ABHI REPORT: GROWTH OPPORTUNITIES FOR HEALTHTECH

ABHI

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INTRODUCTION

This paper highlights specific areas relevant to the HealthTech sector as we look towards the future following the COVID-19 pandemic, the end of the EU exit Transition Period, and the building of a new partnership between the HealthTech sector, Government and the NHS. We define HealthTech as medical devices, in-vitro diagnostic medical devices and digital health technologies.

We address the opportunities for our health and care system, process changes, technology adoption, system working and collaborations, that have been beneficially deployed in response to the pandemic.

We do not address issues over the immediate restart of planned care following the crisis, but it should be noted that this is of significant concern due to the impact of delayed care to patients and the economic shock to the sector. We would stress, however, that the HealthTech sector can play a significant role in supporting the NHS to address some of the backlog in procedures arising from the pandemic and enable elective care to be delivered in a clean, safe environment as the threat of the virus remains. Plans for the resumption and restoration of this activity to pre-COVID levels should be shared with industry to ensure the necessary equipment and supplies are available at a time of increased global demand.

We outline the issues and recommendations for future work, but do not lay out a detailed plan for their execution. This is activity that will need to be conducted by appropriate working groups of bodies such as the Health Technology Partnership and Life Sciences Council. This paper, therefore, represents our views at a specific point in time, and serves as a background to our substantive input into work that supports our sector and the customers we serve.

Background

UK society experienced an unprecedented shock with the outbreak of COVID-19 in March 2020. For a period of time, the country shut down as the health system worked tirelessly to manage the burden of a wave of COVID-19 positive patients. Industry has created new partnerships with the Government and the NHS to rapidly scale up UK diagnostic capacity and responded to unprecedented demands for the supply of critical medical products, such as ventilators and Personal Protective Equipment, in very challenging conditions.

We have also had insights into what future healthcare delivery might look like, from the use of AI and machine learning, to the switch from face-to-face interactions in primary and outpatient care to a digital first approach. True system working, supported by appropriate funding mechanisms, has helped expedite the creation of Integrated Care Systems.

The COVID-19 crisis has powerfully demonstrated the strategic importance of the HealthTech sector to both the UK's health security and its economy. The Government's COVID-19 recovery strategy states that protecting the UK's economic competitiveness means supporting "the UK's world leading pharmaceutical and medical-device manufacturing sectors." This paper offers suggestions of some of the ways in which this might happen, focussing on five areas.

1. The rapid implementation of clinical and technological innovation supported by a value-based approach and an agile regulatory and decision-making framework
2. Consolidating and accelerating the use of digital HealthTech
3. Investment in supply chain resilience and UK manufacturing capability
4. A comprehensive set of trade agreements that facilitate easy movement of goods
5. Development of a UK diagnostics capability as a strategic priority.

RAPID IMPLEMENTATION OF CLINICAL AND TECHNOLOGICAL INNOVATION

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. A value based approach is needed in the identification, assessment, prioritisation and procurement of new technologies and clinical interventions, one based on patient outcomes and whole system efficiencies. This approach needs to be adopted through a multi-agency, cross-sector strategy, with the objective of maximising rapid patient access to the latest, proven innovations. A more flexible approach to technology assessment enabling new forms of real-world evidence and wider definition of value, also needs to be developed in conjunction with industry. There needs to be substantive linkages between the output of formal assessment programmes and commissioning and reimbursement processes, accompanied by a clear implementation strategy. Future procurement strategy should not be based on cost alone, but should also consider value and, where it exists, cost effectiveness as determined by formal health technology assessments.

Furthermore, it should consider securing plurality of supply and a multi-vendor approach. The drive by the NHS to purchase the lowest priced product and single supplier contracts, has resulted in manufacturing being driven to low cost labour markets, weakening local resilience and largely ignoring strategic considerations to improve robust, ethical and sustainable supply chains. 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 blended 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 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.

