The Medical Technology Group

Improving patient access to medical technology

Medical Technology Access Accelerator

www.mtg.org.uk

Advances in technology have been improving patients' lives for centuries. It's not hard to see the impact these advances have had: the X-ray revolutionised the way clinicians could diagnose patients and this in turn has been superseded by the Magnetic resonance imaging (MRI) as the most advanced imaging system. Treatments that once required patients to undergo intensive surgery have been replaced by minimally invasive techniques that support quicker recovery and a greatly improved patient experience. Most recently we have seen advances in diabetes monitoring that reduced the need for people to disrupt their daily life and frequently draw blood to monitor their glucose levels. One of the key stories of the COVID-19 pandemic has been the use of technology to change the way we interact with our healthcare professionals.

The benefits are clear for all – for patients it means an improved experience of care or a better outcome, and less time in hospital and away from families. For the NHS it supports the more efficient delivery of treatment, freeing up vital resource. And for the wider economy it allows people to get healthy quicker and continue to lead a full and active life.

The NHS has wrestled with the challenge of creating a system that allows for the systematic uptake and spread of innovation for many years. Over many years a number of reports have been published that have given rise to new organisations and Departments charged with solving this problem. At present, however, the NHS has not found a way to pull through innovative products – meaning patients miss out. For innovators the system remains difficult to navigate and uptake is at best patchy, and at worst non-existent.

The MTG has developed the elements of the system we would like to see implemented to take best advantage of innovative medical devices.

Overview

The MTG has defined the 11 core elements of the Access Accelerator:

- Single front door: one of the biggest challenges face by innovators is 'where to go?' A single pathway should have a single entry point that allows for effective triage of devices. The single front door would not simply sign post innovators, but work with them to establish what the most effective route to patients looks like and which agencies and processes are best placed to support them.

- Single model: the system needs to be clearly defined and understood by innovators and the NHS. Whilst it will require flexibility around eligibility criteria and processes undertaken, there should be a well-defined model in operation that gives people clarity on when to engage and the likely outcomes.

- Comprehensive system approach: any system that is limited to a handful of technologies won't be able to make a system-wide impact. The model developed should be comprehensive and cover a large number of technologies each year.

- Clarity on timelines: for innovators, establishing a route to patients is complex. Currently, there are uptake mechanisms that could prove damaging to a technology's use through lack of impact and lost time. The system established should, as part of a clear process, give clarity on timelines around initial funding commitments and an eventual decision making process.

- Guaranteed Funding & Commissioning: Support for temporary commissioning during evidence development then permanent commissioning once a final decision is made. All technologies coming through the Access Accelerator should get mandatory funding and coverage by commissioners whilst any additional evidence is being developed. Where there is a clear benefit to using a technology, funding should be made available to all NHS organisations.

- Single Responsible Agency: at present in the NHS there is no single decision maker with oversight of the uptake and use of recommended technology. The system should have a single executive agency that is responsible for overseeing that the system works and that patients are able to access technology.

- Rapid pathway to decision making: the assessment and commissioning of devices is a complex process. At present it can take many years to get a positive commissioning policy. Previous NHS initiatives have seen technologies used temporarily and then stopped whilst a decision is made. The pathway should ensure continuous usage throughout any evidence development phase and into the permanent decision phase.

- A clear role for patients: often patients are the last to be consulted on the technology that is available to them. Decisions on the technology available and the true impact should always include a clear patient voice.

- Fast-tracked value-based procurement process: decisions on technology should support effective commissioning decisions. This, in turn should be supported by an effective procurement team that are procuring for value, not at unit cost.

- Capturing outcomes: the ultimate aim of any medical device is to improve patient outcomes. Too often metrics have looked at capturing raw numbers of devices used. As the NHS looks to create a better system for tracking outcomes, this should be linked to the treatment provided.

- Clear understandable information in plain English: relevant information on technologies and treatments available to patients should be easy to access and in plain English. This should include data on where treatment is available.

