AAC (008)

ACCELERATED ACCESS COLLABORATIVE

IMPROVING ACCESS TO DIGITAL HEALTH TECHNOLOGY: APPROVALS, REIMBURSEMENT AND UPTAKE

Executive summary

- Well-evidenced digital health technologies (DHTs) can empower patients to manage their own health and help frontline staff to provide high quality care and make best use of their time. However, the current policy framework shaping regulation, access, funding, adoption and evidence for DHTs does not support the uptake of well-evidenced DHTs as well as it could, and uptake is variable across the NHS.
- We presented a paper to the AAC Steering Group meeting on 2nd June 2021, which outlined the case for change and key issues to resolve. This paper provides an update on our emerging proposals for a policy framework to address these issues.
- **Regulation and access:** the relevant statutory bodies are making a range of improvements to the regulation of DHTs and requirements for their access to NHS markets, including:
    - Reforms by MHRA to ensure regulation is fit for purpose for software and AI
    - The introduction of the Digital Technology Assessment Criteria for Health and Social Care (DTAC) by NHSX
    - Work by NICE to ensure that the assessment frameworks and evidence standards in place for DHTs are robust, proportionate, support the needs and priorities of the NHS, and reflect the characteristics of different types of digital technologies.
    - The AAC is performing a mapping exercise to create a flowchart of the 'MedTech pathway' in order to understand the key standards, timescales and criteria which need to be met through this journey, as well as organisations which provide support for innovators.
- **Reimbursement and pricing of DHTs:** our proposals are that:
    - To be recommended for NHS funding we think DHTs must be authorised by MHRA, pass DTAC and be recommended by NICE. To meet these criteria, DHTs will need to be backed by robust evidence showing they are safe, effective and represent a good use of NHS resources.
    - For DHTs which are endorsed for funding by the NHS in England, maximum prices should be set nationally, informed by the NICE value assessment. Local commissioners would be free to negotiate an improved price with suppliers.
    - To support innovators to generate the evidence needed to secure approval, funding could be recommended for certain DHTs pending a full assessment. We are working with the AAC and partner organisations to develop the details of any such scheme.
- **Adoption and funding flows within the NHS:** our proposals are that:
    - Specific DHTs should be paid for from the same budgets as pay for their substitutes and complements.
    - No further financial controls over NHS spend on DHTs are currently warranted, but we will monitor the cost impact of DHTs as adoption spreads.
    - We will work closely with the AAC on the wider barriers and facilitators of adoption,

including behavioural factors.

- **Data flows:** We need to ensure that the data and data flows generated by DHTs are handled in ways that meet defined standards while maximising usability. We will consider whether any further work is needed to make sure all these data and data flow issues are dealt with adequately.
- Our next steps are to continue developing the policy framework, taking into account stakeholder feedback, with the aim of finalising the policy proposals by the end of the financial year 2021/22.

Steering Group members are asked to:

- Note the contents of this paper and offer comment on the proposed policy framework and next steps

Background

1. Well-evidenced digital health technologies (DHTs) empower patients to manage their own health and get rapid access to peer support and clinical advice. They also help frontline staff to provide high quality care and make best use of their time.

2. However, the current policy framework shaping regulation, access, funding, adoption and evidence for DHTs does not support the uptake of well-evidenced DHTs as well as it could. Uptake of DHTs is at present highly variable across the NHS, indicating a significant need to boost adoption and increase the range of technologies available.

3. We see this situation as an opportunity for the UK to position itself as a leader in the development and adoption of well-evidenced DHTs. By setting a responsive, flexible and proportionate approach for DHT approvals and applying consistent regulatory, evidence and access standards in a timely manner, we can take a leading role in shaping the emerging global regulatory environment for DHTs. Achieving that vision rests on creating a DHT policy framework driven by value propositions, proven outcomes for patients and ease of use for clinicians.

4. We presented a paper to the AAC Steering Group meeting on 2nd June 2021, which outlined the case for change and key issues to resolve. At the Digital Therapeutics Summit held on 15 July, we sought further stakeholder input and feedback on the key challenges facing DHTs in the UK. We have since developed the hypotheses for tackling the challenges, as set out in this document.