Agile regulatory systems can support the UK in the development and manufacturing of HealthTech, remove unnecessarily burdensome bureaucracy and rapidly iterate products. 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. An innovative approach to regulation will be central to enhancing the UK's attractiveness as a destination to develop and distribute HealthTech as envisioned in the Medicines and Medical Devices Bill. The approach should consider the role of the MHRA as an independent member of the International Medical Device Regulators Forum (IMDRF) and participation in initiatives such as the Medical Device Single Audit Programme (MDSAP).

RECOMMENDATIONS

1. 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 patient outcomes, supply chain resilience, evidence, ethics and quality.

2. A more flexible approach to technology assessment, enabling the consideration of new forms of real-world evidence and a wider definition of value, needs to be developed in conjunction with industry.

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

4. Rather than cumbersome funding mechanisms 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.

5. We believe that every NHS Trust should appoint a Board level Chief Innovation Officer.

6. An innovative approach to regulation will be central to enhancing the UK's attractiveness as a destination to develop and distribute HealthTech as envisioned in the Medicines and Medical Devices Bill. The approach should consider the role of the MHRA as an independent member of the International Medical Device Regulators Forum and participation in initiatives such as the Medical Device Single Audit Programme.

DIGITAL HEALTH TECHNOLOGIES

Realising the full benefit of digitally enhanced health technologies will be dependent on access to robust, well curated datasets, on suitable commercial terms, and with appropriate consent for use. The potential within the NHS is significant given the large number of longitudinal datasets it has access to, and there should be a systematic exercise of data management to ensure usability. This needs to be supported by regulation and market access mechanisms to ensure that the NHS becomes a 'living laboratory' for the best digital technologies, bringing benefits to both patients and the health and care system. Technology use broadly falls into four interlinked areas:

- Population management: identification of an at-risk group to enable early intervention and preventative measures
- Remote services: manage people that would otherwise be visiting hospitals either as outpatients or via A&E, and to monitor patients whose treatments have been delayed
- Triage and clinical decision-making systems: Artificial Intelligence (AI) systems that have been trained via machine learning to offer "clinical decision support"
- Digital Diagnostics: the use of AI and deep learning to enhance the detection and diagnosis.

Digital HealthTech has shown great value in enabling care in out-of-hospital settings, relieving wider system pressures. Many examples have been implemented rapidly during the COVID-19 pandemic, more patients have been offered virtual appointments and are using home monitoring. Electronic prescribing has been much more widely utilised and may be contributing to improved adherence. It is widely accepted that the acceleration in the use of digital HealthTech has been one of the critical factors in supporting the system, and has been welcomed by patients and practitioners alike.

Fundamental to realising the full potential of digital 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. Value assessment needs to be based on wider UK economic benefits and not solely on those accruing to the NHS.

The potential for NHS data is significant, however it requires investment in data cleansing and curation, and Government should assign funding for this exercise and support for the delivery of critical health data infrastructure should be continued.

The use of data goes beyond research and, in the HealthTech sector, robust data are also required for prototyping, training of algorithms, validation and verification and post market surveillance. It is important that consented, or appropriately anonymised datasets, are readily available for these wider purposes.

Essential to the integrity of datasets is as wide as possible 'data donation' by the public. There should be a public awareness campaign by the Government to highlight the benefits of data sharing to the individual, peer groups, the NHS and wider society. During the pandemic there has been a significant shift in the use of digital technologies and in the discussion over the use of data driven by programmes such as 'Track & Trace'. Working with third sector organisations, Government should make a rapid assessment of the impact of COVID-19 on the public debate.