Overview

The key challenge for any system is to provide clarity for innovators, clinicians and patients. The creation of an Access Accelerator that establishes a single pathway for innovative technology would support innovators to effectively navigate the system. Key elements of the new system would include clarity on the level of data required for interaction with the pathway. Where a model is developed to generate more data, the programme of work should cover usage right through from the data gathering stage up to the final commissioning decision. When the challenge is around the adoption of more mature technology, elements such as funding and enforcement should become more impactful and effective.

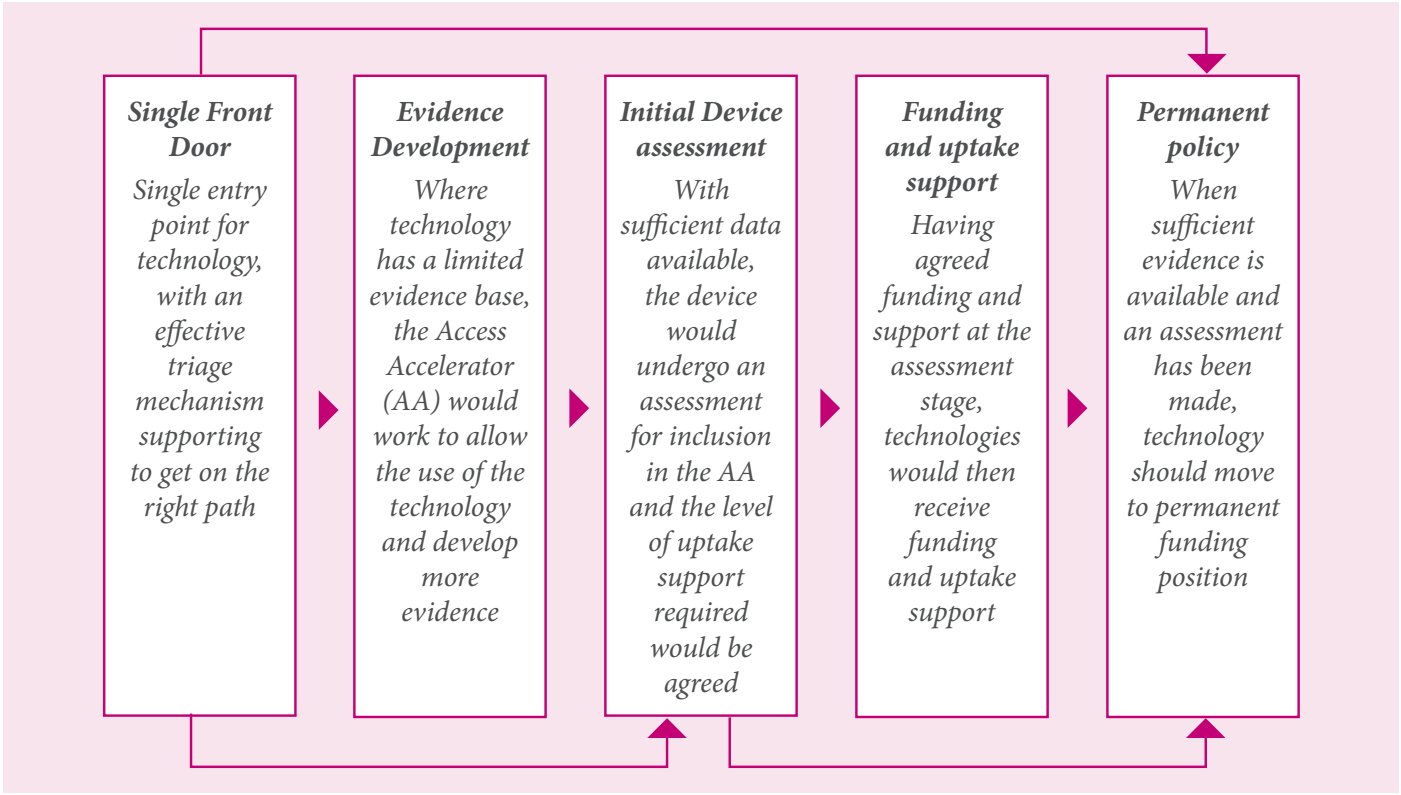
Flexibility

The system must provide flexibility for innovators. Different devices at different stages of maturity will have different levels of data available. The Access Accelerator should be flexible enough to take this into account and to create a pathway to patients that supports a period of evidence development if required but can also fast track patient access if the relevant evidence is available.

