HEALTHTECH AND SUSTAINABILITY

The Opportunities and Challenges for the Sector

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ABOUT ABHI AND OUR INDUSTRY

The Association of British HealthTech Industries (ABHI) is the leading health technology (HealthTech) industry association in the UK. We are a community of over 400 members, from small UK businesses to large multi-national companies.

We champion the use of safe and effective medical devices, diagnostics and digital health technologies. The work of our members improves the health of the nation and the efficiency of the NHS.

The HealthTech industry makes a vital contribution to economic growth in our country. The industry employs over 154,000 people across 4,465 companies, mostly small and medium sized enterprises (SMEs). The industry is generating a turnover of over £34.3 billion and has achieved employment growth of greater than 5% in recent years.

ABHI's members account for approximately 80% of the value of the sector as measured by sales to the NHS. As the most highly regarded universal healthcare system in the world, the NHS in turn is dependent on technology produced by the industry to enhance the efficiency of services and to drive continuous improvement in their delivery.

HealthTech is an industry characterised by rapid, often incremental product design and development. It is one of two distinct sub-sectors of the broader Life Sciences, with evidence, regulatory and adoption needs that differ significantly from those of the other, biopharmaceuticals.

EXECUTIVE SUMMARY

Climate change is having devastating effects all over the world, negatively impacting not only the planet we live on but our health as a population. The contribution of healthcare to climate change cannot be ignored, and it is the task of all those working in the sector to lessen our environmental impact.

The National Health Service (NHS) has committed to becoming net zero by 2045 for all the emissions it can influence, which includes its suppliers, and therefore HealthTech companies. The industry is supportive of the move to net zero, but there are many challenges to overcome in order to achieve this. Whether through NHS requirements, wider government policy or device regulation, a new approach needs to be taken by the ecosystem to encourage suppliers to move away from business as usual.

This paper details the challenges that industry is facing and makes a number of recommendations for the health system, government and MHRA to implement to support the HealthTech industry in making a positive change and reducing its environmental impact.

1. The UK and the NHS cannot operate in isolation, making demands of suppliers that are inconsistent with those made by other jurisdictions. Global companies require sustainability goals that match already agreed international standards; diverging is counter-productive and diverts resources away from meaningful actions that reduce emissions. International co-operation and agreement is vital.
2. Waste needs to be considered in its broadest sense when the NHS is setting sustainability goals and targets. The overall aim of the programme should be to reduce burden for healthcare practitioners and suppliers, not increase it.
3. Suppliers require consistency and certainty from the NHS to reduce their carbon footprint and publicly commit to goals.
4. Earlier supplier engagement will reduce unintended negative consequences from the implementation of policy and stimulate faster results in reducing waste and carbon footprint.
5. Ensuring patient safety, shortening hospital stays and reducing readmissions all have a positive environmental impact which must be considered.
6. Collaboration across the ecosystem is vital to make positive, systemic change to the overall environmental and social impact of the HealthTech sector.

Recommendations for the NHS

- Align sustainability requirements for suppliers between NHS England and the devolved nations.
- Health systems should continuously and extensively engage with industry on all new requirements for suppliers through open forums and consultation periods.
- Ensure that all sustainability asks of suppliers by the health systems are consistent, whether regional or national.
- Develop a portal for suppliers to speak directly with sustainability experts about the requests from the NHS, who have a strong understanding of the questions that are being asked, similar to the portals currently used in the procurement process.
- Create clear mechanisms for the adoption of innovations into the NHS which reduce the overall environmental impact of a care pathway, with a standard route applied.
- Sustainability outcomes to be considered more highly in KPIs for procurement teams alongside cost improvement KPIs with appropriate timelines highlighted to industry and an incremental increase.
- Collaborate with industry to scope out the possibility of a 'carbon pound' to be considered as part of the procurement process in the NHS.

Recommendations for Government:

- Create a formal platform for communication and consistent engagement between government, the NHS and wider policy makers in areas such as waste management and environmental policy with regular meeting of an advisory group.
- Establish an online hub for signposting funding and research opportunities for the sector, accessible publicly, to encourage utilisation of available funding and collaboration with academia.
- Establish a cross government forum, led by industry with support from OLS and DHSC, to educate different government departments where requirements are being levied on the HealthTech industry. Attendance should include colleagues from DEFRA, Cabinet Office, Treasury and the Environmental Agency.
- Conduct a review of all existing legislation relevant to net zero that impacts on HealthTech industry.

Recommendations for the MHRA:

- Approve the use of electronic Instructions for Use (e-IFUs) to reduce the excessive use of paper and facilitate the reduction of fuel in the transit of medical products.
- Approve the use of QR codes on medical devices to improve information sharing.
- Implement a regulatory process that takes account of equivalence and predication in alternative material approvals.
- Provide clarification on the definitions for remanufacturing and refurbishment to increase certainty for suppliers.

INTRODUCTION

The climate crisis is not only having a catastrophic effect on the planet, but also on people. Between 2030 and 2050, climate change is expected to lead to around 250,000 additional deaths per year due to malnutrition, malaria, diarrhoea and heat stress. Increased temperatures will result in extreme weather conditions, leading to food shortages, heat-related illnesses and injuries from landslides and flooding. Climate change is therefore inherently linked to health, and so the need to deliver a more sustainable healthcare system is not only the right thing to do, but can also be part of the solution.