The UK has the opportunity to take a global lead on the regulation of digital health technologies, developing new tools, standards and approaches to evaluate digital health products, including AI. The current regulatory system is managed through multiple organisations, based on data, device or service delivery. It will be important for regulators to work collaboratively with industry to provide integrated and accelerated regulatory processes that are aligned across these three domains. The regulatory regime has an important role to play in developing the necessary systems and public trust in the use of data, software and devices as part of digital health solutions and services. Regulation needs to ensure that safety is never compromised, whilst allowing patients and healthcare professionals timely access to high-quality, effective digital health products and services. Current regulatory processes, established for traditional medical devices and diagnostics, do not work optimally for many digital health solutions, and need a shift to a more nuanced, risk-based approach that fits the rapid, iterative and interconnected nature of digital health solutions. Programmes, such as the FDA "Pre-Cert", and the proposals for regulation based on Ethical Business Practice, take a more organisational and principled based approach to regulation. This type of process is more conducive to digital health technologies, allowing streamlined approaches, while still protecting patients through appropriate, risk-based levels of oversight. This will enable developers to rapidly and continuously improve the safety and effectiveness of their products. The HealthTech industry, and the patients it serves, need modernised regulatory frameworks that are swifter, more predictable and transparent to reduce the time and cost of market entry.

A significant barrier to adoption for digital health products and solutions is that payment and procurement processes are not yet established. Individual technologies are not routinely funded as part of existing payment and coding practices (i.e. coding and payment criteria do not exist). Due to the varied nature of digital solutions it is unlikely that a one-size-fits-all approach will suffice, and a range of new mechanisms will need to be examined. Procurement mechanisms are typically geared towards traditional "box-shifting" models that do not necessarily transfer across to approaches such as Software as a Service, value-based pathways or mixed professional/consumer paradigms. Some of the areas that need to be examined are:

- Pathway budgets that can incorporate the use of digital health technologies.
- Value-based, risk share and outcomes-based payment models
- Utilising the existing prescription reimbursement process (the 'Drug Tariff').

In addition to direct payment and contracting mechanisms, considerations must also be given to broader based incentive schemes that can reward system performance and outcomes-based targets. This will mitigate against the disruptive impact of HealthTech and help maintain system stability.

Flexible processes and payment criteria should be developed for assessing the value of digital healthcare products and solutions, taking account of the fast-paced nature of digital product innovation. These payment mechanisms should be the end point of a clear and transparent pathway for assessment and payment decisions, which should utilise the NICE Evidence Standards Framework as its foundation, but be broadened to include wider service benefits and have an explicit link to a payment decision.

These new funding and assessment approaches need to be recognised in the procurement models that are adopted, ensuring that a value-based approach is central to decision making.

The shift towards home care and home monitoring, enabled by digital technologies and expedited by the pandemic, has increased the ability of patients to manage their own conditions with their healthcare teams and reduced the need for hospital attendance and may be a preferable option in the future. As the crisis phase ends, there is an unprecedented opportunity to embed the use of technology and shift in care setting in a sustainable way. Alongside the infrastructure requirements, actions should include giving pharmacists 'write access' to medical records and empowering them to refer people to other healthcare professionals, fast-tracked if necessary. Progress on remote care and monitoring must be maintained and enhanced where appropriate to reduce pressure on acute care, support patient self-management, improve choice and address health inequalities. However, further research is required to assess where remote care is suitable for vulnerable people, such as those with mental health conditions. It is also important that this technology is not allowed to create new demand or provide an alternative route for people with self-treatable conditions to access a GP consultation, when they should be practicing self-care.

To support the shift in care setting, consideration also needs to be given to more flexible arrangements in the Drug Tariff to enable provision of a wider range of products, including Apps, and the ability to prescribe reusable products. This reimbursement mechanism needs to be supported through greater use of electronic prescribing, community pharmacy and dispensing appliance contractors.

RECOMMENDATIONS

1. Access to high quality, well curated data sets should be available to researchers and innovators to help them improve patient care and system efficiency.
2. 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.
3. There needs to be flexible commercial arrangements, based on a value assessment of the wider UK economic benefits of digital HealthTech, and not solely on those enjoyed by the NHS.
4. Intellectual Property should accrue to those that are creating value.
5. Government should make funding available for a significant programme of data cleansing and curation, along with support for the delivery of health data infrastructure.
6. A public awareness campaign by the Government to highlight the benefits of data sharing to the individual, peer groups, the NHS and wider society.
7. The UK should take a global lead on the regulation of digital health technologies and AI.
8. Regulatory processes need a shift to a more nuanced, risk- based approach that fits the rapid, iterative and interconnected nature of digital health solutions. The MHRA should consider programmes, such as the FDA "Pre-Cert", and the proposals for regulation based on Ethical Business Practice, as it develops such an approach.
9. 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.
10. Processes and criteria should be developed for assessing the value of individual technologies, based on wider service value and have an explicit link to payment and/or procurement decisions.
11. Progress on remote care and monitoring must be maintained and enhanced to reduce pressure on the acute sector, support patient self-management, improve choice and address health inequalities.
12. To support the shift in care setting more arrangements in the Drug Tariff are required to enable provision of a wider range of products, including Apps.