Definitions / Scope

5. The scope of this work encompasses DHTs falling within Tier C of the NICE functional classification (including those that use artificial intelligence)[1]. Tier C comprises products that provide interventions, including:

    A. Preventative behaviour change
    B. Self-management

[1] The Tiers are explained in NICE's evidence standards frameworks for digital health technologies, which can be found here: Evidence standards framework for digital health technologies

C. Treatment
D. Active monitoring
E. Calculating
F. Diagnosing

6. Products falling into NICE Tiers A and B are excluded from the scope because they do not contribute directly to patient care through a therapeutic or diagnostic function but are enabling technologies. As such, they would not be 'prescribed' or offered to patients as a substitute or complement for other treatments.

7. This scope means that the work will impact many AI products, including some supported by the AI Award, and we are working with the AI Lab and AAC to manage this. It also impacts the remote monitoring products deployed as part of the COVID-19 response, and potentially other products being supported by policy teams such as mental health and diabetes; we will continue to work with the relevant teams to manage the impact.

Regulation and access

8. The relevant organisations are making a range of improvements to the regulation of DHTs and requirements for their access to NHS markets. We propose that the statutory bodies continue to collaborate closely to make sure all their improvements cohere in a single, consistent policy approach. The key changes are as follows:

    a. MHRA is delivering a set of reforms to ensure medical device regulation is fit for purpose for software and AI[2]. The reforms aim to clarify for developers of software as a medical device how medical device regulation applies to software and AI, identify the tools and standards for meeting those requirements, and align with other regulatory requirements. Similarly, NICE is upgrading its evidence standards framework for DHTs to make sure it accommodates all relevant digital and data driven technologies, including those incorporating adaptive algorithms.

    b. In February 2021, NHSX introduced the Digital Technology Assessment Criteria for Health and Social Care (DTAC)[3]. This brings together legislation and good practice into a single set of questions for assessing all DHTs designed for use by all NHS organisations piloting, procuring or using DHTs. The DTAC aims to make sure selected DHTs meet expected standards of clinical safety, data protection, security, interoperability, accessibility and usability. For instance, in order to comply with NHS clinical safety standards, organisations should ensure the DHT meets the requirements of DCB:0129. In addition, if the DHT qualifies as a medical device, the DTAC provides a validation check of the device classification and subsequent regulatory approval process. The DTAC has been widely adopted and is driving an increase in the use of DHTs that comply with clinical safety legislation among NHS organisations.

    c. NICE is currently working with NHSX, MHRA and the AAC to ensure that the assessment frameworks and evidence standards in place for DHTs are robust,

[2] Software and AI as a Medical Device Change Programme
[3] Digital Technology Assessment Criteria (DTAC) - NHSX

proportionate, support the needs and priorities of the NHS, and reflect the characteristics of different types of digital technologies. This includes making better use of real world evidence to inform assessment of DHTs. NICE proposes to be completely flexible in how it redesigns its products and methods for the regulation and access of DHTs to make sure these reliably assess the value of DHTs to the health system.

d. The AAC is performing a mapping exercise to create a flowchart of the 'MedTech pathway' in order to understand the key standards, timescales and criteria which need to be met through this journey, as well as organisations which provide support for innovators. The aim of the work is to identify where partners are tackling issues and supporting a coordinated approach to improvement, and to identify bottlenecks and issues in the current pathway that prevent rapid access and uptake of innovations and support the development of new programmes to address issues. This work will be brought to the AAC board in 2022.

Reimbursement and pricing of DHTs

A. Which DHTs should the NHS pay for?

9. We think there is a need for clear standards to determine which DHTs should be recommended for funding by the NHS, whether at a national level via specialised commissioning or locally via CCGs/ICSs. To be recommended for NHS funding we think DHTs must meet the three following criteria. They must:

    a. where applicable, be appropriately CE/UKCA marked to be placed on the market in the UK, ensuring that the device is safe, and works as described by the manufacturer;
    b. pass DTAC, to ensure that they meet core standards for clinical safety, data protection, security, interoperability, accessibility and usability; and
    c. be recommended by NICE, to ensure they are plausibly cost-effective and therefore represent value for the NHS.