In response to this crisis, 2020 saw the NHS become the world's first national health system to commit to becoming net zero, with a target of the year 2045. This is now also a requirement of the Health and Care Act 2022. As part of this commitment, the NHS published its Net Zero Supplier Roadmap, which includes several milestones that suppliers will need to abide by in order to continue supplying to the NHS. Though these requirements are ambitious, they are designed to reduce the environmental impact of the health system, which currently accounts for more than 4% of all carbon emissions in England alone.

The HealthTech industry recognises the vital role it has to play in combatting climate change and takes this responsibility seriously, since improving the health of both patients and the wider population is the ultimate aim of the industry.

Businesses are undertaking significant efforts to support the journey to reach Net Zero and it is only reasonable that such work is recognised by the NHS within its procurement frameworks.

Companies are investing both time and money to reach mandated milestones, and whilst it is recognised that the NHS needs to be responsible in the way that it spends tax revenue, if it is to meet its own commitments it should not continue to focus on price alone. Companies winning tenders must have proven themselves to be supporting the sustainability drive.

The sector also faces a number of peculiar challenges. Whilst economic difficulties and a cost of living crisis are not unique to HealthTech, what is distinct is that the industry has one substantive customer in the UK, the NHS. The health service has, for over a decade now, had a policy of accepting zero inflation from its suppliers. With the cost of raw materials and shipping soaring in recent years, wage inflation and regulatory fees also rising, adding further costs to doing business in the UK has made selling to the NHS increasingly challenging. Fighting climate change is essential, but it cannot be taken in isolation of the wider costs to serve the NHS.

The NHS is world leading in delivering net zero healthcare, thus presenting an opportunity to become the benchmark for other nations. Being the first means there is no blueprint to follow, so while the sector understands how difficult this may be, it wishes to emphasise the requirement for a programme of consistent engagement, consultation and collaboration at the stage of goalsetting. Such engagement should include all parts of the system; industry, NHS, government, academia, regulators, sustainability experts, patients, clinicians, international counterparts and other relevant bodies such as the Sustainable Healthcare Coalition.

HealthTech organisations work globally, across many jurisdictions, so aligning requirements and avoiding duplication is essential. In order for the UK to continue as a desirable place to do business, it must be ensured that what is asked of suppliers is appropriate, proportionate, and not done in isolation.

The HealthTech sector has the capabilities to greatly reduce the carbon footprint of healthcare delivery. Innovations from the sector can improve the prevention and diagnosis of diseases through optimising treatment, which can reduce the environmental impact of the patient pathway while also benefitting the health of both patients and the general population. Similarly, a focus on infection prevention will reduce avoidable care and hospital readmissions, improving the system's efficiency. By adopting such innovations, the NHS can transform the way in which it operates, increasing capacity and capability. Earlier diagnosis and improved monitoring and management of patients gives rise to lower rates of hospitalisation and a reduced burden to the healthcare system. All such improved outcomes reduce the carbon footprint of healthcare in meaningful and measurable ways.

Throughout this paper, there are a number of overriding themes that need to be considered. They are:

International Collaboration

HealthTech operates in a global market, with global supply chains and global customers. The UK cannot operate in isolation, so the ask of suppliers needs to be forward thinking while not diverging from other asks globally. Cooperation and agreement internationally is vital.

Reduce Waste

Waste in its broadest sense is detrimental to both environmental and social considerations. To be more sustainable, for both people and planet, there should be a reduction in all kinds of waste; wasted time, wasted resources, wasted products, wasted opportunities and wasted innovations. The more efficiently the healthcare system is running, the less wastage there will be.

Reduce Burden

The overall aim of any work in this area is to reduce the burden placed on the environment and stakeholders, from suppliers and procurement teams, to healthcare professionals, clinicians and patients. Although in the short-term education will take time and resources, the longer-term should see the lives of individuals made easier. The burden on clinicians could be reduced by adopting innovations that will treat their patients more reliably and more quickly. Supplier burden could be reduced by lessening the administration required by using systems such as the Evergreen Sustainable Supplier Assessment. The aim should be to simplify, not complicate people's lives.

Consistency Across the NHS

Whilst understanding the difficulties the NHS faces in implementing the NHS Net Zero Roadmap, it cannot be ignored that suppliers have had to deal with the consequences of this. The inconsistency of approaches and implementation across the NHS has caused particular problems for suppliers and led to considerable uncertainty about requirements. Consistency of assessments and systems is important for suppliers to know what they need to prepare for. When operating in a global industry, consistency is important across not only the NHS in England, but across the devolved nations and internationally. For this reason, it is even more vital that there is extensive industry engagement to ensure that the asks of suppliers are reasonable, appropriate, and will not need to be altered in the future.

Patient Safety and Access to Care

Throughout the considerations and recommendations within this report, it is important to remember that the safety of patients should never be compromised. The best option will be the product that does not compromise patient safety and delivers effective care, while having the least detrimental impact both environmentally and socially.

Supplier Engagement

To inform this paper, ABHI hosted five roundtables with members. The attendees represented the breadth of the industry, including SMEs and large medical device manufacturers, regulatory consultants, lawyers, product designers, standards experts, sustainability leads and experienced HealthTech individuals. We actively sought the views of all organisations to ensure that this paper is as representative as possible.

