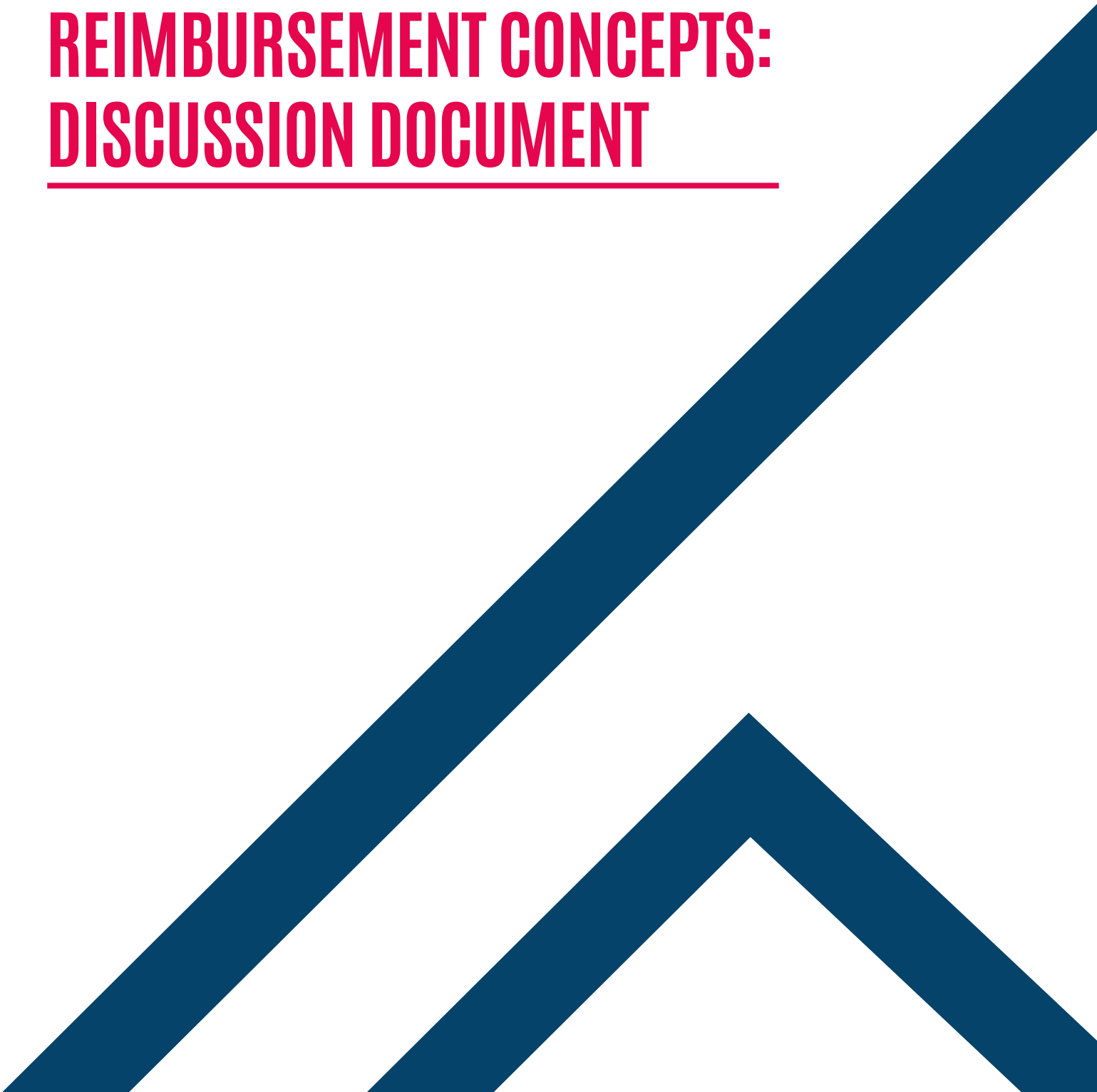
ABHI
DIGITAL HEALTH

DIGITAL HEALTH REIMBURSEMENT CONCEPTS: DISCUSSION DOCUMENT



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EXECUTIVE SUMMARY

Digital health technologies (DHTs) promise to make healthcare delivery better, safer and more efficient.[1] Yet they do not fit easily into existing funding pathways which have traditionally tended to focus on services, medicines, devices and diagnostics, which is a major hurdle to adopting a wide range of clinically effective digital health solutions.[2]

In this paper we look at current UK funding mechanisms and best practice for DHT funding from three European countries and the US.