10. To meet these criteria, DHTs will need to be backed by robust evidence showing they are safe, effective and represent a good use of NHS resources. Technologies for which the evidence base is still maturing, that are plausibly cost-effective given current evidence, and are also of significant importance to the NHS may be eligible for contingent approval for NHS funding (see below).

11. We think that setting these criteria will support two key elements of the vision:

    a. Endorsement of DHTs for funding by the NHS can be read as a global 'gold standard' of merit by both DHT developers and other purchasers around the world, because these criteria for recommending NHS funding set a high bar.
    b. A rapid uptake of products that meet the criteria will be facilitated by the creation of national access and reimbursement mechanisms. We think this will make it attractive for innovators to invest in developing the required evidence and putting products through the appraisal process.

12. NICE cannot and will not evaluate all DHTs that are currently in use and we know there is more work to be done to determine what types of NICE evaluation will be required for DHTs, what proportion of new and existing products they will assess, and how to adapt their evaluation process to different types of products. We do not think there will be a one size fits all approach for all DHTs. NHSX and NICE are currently working closely to develop solutions.

13. For new products that do not currently meet the evidence requirements set by NICE, but which show strong potential, we propose to introduce the time-limited contingent reimbursement scheme to support evidence generation described below.

14. For products currently in use within the NHS, NHSX, NICE and the AAC are together exploring a viable longer term approach to their assessment. We believe that it will be in the interests of patients, commissioners and innovation generally for the NHS to prioritise scarce resources for products which have robust evidence demonstrating patient benefits and cost effectiveness. However, we are conscious of the need to avoid creating any 'cliff-edges' or new barriers to the use of suitable DHTs by the NHS. We also recognise that a proportion of older DHTs and software in the NHS will be naturally superseded as new DHTs are adopted but the extent and timing of this effect is uncertain. Resolving these issues and developing detailed proposals on retrospective product assessment will be a priority for the next phase of this work.

B. How will prices be agreed?

15. For DHTs which are endorsed for funding by the NHS in England, we think maximum prices should be set nationally, informed by the NICE value assessment (i.e. the maximum price would be at a point where the product is still cost-effective). National price-setting would allow the NHS to benefit from its scale as a purchaser. It would also provide a level of certainty for product vendors and reduce the burden for them of negotiating prices with numerous local commissioners. That said, there would be scope for CCGs/ICSs to reach their own agreements with product vendors if they could negotiate an improvement on the national price.

C. Contingent reimbursement

16. We know from talking to innovators that generating enough evidence to secure approval for a product can be difficult unless there are opportunities for the product to be used within the NHS while in development. To support innovators in finding these opportunities, funding could be recommended for certain DHTs pending a full assessment. A paper was tabled at the AAC Steering Group in October 2021 discussing in more detail how this might operate.

17. Any such scheme would need to be carefully designed to meet the needs of the NHS as well as innovators, and make sure the NHS gets good value for any resources invested in the scheme. How the scheme will operate has not yet been agreed, but our preferred approach is to adopt the following principles:

    a. New products may only enter the scheme where there is a reasonable prospect that further evidence will enable the product to meet NICE standards. This judgement will be informed by an early NICE value assessment, which will identify evidence gaps. The existing evidence must demonstrate proof of concept and plausible

potential for good use of NHS resources.

b. Eligible products must have a relevant UKCA/CE mark where appropriate and have passed DTAC.
c. All products on the contingent reimbursement pathway must be reassessed annually.
d. The costs of providing products, redesigning pathways and generating evidence will be split appropriately between NHS bodies and suppliers. We also need to consider whether and how the NHS should recoup any contingent funding investments from suppliers whose products are successfully adopted at scale.

18. The AAC has convened a working group with representation from NHSE/I, NICE, OLS, NHSX, NIHR and the DHSC MedTech directorate to progress these proposals.