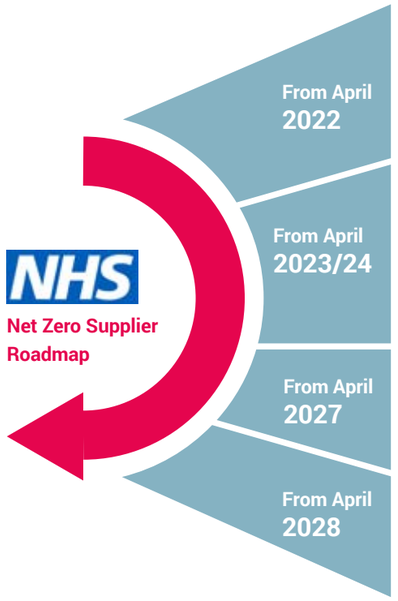
The roundtables covered:

- **Regulatory Barriers**
- **NHS Net Zero Roadmap**
- **Adoption of Innovations into the NHS**
- **Funding and Research Pathways**
- **Government Policies**

Alongside the roundtables, our work has been informed by regular discussions with stakeholders and our wider membership. The ABHI Sustainability Group, which represents over 100 different member organisations, meets on a quarterly basis, and ensures that we have regular dialogue with companies that are working to meet the NHS Net Zero Roadmap.

The paper is laid out into three sections, for three different audiences; the NHS, government and regulators. There is, necessarily, considerable overlap which emphasises the need for a multi-stakeholder approach.

NHS NET ZERO SUPPLIER ROADMAP



Net Zero and Social Value

All NHS procurements include a minimum 10% net zero and social value weighting. The net zero and social value guidance for NHS procurement teams helps unlock health-specific outcomes (building on PPN 06/20. Net Zero and Social Value will be applied via the Evergreen assessment for NHS England Medicines tenders.

Carbon Reduction Plan

For all new contracts above £5 million per annum, the NHS requires suppliers to publish a Carbon Reduction Plan for their UK Scope 1 and 2 emissions and a subset of scope 3 emissions as a minimum (aligning with PPN 06/21).
From April 2024, this requirement will be proportionately extended to cover all new procurements

Carbon Reduction Plan for all emissions

All suppliers will be required to publicly report targets, emissions and publish a Carbon Reduction Plan for global emissions aligned to the NHS net zero target, for all of their Scope 1, 2 and 3 emissions.

Product-level requirements

New requirements will be introduced overseeing the provision of carbon footprinting for individual products supplied to the NHS. The NHS will work with suppliers and regulators to determine the scope and methodology.

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THE NHS

The NHS Net Zero Roadmap is ambitious, and though suppliers are supportive of the journey to net zero, the implementation of the roadmap has been difficult for those on either side of the procurement process. Whilst understanding that procurement teams are not necessarily sustainability experts, the advanced requirements of the roadmap have, at times, been challenging on those responding to tenders, as well as those writing and scoring the bids.

We recognise and support that the social value guidance for implementing PPN06/20 pertaining to the first milestone of the Net Zero Roadmap is being improved upon with industry engagement. Although moving in the right direction, this exemplifies how necessary it is for the NHS to engage with industry to ensure the asks placed are relevant, appropriate and, crucially, attainable before implementation.

As well as supplier engagement, industry needs reasonable timelines in order to achieve targets. We have seen, for example, questions asking for suppliers to be ISO 14001 compliant, or equivalent, in order to enter into a contract with the NHS. There is not enough time for an organisation to attain this certification if they do not already have it before entering into the contract. If it has not been noted anywhere as a requirement for suppliers previously, then this is unreasonably excluding suppliers from the market. Such issues present the very real possibility of problems with the future supply of products.

The introduction of Carbon Reduction Plans (CRPs) into the procurement process highlighted nuances that are specific to the HealthTech sector. The NHS has implemented PPN06/21, a government wide procurement policy note, which was written and issued without taking account of the way in which frameworks are managed by NHS Supply Chain. Because of this, and NHS Supply Chain being unable to know how much a supplier will sell under a framework that in itself is significantly higher in value than £5 million per annum, many companies that will sell well under £5 million per annum on a contract have had to produce a CRP for the April 2023 roadmap milestone, rather than April 2024, with very little notice. The way the NHS buys is often different from other government contracts.

The requirements on suppliers from the NHS, primarily through the roadmap, have a strong focus on carbon emissions, particularly at an organisational and product level. This does not include the impact of water, chemicals and materials on the planet. There are questions on these areas as part of the Evergreen assessment, which although helpful, the score of a supplier does not carry any value in the procurement process evaluation unlike social value questions and Carbon Reduction Plans at this point in time. Thinking about the broader impact of suppliers and their products on both population and planet needs to be considered.

A further ask of the NHS is support for industry in how to reach these milestones. The roadmap dictates what it is that industry needs to do, but there is less assistance with how to do it. We know that the NHS Sustainable Procurement Team is focusing on supporting industry over the coming year, and the sector appreciates this move; it needs to be emphasised how vital this kind of support is at scale. Types of support could include webinars and courses as to how organisations can measure and reduce their environmental impact, as well as guidance and signposting for how suppliers can add social value to their organisations.

The role of the NHS in measuring a supplier's scope 3 emissions also needs to be considered. The healthcare system needs to ensure that it provides data such as downstream transportation, end of life treatment and processing. Without this collaboration, an accurate depiction of scope 3 emissions will be difficult to report.

Whilst understanding that looking at the impact of organisations and products is important, HealthTech should not be considered in isolation of the care pathway it sits in. Many innovations in the sector have the capability of transforming the way care is delivered, through such things as early diagnosis, remote monitoring, prevention and shortening the time and impact of treatments – for example moving an operation from an inpatient overnight procedure to a much shorter day case procedure – and suppliers should be recognised for these capabilities.

