# NHS Innovation – the missing piece of the puzzle

A review of NHS adoption of Innovation and the HealthTec Connect process

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## Purpose

The primary driver for Innovation is to ensure the adoption and use of the invention.

This review highlights flaws in the operation of the HealthTec Connect innovation adoption process and suggests remedies which, if adopted, would provide an opportunity to enshrine improvements for the NHS adoption of Innovation, permitting the Secretary of State to meet the aspirations contained in Part 3 of the new Medicines and Medical Devices Bill.[1]

In March 2021 a new report published by the Medical Technology Group (MTG) states "the system for introducing new medical technologies into the NHS remains complex, crowded, and difficult to manage. Current NHS mechanisms to support the uptake and use of innovative technology are severely limited in scope and are focused on 'picking winners' rather than the broad system-wide adoption of new technology".[2]

This review summarises the progress made by initiatives such as the Accelerated Access Review and by Academic Health Science Networks (AHSNs) but finds evidence to support the MTG contention that due to resource constraints these agencies are focused on a limited number of established winners whilst most true innovations, often from UK start-up companies are usually overlooked to the detriment of NHS patients and to the benefit of investors, healthcare providers and patients overseas.

This review provides evidence of the absence of a clear and simple path to commercial adoption, identifies the missing link and makes a series of recommendations including a simple process change that exists in other countries that would quickly lead to the immediate uptake of true innovations, and more speedily obtain evidence to determine their efficacy or otherwise, making their adoption nationally, more objective, and less reliant upon serendipity.

## Background

In June 2016, the Medical Technology Group (MTG) a unique coalition of industry, research charities and patient groups that campaign for appropriate and timely patient access to medical technologies, published its report 'Déjà Review – what lessons can be learned from the past?'[3]

Their report identified 17 different organisations or initiatives that had been launched with the aim of promoting innovation in the NHS over the previous ten years and noted that the NHS had historically and consistently failed to apply any learnings from the previous reviews, including 2011's much-quoted 'Innovation, Health and Wealth' (IHW).[4]

Barbara Harpham, Chair of the MTG, said in their 2016 report; "Despite a series of measures being set out in IHW, NHS leaders have failed to carry through many of the recommendations and instead moved on to the next initiative – The MTG strongly recommends that Ministers and

NHS officials learn from previous reports and initiatives and commit to the Accelerated Access Review (AAR) and ensure that in five years we're not looking back at another failed programme."[5]

## Adoption and spread

The primary purpose for Innovators to engage with any of the myriad of NHS Agencies involved with innovation is to achieve commercial engagement with the NHS which, in the case of devices, is normally via an NHS Supply Chain Framework Agreement contract.

The Accelerated Access Review (2016) made recommendations to make it easier for NHS patients to access innovative medicines, medical technologies, diagnostics and digital products, improving efficiency and patient outcomes.

The Accelerated Access Collaborative (AAC) Review report acknowledged that many of the existing horizon scanning tools and systems only consider pharmaceuticals. Consequently, **HealthTech Connect** (HTC) was developed to address this gap and improve horizon scanning for devices, diagnostics, and digital health technologies. HealthTech Connect was launched in April 2019 with the aim to help innovators connect with relevant people and organisations that may be able to offer help and support in getting a technology developed, assessed, and used.

In its first 12 months the HealthTec Connect portal directed more than 600 so called innovations to the various agencies of which, according to its own website, more than 400 such were referred to either AHSN's or Department for International trade for 'Further Support' and 142 were shared with NHS Supply Chain but significantly, **none were adopted by NHS Supply Chain.**[6]

In its report 'Our Year in Focus 2019/20' The AAR records a series of achievements including its support for more than 2,700 innovations and inventors.[7]

