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Looking ahead to changes in HealthTech

HealthTech is an innovative sector that makes up for approx. 150,000 jobs in the UK, with a turnover of £34 billion. An innovation engine with approx. 95% Small and Medium-sized Enterprises (SMEs).

One of the inherent challenges with the adoption of innovation in HealthTech is that often it is not just about a change in technology, but a change in the patient pathway, of productivity and efficiency or in skills that may also be needed. A new HealthTech may require changes to a surgical procedure, therefore surgeons need to be trained to enable adoption.

The impact of a technology may be in one part of the system, but the benefit may be somewhere else. For example, a change in diagnostics, might lead to earlier diagnosis and therefore less intensive treatment for a patient, but the diagnostic is paid for in secondary care and the benefit could be seen within primary care.

In the budget earlier this year, the government offered £3.4 billion of additional investment into digital health, but if you look at the actual capital backlog that's in the system, this will not solve all the current challenges. There has been clear recognition from the government this year that there needs to be investment in digital health, upgrading the IT infrastructure and that the digital health ecosystem is essential for the ongoing efficiency of the system.

Changes in HealthTech

Currently within healthcare there are huge workforce challenges and technology has an important part to play in supporting the workforce. AI can do tasks such as discharge letters, and technology can be used to treat patients. Through the use of technology, there is an opportunity to use less invasive procedures so that patients avoid admission to intensive care after a procedure. This not only benefits patients as it improves care, but it increases workforce capacity and there are productivity gains for the NHS.

These technologies might have a cost, but they reduce spend elsewhere.

Health technologies need to be considered in the context of value and the outcomes that they deliver as opposed to just the cost. HealthTech is frequently perceived as something that is expected to deliver an immediate cost saving for the purchasing healthcare organisation but often the savings for using new health technologies are realised further down the care pathway in another care organisations budget.

Through NHS Supply Chain, there has always been a perception that buying once and buying big will save money, but it is actually buying the right thing to get the right outcome that is important. There has been some positive collaborative work recently between the Department of Health and Social Care, NHS England, NHS Supply Chain and the Life Science industry on a value based approach to procurement. NHS England recently published the 'value and savings methodology1 that clearly sets out a cashable value to non-cash releasing savings.

This is a positive sign that the system is starting to value technologies that, for example, alleviate the need for an intensive care bed or potentially allow something to be done in an outpatient setting rather than in the inpatient setting. It is a step forward and there will soon be a soft launch of this, which includes a set of questions that are aimed at the non-cash value of technologies to be assessed in tenders. This is an encouraging signal that the system is moving towards valuing more than just the upfront price of HealthTech.

> There needs to be a shift in focus to start thinking about how a device or technology really drives value to the whole system. For industry this is a different way of working - providing real world evidence, looking at the pathway, understanding the runway for the products that are being brought to market and having confidence from this new value and savings methodology.

Hopefully this will provide a more consistent view towards value that will help support and spread innovation within the system.

The NHS often struggles to be consistent as different Trusts have different approaches, so if this can support to bring consistency it will make spreading innovation easier, particularly for those SME's that do not have deep resources.

Real-World Evidence

The NHS will buy a product that can evidence value which is often whether it can make a patient live longer, make a patient better and/or does it release resources. Releasing resources doesn't necessarily happen just at the point of acquisition, but it could happen later in the treatment pathway and to demonstrate this here will need to be real world evidence of the long-term benefits to patients. HealthTech has traditionally had a lower evidence base than pharma, although this is now starting to change.

With 95% of the HealthTech sector being dominated by SME's, the system is currently very good at supporting the early stage and it is not as well set up to support the evidence gathering at the latter end of the spectrum. The evidence base in HealthTech is not the same as it is in pharma, in most cases, HealthTech

cannot run randomised controlled trials in the way that pharma can due to the type of innovation and therefore data needs to be gathered in other ways.

The high proportions of SMEs in the sector means that they do not have access to large budgets for extensive data gathering and companies need to be able to also generate revenue. Registries are a great way of having real world data and some of the work in digital health is an example of gathering data as innovations are being iterated and brought to the market.

The healthcare system is starting to recognise that there is a need to support the development of post market evidence so that the burden of this doesn't sit with the innovators alone. The reality is some of these technologies are not inherently expensive, and the profit margins are also not very high.

The ability to invest in extensive data collection is reduced compared to a medicine, especially when the long-term outlook for HealthTech is also unpredictable. If you receive a positive appraisal from NICE for a medicine, there is a requirement to make it available to patients within 90 days, for HealthTech there is no timeframe and while there is the MedTech funding mandate, its scope is relatively small and there are financial levers that can be challenging to navigate.

Real-World Evidence also provides information about how something works in practice, how it integrates in the NHS, what the outcomes will be for patients and what its impact will be on the system, which you don't get from randomised controlled trials. A balance between more controlled evidence and Real-World Evidence can be invaluable in understanding the true value of a product.

The adoption ecosystem in the UK

Innovation is key across UK HealthTech, but there is a challenge from moving beyond innovation to incubation and acceleration. HealthTech is recognised by the healthcare system as part of the answer to some of the current challenges, particularly around workforce capacity.

