Written evidence submitted by Association of British HealthTech Industries (ECS0032)

Summary

1. ABHI welcomes the opportunity to submit evidence to the Health and Social Care Committee's Expert Panel Assessment of cancer services in England.

2. ABHI is the UK's leading industry association for health technology (HealthTech). ABHI supports the HealthTech community to save and enhance lives. Members, including both multinationals and small and medium sized enterprises (SMEs), supply products from syringes and wound dressings to surgical robots and digitally enhanced technologies. We represent the industry to stakeholders, such as the government, NHS and regulators. HealthTech plays a key role in supporting delivery of healthcare and is a significant contributor to the UK's economic growth. HealthTech is the largest employer in the broader Life Sciences sector, employing 138,100 people in 4,140 companies, with a combined turnover of £27.6bn. The industry has enjoyed growth of around 5% in recent years. ABHI's 320 members account for approximately 80% of the sector by value.

3. The HealthTech industry supports the delivery of cancer services through the provision of diagnostic technologies, interventions and therapies as well as services to give people with cancer the support they need.

Executive Summary

4. Progress over the last 50 years has transformed the prospects for people diagnosed with cancer in the UK. In the 1970s, only one in four cancer patients survived their disease for 10 years or more. By 2010, this had risen to two in four, and survival continues to improve[1].

   This is due to groundbreaking research, screening programmes, data-led improvements to healthcare pathways, innovative new treatments, and the tireless efforts of staff across the National Health Service (NHS) and partner organisations.

   However, there is still much to be done. In the UK, cancer is the leading cause of avoidable death and the most common cause of death[2]. A growing and ageing population with increasingly complex needs means that cancer incidence continues to rise at an alarming rate, with a stark projection of rising incidence to over half a million cases per year by 2035[3].

   We also see lower survival in the UK than in comparable countries around the world, and significant variation in outcomes across the UK too[4].

5. The health technology industry has a key role to play in supporting cancer diagnosis, treatment and in helping people live with cancer. The ABHI publication, "Enhancing Cancer Care Through HealthTech"[5] details the role our industry plays. We call for:

   - Action to be taken to resolve chronic workforce issues that are hampering cancer diagnosis and treatment.
   - A systematic approach to addressing the backlog of cancer diagnosis and treatment through diagnostics and medical technologies.
   - A re-doubling of effort on early detection and diagnosis of cancer through embedding diagnostic innovations in the NHS, progressing the recommendations in the independent review of adult screening programmes and provision of comprehensive genomic testing for patients with advanced cancer available across England.
   - Parity with cancer therapeutics for NICE approved medical technologies and diagnostics in terms of mandating their use and associated funding.

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[1] www.cancerresearchuk.org/health-professional/cancer-statistics/survival#heading-Zero
[2] Avoidable mortality in the UK - Office for National Statistics (ons.gov.uk)
[3] C. R. Smittenaar, K. A. Petersen, K. Stewart and N. Moitt, "Cancer incidence and mortality projections in the UK until 2035," Br J Cancer, vol. 115, no. 9, pp. 1147-1155, October 2016.
[4] M. Arnold, M. J. Rutherford, A. Bardot, J. Ferlay, T. M.-L. Andersson, T. Å. Myklebust, H. Tervonen, V. Thursfield, D. Ransom, L. Shack, R. R. Woods, D. Turner, S. Leonfellner and S. Ryan, "Progress in cancer survival, mortality, and incidence in seven high-income countries 1995–2014 (ICBP SURVMARK-2): a population-based study," Lancet Oncol, vol. 20, no. 11, pp. 1493-1505, November 2019.
[5] https://www.abhi.org.uk/media/2909/enhancing-cancer-care-through-healthtech.pdf

Develop and implement a long-term plan to address workforce shortages

6. The NHS Long Term Plan aims to save thousands more lives each year by dramatically improving how cancer is prevented, diagnosed and treated, with an ambition that by 2028, an extra 55,000 people each year will survive for five years or more following their cancer diagnosis.

   Crucially, having access to more skilled staff in the right areas will be key to delivering on that strategy. There are significant workforce shortage across the NHS, meaning that the delivery of safe, high quality care and services to patients is stretched.