For example, a technology that is several years old may have been in use across the NHS for many years without a permanent commissioning policy, a situation that often leads to regional variation and some patients missing out. The Access Accelerator would be able to look at that device, assess the evidence available and potentially jump the device to the final stage of the process – the creation of a permanent, national, commissioning policy.

A newer device, that has not been widely used, would come with a lower level of evidence. In this scenario, the Access Accelerator could take the device through a series of steps, including a period of funded evidence development. This would support a journey towards permanent, national commissioning.

The Process



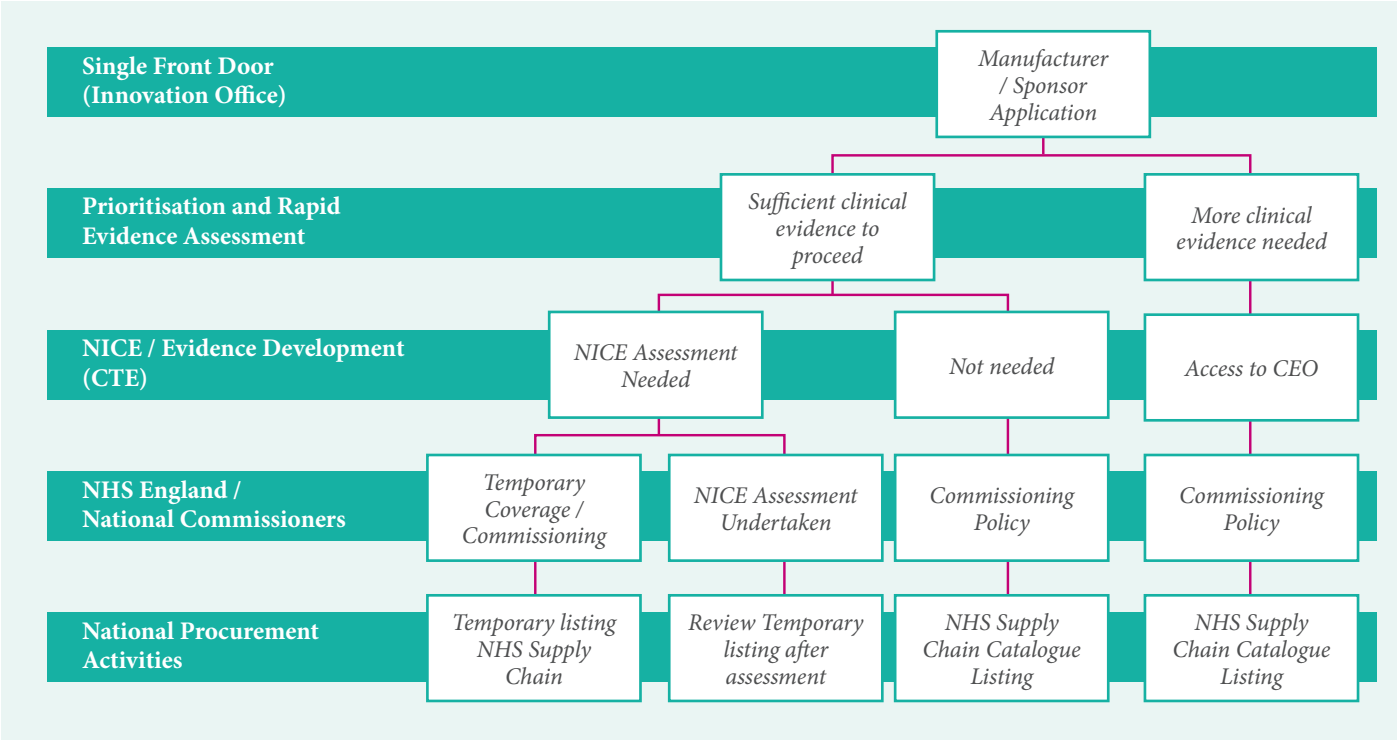
Putting medical devices on a level playing field to drugs

The NHS does not have a medical device specific mechanism to support the uptake of innovative products on a system-wide basis. The Accelerated Access Collaborative is highly limited in the number of devices that it supports and is currently open to medicines as well as medical devices.