SUPPLY CHAIN RESILIENCE AND UK MANUFACTURING CAPABILITY

The demands of the COVID-19 pandemic have highlighted some fragilities in the UK supply chain such as dependence on a large amount of supply from a small number of overseas jurisdictions and a lack of indigenous capacity in critical sectors.

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 new, increased volumes.

The following areas need to have a clearly defined cross-Government response:

- Identification of the core manufacturing competencies and capabilities where UK indigenous capability needs reinforcement to support the NHS
- The UK should prioritise the establishment of a diagnostics industry at scale
- Support for manufacturing networks to deliver flexible and expert capacity in the UK
- Enhancing key global supply chains and jurisdictions where international cooperation is required to ensure a robust flow of raw materials and component parts
- Demand forecasting and supply chain management.

There is a significant opportunity for the UK to improve the attractiveness of medical device and diagnostics manufacturing to enhance future supply chain resilience and generate economic growth. The Life Sciences Industrial Strategy set the ambition to attract ten large and ten smaller manufacturing facilities to the UK. On-shoring of manufacturing should not be viewed as a way of securing complete UK self-sufficiency for the management of future health emergencies, rather one of a number of measures to strengthen our resilience.

The Government's COVID-19 recovery strategy aims to ensure the UK has robust supply chains across medicines and healthcare products. The HealthTech sector should be closely involved in the development of this strategy to ensure proposals are practical and implementable. Strengthening supply chain resilience is critical.

The UK cannot produce all the technologies required and where UK-based manufacturing is in operation, it maybe reliant on raw materials and component parts from across the globe. The strategy should aim to support increasing diversity of supply and flexibility in capacity, enabling manufacturers to manage international inventories.

The economics of establishing and continuing to run flexible, pandemic-ready manufacturing, whilst not hampering the normal successful operation of the competitive market, will be a challenge that will need to be further investigated. If significant investments are made, the willingness and ability of the NHS to purchase the resulting products also needs to be considered. Skills, costs, regulation and technology are central to the attractiveness of a manufacturing location, alongside the terms of trading, including the ability for companies to export to global markets. The Government should also be aware of the actions and manufacturing incentives provided in other global locations and provide a competitive offering to retain and build on the current base. This support is particularly valuable to SMEs, which dominate the HealthTech sector. In a recent survey of SMEs by MedCity, 36% of correspondents identified 'key operations' such as manufacturing as a significant challenge facing their businesses. The experience during COVID-19 has shown that combining specific medical device experience with manufacturing capacity from wider industry has been a successful combination. Creating stronger networks and clusters across the sector can create flexible capacity and response mechanisms for any future crisis, and would create an attractive investment environment. One suggestion is Government loans to SMEs over a 10-year period in which repayment does not start until year three to allow manufacturing scale up and purchase of capital equipment. This practical solution would allow companies to invest in UK manufacturing, offering innovative technologies to the NHS within short time frames.

Accurate demand forecasting and transparency can only be achieved by a balanced focus on both supply and demand side factors. Supply reliance will be greatly supported by more accurate and timely NHS demand forecasts. This is particularly true in times of supply disruptions and uncertain demand profile, such as during, or in the aftermath, of a pandemic. This can be achieved through collective dialogue as to which equipment needs to be produced and in what quantity, with improved transparency along the entire supply chain. A joint NHS/NHS Supply Chain and industry taskforce should be established to review and action workforce development, processes and systems as the NHS restarts elective procedures.