Challenges to Overcome

Lack of Consistency in Approach

Moving targets and timelines for suppliers makes implementing sustainable change in their business practices incredibly difficult. Across Trusts, Integrated Care Systems, Procurement Hubs, the Devolved Administrations and globally, differing net zero targets are unhelpful. As well as this, with the social value questions now asked as part of the tendering process, if suppliers are unaware of the questions that might be asked, or they differ greatly depending on the organisation procuring, it is unreasonable to believe that companies can meet all of the demands.

Social Value Questions

Everyone is on the journey to net zero together. And whilst understanding that procurement specialists are not necessarily experts in sustainability, it is important that those asking the questions, and assessing responses, have a strong understanding of the impact and feasibility of what they are asking for. We have seen examples where this is not the case; where suppliers have queried social value questions and the answer from the contracting authority is an echo of the original question asked with limited additional explanation of the expectation of suppliers.

Questions that do not make sense or are not applicable for the tender are incredibly wasteful of resources, be it one person or a team of people dedicating their efforts in attempting to answer it.

Although we are aware there is training in place for procurement teams and the social value guidance is currently being rewritten with increased industry engagement, education in this area needs to continue. The questions being asked need to be clear for both suppliers and procurement teams. As has been seen through these questions, and through wider procurement, we need to ensure there are no negative, unintended consequences from the questions being asked.

To provide further clarity on this issue, below are some examples of Social Value questions seen in NHS tenders:

'During the lifetime of the Framework Agreement, what is the anticipated number of green spaces created under the contract.'

This raises a number of questions; what qualifies as a green space? How will this be marked? Where is an SME supposed to create said green space? How big does a green space need to be?

'What number of Circus tickets for children and young adults with disabilities will be provided.'

Amongst many others, this raises questions around compliance, and indicates that those with the deepest pockets may have preferential treatment when answering these questions.

'Please confirm the percentage of virgin plastic that currently cannot be recycled' and 'Please confirm the percentage of packaging that you will commit to being from a sustainable source over the lifetime of the agreement.'

These questions show a misunderstanding of device regulation and the materials that suppliers are able to use and still adhere to patient safety requirements.

Carbon Reduction Plans (CRPs)

Currently, CRPs require suppliers to start measuring their carbon emissions, and getting Board level or equivalent commitment, to reaching net zero by 2050 at the latest. By 2027, there is a requirement for companies to commit to net zero globally by 2045. This, however, appears unachievable, given many members have ambitious, but differing carbon reduction targets. Through feedback from ABHI members the requirement for CRPs has led to an increased level of engagement from senior leaders, colleagues and their supply chains on the topic of sustainability – which is essential to forwarding this agenda – but it has not been without difficulties.

In the lead up to 1st April 2023, when the first requirement for CRPs in contracts over £5 million per annum was introduced, the remits of the milestone changed. Originally there was to be a two-year grace period for SMEs, meaning they were not required to produce a CRP until at least 2025, but this was removed in order to align with PPN 06/21.

Furthermore, at the start of a tender process, NHS Supply Chain cannot know which organisations will be awarded a contract over £5 million per annum. As the CRP requirement is a pass/fail before the award, in reality CRP is a de-facto requirement for SMEs. This demonstrates how the HealthTech sector, dominated by SMEs, needs to be considered differently in comparison to other contracts across government, where it is likely to be clear whether a supplier will get a contract more or less than £5 million per annum at the start of the process.

According to PPN 06/21, suppliers were required to report on their UK emissions only. For global suppliers, some of whom had been measuring their emissions for years, this was incredibly difficult to apportion down to a UK level. This parameter was removed, which we supported, but came only a matter of weeks before the milestone came into effect. This reflects earlier sentiments that, without reasonable timelines, any change is difficult and highlights why early engagement with industry is critical. With a requirement of CRPs to gain Board level or equivalent support, faith in the system is necessary.

Whilst understanding that the NHS has limited resources, there are concerns around how CRPs will be monitored to ensure they do not become a 'tick box' exercise. Organisations committing to the carbon reduction measures they have outlined in their CRPs is the next step on this journey. The NHS needs to employ robust mechanisms to ensure that the commitments are being met and that those who are delivering on their commitments are rewarded with NHS business and those who are not, are not. Equally, organisations that have taken great strides to reduce their carbon emissions before the NHS Net Zero Roadmap came into effect should not be penalised for the rate at which they are continuing to reduce them.

For example, organisations that are beginning their carbon reduction journey will be able to reduce their emissions by a certain percentage much faster than those who have done so previously and may not, therefore, be able to show this in the change from their baseline year. However, considering this, there needs to be clarification from the NHS as to whether CRPs will be audited at any point. If so, clear timelines and guidance on implementation will be necessary.

The introduction and implementation of CRPs has, again, highlighted the need for continuous and extensive industry engagement to ensure that what is asked is achievable and collaborative in nature. This is essential as we move forward with the roadmap to the next milestones, that will require suppliers to report on all their applicable scope 3 emissions (beyond the current subset of five from the Greenhouse Gas Protocol).

Evergreen Sustainable Supplier Assessment

The introduction of the Evergreen Sustainable Supplier Assessment is a welcome step. Having one centralised system in which suppliers enter their sustainability related information reduces the administrative burden and the negative implications of Trusts using different systems, while keeping those in procurement aware of all the positive work that industry is doing. Replacing legacy systems such as Carbon, Waste and Water documentation also reduces the administrative burden. The fact that not only NHS England can access this data, but also the Devolved Administration, is a positive step towards alignment across the UK.