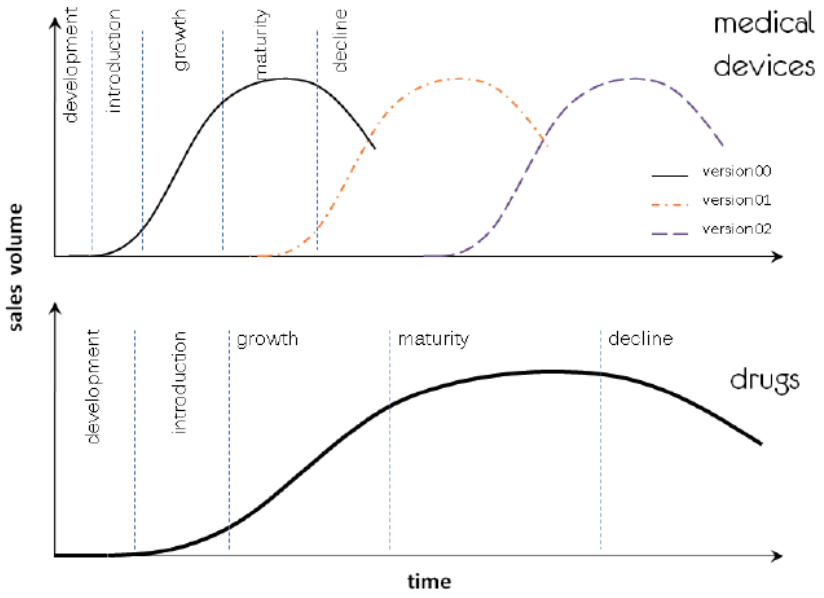
This review and The AHSN Network Impact Review 2018-20, highlights ten Medical Device innovations benefiting from 'Fast-tracking roll out' and which have recently received The NHS Innovation and Technology Payment (ITP) approval.[8]

- 3/10 devices were invented in the UK and two remain as start-ups in UK ownership.
- 8/10 devices are owned by large international corporations including Olympus, Boston Scientific, and J&J.
- 8/10 have been available to patients overseas before being adopted in the UK. All ten devices are more than ten years old.
- In its report 'Our Year in Focus 2019/20' The Accelerated Access Review reports its collaboration with the Care Quality Commission (CQC) is to co-produce a review

which highlights six evidence-based principles that underpin innovation and adoption.

- The review gives providers a starting point for how to innovate well and uses case studies to demonstrate that providers don't have to be the biggest or best resourced to innovate and have a real impact on people who use services.
- The AAR report their collaboration review with the CQC on evidence will be published 'imminently'. [9]

The problems that non-adoption by HealthTec Connect creates are myriad. Firstly, the product Life Cycle for Medical Devices is typically half that of pharmaceuticals and is estimated to be less than ten years. [10,11]

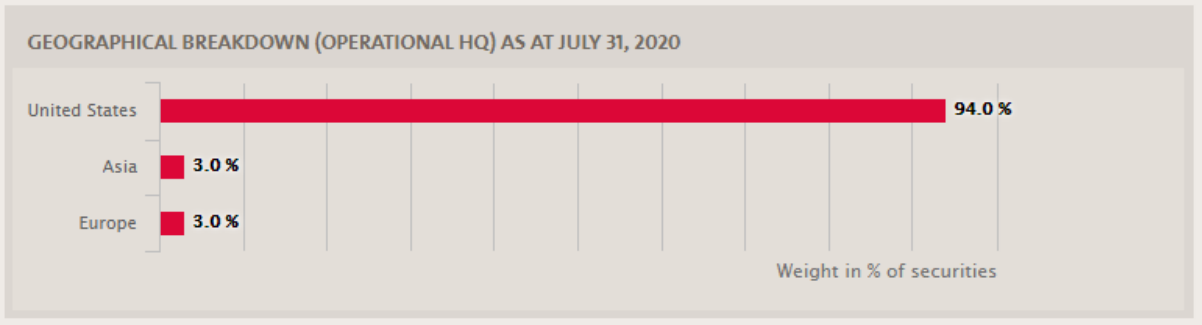



This shorter life cycle can make investment strategy problematic and discourage investors.

Separately and more fundamentally the NHS's notoriously slow commercial adoption rate of Innovation appears to have ground to a halt under the HealthTec Connect scheme leaving innovators and manufacturers with recourse to only one of two options. They may choose a 'back door' route if that 'back door' is open to them. If not their only other recourse is either to take their innovation to other more open markets, typically the USA or, if funds are unavailable to abandon their innovation.