RECOMMENDATIONS

1. Government, the NHS and industry should collaboratively develop robust, parallel strategies for supply resilience and HealthTech manufacturing. This should be delivered by adding sub-groups to the Health Technology Partnership, the Life Sciences Council and the Medicines Manufacturing Industry Partnership as appropriate.
2. The economics of establishing and continuing to run flexible, pandemic-ready, UK-based manufacturing should be factored into the willingness for the NHS to purchase the resulting products.
3. The Government should provide a competitive offering to retain and build on the current industrial base, taking into account the actions and incentives provided in other global locations and with a particular emphasis on SMEs.
4. Support should be made available to create stronger networks and clusters across the sector that can deliver flexible capacity and response for any future crises, combining specific medical device experience with wider manufacturing capacity.
5. Establish 10-year Government loans to SMEs with repayment commencing in year three to allow manufacturing scale up and the purchase of capital equipment.
6. A joint NHS/NHS Supply Chain and industry taskforce should be established to review and action accurate demand forecasting and the transparency of processes and systems as the NHS restarts elective procedures.

TRADE

As companies try to recover from the impact of COVID-19, we must ensure that the end of the EU exit Transition Period delivers new opportunities and maintains seamless access to global markets and brings online new trading partners. To support economic growth, it is also important to encourage inward investment, this needs both the local market conditions to be favourable but also the necessary trading agreements to be in place.

The UK has long been a voice for global trade and we urge Government, as part of an international pandemic response, to continue to actively support any actions possible to facilitate free trade, along with opposing the imposition of export restrictions that disrupt global supply chains. The Government should commit to prioritise HealthTech in future trade negotiations to maintain the UK as a global hub for innovation, and should develop trade deals that allow this innovation the greatest possible global reach. Regulation is a key element of any Free Trade Agreement (FTA), especially for a sector such as HealthTech that is subject to very high levels of scrutiny. There is a trend towards the global harmonisation of standards which should be recognised and embedded in any agreements and supported by good regulatory practice with open and transparent processes, advance planning, regulatory impact assessments and retrospective reviews and the mutual recognition of quality management system audits that conform to the Medical Device Single Audit Programme (MDSAP). Mutual Recognition Agreements (MRAs) should be leveraged to extend the UK's global reputation and influence through international networks and partnerships.

The UK must maintain a strong voice for global trade, advocating measures such as ensuring that standards and technical regulations are developed in a fair and transparent manner and based on international standards, with non-discriminatory conformity assessment. These measures would facilitate free trade and should be actively encouraged by the UK Government. Consideration of global supply chains and ethical trade should be a significant component in Government strategy.

As digital HealthTech play an increasing role in delivery of our health service, particular consideration needs to be given to this area. A dedicated digital trade provision within any agreement should allow for the transmission of information across borders to maximise patient benefit and facilitate medical research and clinical trials whilst still protecting personal privacy. It should also address the specific challenges of how we regulate technologies based on AI and deep learning.

Government support for HealthTech exports through Tradeshow Access Programme (TAP) grants has been critical in supporting companies with exports. These grants have allowed small companies to attend international trade shows and overseas missions. Funding for this programme, amongst others, has fallen, and should be increased, alongside evaluating other initiatives to help kick-start exports. In the short-term it will be challenging for UK HealthTech companies to travel to international trade shows due to travel restrictions, and the inevitable reduction in numbers of healthcare professionals attending these meetings. Therefore, online initiatives need to be developed and supported to showcase the best of UK SME HealthTech.