Adoption and funding flows within the NHS

A. Who pays for DHTs within the NHS?

19. We think that the most straightforward and logical long-term approach is for specific DHTs to be paid for from the same budgets as pay for their substitutes and complements, i.e. from CCG/ICS allocations, primary care prescribing budgets and specialised commissioning budgets. The alternative is for DHTs to be paid for from a separate ring-fenced budget. However, this approach would reduce the ability of local decision-makers to choose the best mix of treatments for their patients and would discourage the smooth integration of DHTs into treatment pathways.

20. At present, products included within the MedTech Funding Mandate are excluded from national prices and reimbursed separately by NHS commissioners. NHS trusts are expected to agree reimbursement of the products with their commissioners based on the cost of the products and adjust the value of the fixed payment elements of their contracts accordingly. Work is also underway to produce guidance on how the costs of implementing innovations should be reflected in the variable elements of contracts. We anticipate reimbursement of DHTs prescribed by secondary care providers (including acute, community and mental health providers) to operate in the same way. For products accessed via primary care, we expect reimbursement to flow through the primary care prescribing budget.

B. What other measures will be taken to control NHS spending on DHTs?

21. Additional measures could be considered, if necessary, to control NHS spending on DHTs, for example, a scheme similar to the Voluntary Scheme on branded medicines (VPAS) that helps to control spending on medicines by setting a spending cap for branded drugs. However, given the uncertainties, we don't think now is the time to introduce such measures. We don't know the likely scale of spending on DHTs across the NHS in England, but we anticipate that much of it will displace existing expenditure and we are currently mapping the likely impacts on budgets. In addition, we don't want to place more constraints on uptake at this time, given our priority to increase clinician and patient use of well-evidenced products. However, we will monitor the cost impact of DHTs as adoption spreads, and may introduce additional measures such as those described above if they become necessary.

C. What other steps are needed to support adoption of DHTs?

22. There is a risk that, even with a well-designed regulatory and funding process, adoption of DHTs may remain lower than desired. NHSX is currently researching adoption barriers and facilitators and will draw the findings into a set of recommended actions for system partners.

23. Widespread adoption of DHTs depends on changes in behaviour of three groups:

    a. Commissioners need to purchase new approved products;
    b. Clinicians need to recommend or prescribe new products; and
    c. Patients need to request and use new products.

24. Behavioural science shows that desired behaviour changes can be accelerated through 'nudge' type interventions that are cheap and simple to apply at scale, for instance, minor adaptations to existing or planned communications, governance, or training. NHSX's recommendations may also include other measures that are more costly to apply, for instance new training or regulatory arrangements, but these may take longer to implement.

Data flows

25. We need to ensure that the data and data flows generated by DHTs are handled in ways that meet defined standards while maximising usability, including standards on:

    a. Patient privacy and data security;
    b. Alerts and clinician liability;
    c. Clinician capacity and workload;
    d. Integration into existing systems, such as electronic patient records; and
    e. Support for population health management and research, including capturing data on DHT use through the national data architecture to support analysis of DHTs' effectiveness.

26. Some of these requirements will be addressed through DTAC, and some through NHSX's work on interoperability. We will consider whether any further work is needed to make sure all these data and data flow issues are dealt with adequately.

Next steps

27. The current proposals leave a number of questions unanswered, in particular:

    a. Which products and therapeutic areas to start with when implementing the policy framework
    b. Timeline for implementation
    c. DHT market assessment, including what's currently in use and potential volumes and costs of DHTs under the proposals
    d. What the NICE evaluation process will be for new and existing DHTs
    e. Design and implementation approach for any contingent reimbursement arrangements
    f. How to manage data flows from DHTs

28. We intend to develop our thinking on these questions, taking on board stakeholder

feedback, over the next 2-3 months. We will share a more detailed set of policy proposals towards the end of 2021 or early in 2022. At that point we propose to hold a second Digital Therapeutics Summit to engage further with stakeholders, which is likely to be scheduled for late January 2022.

29. We aim to finalise the policy proposals by the end of the financial year 2021/22, and to pilot the new policy approach with a limited selection of products during FY 2022/23.

Steering Group members are asked to:

- Note the contents of this paper and offer comment on the proposed policy framework and next steps

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