In an article published in the Times in August 2020 entitled *'The NHS will benefit from new technologies, but only if we back it'* the author Paul Major states; *"The NHS and British instinct for innovation could play an important role in contributing to the nation's economy post Brexit whilst improving the outcomes for patients in the UK."*

Paul Major leads the investment team at BB Healthcare Trust which was established in 2016. Despite the authors entreaties for investors to fund NHS Innovation BB Healthcare Trusts own investments are focussed 94% in the USA with only 3% invested in Europe. Their Investment in the UK is not Identified. [12]




[13] http://www.bbhealthcaretrust.com/en/investment-strategy/portfolio/

This contradiction perfectly demonstrates the juxtaposition for inventors and investors, The NHS from the outside appears to be an attractive market for Innovators and Investors. The reality is those experienced in Healthcare Innovation investment usually steer clear of the NHS in the start-up phase, preferring to invest where they are likely to see a return in a reasonable period, i.e., five years, equivalent to half of the life cycle of most Medical Devices. If the NHS is not adopting either its own or other UK innovation this often discourages and disincentives Angel Investment.

A **'Back door' route** is provided for existing contractors to accommodate innovation on current NHS Supply Chain Framework Agreement Contracts to add new products, without being subject to the rigours of the HTC process. [14]

This 'back door' route pre-existed HTC and has been part of the NHS Supply Chain Framework process and was most often exercised at the time a current Framework contract was being extended, usually for an additional two-years. As part of that process suppliers which were already on a Framework contract were permitted to add a 'product line extension' or 'range extension' for the extended period of the contract. For example, the recent NHSSC Advanced Wound Management Framework Contract was tendered in 2016 and launched in 2017.

One year later in 2018, a well-known Wound Management Devices Manufacturer launched their 'next generation' Single Use Negative Pressure Wound Therapy System. This product became available on the Framework Contract in 2019 until the contract ended in 2021. It might have been argued that despite a well-publicised launch campaign to promote it as an innovation the product was introduced onto the Framework as a 'product line extension'? Either way the supplier immediately benefitted from access and sales to the NHS, avoiding the need to submit to HTC or provide any incremental evidence of efficacy, benefits denied to non-contracted start-ups or other companies who tried to introduce new advanced wound management products at the same time.

Ironically, the authors believe that, in the absence of a properly functioning Innovation adoption route this 'back door' route is still necessary. However, this is seen by some start-ups as the NHS operating a system of 'double standards' favouring existing and more established suppliers, whereas no such benefit accrues to 'start-ups' or other innovators who are not currently on such contracts.

## Clinical evidence and value-based procurement

Evidence based and value-based procurement (VBP) are frequently used terms by NHS Procurement staff including many in SCCL and NHS Supply Chain, but little is published to determine what means in practice.

When challenged by the authors of this review about their Zero uptake from the HTC process SCCL advised that the primary reason none of the more than 600 submissions were adopted by NHS Supply Chain was because they were determined as having "insufficient evidence" to warrant adoption.

When asked what type and level of evidence was considered as 'sufficient' the authors were referred to **SCCL Policy and the Clinical and Product Assurance (CaPA) Framework for Category Tower Service Providers (CTSPs).** [15]

This document refers to 'National Data Intelligence' for sourcing evidence including referring to 'National Strategy and Expert reference groups', 'National best practice guidance' and 'Literature search/current research' and though the term 'Evidence' is referred to 15 times in the document, there is a complete absence of any description or definition of the type or level of evidence which is required.

Neither is the level of evidence segmented by stage of development, product type, medical device classification, or pre or post market surveillance requirement, nor does it describe if and how that evidence may be assessed, against which criteria or by whom?

In the meantime, the data referring to the 0/600 adoption rate by NHS Supply Chain was redacted from the HealthTec Connect website and remains so redacted. [16]

By contrast, in the United States the FDA is now committed to pave the way for innovation to appear first in US. They have adapted the regulatory requirements, **shifting clinical evidence into the post-market approval phase.** [17]

Regarding value-based procurement (VBP) according to the NHS Supply Chain website Key findings of a report which was due to be published in February 2021 include:

- clinical support and engagement are critical to the adoption of VBP
- a need for common understanding of value between buyers and suppliers
- assurance from suppliers to substantiate claims will aid VBP adoption for NHS trusts. https://www.supplychain.nhs.uk/news-article/value-based-procurement-report-autumn-2020/

In 2019 in a review of the process of engaging with HealthTec Connect, The Association of British HealthTec Industries, (ABHI) published a report, including the summary below.