Evergreen has become a mandatory requirement for all NHS Supply Chain suppliers, and although not mandatory for all other procurements, it is encouraged. What is important with Evergreen is how it is taken forward. If suppliers will be marked against the data they provide, industry engagement on how this will be done and reasonable timelines are essential.

Carbon Footprinting and the 2028 Milestone

The NHS Net Zero Roadmap states that:

*'**From April 2028:** new requirements will be introduced overseeing the provision of carbon footprinting for individual products supplied to the NHS. The NHS will work with suppliers and regulators to determine the scope and methodology.'*

Carbon footprinting HealthTech is a very difficult and onerous task. One ABHI member reported that to conduct a lifecycle analysis for one product would cost $30,000 and a team of people. Expanded to their whole portfolio, this would equate to $30 million. Another member stated that it took them as long to undertake a single product carbon footprint as it took to build the Empire State Building. The time and cost to undertaking product level carbon footprinting is not a reasonable or sustainable ask by any means, and we do not believe that this is in keeping with the spirit of the NHS Net Zero guidance.

NHS England has positively engaged with ABHI on working towards the NHS Net Zero Roadmap 2028 milestone, and we hope this continues in the lead up to its implementation with wider industry engagement.

Alternatives to carbon footprinting each product, such as creating proxies for products or manufacturing methods that organisations can use when measuring their impact, could be a potential way forward. Again, it is important to remember that HealthTech only plays a part in the care pathway. The impact of its production compared to, for example, its impact in shortening the length of surgery or amount of nights a patient needs to stay in hospital, need to be considered. The carbon impact that a product has on a patient pathway is far more crucial than its in-use carbon impact, or the resources it took to make the product. How comparisons are made between products and their impact needs to be considered outside of the procurement process.

Adoption of Sustainable Innovations into the NHS

The NHS Net Zero Supplier Roadmap focuses on environmental impact at an organisational level, before moving to a product specific level. None of the milestones take into account the positive environmental impact that a new innovation can have on a care pathway.

The HealthTech sector excels at producing innovative products which, in turn, need to be adopted by the health system. Be it through changing the design of products to reducing the amount of material used, developing more sustainable materials, creating closed loop circular economy systems for devices, or improving diagnostic capabilities, suppliers are continuously evolving to develop products that will pave the way to net zero.

For this reason, the focus should be on the impact a HealthTech product or service has on a patient pathway, rather than solely on the making of it. Whilst understanding that it is still important to understand the individual impact of HealthTech, and a somewhat easier metric to attain and place value on, looking at how it fits into the bigger picture is vital.

Ownership of innovation is a perennial challenge in the health service, and until this is actively built into a senior job description, it is unlikely to become business as usual. It is also well recognised that adopting HealthTech at pace and scale, particularly when it involves changing the patient pathway, is enormously difficult. Support at a central level through NHS England, and via the Devolved Administrations, is essential to moving this forward. Another avenue is to utilise Integrated Care Systems to play a major role in the implementation of HealthTech that truly delivers a more sustainable healthcare system.

Industry is willing to work collaboratively with the NHS to see where most impact can be made. In particular, as we move to servitisation models and a circular economy in healthcare, collaboration between all stakeholders will need to increase beyond what has come before.

Price

The assessment of innovations in the NHS is still often based on price. The environmental and social impacts of a product need to be considered, particularly when there is a financial return in the long run. The NHS also needs to be adaptable when considering how it buys goods and services. For example, take back schemes, remanufacturing models and new ways of procuring maintenance contracts will help the sector move from a linear to circular economy.

Key Performance Indicators (KPIs) for procurement teams are too focused on price and delivering cash releasing savings. These need to be expanded to ensure there is flexibility for long-term spending and achieving outcomes such as net zero.

There are huge savings that can be made from having a healthier population too. Studies have shown that the productivity loss due to physical and mental health issues is costing the UK economy an estimated £77.5 billion a year. Improved diagnostic capabilities can lead to earlier diagnosis, meaning treatment can begin sooner, resulting in less hospital stays and an overall improvement in patient welfare, all while reducing the amount of waste and energy from a hospital stay. Procuring devices that are shortening surgeries and reducing complications are also vitally important. As has been seen in a study by the Sustainable Healthcare Coalition, well managed type 2 diabetes still has a lower carbon impact over a patient's lifetime than poorly managed diabetes, even with the patient living longer. Often it is the emergency care and surgery that have the most severe environmental impact, with operating theatres estimated to be three to six time more energy-intense than hospitals as a whole.

The weighting of assessment towards non-price elements needs to be considerable enough to make an impact. If it is too small, the decision will still lean towards price and it may still be the product with limited improvements to the environment that will be bought. Through collaboration with the health system and industry, the concept of a 'carbon pound,' could be introduced as a metric through the procurement process. Giving a product its true value, inclusive of its environmental impact, could aid procurement teams in not choosing products based purely on their monetary value.

The Delivery of Care

As innovations advance, we can change the way that care is delivered. In a post-COVID world, we have seen the changes that can be made; through remote triage and monitoring, at home care and community diagnostic centres, there are environmental and patient benefits to be had. Decreasing travel, increasing the speed at which a patient is diagnosed and the ability to be treated in their own home, can all reduce energy and resources used while improving patient satisfaction.