RECOMMENDATIONS

1. The Government should prioritise HealthTech in trade negotiations and should develop deals that allow UK companies the greatest possible global reach.
2. A critical item in any FTA is regulation and we would encourage an explicit collaboration between regulators to be written in and MRAs should be leveraged to extend the UK's global reputation and influence through international networks and partnerships.
3. The UK must maintain a strong voice for global trade, advocating measures such as advocating measures such as ensuring that standards and technical regulations are developed in a fair and transparent manner and based on international standards, with non-discriminatory conformity assessment.
4. Measures that facilitate free trade should be actively encouraged by the UK Government with consideration of global supply chains and ethical trade a significant component in Government strategy.
5. A dedicated digital trade provision within any agreement should allow for transmission of data across borders to maximise patient benefit and facilitate research and clinical trials.
6. There should be increased Government support for SMEs through measures such as the Tradeshow Access Programme.
7. An active Technical Barriers to Trade (TBT) Chapter Committee should be established for each FTA, that will discuss bilateral and third-party specific trade concerns, coordination of regional and multilateral activities, regulatory cooperation, and implementing Good Regulatory Practices (GRPs).
8. The Department for International Trade's "Global Sales Pitch" for the UK as a prime location for life science investment into research, development and manufacturing should be restarted.

DEVELOPMENT OF A UK DIAGNOSTICS CAPABILITY AS A STRATEGIC PRIORITY

Testing for SARS-CoV-2 and screening for COVID-19 antibodies are widely acknowledged as key tools to manage both the human and economic impact of the global pandemic. The diagnostics industry, both multinational organisations and smaller companies, has mobilised to make tests available in the UK. The Government acknowledges that the UK went into the pandemic with a shortfall in testing capacity and capability due to less investment in diagnostics compared to countries such as Germany. Today, strong partnership working between industry and Government, has expedited the availability of tests for UK citizens.

The NHS Long Term Plan rightly acknowledges throughout, the importance of early diagnosis, a sentiment reinforced through the subsequent prevention Green Paper. Approximately 70% of clinical decisions are influenced by in-vitro diagnostics (IVDs), yet only 1% of the NHS' budget is spent on them. The situation is echoed in in-vivo diagnostics, for example data from the Joint Advisory Group on Gastrointestinal (GI) Endoscopy (JAG) 2019 census showed that the NHS was struggling to cope with the increase in demand for bowel cancer screening colonoscopy, even prior to the limitations enforced by COVID-19. There has been significant under investment in diagnostics (technology, infrastructure, and people) over many years.

The COVID-19 pandemic has highlighted the integral value of diagnostics to a well-managed health and care system. Significant capacity and capability continues to be built to support COVID-19 Test and Trace services. However, as routine NHS activity was put on pause, patients face long waits for routine tests and imaging, and an already overstretched workforce is under further strain. For example, the Radiologist workforce alone is thought to be understaffed by 43%. Similarly, only 3% of histopathology departments said they had enough staff to meet clinical demand. Government must now continue the strong partnership working between the NHS, academia, and industry to learn lessons from COVID-19 and build a diagnostics industry of the future.

For diagnostics to play its role within a broader health system, its value must be placed at the centre of disease and patient pathways, to detect diseases as early as possible and accurately guide the right treatments.

The Government must now set out a diagnostics strategy with clear deliverables to achieve by 2025. To measure success, we recommend Government aims for:

1. An increase in the per capita spend on diagnostics benchmarked against other, comparable nations
2. Equity of testing access across all regions of the UK including the devolved nations
3. An increase in the level of investment in both manufacturing and Research and Development in the UK
4. A significant shortening of the technology adoption timeline
5. Full implementation of MedTech Funding mandate for all NICE approved diagnostics
6. Recovery of waiting times for diagnostic testing to pre-COVID levels and meet the various targets laid out in the Long Term Plan related to early diagnosis.

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

Leadership and resourcing is much needed to ensure alignment and strong co-ordination of strategy implementation. There are a number of initiatives which we feel might be helpful, in this regard, for example the appointment of a 'National Diagnostics Director' operating jointly from the Department of Health & Social Care (DHSC) and NHS England. Also helpful would be the delivery of clear guidance on the intended roles and responsibilities between different Governmental departments and NHS Authorities and ensuring there is close working between devolved nations on a UK diagnostic strategy so learnings can be shared. Finally, there should be an acceleration of the consolidation of the national pathology networks across England and the IT infrastructure and connectivity that will need to underpin their work.