**Summary Feedback on the experience of making a HealthTech Connect Submission**

| Issues | Solutions |
|---|---|
| It is not clear whether accessors have assessed the technology, or do not intend to consider it further. | Confirmation of when an assessment has taken place would be helpful. |
| If the decision is not to proceed, feedback from the accessor is important. | While accepting accessor capacity is a limiting factor, the feedback needs to answer the company's questions sufficiently for them to take action to rectify gaps and / or work with other stakeholders.<br><br>It would be helpful to have a common understanding of what evidence is required for different types of devices (perhaps as per typography prepared by NICE for digital devices).<br><br>Some follow-up discussions appeared to infer a large randomised controlled trial was required for any progress to occur.* |

| | |
|---|---|
| It appears that the HTC system limits the amount of information on available data to be submitted, and in some cases the word count limitation does curtail the provision of information that could impact the assessor's decision. | Flexibility to provide additional information would be helpful. |

*Clarity on evidence requirements is needed, both to support innovators but also to ensure that HTC is effective as possible. This requirement is not just limited to HTC. [18]

A recent MTG publication entitled '**Our NHS: A Spotlight on the Innovation Landscape'** [18] makes a series of recommendations including:

- Industry should be supported to develop the right evidence and be given guidance on what is needed to meet the NHS standard on what evidence should look like.
- There should also be a review of how evidence is used. For many products blind randomised controlled clinical trials are impossible. Where this is unavailable, registry and real-world data should be given equal weighting to blind randomised clinical trials.
- Health technology assessment should take place once and be used by all NHS organisations. Too often individual NHS organisations are conducting their own, smaller health technology assessments (HTAs), which increases the burden on already stretched resources.
- Commercial discussion should take place early in a products life cycle. NHS procurement mechanisms should consider the value that products bring and not just focus on upfront costs.
- Uptake Support: NHS incentivisation should support the use of innovative technology. This needs to go beyond a specific funding mechanism for a small number of technologies and look at how the system works for all products.
- Tracking and reporting of the use of technology should be improved, so NHS organisations that are resistant to technology are highlighted. [19]

## The missing piece of the puzzle

### Commercialisation

The sole reason for Innovation is to get the innovation onto the market and into use.

Successive independent reports over the past 20 years, including those referenced in this review [2,3,4] provide evidence that the system for innovation adoption by the NHS is broken. Various attempts to fix it over the past 20 years have failed to generate early adoption i.e., commercialisation.

That none out of 600 Submissions through HealthTec Connect in its first year were adopted by The NHS Supply Chain is a strong indication of a primary fault line.

## Suggested remedies for consideration by AAC and NICE

The MTG reports[2,3] make eleven recommendations for a new Medical Technology Access Accelerator in its report, including:

- **A single front door** – an 'Innovation Office' to triage new devices and support innovators – who find the current system difficult to navigate – by providing a pathway for technologies and a route to patients, connecting them with the relevant agencies and support. We welcome the work currently underway to develop and Innovation Service as this single front door into the UK for HealthTech innovators and hope that it recognises and address the challenges we document herein.
- **A single model** – while there is no 'one-size-fits-all' approach, there is a need for a clear pathway for innovators, so that they receive support from the most appropriate organisation. The system should be clear about the level of data and evidence needed for a technology to be adopted.
- **Guaranteed funding and commissioning** – all technologies coming through the Access Accelerator should receive temporary commissioning during evidence development, then mandatory funding and permanent commissioning once a final decision is made.

*The authors of this review suggest these additional remedies for consideration.*

- Include a **definition of Innovation** which recognises true Innovation and not simply a product line extension. Often a truly innovative device will not have a direct competitor or predicate which has implications in seeking to secure sufficient levels of clinical evidence.
- **Define and describe levels of evidence** relative to each stage of the innovation pathway. For those Innovations without a predicate or comparator clinical trials are at a disadvantage which makes the gathering of relevant evidence more prolonged and expensive, 'eating' into the product life cycle. The inclusion of a Hierarchy of Evidence[20] is already recognised by NHS Supply Chain but is not published or recommended for HTC submissions. Alternatively, consideration should be given to the provision of other qualitative Indicators which may be determined as providing 'sufficient levels' such as the number, type, and level of evidence appropriate to truly innovative devices.