Reimbursement needs to address cost of NHS activity as well as external costs including capital, consultancies/data analytics, licences and revenue. This will require a range of mechanisms to ensure that funding can flow appropriately through the system, provide an incentive to switch to digitally enabled pathways and data driven interventions and ensure access to different technologies, in different circumstances and care settings.

While some technology-level reimbursement already exists (e.g. the MedTech Funding mandate) there is a long process to get awarded and it is only applicable for one technology/company. This limits digital transformation at pace and scale, and decreases the attractiveness of the market for investment in the sector.

Mechanisms need to be developed with transparent criteria, assessment processes and direct links to funding. The specifics of digital health products and solutions must be considered when developing instruments for assessing and rewarding the value they provide for patients, healthcare actors, health systems' sustainability and society.[3]

KEY RECOMMENDATIONS

1. There should be a range of payment mechanisms to cover NHS activity, capital, consultancies/data analytics, licences and revenue and support access in different care settings.
2. A clear and transparent pathway for assessment and coverage decisions is needed with a tiered approach based on clinical risk, and with a direct link between assessment and reimbursement.
3. Flexible and rapid processes should be developed, taking account of the fast-paced nature of digital product innovation.
4. Build on existing processes such as NICE Evidence Standards Framework (ESF), Digital Technology Assessment Criteria (DTAC) and Drug Tariff.
5. Schemes should be supported by legislation.
6. Reimbursement schemes should play a role in incentivising appropriate uptake of digital innovations and include early access schemes such as coverage with evidence development.
7. Reimbursement mechanisms for market ready products should not be capped, enabling competition in the market and ability of local systems to choose solutions appropriate to their situation.
8. Assessment methodologies need to be able to address both cost effectiveness and cost saving approaches, and be flexible enough to cater for a range of appropriate endpoints, for example, prevention.
9. Financial criteria should be based on value/cost effectiveness, not on affordability (this is to be determined at local adoption level).
10. Pricing and procurement should be considered as two separate, but linked, steps.
11. Flexible approaches to procurement are needed and Dynamic Purchasing Systems should be given wide consideration, as these have several advantages for both suppliers and purchasers[4].

INTRODUCTION

DHTs promise to make healthcare delivery better, safer and more efficient.[5] Yet they do not fit easily into existing funding pathways which have traditionally tended to focus on services, medicines, devices and diagnostics. DHTs often provide multiple benefits beyond meeting clinical needs and accelerate the transition towards value-based procurement. For example, providing patient health apps in addition to data-enabled medical equipment can provide better adherence to therapy and deliver better patient outcomes.[6]

With the significant increased interest in DHTs there is a need to unlock funding pathways. The current system in the UK, with reimbursement decisions mostly made at a local level, proves to be a major hurdle to adopting a wide range of clinically effective digital health solutions.[7]

The HealthTech industry is a key stakeholder in these initiatives and would like to offer its views and expertise. In this paper we look at current funding mechanisms in the UK and assess their applicability for DHTs and also review best practice for DHT funding in three European countries– Belgium, France and Germany, as well as the US. In recent years, these countries have initiated dedicated funding mechanisms for health apps and data-enabled HealthTech tools, with a view to standardising such funding streams. Work has been undertaken by MedTech Europe to assess the impact and efficacy of these initiatives, how these countries and regions are assessing digital health apps and the frameworks in place.

Scope

This document aims to cover general reimbursement principles, including related pricing assessment and procurement activities for DHTs. The scope of technologies covered is aligned to the Functional classification of DHTs within the NICE Evidence Standards Framework[8] with the addition that it also includes adaptive algorithms, which are currently excluded in the NICE definition.

Reimbursement Overview

Reimbursement needs to be looked at holistically to address the cost of NHS activity, as well as a range of external costs including capital, consultancies/data analytics, licences, revenue.

This will require a range of mechanisms to ensure that funding can flow appropriately through the system. Consideration also needs to be given to the use of reimbursement mechanisms to provide incentives to appropriately switch to digitally enabled pathways and data driven interventions, and incentivise the use of technology to drive system efficiency. Systems should be put in place that will support access to technologies across home care, primary care, community and acute settings.