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 recruit talent, upgrade infrastructure, and adopt new technologies. Expertise is crucial for the success of population health management, however staffing and resource constraints in radiology and pathology are well documented. There is a need to develop and implement an NHS diagnostics workforce plan to boost this expertise.

NHS laboratories are integral in delivering high quality tests, they conduct around 80% of in-vitro analyses. They have high standards of accreditation, governance, and data connectivity to patient records. Yet, they have been under-invested in. Alongside this, new technologies and partnerships are changing how diagnosis happens, for instance through digitalisation and the application of machine learning techniques, and these factors must be taken into account when recruiting, training or up-skilling.

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 (DHSC), Public Health England, academia, and industry, small and large. Whilst national leadership will help alignment and coordination, a broader forum to ensure the different groups continue to co-ordinate, share learnings, and work collaboratively will be crucial to ensure the achievements and progress made are not lost.

A significant opportunity exists to formalise a diagnostics group, under the auspices of the Health Technology Partnership, bringing together relevant organisations and build resource and capability within the Office for Life Sciences and broader Government as necessary. Beyond this formal platform, it will be important to forge new partnerships to improve analytics and information sharing so that the utilisation of diagnostic technologies informs population health management, screening and surveillance. Industry / NHS accelerator programmes can develop innovations that deliver diagnostics in different ways and closer to patients, whilst there remains considerable potential in existing programmes such as "Accelerating Detection of Disease," the "Accelerated Access Collaborative" and CONDOR network.

Diagnostic delivery models have been changing over many years. The place where diagnosis occurs is moving closer to the patient. Point of care in-vitro tests are an example, as are smaller, more portable imaging devices which can be used in community settings. Earlier disease detection can help shift health focus from intervention to prevention.

The COVID-19 pandemic has seen an acceleration of the implementation of some of the new ways to conduct tests. The distribution and management of home testing kits, assembled from scratch, is an example of an effective channel to reach citizens. Work is also underway to improve IT connections so that data capture and test analysis by Lighthouse Laboratories is linked to personal health records.

We have also seen a dramatic increase in the use of virtual GP appointments. The process to order COVID-19 test kits online has proven that different models for providing diagnostics can, and should, be implemented. There is now an opportunity to facilitate more diagnosis to be conducted in a convenient and efficient manner, without the need for patients to attend physical consultations.

Fundamental to building indigenous industrial capability, is having a receptive local market to new technologies. This demand supports return on investment and spurs further innovation. To do this, the UK must increase the adoption of diagnostic technologies across the system. There are numerous existing initiatives and platforms that could be better utilised or developed to support better adoption. The Accelerated Access Collaborative (AAC) and NHS 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, whilst developing an early access scheme for diagnostics equivalent to that for medicines will encourage the development of innovative testing.

Particular emphasis needs to be placed on helping smaller business gain commercial traction and we would support continued investment in the Academic Health Science Networks and Medtech and In-vitro Diagnostics Cooperatives to help in this regard. There is also scope to work with the investment community and ensure appropriate incentives are in place, where necessary, bespoke to the diagnostics sector.

Adoption and spread of diagnostic innovation will be further supported as digitally supported pathways become the norm and the necessary data, IT infrastructure and information governance systems become routinely available. This needs to be backed up by a new, innovative approach to regulation, which accounts for the rapid iteration of products facilitated by digital technology.

RECOMMENDATIONS

1. Develop national oversight and leadership of a holistic approach to diagnostics, aimed at reducing fragmentation and aligning and co-ordinating outputs alongside a bespoke diagnostics workforce plan.
2. Place diagnostics at the centre of population health management by developing expertise and increasing investment in the sector.
3. Ensure systems and resources are in place to retain and build upon the existing partnership and collaboration.
4. Retain the infrastructure built to support COVID-19 testing to accelerate adoption of new diagnostic delivery models.
5. Develop methodologies and infrastructure to enhance the adoption and spread of innovative diagnostics, supported by access to relevant data and an agile regulatory system.

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

A company limited by guarantee.
Registered in England no. 1469941. Registered office as above.

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

ABHI