   Macmillan highlight that the specialist cancer workforce currently needs an additional 2,500 specialist cancer nurses, an increase of 84%[6].

   The issue of workforce is not a new one[7&8], but neither is it one that will go away until action has been taken. This will require a concerted and coordinated approach across government, professional colleges, NHS England and Improvement, Health Education England and other bodies to resolve.

   With Health Education England set to be merged with NHS England and Improvement, there is an opportunity to put long-term planning and strategy for healthcare staff recruitment and retention at the forefront of the national NHS agenda.

The radiology workforce

7. Clinical radiologists, clinical oncologists and interventional radiologists are crucial for the diagnosis and treatment of cancer, as well as stroke and heart disease. Three of the most common diagnostic imaging tests carried out in the UK are x-rays, CT scans and MRI scans, with CTs and MRIs growing in demand at 7% each year over the past 5 years[9].

   Workforce increases have not kept up, and the NHS radiologist workforce is now short-staffed by 33% and needs at least another ~2,000 consultants just to keep up with pre-coronavirus levels of demand for scans and surgery[10].

   The necessary staff with the skill base to deliver nuclear/molecular radiotherapy treatments are not available in the UK, with Royal College of Radiologists data indicating an 11% decline in Administration of Radioactive Substances Advisory Committee (ARSAC) license holders over a 5-year period (2015 to 2020). In addition, the application process is rigorous and lengthy, creating barriers to prompt certification of radiologists. To ensure patients continue

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[6] www.macmillan.org.uk/_images/addressing-the-gap-report_tcm9-358808.pdf
[7] www.england.nhs.uk/ournhspeople/
[8] www.hee.nhs.uk/our-work/cancer-workforce-plan
[9] www.rcr.ac.uk/sites/default/files/documents/clinical-radiology-uk-workforce-census-2020-executive-summary.pdf
[10] www.rcr.ac.uk/press-and-policy/policy-priorities/workforce/radiology-workforce-census

to benefit from nuclear medicine techniques, succession plans need to be in place for ARSAC license holders and the certification process needs to be more expedient.

The pathology workforce

8. Operating across 105 hospitals and delivering over 1.12 billion tests per year[11], the UK's 28,000 pathologists[12] are essential to preventing, diagnosing and treating diseases, improving patient outcomes and driving greater efficiencies in the NHS. The pathology sector also plays a critical role in undertaking research and devising new treatments to fight viruses, infections and diseases. But their contribution to UK health outcomes has not been matched by investment in the sector. Despite 95% of all clinical pathways relying on patient access to pathology services[13], including cancer diagnosis, funding for pathology only accounts for 2% of the NHS budget[14].

   Demand for pathology services in the NHS has increased on an annual basis, and pathologists face an increasingly complex workload. There is an urgent need to grow, expand and champion the sector to support innovation and build future resilience in the pathology sector. The Royal College of Pathologists UK-wide histopathology workforce survey found only 3% of histopathology departments had sufficient trained staff to meet clinical demand[15].

[11] www.england.nhs.uk/pathology-networks/),
[12] https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-018-3683-8)
[13] www.rcpath.org/discover-pathology/news/fact-sheets/pathology-facts-and-figures-.html)
[14] www.rcpath.org/discover-pathology/news/fact-sheets/pathology-facts-and-figures-.html
[15] https://www.rcpath.org/profession/workforce-planning/our-workforce-research/histopathology-workforce-survey-2018.html

Move to an early diagnosis model

9. There is broad consensus that detection and diagnosis of cancer at an early stage provides patients the best chance of curative treatment and long-term survival. For example, 92% of patients with bowel cancer diagnosed at stage 1 survive their disease for at least five years, compared to 10% of patients diagnosed at stage 4[16]. However, in England, for example, just over half of patients are diagnosed at an early stage[17], demonstrating significant opportunity for improvement.