Having a range of reimbursement tools can address access to different technologies, in different circumstances, and ensure budgets are appropriately reimbursed for activity. Inclusion of technologies within a reimbursement structure not only provides an important financial support for innovation adoption, but also delivers a signal to users and commissioners of the technology that it was been robustly assessed.

Generally, HealthTech operates in a world of fee-for-service and procedure-based reimbursement, and we see many device and diagnostics companies struggling to look beyond this to develop new reimbursement strategies. Digital health companies, on the other hand, have taken innovative approaches to unlocking existing funding pathways among public and commercial payers.[9] However these initiatives can be blocked if the health system does not have the flexibilities within their payment mechanisms. While some technology-level reimbursement already exists (e.g. the MedTech Funding mandate) there is a long process to get awarded and it is only applicable for one technology/company. This limits digital transformation at pace and scale and decreases the attractiveness of the market for investment in the sector.

Routine digital interventions/activities and pathways need to be funded at a category level, as opposed to specific technologies. For example, a remote monitoring intervention should have a tariff for all the relevant therapeutic areas (cardiovascular, diabetes, respiratory etc.). Detailed costing data (pathway and/or patient) should be collected to ensure that funding levels are appropriate. Where technologies are being directly reimbursed specific criteria is needed to make appropriate reimbursement decisions for digital health products and solutions. The specifics of digital health products and solutions must be considered when developing instruments for assessing and rewarding the value they provide for patients, healthcare actors, health systems' sustainability and society.[10]

INTERNATIONAL BEST PRACTICE

There are a number of jurisdictions that have elements of reimbursement that support the adoption of DHTs. In this section we highlight some of those elements that could be adopted by the UK.

As source material we have used the MedTech Europe paper "Recognising the value of digital health apps: a look at four European health systems" (currently in draft). Redacted information from that paper is outlined in Appendix 1. In general, the countries have considered three aspects for assessing digital health apps for reimbursement:

1. **A safety and efficacy assessment:** This addresses medical safety, but also includes quality and reliability. Most European markets require that digital health apps considered for reimbursement are CE-marked under the applicable EU medical device (MDR) or in vitro diagnostic device (IVD) directives and regulations.

2. **A technical and legal assessment:** This addresses requirements that health apps meet appropriate data security, cybersecurity and data privacy conditions, and that they deliver health data to their health IT systems (such as electronic health record systems).

3. **A benefits and outcomes assessment:** This addresses requirements for evidence that health apps deliver positive benefits and outcomes, including effects on ease of access, quality of life, and impacts on outcomes from a societal perspective.

International Best Practice Key Characteristics

No one system, from those reviewed, provides a blueprint that we would recommend the NHS adopt wholesale, as there are notable limitations, particularly the focus on out of hospital care. However, there are elements that can be applied and/or adapted to the UK context. These elements are both at a system level and at a granular process level, the key characteristics that should be adopted into UK practice are:

- Supported by legislation.
- Published criteria.
- Rapid assessment process.
- Direct link between product assessment and reimbursement.
- Option for coverage with evidence development.
- Tiered approach based on clinical risk.

EXISTING UK REIMBURSEMENT MECHANISMS

There are a number of existing funding and reimbursement systems. The national tariff payment system is used to fund acute activity and direct funding of a limited number of medical devices and diagnostics. Drug Tariff is used to support payment of prescription drugs and devices for use in community setting. In addition to these there are a range of awards, competitions and funding rounds that provide direct funding to certain types, often on a time limited and number constrained basis. Further details of these can be found in Appendix 2.

Lessons from Existing UK Mechanisms

The UK employs a range of different reimbursement mechanisms to respond to the needs of different settings, technological maturity as well as clinical and financial risk. In reviewing these mechanisms it appears that most have been developed to support innovation and address inadequacies in the National Payment system. There are a number of lessons to be taken forward from these mechanisms, both areas to adopt and some elements to avoid.

Areas to avoid	Elements to adopt
› Competitive processes for 'market ready' products. › Resource bottlenecks in process that are not risk justified. › No transparent process to 'mainstream' from the time limited/early access schemes. › Long timelines for reimbursement assessment and award.	› Range of mechanism. › Early access schemes. › Flexible reimbursement via Tariff. › Routes applicable for different care settings.