In contrast to devices, there are a number of opportunities for medicines to gain a fast track to patients. The Early Access to Medicines Scheme and the Cancer Drugs Fund are support to provide significant numbers of patients to access treatments with a limited evidence base on an annual basis.

Alongside this, the National Institute for Health and Care Excellence (NICE) Technology Assessment process is designed for medicines and most treatments undergoing a full assessment are still medicines. Most treatments supported by a device undergo an Interventional Procedure Guideline. Where a treatment is awarded a positive NICE Technology Assessment, funding is then mandatory from NHS organisations. This is not the case with an Interventional Procedure Guideline.

How the system flows



Easy access and comprehensive triage

The Accelerated Access Review set a clear ambition to develop a 'set of clear national and local routes to get medical technologies, diagnostics, pharmaceuticals and digital products to patients.' The establishment of Health Tech Connect and the ongoing work to simplify the entry process for companies seeking support is welcomed by the MTG. Work to create a 'single front door' is in development by the NHS Innovation Service and will help to simplify entry for innovators.

Whilst the single front door approach is welcomed, the initial entry point for innovative technology should not simply act as a sign posting mechanisms that introduces innovators to parts of the system that can help. A comprehensive triage system that sets out a clear pathway for technology and performs an overseeing role as the process of support develops is required if the system is to be effective.

Too often the experience of innovators is that they are forced to undertake multiple conversations with multiple organisations and often these are fruitless. There is very little to join up the different branches of the NHS which requires innovators to 'start over' once one avenue has been ruled out. A comprehensive triage system should support the development of a pathway that is most likely to lead to success and then support the journey through this process. This system would also save resource for innovators and the NHS and avoid duplication.

As the initial triage process will have a role in the prioritisation setting around technologies, patients should be given a strong voice in this process and have a formal say in all technologies selected for support. Selecting patients with relevant clinical experience to help make decisions on which technologies should be prioritised is the most effective way of supporting uptake at the end of this process.

Single Model

The current infrastructure for supporting the assessment, uptake and spread of innovative technology currently looks crowded and difficult to navigate. There are multiple organisations with similar remits all operating in the same space. The challenge for innovators is to understand and navigate the system. The creation of a single pathway for the promotion of innovative technology does not necessitate that there is a single organisation that administers the system. Multiple organisations, such as those already in existence, could be involved. For example, technologies assessed by NICE, either through the Medical Technology Evaluation Programme (MTEP) process or a full technology appraisal, could be included in the pathway with mandated funding and tracking of uptake. The key requirement is to create an effective mechanism to support innovators to get into the pathway and then work with the organisation most appropriate for their needs. Managing this effectively would require a system that can understand and give clarity on:

- Data and evidence: the level of data required to support the effective uptake of technology is not clear to innovators. Any system seeking to do this should provide clarity on the data required for a technology to be pushed for broad adoption or to take part in a programme driving uptake. For newer technology, where current evidence is limited, the pathway could support the development of additional evidence to shape commissioning decisions. Where technologies are more established and already have a significant amount of evidence, the focus would be more downstream and looking at driving uptake rather than gathering evidence.

- Clear process: when entering into the 'single pathway' the process that innovators will undertake should be made clear. Given the broad spectrum of devices that could be supported by such a scheme, there is no 'one size fits all' approach that could provide an adequate solution. The process could involve multiple agencies throughout the implementation, but this should be made clear with innovators so they understand and support the process.