   The importance of this challenge is recognised by the UK and devolved nations' governments[18]. It requires coordinated action across a range of sectors and organisations, in order to make progress. Cancer Research UK, through their document "Early Detection and Diagnosis, A Roadmap to the Future"[19] has done great work to set out the possible future of ED&D and a series of actions that provide a route to get there.

   ABHI and its members applaud the commitment set out in NHS England's Long Term Plan to detect 75% of cancers at an early stage by 2028[20]. Several initiatives will play a part in progressing this ambition.

Screening

10. Screening of at-risk populations has shown to be effective for early detection of cancer, and results in improved patient outcomes. Screening programmes however bring challenges of their own, including false positives and overdiagnosis and treatment.

    An independent review of adult screening programmes in England was commissioned by NHS England in 2018 with the report published in October 2019[21]. The chair of the review, Professor Sir Mike Richards, points out that although current screening programmes save around 10,000 lives per year through prevention and early diagnosis, they are far from realising their full potential.

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[16] www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/datasets/cancersurvivalratescancersurvivalinenglandadultsdiagnosed. [Accessed September 2020].
[17] Public Health England, "Case-mix adjusted percentage cancers diagnosed at stages 1 and 2 by CCG in England," May 2020. [Online]. Available: https://www.gov.uk/government/statistics/casemix-adjusted-percentage-cancers-diagnosed-at-stages-1-and-2-by-ccg-in-england. [Accessed September 2020].
[18] A. Downey, "Government pledges £50m for AI to improve diagnosis of deadly disease," September 2020. [Online]. Available: https://www.digitalhealth.net/2020/08/government-pledges-50m-for-aito-improve-diagnosis-of-deadly-disease/
[19] https://www.cancerresearchuk.org/funding-for-researchers/research-opportunities-in-early-detection-and-diagnosis/early-detection-and-diagnosis-roadmap
[20] www.longtermplan.nhs.uk/publication/nhs-long-term-plan/ [Accessed September 2020].
[21] www.england.nhs.uk/wp-content/uploads/2019/02/report-of-the-independent-review-of-adult-screening-programme-in-england.pdf

The report acknowledges that several issues affect and hinder the effective functioning of screening programmes and lead to delays in making improvements which are already proven to work.

In looking to the future, the report highlights:

- opportunities to improve governance, accountability and overall responsibility of screening programmes,
- the need to invest in IT systems,
- ideas to reverse the decline in screening take up by citizens,
- financial measures to incentivise screening provision, and
- emphasises the importance of audit and research to monitor progress and identify opportunities to make even further improvements, including potential new screening programmes.

Implementation of these recommendations carry financial and resourcing implications. NHS England has stated they will be working closely with government and public health bodies to consider the 22 recommendations in full as part of existing work which is already underway. However, it is not clear what progress has been made against the recommendations of this independent review which was published just prior to the COVID-19 pandemic.

Advances in diagnostics

11. In recent years, several advances in technologies are yielding new opportunities for diagnostic tests and techniques to complement tissue-based cancer diagnosis approaches. Next-generation sequencing (NGS) platforms and liquid biopsy-based techniques are allowing us to build on our improved understanding of genomics for health and clinical purposes.

    In September 2020, the government published the Genome UK Strategy[22], which sets out the 10-year vision to create the most advanced genomic healthcare system in the world, delivering better health outcomes at lower cost. A significant pillar of that is incorporating the latest genomics advances into routine healthcare to improve the diagnosis, stratification and treatment of illness, in particular cancer.

    NGS enables rapid, affordable, and actionable information on individual tumours (known as molecular tumour profiles), through the identification of critical cancer-gene alterations, so that clinical decisions, or molecularly guided treatment options (MGTOs), can be tailored to each patient.

[22] www.gov.uk/government/publications/genome-uk-the-future-of-healthcare

NGS is a high-throughput technology that can allow integration of molecular tumour profiles into clinical decision-making as part of precision oncology [23]. Comprehensive genomic profiling is an NGS approach that detects novel and known variants of the four main classes of genomic alterations, as well as genomic signatures, to provide prognostic, diagnostic, and predictive insights that inform research or treatment decisions for individual patients across all cancer types.