REIMBURSEMENT RECOMMENDATIONS

There should be a baseline requirement for all DHTs reimbursed by the NHS to have appropriate regulatory approval. This would, in the main, be the UKCA mark for medical devices or diagnostics, however there are also categories of digital technologies that support either public health or system efficiency that would not fall within the scope of the UKCA regime. These should not be excluded from funding frameworks. Further, these technologies should comply with all applicable laws and regulations regarding interoperability standards, information security and data protection.

Building on both UK and international practice, we would recommend that a range of reimbursement mechanisms are developed to support DHTs, to address:

- Different risk profiles/technology maturity.
- Different settings.
- Reimbursement of both technology and system activity.

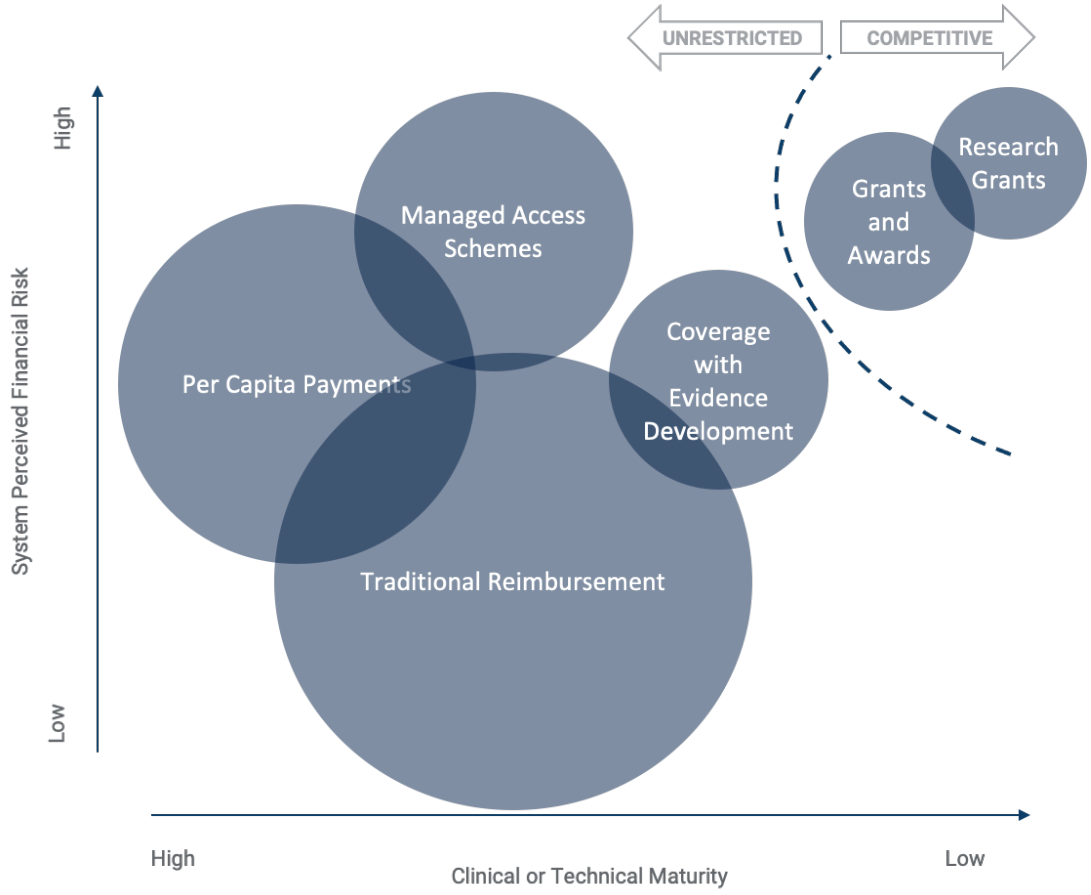

Figure 1: Reimbursement Schematic

General Approach

The general principles that should apply are:

- Reimbursement mechanisms for market ready products should not be capped, enabling competition in the market and ability of local systems to choose solutions appropriate to their situation.
- There should be no financial disincentive to choosing digitally enabled solutions over traditional approaches.
- Reimbursement mechanisms should be supported by legislation where appropriate, and should have a transparent criteria and process.
- Identification, assessment and listing processes should be streamlined to align with the iterative nature of DHTs and based on risk profile.
- There should be a direct link between the assessment process and eligibility for reimbursement.

The engagement to date with NHSX on this topic has been welcome and we look froward to ongoing collaboration in the development of specific mechanisms and the launch of 'Who Pays For What' to address the overall funding flows.

