NHS NICE consultation: Building an integrated, rules-based medical technology (medtech) pathway

Written evidence submitted by The Health Tech Alliance

1. **Are there any other important principles that should guide the development of an integrated, rules-based medtech pathway?**

   The Health Tech Alliance (HTA) supports the core principles and the overall rationale behind the development of an integrated, rules based pathway, as the current situation is haphazard and unclear.

   The pathway should make it clearer and easier for the medtech industry to bring innovation to market at scale, and should do so in a way that is supported by evidence to assure value for the taxpayer. In addition to the stated principles, there should be an emphasis on patients and ensuring that their needs and health outcomes are at the forefront of technology assessment and adoption.

   Our Members have identified a number of issues with the pathway, including around budget limitations and funding. For example, the £10m budget impact is too restrictive as the impact would rely on widespread adoption across the health service, which is not achievable in most cases with this level of funding. There should also be further clarification on the budget impact to avoid excluding high-cost innovations that deliver long-term clinical benefits.

   On funding, for this new pathway to be successful for medtech, products receiving a positive NICE recommendation should receive mandated, automatic (ringfenced) funding within three months, similar to medicines.

2. **What positive or adverse impacts could the integrated, rules-based medtech pathway have on protected characteristic groups and people at particular risk of health disparities? How do you think those impacts should be addressed?**

   If developed thoroughly and in close consultation with industry and patients, the pathway should improve access to cutting-edge technologies which have the potential to enhance healthcare outcomes for all groups and reduce health disparities.

   However, the proposed limit to the budget impact could lead to a postcode lottery in access to innovative medtech. In many instances, this technology exists and is available, but there are inefficiencies within the service and issues with adoption within Integrated Care Boards (ICBs) that lead to inequalities in its use for patients in different regions. Thus, the stated end goal of providing a route to which developers get clear reimbursement is not guaranteed.

Creating barriers to the introduction of such technology will also see other countries accelerate ahead of the NHS, and will render the UK as an unattractive place to do business. For example, SMEs may choose to prioritise investment in countries where innovation is genuinely supported, rather than rationed. The overall adverse effect of the above is the patients won't achieve the best health outcomes.

3. **Do you agree that the timely and accurate provision of information by industry should be a prerequisite for National Institute for Health and Care Excellence evaluation?**

   Firstly, further information on the type of information required should be provided, as some may be inappropriate for NICE evaluation.

   Second, there should be sufficient time dedicated for the timely and accurate provision for both notification of information and subsequent submissions. The level of resources available will differ across the medtech sector, so a standard process timeline provided well in advance would be beneficial. For example, SMEs face particular difficulties in navigating the NHS procurement landscape, and the need for evidence-based approaches and scalability can be particularly challenging resource-wise for these companies.

4. **How could all partners work with industry to ensure data coming from emerging innovations is robust and supports high quality horizon scanning?**

   To ensure data from emerging innovations is robust and supports high-quality horizon scanning, partners should engage in regular consultation and market engagement exercises with industry, be that via trade associations or otherwise. Feedback should be sought through targeted and consistent questions and discussions to ensure that partners gain a comprehensive understanding of the industry's current needs and developments, thereby ensuring that the collected data is reliable, timely, and aligned with the latest advancements and trends.

   This greater level of transparency will also support the approval process and encourage earlier submissions to the Innovation Service and NICE Advice. This could reduce the burden on organisations making submissions for lower priority objectives.

   The level of evidence for medtech products is often real-world evidence (RWE), and NICE/DHSC/MHRA should work with industry to define acceptable RWE standards. Research charities like UKRI and AMRC could assist with research protocols, and NICE Advice could ensure industry data meets expected standards.

5. **Should the NHS Innovation Service provide any additional functionality to act as the 'centralised front door' for all innovative technologies in the NHS?**

   The Innovation Service is a useful tool, but there should be mechanisms in place to collect more feedback from users of the services in order to better understand the Service's effectiveness in accelerating innovation adoption.

For early-stage medtech products that have been approved but are not in use due to lack of evidence, the Innovative Service could partner with the developer to provide enhanced support and identify early adopter sites for generating the necessary RWE.

6. **How can stakeholders inform a shared understanding of the value of medtech to the NHS earlier in a product's development cycle?**

   Early engagement between developers and NHS stakeholders should be facilitated to align development with clinical needs.