- **Increase the amount of evidence that can be submitted** via the HTC Portal and permit evidence that rebuts traditional or unsubstantiated perceptions. In one recent example a device for delivering humidified oxygen to the wound bed was developed by NHS Vascular Surgeons for the treatment of Chronic Diabetic Foot Ulcers. Topical Oxygen was considered lacking in good evidence of efficacy and so the new device adopted a novel design which functions completely differently from every other type of topical oxygen delivery system. Despite benefiting from a NICE MIB and 2 Multi-Centre RCT's demonstrating statistically significant efficacy above the standard of care, the HTC panel reviewing the evidence rejected the adoption of the device on the grounds that 'there is insufficient evidence for Topical Oxygen in general'. A Classic 'Catch-22'. This novel device has successfully treated over 1,000 patients in the USA. This NHS Innovation is still not available to NHS Patients.
- **Include in the selection criteria** an assessment incorporating the concept of value-based procurement including life-time cost savings, and QUALYs.
- **Revert from the present 'Pull' system**'s dependency upon an opportunistic selection by an otherwise unresponsive Agency **to the more conventional 'Push' System** where the onus remains with the inventor / instigator to 'push' the innovation through the process learning, improving, and overcoming barriers until the innovation is either adopted or abandoned by default because of lack of interest, evidence, or funding.
- **Fast Track any 'true innovation'** which is supported by NICE MedTech Innovation Briefing (MIB) or other 'sufficient' evidence onto the relevant currently running NHS Supply Chain Framework.
- **Establish a new 'Innovation Lot' in each NHS Supply Chain Framework agreement** specifically for truly innovative devices to provide a compliant purchasing route, enabling access to NHS Patients for the purpose of obtaining 'sufficient' clinical data and relevant evidence. At the present time, given the pressure to reduce the number of suppliers and aggregate purchasing to increase discounts and savings it can be argued that there is a perverse incentive not to adopt innovation, given the limited spend and savings derived in the short term. A Specific Lot dedicated to Innovation would mitigate the impact of lack of savings and facilitate the compilation of patient data and evidence.

## Conclusions

As stated, the primary driver for Innovation is to ensure their adoption and use.

The current system for introducing new medical technologies into the NHS remains complex, crowded, and difficult to manage resulting in a persistently low adoption rate.

Current NHS mechanisms to support the uptake and use of innovative technology are severely limited in scope and are focused on 'picking winners' rather than the broad system-wide adoption of new technology.

In an article published in Health Business UK in 2020 Barbara Harpham, Chair of the MTG, said *"More needs to be done to create a 'culture of innovation'. A challenge given the NHS employs 1.5 million people. Nevertheless, this needs to come from the very top and the buck stops with Secretary of State for the Department of Health and Social Care, Matt Hancock. Mr Hancock's commitment to technology has been welcomed, but he needs to look at how he can go beyond the implementation of exciting initiatives to embed a change of culture within the UK health system."* [21]

This review highlights flaws in the operation of the HealthTec Connect innovation adoption process, in particular its failure to gain any commercial adoption for more than 600 submissions submitted to HealthTec Connect in its first year of operation.

The authors of this review have proposed remedies which if adopted would provide an opportunity to enshrine improvements for the NHS adoption of Innovation, permitting the Secretary of State to meet the aspirations contained in the new Medicines and Medical Devices Bill, Part 3 Chapter 1 sections 12 and 13 regarding (a) the safety of medical devices; (b) the availability of medical devices; and (c) the attractiveness of the United Kingdom as a place in which to develop or supply medical devices.

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Michael Clancy's career in the HealthTech Industry started with The Boots Company in 1976 after which he pioneered the rental of specialist beds and services by launching Clinitron Therapy to the NHS in 1982. Michael managed Hill-Rom's commercial operations in Europe until the early 2000's and continued in the Beds and Support Surfaces arena serving as a Director of the Frontier Medical Group. Michael also served on the Board of the BHTA and continues to provide mentor support to Innovators in wound management technology.

In 2013 The Journal of Tissue Viability published Michael's article entitled; Pressure redistribution devices: What works, at what cost and what's next? J Tissue Viability. 2013 Aug;22(3):57-62. doi: 10.1016/j.jtv.2013.04.002. Epub 2013 May 29. Clancy MJ.

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