The adoption of innovations in both digital health and diagnostics has the capability to improve the availability of accurate and timely patient information. With the rise in artificial intelligence (AI), the better the data we have on disease areas and co-morbidities, the better patient management can be and in turn, this will improve population health, alongside our social and environmental impact.

Behaviour Change

There needs to be behaviour change from all stakeholders. The last few years have been difficult, with significant external factors, such as Brexit, COVID and the ongoing war in Ukraine, leading to the NHS effectively having to procure in crisis mode. The result has been an excess of emergency and last-minute ordering, and we must ensure that this behaviour does not become business as usual.

Last mile deliveries have a much higher carbon emission, and unpredictable volumes of last mile deliveries make it difficult for suppliers to plan and measure their emissions, and also involve a much higher cost. Faster delivery methods, such as air freight, have a much higher carbon impact than via shipping containers. While hospitals are ordering with this level of urgency and lack of planning, suppliers have very little influence as to reducing their emissions through transport.

Unintended Consequences

There is an understandable interest in reusing devices. However, single-use products are in some instances the best option clinically, environmentally and economically. There is a significant carbon footprint associated with the sterilisation and reprocessing of medical devices. There also needs to be available infrastructure and workforce to undertake sterilisation and reprocessing. Procurement teams cannot suddenly decide to move entirely away from single-use products without understanding the clinical risks and available resource capabilities. It may also be the case that reusable products are not available to replace certain single use devices.

Similarly, we are all used to recycling in our everyday lives and the same approach will be important for medical products. However, here too, there can be unintended consequences. One company was approached with a request to introduce a take back scheme for compression stockings that patients take home with them after a hospital stay. Not only would there be significant GDPR issues with data sharing of individual patients' names and addresses, but the carbon impact of collecting these products from patients homes across the country would far outweigh the environmental benefits of recycling.

Recommendations for the NHS

- Align sustainability requirements for suppliers between NHS England and the devolved nations.
- Health systems should continuously and extensively engage with industry on all new requirements for suppliers through open forums and consultation periods.
- Ensure that all sustainability asks of suppliers by the health systems are consistent, whether regional or national.
- Develop a portal for suppliers to speak directly with sustainability experts about the requests from the NHS, who have a strong understanding of the questions that are being asked, similar to the portals currently used in the procurement process.
- Create clear mechanisms for the adoption of innovations into the NHS which reduce the overall environmental impact of a care pathway, with a standard route applied.
- Sustainability outcomes to be considered more highly in KPIs for procurement teams alongside cost improvement KPIs with appropriate timelines highlighted to industry and an incremental increase.
- Collaborate with industry to scope out the possibility of a 'carbon pound' to be considered as part of the procurement process in the NHS.

GOVERNMENT SUPPORT

The HealthTech industry is unique in its opportunities and barriers to reaching net zero, and it is vital that government is informed and supportive of these. As outlined in our Net Zero Review: Call For Evidence consultation response, whilst industry is finding new environmentally friendly innovations and ways of operating, it does have the challenge of ensuring patient safety and complying with strict product regulation. Whilst, of course, other industries also battle with this, it is often not on the same scale.

No matter the size of the organisation, suppliers are having to dedicate a huge amount of funding, time and learning to this agenda, given such ambitious requirements from the NHS. As well as this, being a company working in the UK, suppliers are having to ensure they keep up with other government requirements, such as the Plastic Packaging Tax and Extended Producer Responsibility (EPR). Whilst understanding the aim of these policies, for a sector that is restricted in how much it can do alone and how quickly, paying for these schemes is an unavoidable cost burden.

Unlike the pharmaceutical industry, medical devices are not exempt from the Plastic Packaging Tax, albeit the industry faces similar barriers and challenges. The cost of this policy, both in terms of the cost for an organisation to gather and report the data as well as pay the fees, can greatly impact costs for an organisation. Similarly, with EPR, the current implementation plan will create a number of challenges for the sector, outlined in the ABHI EPR consultation response, that will also not lessen the environmental impact of the industry.

Positive government support and funding is essential to enable industry to reach net zero. Sustainability in healthcare is still a relatively new endeavour, and as such, liability does not lie with any one party. Government central programmes, such as Design for Life with the Department for Health and Social Care (DHSC), is an example of government working collaboratively with industry. This is essential to overcoming system wide changes, and also ensures a level of credibility, while reducing duplication of efforts. In order to move forward, all parties need to take accountability for their role in it; government needs to ensure there is appropriate funding for industry so it does not bear all the burden.

Government policy and funding need to be enablers of change on this important agenda, to help suppliers overcome barriers, and not create additional complexity without reasonable purpose in an already overcrowded policy landscape. HealthTech and the NHS in the UK have a unique opportunity to exhibit best practice to the world in how to move to a sustainable nationalised healthcare system, but it needs to be supported by all stakeholders.

Challenges to Overcome

Government Policy and Legislation

HealthTech is a heavily regulated industry, and companies doing business in the UK are also subject to wider government legislation. Alongside the DHSC, policies that affect the industry may come from Cabinet Office, DEFRA, the Environmental Agency, Treasury, and the Department for Science, Innovation and Technology. These can be difficult to stay up to date with, particularly as the vast majority of HealthTech companies are SMEs, and there is no systematic means by which industry can see all the policies that will affect them as a HealthTech business working in the UK.

With requirements and initiatives coming from different departments, this is increasing duplication in the system, which is leading to a waste of time and resources.

