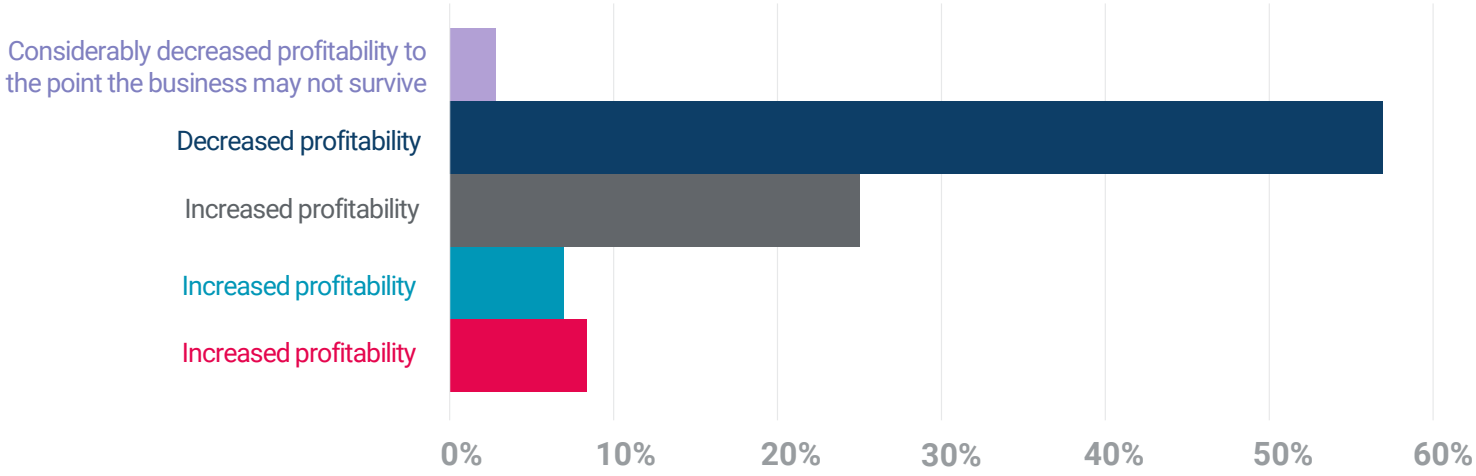
Research & Development
Manufacturing
Sales & Marketing
Corporate Functions