Technological advances are not limited to new approaches to the investigation of solid tumours. Specifically, tumour-derived biomarkers contained in liquid biopsies collected from a patient, prove the basis for developing effective diagnostic biomarkers from these specimens. Thus, progressing the precision medicine treatment shift.
A biomarker is a biological characteristic of the body that can be objectively measured and quantified; essentially, any gene, molecule, or characteristic derived from tissues or bodily fluids, including blood. In oncology, biomarkers are abnormalities or mutations found in cancer cells.

Compared to tissue-based cancer diagnosis approaches that may be limited by the issue of tumour heterogeneity, accessibility to a tumour, and possible complications associated with the biopsy procedure, approaches targeting liquid biopsies such as blood, urine, cerebrospinal fluid, saliva, sweat have been demonstrated for their clinical potential as a non-invasive, or minimally-invasive alternative.

Despite efforts to provide equitable access to these technologies, gaps exist across the UK meaning not every eligible cancer patient will receive the same genomic profiling tests due to either lack of capability at a local level, or lack of awareness by treating clinicians on what tests are available. Similarly, access to other biomarker testing is inconsistent and contributes to health inequities across Europe.

The International Quality Network for Pathology (IQN Path), the European Cancer Patient Coalition (ECPC), and the European Federation of Pharmaceutical Industries and Associations (EFPIA) have partnered on a study[24] to analyse the current state of biomarker testing in the EU and the UK, and to lay out recommendations to achieve a vision of universal access to precision medicine in cancer care for all European cancer patients. They found that the UK lags behind countries such as France, Germany, Austria, Denmark, Sweden and Finland in terms of access to biomarker testing for cancer.

Digital diagnostic capabilities

[23] www.mdpi.com/2075-4426/12/1/72/html#B1-jpm-12-00072
[24] www.efpia.eu/media/589727/unlocking-the-potential-of-precision-medicine-in-europe.pdf

12. Digital and automated solutions exist that could be more widely deployed within the NHS to speed up diagnosis and at the same time help address the chronic workforce shortage in pathology.

    Digitalisation of glass pathology slides, in combination with the application of machine learning, has given pathologists the ability to utilise digital image analysis on tissue sections. Tissue image analysis, when performed correctly, results in the generation of tissue-derived readouts that are precise and reproducible.

    The combination of image analysis software and pathology expertise provides an opportunity to transform a traditionally qualitative assessment towards a more quantitative approach, analysing complex biomarker expression, patterns, and tissue phenotypes. Image analysis and machine learning algorithms can automatically identify tissue compartments of interest, segment individual cells, or anatomical features and categorise these features based on biomarker expression levels and localisation.

    Image analysis tools not only reduce bias introduced by both visual limitations and cognitive traps, they also enable the capture of data from tissue slides that may not be accessible via routine microscopy. They equip pathologists with tools that can improve accuracy, precision, and reproducibility in the interpretation of biomarkers using image analysis**.**

    Similarly, radiographic assessment of disease most commonly relies upon visual evaluations, the interpretations of which may be augmented by advanced computational analysis. In particular, artificial intelligence (AI) promises to make great strides in the qualitative interpretation of cancer imaging by expert clinicians[25]. The Royal College of Radiologists believes that artificial intelligence (AI), machine learning (ML) and associated health technologies represent one of the most potentially fundamental changes in medical care since the inception of the NHS, though their introduction needs to be appropriately regulated and governed to augment clinical practice. Accelerating the research, and subsequent deployment, of digital and automated solutions will potentially support a shortening of the time to diagnosis[26] and optimise treatment[27].

Capacity

13. Professor Sir Mike Richards was also commissioned by NHS England to undertake a review of NHS diagnostics capacity and his subsequent report[28] highlighted a clear need for increased capacity, both in terms of equipment/facilities and workforce.