   Stakeholders should be more open to evidence originating outside of the UK, and RWE. RWE and Patient Reported Outcomes Measures (PROMs) that are defined and valued by the patient should be considered alongside technical data to demonstrate a medtech product's efficacy.

   To mitigate the access and implementation challenges that the industry is most likely to encounter, it is crucial to establish direct contact routes and secure endorsements across Integrated Care Systems (ICSs) and Health Innovation Networks (HINs). The MHRA's proposed International Recognition Scheme should also be taken forward to allow for products' earlier use within the NHS, alongside a robust NHS registry/database.

7. **How can all partners better signal demand to industry, academia, innovators, and investors? What information channels should NHS England and the National Institute for Health and Care Excellence use?**

   Demand signalling needs more granularity and should be provided within individual disease areas. Stakeholders must be kept informed of these developments, and a well-communicated plan for upcoming reviews, disseminated through NHSE, NICE, AAC, partner channels, and trade associations, would facilitate proper planning and preparation. This could include the use of digital platforms and social media to disseminate information broadly and quickly.

8. **What additional factors should NHS England, the National Institute for Health and Care Excellence and the Department of Health and Social Care consider when selecting technologies and categories of technologies for the pathway?**

   Any pathway designed to accelerate the adoption of innovative technologies to the benefit of patients should do just that. However, the introduction of the Late Stage Assessment (LSA) and £10m budget impact will only serve to restrict technologies from gaining market access.

   LSAs are for products that are widespread and already in common use within the NHS, so it seems inappropriate for these to be included in this pathway. There are concerns that the inclusion of LSAs in this process will be used to decommission products and create price

reductions. At the same time, our Members are still very unclear on the methodology NICE is using for LSAs. so further clarification is needed.

The value of technologies should also be assessed holistically across the entire pathway. This includes understanding how each technology impacts patient outcomes, experiences and overall health costs. In short, the budget impact should not be restrictive and should consider cost effectiveness.

9. **How can products that receive a positive early value assessment recommendation best be supported to develop evidence?**

   As previously mentioned, for early-stage medtech products that have achieved recognition, but are not yet implemented at UK sites, collaboration between the NHS and industry partners is crucial to identify early adopter sites for generating necessary RWE for a full Health Technology Assessment (HTA).

   Direct access to trusts and research networks can support further RWE generation. NICE advice can also help expand a device's evidence base. Proper infrastructure for data collection, adequately resourced and supported by both the NHS and industry partners, is essential.

10. **What extent do you think there is an opportunity to streamline existing innovation funding streams to provide a more systematic approach to supporting conditional reimbursement?**

    Streamlining innovation funding streams and simplifying access routes for industry would not only boost confidence among innovators but would also ensure that the NHS adopts effective and efficient technologies more rapidly. One suggestion is creating a single portal for all innovation funding applications.

    A portion of R&D funding should be allocated early in the academic discovery phase to aid the development of evidence for late-stage adoption.

11. **Do you envisage the proposed commercial activities will help the NHS to maximise value for money from new medtech?**

    The true definition of value is not clear - by rationing the use of medtech to go through the EVA programme, the pathway appears to be prioritising cost containment over cost effectiveness. This not only goes against the Accelerated Access Collaborative (AAC) objective of accelerating the adoption of innovative technologies, but also could lead to poorer health outcomes for patients.

12. **Please provide comments on what, if any, other commercial mechanisms/activity NHS England and the National Institute for Health and Care Excellence should consider to maximise value for money from medtech through the pathway.**

When evaluating medtech, timescales need to be longer to take into account the real value that medtech delivers to patients, the system and the population.

The current in-year budget only serves to procure on price rather than value. It also compounds the inefficiency of the NHS. Providing a real, ring-fenced budget for medtech would maximise value and allow the NHS to plan over the longer term.

13. What further work could help to inform an understanding of the value of medtech to support sustainable commissioning, funding, and adoption through the pathway?

Case studies of successful technology adoptions could be developed to highlight best practices and lessons learned. In addition, regularly surveying stakeholders would help gather insights on the perceived value and challenges of adopting new technologies. Industry needs to be clearly informed about how this pathway will operate and what the implications/outcomes of the NICE assessment routes mean for products, i.e. conditional access, mandated discounting, decommissioning, local vs centralised procurement models, etc.