Companies Looking to Increase by Function in the UK

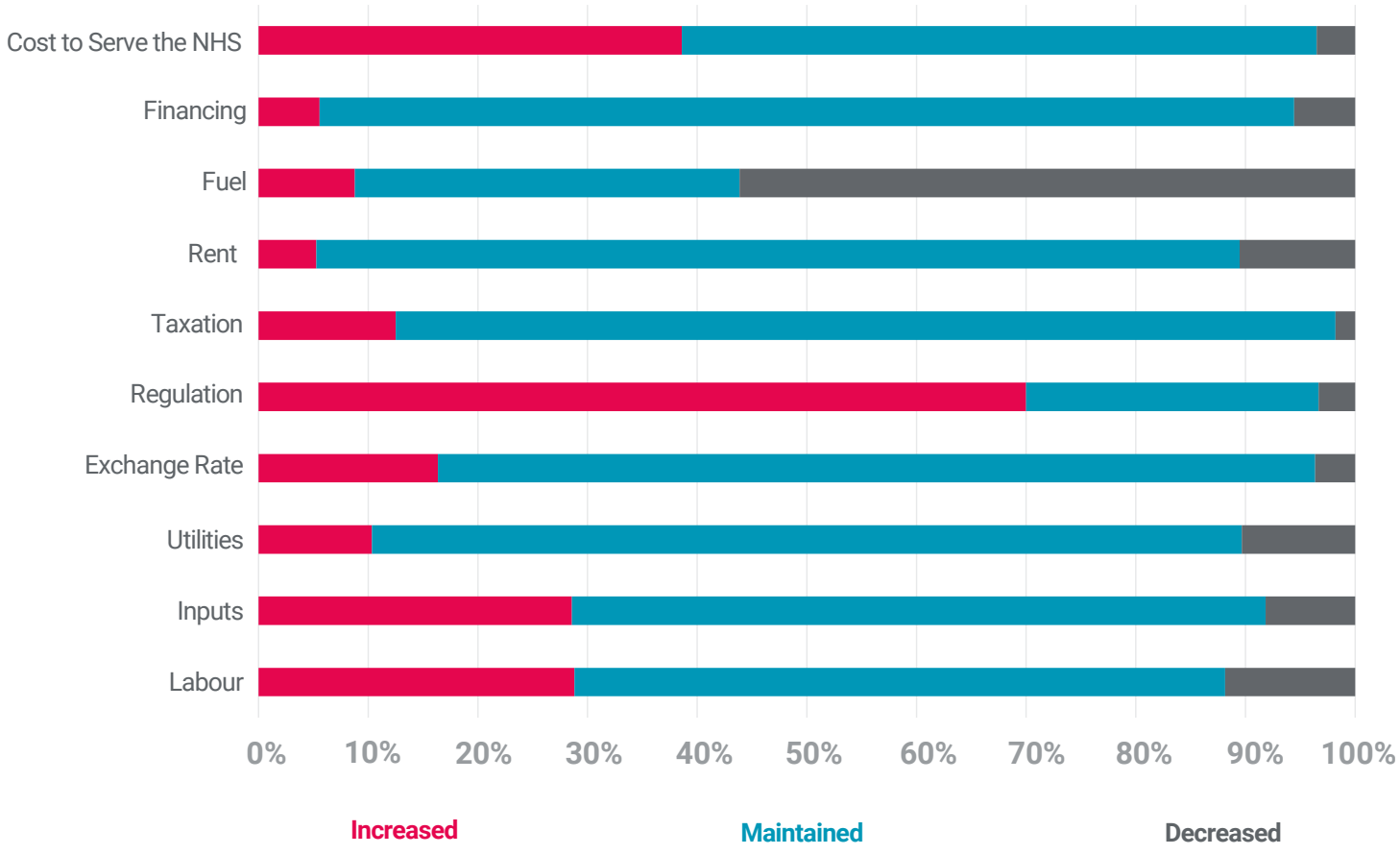


Confidence in the UK Market

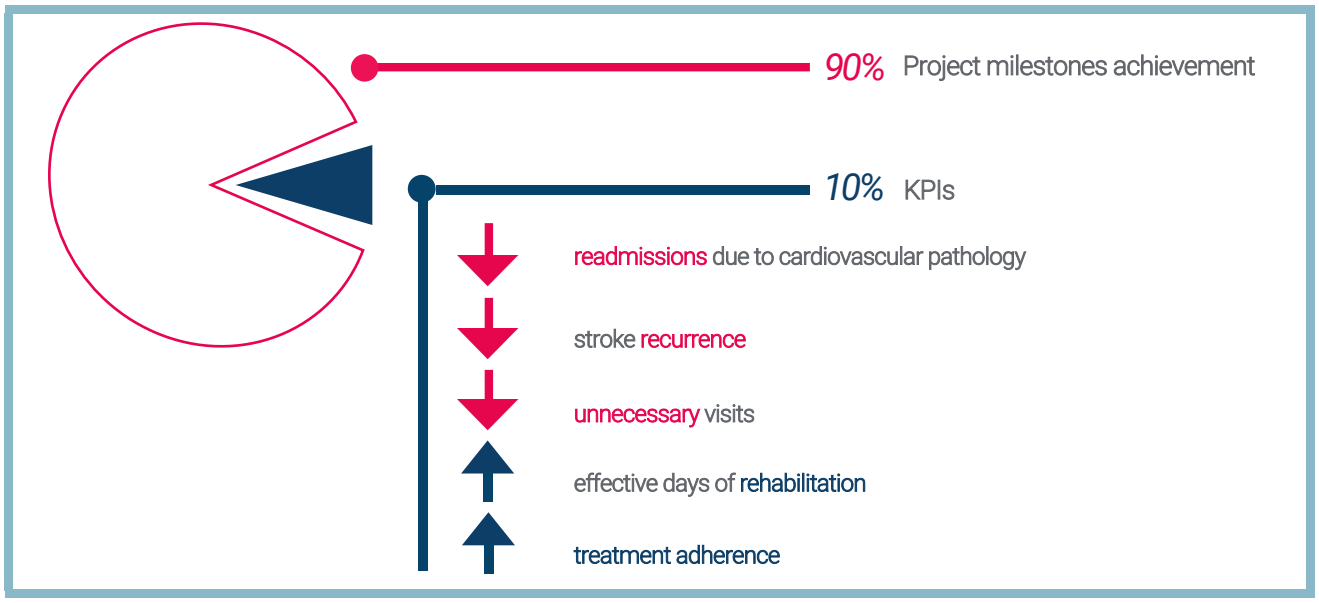
The Impact of COVID-19 on the HealthTech Industry



The Factors impacting Cost Base over the past 12 months



APPENDIX 2:
VARIABLE PAYMENT BASED ON PERFORMANCE



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