Due to regulations, recycled plastics often cannot be used in HealthTech, which means that measures like the Plastic Packaging Tax are punitive. The fact that pharmaceuticals, on the other hand, are exempt from the tax, highlights a discrepancy with how polices are applied across life sciences, and also why it is important to understand the nuances of HealthTech. Engagement with industry is therefore vital.

If organisations are having to pay a tax that cannot be avoided on the grounds of reducing waste and increasing circularity, then the money collected from these taxes should be ringfenced to enable this change, such as investing in materials development or waste management organisations to find more sustainable materials that are also safe for patients.

A further example is the application of PPN06/20 and PPN06/21 to the sector and those supplying to the NHS. In both cases, amendments have been made to how they are applied through the NHS and arguably more amendments need to be made in order for it to be achievable for industry.

Funding

Funding and signposting, for both industry and stakeholders, is essential for both the short and long-term. Although there are some funding opportunities, feedback from ABHI members has been that many of the parameters of grants are not appropriate or relevant for the industry, and the funding opportunities are often difficult to find. The ask of government is support in navigating the funding landscape. A centralised hub where suppliers could find various funding opportunities would be useful for industry.

Short-term funding and grants, such as for renovating manufacturing sites to run on renewable energy, investing in apprenticeship schemes in sustainable manufacturing or helping with the cost of re-regulating a product that has had a material change, is essential. Long-term funding, such as for collaborative programmes between academia and industry to discover recycling solutions, and material development to be able to implement a sustainable economy in HealthTech products, is also vital. There are a number of challenges to overcome with different timelines, so funding to support this needs to match accordingly.

Organisations should also not be penalised for being the first mover in developing environmental solutions such as novel materials, especially when considerable changes will mean that companies need to battle policy and regulation, which comes with a resource and cost burden, especially when the outcomes benefit the whole industry. For example, there are significant barriers in waste legislation meaning there is a distinctly grey area as to whether HealthTech manufacturers can collect their products at end of life, or if they would need to be a certified waste management organisation to collect ‘clinical waste’. A further example is organisations that are investing in novel recycling techniques creating recycled plastic that has virgin material quality, but due to current medical device regulation this plastic would not be compliant. Every time an organisation investigates the possibilities of doing such things, they incur a cost. Funding in this area is needed to ensure that companies are encouraged, not discouraged, to make these changes.

Long-Term Planning and Collaboration

Industry, as well as all other stakeholders in the ecosystem, need to know that they have long-term government support, as many of the changes needed will be implemented over a long period of time. If companies are relying on government funding that suddenly gets removed, it will be very difficult to fill this void or to commit to company investment in the first place.

Environmental commitments made by government need to be carried through. If such pledges are suddenly changed or scaled back, it makes the business environment in which to plan, very difficult.

There is a role for government to play as a convenor of different sectors to tackle similar problems. For example, ensuring the quality of recycled plastic is high enough to come into contact with humans is a problem that both the healthcare and food and drink industry face. With government playing a central role in bringing sectors together, it will enable cross-sector collaboration and reduce replication of projects.

The HealthTech sector is global in nature, and therefore suppliers are working across many different jurisdictions. Governments across the four home nations and beyond need to work in a productive manner to ensure that their asks align across borders to give suppliers reasonable targets to attain.

Recommendations for the Government

- Create a formal platform for communication and consistent engagement between government, the NHS and wider policy makers in areas such as waste management and environmental policy with regular meeting of an advisory group.
- Establish an online hub for signposting funding and research opportunities for the sector, accessible publicly, to encourage utilisation of available funding and collaboration with academia.
- Establish a cross government forum, led by industry with support from OLS and DHSC, to educate different government departments where requirements are being levied on the HealthTech industry. Attendance should include colleagues from DEFRA, Cabinet Office, Treasury and the Environmental Agency.
- Conduct a review of all existing legislation relevant to net zero that impacts on HealthTech industry.

REGULATION

The UK HealthTech regulatory environment is in a period of change. As we move away from the EU framework, we have the opportunity to develop UK specific rules while becoming an exemplar internationally.

Sustainability requirements however, should not be enacted through technical product regulation, which is focused primarily on patient safety. Policies coming through the NHS and government are the mechanism of choice for sustainability, but, as with all regulation, they should be seen as an enabler, not a barrier, for suppliers on their journey.

Acting as an enabler to drive the sustainability agenda will, however, still require a change to some device regulations.

Challenges to Overcome

There are some regulations that, if changed, would not impact patient safety or product performance, yet will enable organisations to change their current models of working. This is needed as technological advances in the sector progress. Currently, for example, regulation requires manufacturers to package their products according to tightly controlled specifications, which is difficult unless non-recycled plastics are used. Flexibility in the safe allowance of plastics in some areas of packaging may therefore facilitate a more environmentally favourable approach.

The cost of obtaining regulatory approval for a product when there is a significant change cannot be underestimated, nor the time and resources required. It is a considerable challenge for suppliers changing their products and packaging, particularly as the additional cost is unlikely to be accepted by the NHS. Ensuring that there are mechanisms to support companies making these changes is vital. The NHS Net Zero Roadmap is focused on carbon emissions at an organisational and product level, so in terms of procurement, the recyclability of a material is not accounted for in willingness to pay.

ABHI recently prepared and forwarded a paper of sustainability recommendations to the Medicines and Healthcare products Regulatory Agency (MHRA). This paper detailed the asks of the regulator, both in terms of regulatory changes and further and more detailed guidance.