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[25] https://pubmed.ncbi.nlm.nih.gov/30720861/
[26] https://www.cam.ac.uk/research/news/ai-could-help-cut-waiting-times-for-cancer-by-automating-mark-up-of-patient-scans-prior-to
[27] https://crukcambridgecentre.org.uk/news/pioneering-transformative-technologies-improve-cancer-treatment-pathways
[28] www.england.nhs.uk/wp-content/uploads/2020/11/diagnostics-recovery-and-renewal-independent-review-of-diagnostic-services-for-nhs-england-2.pdf),

NHS England is establishing Community Diagnostics Centres (CDCs), expanding Rapid Diagnostics Centres and investing in capital equipment such as MRI and CT scanners. CDCs are part of a new diagnostics delivery model where more facilities are created in free standing locations away from main hospital sites, including on the high street and in retail locations, providing quicker and easier access to a range of tests on the same day, supporting earlier diagnosis, greater convenience to patients and the drive to reduce health inequalities.

The exact configuration of services within a CDC will be for local decision making.

ABHI and our members are encouraged that a key objective is the provision of services for which demand is outstripping capacity, though this risks a fragmented and broad approach which overlooks delivery of tools and systems which can make a real difference to early diagnosis of cancer.

Research and real world evidence generation

14. The UK has a well established and capable research infrastructure which is strongly positioned to work in partnership with industry and deliver the UK Government's vision for 'The Future of UK Clinical Research'. This is essential to ensure the UK remains a leader in innovative health research.

    Partnerships with industry include the deployment of digital and decentralised trials, precision medicine and advanced therapy research as well as the development of molecular prognostic and diagnostic tests to aid treatment decisions.

Early diagnosis Recommendations

Embedding cancer diagnostic innovations within the NHS

15. Once NICE approval of a new product has been secured, innovations should then be fed directly into the Accelerated Access Collaborative (AAC) to assess the real-world impact of the product. After AAC approval is confirmed, NHS Trusts should be mandated to implement a new innovation.

    Commissioners should have a statutory responsibility to make funding available for new diagnostic products as set out in the NHS Long Term Plan, with a designated diagnostics transformation lead, who will promote diagnostics and adoption of new, NICE-approved tests within their hospitals.

Implementation of the recommendations in the Independent Review of Adult Screening Programmes

16. A review of progress against the 22 recommendations in the report published in October 2019 would be useful. It would also be beneficial for all stakeholders supporting, or delivering screening programmes, to see a detailed implementation plan with key milestones and key performance indicators against the recommendations in the report.

Look at best practice examples across Europe and the rest of the world who are achieving early detection and diagnosis of cancer at stages I and II

17. The IQN Path, ECPC, and EFPIA study highlights key recommendations for improving access to cancer biomarker testing and highlighted that the UK is lagging behind counterparts in other parts of Europe. A review of best practices might be a useful exercise to bring the UK on par with the best in Europe in terms of enabling all eligible patients to have biomarker tests.

Provision of comprehensive genomic testing for patients with cancer available across England

18. The European Alliance for Personalised Medicine (EAPM) set up expert panels during the first half of 2021, including key stakeholders from across 10 European countries covering medical, economic, patient, industry, and governmental expertise. They explored the necessary conditions for NGS implementation into routine clinical care to enable patient access, identify specific challenges in achieving them, and made short and long-term recommendations.

    Challenges identified relate to the demand for NGS tests (governance, clinical standardisation, and awareness and education) and supply of tests (equitable reimbursement, infrastructure for conducting and validating tests, and testing access driven by evidence generation).

    In their publication they make 12 key recommendations and we highlight a number that we feel that England could usefully look to incorporate as part of the wider Genomic Medicine Service.

I. Evidence generation demonstrating the clinical value of NGS through traditional and innovative clinical trials and standardized, guideline-driven Real World Data-based studies.
II. Converging approval of diagnostics and medicine to secure availability.
III. Integration and ongoing update of national guidelines covering NGS testing, in collaboration with scientific medical societies.
IV. Use of Molecular Tumour Boards and clinical decision-supporting systems to align treatment strategies, based on profound expertise in cancer genomics.
V. Up-to-date guidance specifying when and where NGS should be performed, along with minimum standards for testing.
VI. Sufficient and consistently adjusted budgeting for molecular testing, with significant investment in bioinformatics and artificial intelligence-based infrastructure for NGS data storage, analysis, and interpretation.
VII. Utilization of horizon-scanning techniques to identify future challenges related to innovative testing techniques, such as NGS, thus preparing stakeholders for their implementation into healthcare [115].

