Board meeting

11 December 2024

Integrated Rules-based Medtech Pathway

Purpose of paper

For decision

Board action required

The Board is asked to:

1. Approve our approach to responding to the consultation
2. Approve our next steps for the pathway

Brief summary

NICE, NHS England and the Department of Health and Social Care (DHSC) have been working in close collaboration to develop a clear pathway that overcomes the barriers to adoption and scale for medtech in the NHS, while ensuring value for money for the taxpayer. This pathway is pivotal to ensuring the needs of patients and the pressures in the NHS are sustainably addressed with safe and effective technology, and the postcode lottery in access is reduced.

In May 2024, NICE and NHS England (NHSE) proposed an Integrated, Rules-Based Medical Technology Pathway. The consultation concluded in September, proposing to build a predictable, consistent route of access and adoption in the NHS for a subset of medtech that has transformative impact on care pathways. The consultation proposed automatic identification of funding for technology that meets an unmet clinical need, has been recommended as clinically and cost-effective by NICE and subject to a budget impact test by NHSE. Beyond funding, the consultation proposed coordinated support across partners to streamline the adoption journey through more coherence in demand signalling, earlier commercial engagement and access support. There were 201 responses, the majority from service providers, MedTech innovators and trade bodies, as well as several charities, NHS organisations including Trusts and ICBs, clinicians and academics. There was widespread support for a more streamlined, rules-based approach to the evaluation and adoption of medtech. This paper includes a summary of the key themes raised by respondents.

Since the pathway was proposed, there has been a change in government which has prioritised delivering three key shifts in the NHS – from hospital to community, analogue to digital, and treatment to prevention – and medtech plays a vital role in each of them. It is therefore critical that the Integrated Rules-Based Medical Technology Pathway is aligned with the policies that underpin these three shifts, notably the NHS 10 Year Plan, and also including the Life Sciences Sector Plan and Innovation and Adoption Strategy, all of which are expected to be published early next year. We are now working with DHSC and NHSE to ensure the rich feedback from the consultation informs these policies, and expect to publish a formal response to the consultation following their publication. In the meantime we will continue to develop the foundations of the pathway with NHSE and DHSC.

The NHS 10 Year Plan could provide the opportunity to drive forward the pathway to achieve longer-term benefits for patients, a more sustainable future for the NHS, and a more attractive place for industry to bring their innovations.

Board sponsor

Mark Chapman, Director of Medical Technology

Introduction

1. The integrated rules-based medtech pathway applies across the entire lifecycle from promising technologies for early use in the NHS, to technologies with proven benefit that should be used routinely in clinical care across the NHS, and finally to technologies already in widespread use where there is opportunity to enable greater choice and drive greater value. By establishing the pathway, NHS England and NICE are seeking to improve outcomes for patients, provide greater certainty for medtech innovators and suppliers, and drive better value for money for taxpayers and the NHS.

Background

#### Consultation on the medtech pathway

1. 5 key principles were described in the consultation document:
	1. Principle 1 – the pathway should be supported by evidence-based advice and guidance from the National Institute for Health and Care Excellence (NICE), focused on technologies with the greatest impact on patient outcomes and the most compelling cases for clinical and cost-effectiveness
	2. Principle 2 – the pathway requires a lifecycle approach to support new, early-stage technologies as well as driving greater value from existing technologies in widespread use
	3. Principle 3 – the pathway should lead to automatic identification of funding to support routine commissioning and adoption for clinically and cost-effective and affordable technologies
	4. Principle 4 – the pathway should support the transformation of clinical pathways and services
	5. Principle 5 – the pathway should drive up the quality and use of evidence, helping tackle ethnic and unfair biases in medtech

The consultation received an excellent response from 201 stakeholders, the majority from service providers, MedTech innovators and trade bodies, as well as several charities, NHS organisations including Trusts and ICBs, clinicians and academics. Engagement events and webinars were also held to support the consultation with stakeholders. Thirteen questions were asked relating to six key areas: principles of the pathway; equality and health inequalities; horizon scanning; demand signalling; NICE assessment; and commercial. Overall, support for the pathway was very positive.

#### Principles of Pathway

The importance of core principles was emphasised, such as transparency, patient engagement, and equality considerations. These are an integral part of guidance development and can be expanded across the pathway.

Consultees highlighted that greater clarity on the regulations and standards for medtech, including data security and privacy, should be a principle of the pathway. They also noted that higher importance needed to be placed on interoperability and ‘open systems architecture’ for medtech.

The importance of the patient voice being embedded through every stage of the pathway was emphasised by stakeholders, as well as enabling continuous improvement in the pathway so lessons can be learnt and improvements can be made.

The importance of the pathway promoting competition, diversity of supply and environmental sustainability were also points of focus for stakeholders.

A royal college welcomed a simpler pathway and highlighted that ‘*A major barrier to deploying new medtech solutions in the NHS is the current proliferation of parallel, partially-overlapping pathways. It can be confusing to both developers and adopters, who do not always know which pathway is most appropriate or efficient.’* This aligned with other stakeholders who highlighted that specific support for SMEs and innovators who are unfamiliar with the pathway and its key elements is a key need, and who requested further clarity on which technologies are in and out of scope for the pathway.

#### Equality and Health Inequalities

In addition to the equality considerations highlighted in the principles section, stakeholders also commented that the pathway could enable more consistent uptake of technologies across the NHS, reducing the risk of a ‘postcode lottery’, and that having clear rules should reduce bias and provide greater consistency of decision-making.