Comprehensive System Approach

Current NHS mechanisms to support the uptake and use of innovative technology are severely limited in scope. The Accelerated Access Pathway supports fewer than ten technologies per year. This leads to a mechanism that focusses on 'picking winners' rather than focussing on the broad, system-wide adoption of technology. The Access Accelerator would be based around the concept of building and assessing data on the efficacy of a treatment and then securing funding once it is deemed cost effective and clinically superior to existing treatments.

In doing this, the system should be open to a wide range of technologies and seek to promote the use of a high number of treatments each year. Through the many work streams focussed on this already in operation across the NHS, the system does have the capacity to deliver. The challenge is to create a cohesive, joined up system that operates as a single model that is easy to navigate and delivers impact.

Any system that focusses on a narrow range of technologies will fail to deliver the comprehensive impact that is needed to deliver real change, that's why the Access Accelerator would need to be open to a broad range of technologies.

Clarity on timelines

For innovators, it is critical that the system which supports the uptake of technology is simple to understand, easy to navigate and delivers clarity, both in terms of process and timelines. The Access Accelerator is intended to support a variety of technologies at different levels of maturity and evidence, this will mean the length of time each requires for support to gain uptake will vary. For some technology there will be a period of evidence development prior to the uptake support phase. At the outset of any conditional funding period, a clear timeline should be set on how long will be required before a decision on permanent funding should be made. This timeline should allow for any evidence assessment that needs to be undertaken and ensure that there will be no gaps in provision throughout the process. Where initial funding is given to support early adoption, there should be clarity on how long this will be available and when permanent funding will come into place.

Clarity on timelines will support both industry and the NHS to plan accordingly. Where decisions are made annually, NHS organisations often struggle to commit to the implementation of a pathway and services where they are not sure whether it will be available in year two or not. For innovators this will support their understanding of the system and how to engage with it.

Responsibility

There is no single individual or organisation with overall responsibility for ensuring the uptake and spread of technology. At present the Accelerated Access Collaborative has responsibility for overseeing a number of the agencies involved and several work streams.

At a local level in the NHS there is no system to track the use of technology and individual organisations are not held accountable for adherence with national guidelines. A joined up system under the Access Accelerator, supporting a much larger number of technologies, would be given more powers and responsibilities to drive adherence. Oversight for this should be given to a single agency, reporting to a Government Minister. This agency would be given responsibility driving adherence with guidelines and gathering information on patient access They would be given power to promote the use of technology through payment systems at the same time as overseeing a reporting system that allows them to understand where the technology is being used.

The creation of an executive agency with overall power and responsibility for oversight of the mechanisms supporting the uptake of innovation would not require them to conduct all the activity related to this. The NHS already has a plethora of organisations that are assessing and making recommendations related to technologies, from NICE to the Academic Health Science Networks (AHSNs). The executive agency would mainly be responsible for driving adherence to the guidelines.

Funding

The NHS is yet to establish an effective funding mechanism that can support the broad uptake of innovative technology. In recent years there has been a number of positive developments. The Innovative Technology Payment and the NICE funding mandate for medical technology has shown a willingness to create funding streams that provide support for innovative medical technology. Programs to date, however, have been limited in scope and often required very specific criteria, such as a one year return on investment, and as such they have failed to create wholesale change across the system. They have also required annual renewal – which has led to a lack of clarity for NHS organisations seeking to establish a service. Even Commissioning for Quality and Innovation (CQUIN) payments were often convoluted and difficult to access for NHS organisations.

Technologies that enter the single pathway approach should be guaranteed funding once the evidence demonstrates their efficacy and cost effectiveness – in a similar way to the NHS approach to funding medicines through the NICE Health Technology Assessment process and the Cancer Drug's Fund. Access to funding is a critical issue that will support innovators to engage with any mechanism. Where an assessment is made that the technology does not currently have sufficient data on efficacy and cost effectiveness, a timeline should be set that provides support for evidence development up to the point where a permanent commissioning decision is made. Where technologies have a more mature evidence base, the funding system would be similar to the current Medical Technology Funding Mandate, with permanent funding available.