This paper highlighted specifically;

Electronic Instructions for Use (IFUs)

Physical IFUs require a large amount of resources and energy to produce, as well as being a considerable weight to transport. One ABHI member, for example, found that from just one of their manufacturing plants, the paper consumption to produce IFUs could reach up to 125 tonnes per year, equating to 125 tonnes of CO_2 per year. Furthermore, this does not account for the fuel used in transit and disposal of the IFUs after use.

Enabling electronic IFUs into the regulation will reduce this environmental impact. Additionally, electronic versions will allow the manufacturers of devices to update the instructions in real time, ensuring a higher level of version control, as well as reducing the need for different IFUs to be printed for different languages and geographies. A further benefit could be that those with impaired vision could benefit from electronic read aloud options, thereby improving access to information.

In the EU, paper based IFUs are still required for self-test and near patient IVDs, and for any non-professional use of a medical device. Moving towards greater use of electronic IFU's therefore, represents an opportunity to improve on the EU environmental requirements. To enable electronic IFUs, updates to MHRA systems may be needed to ensure access, such as for the forthcoming major update to the MHRA's public access registration database (PARD).

QR Codes to Improve Information Sharing

QR codes have the capability to hold a vast amount of information. With their introduction, manufacturers could include important information, such as how to recycle products, without having to physically print this information on the product. This could reduce the amount of packaging needed, as well as encouraging reuse and recycling.

As with the adoption of electronic IFUs, the UK has an opportunity to drive QR Code innovation. The ability to use them should be encouraged through guidance, rather than through legislation, to ensure that regulatory requirements do not deviate from global standards. Leading the way in this area, and demonstrating best practice, could encourage other jurisdictions to follow suit.

Again, as with electronic IFUs, updates to MHRA systems may be needed, such as to the aforementioned PARD.

Taking Account of Equivalence and Predication in Alternative Materials approvals

The UK could move to a system that takes account of equivalence and predication in alternative material approvals, meaning that suppliers do not have the same cost or time burden in making the regulatory change. Due consideration should however, be made for the primary adopter. This may encourage manufacturers to use alternative materials, while ensuring that patient safety remains the highest priority.

Updated Guidance on Remanufacturing and Refurbishment

The MHRA has already published guidance in this area, such as the guidance on 'Single-use medical devices: UK guidance on re-manufacturing' (2016).

Other guidance should be considered for updating including;

- 'Managing Medical Devices: Guidance for Health and Social Care Organisations' and
- 'Management of In Vitro Diagnostic Medical Devices' to include more information for end users around refurbishment and repair.

To aid clarity, any guidance should take account of the differences between remanufacturing, reprocessing and repairing medical devices. Furthermore, guidance should be made easily accessible for manufacturers. Highlighting the guidance, particularly around remanufacturing medical devices and the parameters of interactions between hospitals, original equipment manufacturers (OEMs) and remanufacturers, is particularly critical; it needs to be clear what relevant parties can or cannot do in terms of remanufacturing. The guidance could provide additional information around accountability and responsibility for regulatory compliance throughout the device's lifecycle.

CONCLUSION

The HealthTech industry is committed to decreasing its environmental impact, but for a sector with high levels of regulation and working in a complex, global landscape, the challenges are clear. With cooperation and support across the ecosystem, inclusive of regulators, government and the health system, these challenges can be overcome. The detrimental impacts of climate change on human health are only increasing in severity, so steps on this journey need to be taken now.

SUMMARY

of Recommendations

Recommendations for the NHS

- Align sustainability requirements for suppliers between NHS England and the devolved nations.
- Health systems should continuously and extensively engage with industry on all new requirements for suppliers through open forums and consultation periods.
- Ensure that all sustainability asks of suppliers by the health systems are consistent, whether regional or national.
- Develop a portal for suppliers to speak directly with sustainability experts about the requests from the NHS, who have a strong understanding of the questions that are being asked, similar to the portals currently used in the procurement process.
- Create clear mechanisms for the adoption of innovations into the NHS which reduce the overall environmental impact of a care pathway, with a standard route applied.
- Sustainability outcomes to be considered more highly in KPIs for procurement teams alongside cost improvement KPIs with appropriate timelines highlighted to industry and an incremental increase.
- Collaborate with industry to scope out the possibility of a 'carbon pound' to be considered as part of the procurement process in the NHS.

Recommendations for the Government

- Create a formal platform for communication and consistent engagement between government, the NHS and wider policy makers in areas such as waste management and environmental policy with regular meeting of an advisory group.
- Establish an online hub for signposting funding and research opportunities for the sector, accessible publicly, to encourage utilisation of available funding and collaboration with academia.
- Establish a cross government forum, led by industry with support from OLS and DHSC, to educate different government departments where requirements are being levied on the HealthTech industry. Attendance should include colleagues from DEFRA, Cabinet Office, Treasury and the Environmental Agency
- Conduct a review of all existing legislation relevant to net zero that impacts on HealthTech industry.

Recommendations for the MHRA

- Approve the use of electronic Instructions for Use (e-IFUs) to reduce the excessive use of paper and facilitate the reduction of fuel in the transit of medical products.
- Approve the use of QR codes on medical devices to improve information sharing.
- Implement a regulatory process that takes account of equivalence and predication in alternative material approvals.
- Provide clarification on the definitions for remanufacturing and refurbishment to increase certainty for suppliers.

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