Continue to invest in technology-based innovation

19. Surgery is one of the main treatments for many types of cancer. Scientific and technological advancements mean minimally invasive HealthTech treatments, such as selective internal radiation therapy (SIRT), transarterial chemoembolisation (TACE) and cryoablation, are viable alternatives to open surgery.

    SIRT is a type of internal radiotherapy used to treat primary and secondary liver tumours that are not appropriate for surgical intervention[29] . SIRT is also referred to as radioembolisation and involves the delivery of small radioactive beads into the liver via the blood supply to treat the tumour in the liver. SIRT was approved by NICE in 2021[30]. The NHS is mandated to implement and fund a NICE technology assessment within 90 days (60 days in Wales) from March 2021, yet the new funding stream is still awaiting approval as of January 2022.

    TACE is also a treatment for liver cancer that uses a combination of chemotherapy (anti-cancer drugs) and an agent (small plastic beads) to block the blood vessels supplying the tumour. The procedure is conducted by an interventional radiologist.

    Cryoablation is an innovative ablation procedure which uses extreme cold to kill cancer cells when surgery is not an option. During cryoablation, a thin needle is inserted through the skin and directly into the cancerous tumour. A gas is then pumped through the cryoprobe in order to freeze the cancerous tissue. The tissue is then allowed to thaw. The freezing and thawing process is repeated several times during the same treatment session[31].

    These HealthTech innovations are not only clinically and cost effective but can also help address current issues with waiting times, improve patient throughput and relieve hospital bed pressures as they can be carried-out as short-stay or outpatient procedures. Compared to chemotherapy; SIRT, cryoablation and TACE treatments can be delivered locally with great precision reducing side effects that are typically associated with systemic treatments. They are generally, well tolerated by patients as they do not produce the same level of side effects as chemotherapy. This also helps to preserve patients' quality of life. By avoiding surgery and utilising minimally invasive interventional radiology procedures, patients benefit from faster recovery times, shorter hospital stays and better outcomes.

    The All-Party Parliamentary Group on Minimally Invasive Cancer Therapies found that less than 10% of cancer patients, following diagnosis, had been offered any type of minimally invasive cancer therapy.

[29] https://cdn-dev.macmillan.org.uk/cancer-information-and-support/treatment/types-of-treatment/radiotherapy/internal-radiotherapy/selective-internal-radiation-therapy-sirt
[30] www.nice.org.uk/guidance/TA688/chapter/1-Recommendations
[31]

Recommendations

Promoting early adoption of innovations that NICE assess as showing good promise

20. Although NICE's current assessment of diagnostics and medical devices does promote innovation, integration across the wider system must be improved to ensure diagnostic tests and medical technologies are swiftly adopted nationwide and receive parity of esteem with other NICE-approved treatments.

    NHS Trusts should be assisted to develop change management resource to remove the financial and cultural barriers around adopting new innovations. This resource should also establish a comprehensive patient pathway approach which prioritises minimising time spent in hospital settings.

    The Accelerated Transitional Adoption Scheme, proposed by ABHI, supports the creation of a clear mechanism for the rapid adoption and spread of promising health technologies and therefore should be implemented. The intention of the scheme is to ensure timely access to patients for technologies that, having achieved regulatory approval, are identified as promising following an initial accelerated NICE assessment. Initial payments would be made so that further evidence can be gathered with a view that if they reach a successful conclusion, they then enter into routine commissioning and funding mechanisms.

Dedicated funding

21. There is a need for expedient approval of funding when NICE decisions are made, as delays in funding approval are leading to delays in patients accessing vital HealthTech treatments. The full recommendations of the NHS MedTech Funding Mandate should be implemented immediately to ensure that innovations that are both clinically and cost-effective are clearly identified and then adopted by hospitals and commissioners. This should be complemented through the development of a 'ring-fenced' Cancer HealthTech fund for HealthTech as is the case for pharmaceuticals where a Cancer Drugs Fund exists.

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