The funding element of this programme should also refer to the decommissioning of treatments. Where a treatment is agreed to be outdated and to offer very little benefit, it should no longer receive any funding from the NHS and all relevant tariffs and funding streams should be removed.

Rapid decision making

Processes for assessing and commissioning medical technologies are often slow and drawn out with gaps in provision throughout the journey. The challenge is often moving from one phase of the assessment process to another and treatments are often left in limbo as decisions can take a long time. Worse than this, often treatments suffer delays as assessment is taking place and decisions are being made. In the case of Commissioning through Evaluation, there was a gap of several months, in some cases years before decisions were made – leaving patients without access to a potentially lifesaving treatment.

Core elements of the system, such as clarity on funding and timelines, should be supported by a rapid decision making process. How final decisions will be made, the criteria for decisions and who will be involved should be set out at the onset of the process, during the initial phase of assessment. Timelines should factor in the length of time required for decisions to be made and allow for provision during this period.

Delays based on decision making processes can be hugely detrimental to the ongoing use of a product and should be factored in to planning.

Capturing outcomes

The NHS has long been criticised for focussing on activity ahead of outcomes. The system is evolving and the process of capturing patient outcomes and looking at the factors that influence this continues to develop.

Many treatments are based around technology and therefore any system looking to capture patient outcomes should also look at the technology used and analyse this data. There has long been a call for better use of registries to capture outcomes. It is important that registries capture information on the technology that is used to support treatment. This process will support a better understanding of the impact of technology and the benefits, or lack thereof, of using a certain treatment.

Mechanisms that have previously been used, such as the innovation scorecard or links to Hospital Episode Statistics (HES) data, have proved difficult to administer and inconclusive when it comes to assessing the impact of various inputs. The key factor in any healthcare episode is the benefit to a patient. Better capturing of this information will allow for better understanding of the benefits of innovative treatment.

Value-based procurement

Procurement should support commissioners to get the best price for the inputs required to carry out treatment. Procurement should not prove to be a barrier to patient access when decisions on cost effectiveness have already been undertaken. This system should be underpinned by a system of Value Based Procurement that allows commissioners to look to the total value of a treatment to the healthcare system.

A clear role for patients

Patients should be at the heart of all decisions made about treatments. It is impossible to capture the full benefits of any treatment without understanding the full benefit to the people using it. Health economic assessments, whilst necessary and valid, will always struggle to understand the full benefit to patients.

Decision making processes should include patients who have received access to a technology. As set out above, decision making processes need to be established at the start of any process, and this should include a clear role for patients in the decision making process. Where assessment panels are convened patients should be included and given the same weight of voice as any other member of the panel. Too often the patient voice is marginalised , with patients being allowed to consult rather than make a direct impact on the final decisions on the use of technology. The Access Accelerator would see patients placed at the heart of decision making with a clear and defined role in the process.

Clear understandable information in plain English

For most patients making a decisions around their healthcare and their treatment, they are reliant on their clinician. However, patients do not always receive comprehensive information about alternative treatments and the technologies available to them. Information from NHS organisations such as NICE can be difficult to interpret and understand to the lay person.

Information on the technology and treatments available to patients should be available in an easy to understand, plain English version that is accessible to the public. This should also include information on where treatments are available and how people can gain appropriate access to them.

Conclusion

Much work has gone into supporting the use of innovative technology across the NHS. There is infrastructure currently in place. Many elements of the system are already established even if in a limited form, the Funding Mandate for example. The NHS Access Accelerator would not require the establishment of new assessment agencies or regional organisations. It would simplify the current system and stage organisations so they act as a single pathway pushing to an end point of technology adoption. Alongside this there would be a carrot and stick approach to usage – NHS organisations would be able to access funding more easily and usage would be traced and reported.

Connecting up the system and giving real incentivisation and enforcement powers in relation to the use of technology could have a dramatic effect on the way technology is used across the NHS. Time and effort have already gone into the development of a landscape to support this, the challenge is now to continue to evolve this to make a real impact.