There is a range of policy that is very positive, but the challenge is how do we move from policy to practice and how does this translate into actions on the

Real-World Evidence in HealthTech

1

Early-Stage Data Collection

2

Post-Market Real-World Evidence

Real-World Evidence
Could provide information on:
- How HealthTceh works in practice
- How it integrates in the NHS
- Outcomes for real patients
- Impact of HealthTech on the system

With SME's dominating 95% of the HealthTech sector, the system is very good at supporting early-stage data collection.

Resources are currently released at the point where the HealthTech is acquired by the NHS.

However, SME's do not have large budgets for extensive data gathering:

Registries are a great way of having real world data.

ground at an NHS Trust or Integrated Care Board level. Although NHS Trusts are open to working with Industry, there is still a requirement to work with individual Trusts, so there needs to be improved national infrastructures — such as the NICE value access programmes or NIHR.

There are always examples where it has taken a decade or more for a technology to be adopted because the care pathway has had to evolve rather than the system actively transforming to pull it through and supporting it. Through the innovation portal and a more joined up system this is starting to improve but the processes are still cumbersome. There is good policy, but there is work to do in translating this into practice. In the current capacity challenged health environment, there is sometimes not the time to "read the manual" and change the pathway to create greater efficiency. Industry should consider how it can support and manage transformation and training to ensure evidence based impactful adoption.

The innovation ecosystem programme being led by Roland Sinker and commissioned by Amanda Pritchard, CEO, NHS England, is a signal that the system would like to do things differently.

As a result of the pandemic, there was an impact on medical devices, diagnostics and digital health as they all played a critical role in supporting the NHS.

As a result, the Government are looking at HealthTech and seeing it as a transformational change both to the NHS and the economy.

Addressing inequity and inequality in access

Digital can improve access to healthcare services, for example the NHS app provides a gateway into care and personal data and this can help to improve access. But there are people within the population who don't have access to technology, are not technologically literate, but these numbers are reducing year on year.

Digital exclusion is a wider issue than just health and care as more and more government services move online. There is a wider government issue about how populations have digital access. The NHS app was in development for a long time as it was tested across such a wide and diverse population to ensure it is usable and accessible for a diverse audience.

Over the past 18 months, NHS England issued plans to delegate the commissioning of 59 out of 154 specialist services to Integrated Care Boards (ICBs).

From 1st April just over 50% of ICB's took responsibility for the service delivery and the commissioning of those 59 services and the other half will maintain a joint commissioning arrangement with NHSE

to ensure the safety of that transition. The aim of moving the decision making and commissioning of these specialised services closer to the vulnerable patients and the communities who need them, will have a positive impact on patient care but this could see a postcode lottery of access with some people having access to things that are specially commissioned when others don't.

Changing the commissioning of these services enables a local system to have more joined up services and manage a whole patient pathway because there are only certain conditions where part of an intervention is specially commissioned. By linking it up, you can improve the overall experience for a patient.

There is currently no funding mandate in the NHS for most HealthTech, so there is a differential acquisition of different types of HealthTech and that can be an issue for some of the diagnostics, in particular, there can be different levels of diagnostic accuracy which impacts access to HealthTech.

Digital health technologies that involve an algorithm vary depending on the data set that is being tested and trained on. If a training set has any bias in it, that can be replicated into a larger population over time, this could be a real issue for a diverse population like that found in the NHS. There isn't currently a clear steer in healthcare on managing digital health algorithms going forward and how this could affect both access and outcomes.

Post-launch product surveillance

The benefits to increasing post market surveillance can be bountiful for industry. Capturing more data and monitoring products over a longer term creates more evidence and data that can be used as part of that value story to empower the NHS and system leaders with that evidence to implement change at scale.

At the moment, there is guidance set out for recall management, but there is an expectation that there will be more rigorous advice from the MHRA that sets out more specific requirements from industry of how they report and audit on recalls, as well as the timelines in which these have to be achieved. If these come into play, that burden will land solely on industry.

When this MRHA rule comes out, effective recall management is going to be very important, as managing recalls is an incredibly challenging event and the HealthTech industry has the most recalls out of any other[2]. This places a huge burden on all parts of the business to action the steps that are involved to provide the evidence set out by the MRHA. Traceability and automation are key to this and using digital tools to ensure that there is one single source of data will help with that updated timeline for effective management of recalls. Relieving that burden to the whole system will also help, as these companies are trying to solve a problem by delivering products and solutions as alternatives to the recall to prevent further delays in treatments.

Conclusion

HealthTech is an essential part of the solution. There is a positive policy environment that creates the right environment for companies to thrive in and although there are challenges, the reward of getting traction in the NHS can be huge.

Industry needs to consider system readiness and understand the environment and quantify the opportunity to the healthcare system, supported with Real-World Data to transform the pathway.

There is an opportunity to work together to implement change and support the NHS and patients in realising that at a system wide scale.

HealthTech can solve a lot of current challenges in the health system and should be valued based on patient outcomes and system resource to demonstrate the impact for a whole system.

There has been investment and commitment from this government in HealthTech and Digital Health and there is broad alignment within the system of what needs to be done, and an enthusiasm and energy to work together to do it.

References

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