Stakeholders raised that both inadvertent and overt bias in decision making, methods and processes would need to be controlled for as well as ensuring transparency. Being cognisant of potential bias in technology and data was highlighted as a point of importance, particularly with digital and AI technologies. Considering factors outside of legally protected characteristics was also recognised as important to avoid digital exclusion.

1. Encouraging manufacturers and innovators to actively consider health inequalities in all their commercial and investment decisions, including encouraging evidence generation in groups with protected characteristics from the outset was another key theme

#### Horizon scanning and demand signalling

Most stakeholders agreed that timely and accurate information from industry to NICE should be expected, but they also highlighted more could be done to support industry in this by providing clear and reasonable expectations on what data is needed.

Although mostly supported, there were mixed views on the value of a front door for industry to the NHS such as the Innovation Service. Some highlighted that it is beneficial to centralise and streamline the management and evaluation of technologies because it reduces duplication and is more able to support adoption at scale. Others raised concerns that limited direct interaction with the NHS could hinder innovation and be less supportive of companies who are unfamiliar with the relevant organisations and processes.

Stakeholders agreed that extensive engagement would be needed for effective demand signalling but there were mixed views on whether a national top-down approach or direct interactions between clinicians and industry was preferable. In addition, some stakeholders preferred broad, strategic priorities while others called for specific, granular articulation of priorities within a pathway. It was also highlighted that many different demand signals are currently communicated from many different organisations to innovators so there is opportunity to streamline this.

#### NICE assessment

1. In addition to the themes presented in the principles, stakeholders were in favour of NICE prioritising technologies according to NHS and patient need, and should consider focusing on technologies that represent significant innovations or advancements over existing solutions, offering novel approaches to healthcare challenges.
2. Some stakeholders felt that NICE should consider benefits to the wider economy, public health and social care in its evaluations.
3. Further clarity was requested on what the options would be for technologies not evaluated by NICE and that the pathway should not be limited to five technologies.
4. Many ideas and suggestions were put forward to support evidence generation for early value assessment, including: improved access to data by investing in registries and databases to collect real-world data on the impact of a technology; collaborating with clinical networks and directing innovators to pilot sites as part of the early value assessment process; and encouraging academic collaborations to conduct rigorous research. The need for long-term studies as well as real-world evidence generation to capture the evolving benefits of technologies over an extended period of time was also highlighted.
5. Stakeholders also highlighted that dedicated funding and capital to support evidence generation is needed and suggested a range of potential funding sources such as public-private partnerships, grants from research funders and innovation funds. It was also highlighted that these multiple funding streams could be unified for a more streamlined and systematic approach that could work at scale, standardise requirements and reduce administrative burden. Enabling local systems to identify and support innovation rather than a centralised approach was preferable to others. Stakeholders also commented that funding should be prioritised for SMEs and entrepreneurs with new technologies, rather than larger existing providers and that there should be more regular annual funding cycles.

#### Commercial

There was support for commercial activities in the pathway and agreement that they could help maximise value for money. A range of activities were suggested including: considering return on investment over a long-time period; better use of volume commitments; use of ‘added value offers’ such as supplier support; and supporting healthcare professionals and patients to ensure effective implementation. Concerns were raised that the approach to affordability and budget impact was overly focused on price and may not benefit technologies offering the greatest value to patients and the NHS. It was also highlighted that the proposed budget impact is lower than that used for pharmaceuticals and the Medtech Funding Mandate.

1. Stakeholders highlighted that the benefits from medtech might accrue in a variety of ways that are not necessarily captured by a cost-effectiveness assessment, including wider public health benefits, broader societal benefits, reductions in waste as well as impact on the environment. It was also noted that savings might accrue to organisations other than those commissioning the given health technology.
2. Stakeholders also felt that there were opportunities to better communicate the benefit of technologies to commissioners, clinicians and patients, including sharing best practice examples, using exemplar pilot sites to generate ‘real-world evidence’, better industry and NHS collaboration and support from Health Innovation Networks and the Clinical Entrepreneurs Program. Responses stressed the need for initiatives such as training, education and audits to support the introduction of technology as well as benefits realisation.
3. Existing ‘routes to market’ and reimbursement such as the NICE Technology Appraisal process were also noted, and some stakeholders felt that they should be considered alongside the proposed pathway.

#### Summary

The proposed pathway and its principles have been received positively and there is recognition of the many benefits to patients, NHS and industry from establishing a more consistent and coordinated pathway. The consultation on this pathway was launched under a previous government and so the context in which it was written has changed. There is now opportunity to take a broader perspective to HealthTech in the NHS 10 Year Health Plan, in which the proposed pathway could play an important role.

**Next steps**

The pathway will be approached in two phases:

* 1. the first is to continue to build the foundations of the pathway, streamlining and coordinating the activities required to enable adoption of effective HealthTech and ensure value for money, including in existing spend. The focus will be on topic selection, commercials and reimbursement, and adoption, and the governance of the pathway will be reset in the light of the changes.
	2. the second is to align the development of the pathway with the upcoming multi-year spending review and NHS 10 Year Plan.
1. NICE sincerely thanks stakeholders for contributing to the consultation and will respond to their comments following the publication of the NHS 10 Year Plan. NICE will also ensure that stakeholders’ views inform NICE’s contribution to the continued development of the pathway, the NHS 10 Year Plan and the Life Sciences Sector Plan.

Board action required

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