Traditional Reimbursement

National Payment System

The national tariff system is currently moving away from activity-related payments and towards population-based funding. The blended payment framework involves a fixed payment and at least one of; a quality, or outcomes-based element, a risk-sharing element and a variable payment. Currently the approach is limited to certain services (emergency care, adult mental health services, outpatient attendances and maternity services, however, proposals are for a blended payment methodology across almost all secondary healthcare services.[11] In general, this would be a welcome development of DHTs, given the often system-wide approach needed to the adoption of such technologies.

Commissioning for Quality and Innovation (CQUIN) and best practice tariffs would continue to incentivise care quality. The proposals would bring an end to the use of national prices as specified in tariff and replace it with a set of pricing rules.

It should be noted that current proposals suggest a threshold of £10million before the use of a blended model is required.

Use of Blended Payments for Digital Health

	Overview	Digital Health Application
Fixed Payment	Locally determined and set at a level to cover ICS activity plans. This should include funding for new ways of delivering services, but exclude activity undertaken using the elective framework agreement.	This should ensure appropriate funding for the necessary IT infrastructure and provide routine funding for, and incentivise use of, digital technology and pathways.
Variable	Centrally-designed default arrangements that could be locally modified. Could be used to: incentivise elective activity; allow funding to follow the patient; mitigate financial risks of activity above or below plan; provide incentives to collectively manage demand.	This could be used to support specific initiatives aligned to demand management and elective activity such as population management or virtual wards.
Financial Incentives	Incentives for commissioners and providers for quality improvements and transformation that deliver improved patient experience, clinical quality and safety goals - particularly those objectives in the NHS Long Term Plan.	Support specific projects such as primary care digital transformation, population health management and system 'exemplar' projects.

In future developments of the national payment system, two areas are highlighted that may have relevance for DHTs.

- Enhancing data infrastructure and exploring ways to use existing data in innovative ways.
- Exploring approaches to calculating the fixed payment, such as pathway or year of care approaches for certain patient groups.

This should primarily be used to reimburse provider activity. HRG/OPCS codes should be introduced for digitally-enabled pathways to ensure accurate capture of the cost based and value delivery of data and digital technologies. This can highlight activities that can be performed more effectively or efficiently through use of digitised pathways and ensure there is appropriate funding in the system. These codes specific to digital health will also allow monitoring of the adoption and use of digitally enhanced procedures and interventions across the NHS, driving opportunities for levelling-up care across regions and enriching the NHS data landscape.

For innovate or disruptive technologies that could create financial anomalies consideration could be given to creation on specific technology payments (similar to the current High Cost Device and Drug lists), access to these would be via NICE assessment.

Drug Tariff

This would be direct reimbursement for the technology. With increased emphasis on self-care and care at home it is important that patients have access to technologies that can support management of their conditions. It is recommended that certain categories of "Apps" are made available on prescription to support ensure patients can easily access relevant support tools. Criteria for inclusion is as follows:

- Designed for direct patient use (or assisted by carer/ HCP).
- Passed DTAC assessment.
- Passes NHS Business Services Authority criteria: products are safe and of good quality; appropriate for GP and, if relevant, non-medical prescribing; are cost effective[12], or where appropriate, apps that have been evaluated by NICE.

The existing digital pathways and NHS App Store could be developed to provide an appropriate 'dispensing' mechanism. Exact mechanism differ slightly between nations but overall principles above, based on English mechanisms, could be transposed.

Drug Tariff is a national pricing scheme and has established processes for price setting, which could be adapted for DHTs. There are also existing mechanisms to manage prescribing budgets which can apply irrespective of technology type. There may be a requirement for additional support to ensure relevant expertise is available.

National/Regional Funding

A regional fund, similar in concept to the funding of companion diagnostics, available to ICS for payment of specific DHT to pay for activity costs where it is not covered within national payment scheme. This would have specific application to bridge the gap between awards and grants and inclusion in the mainstream where there is a time lag in process (for example to gather cost data) but when there is sufficient evidence for the system to recommend a product.

Payment with Evidence Development

These mechanisms should apply to DHTs where there is a high level of unmet need, but when there remain important uncertainties about clinical and cost-effectiveness[13]. If the manufacturer cannot immediately prove the benefit, but there is initial evidence to show benefit, funding should be made available on a time limited basis - minimum 12 months - but with the option for the commissioner to extend this if benefits have not been evidence sufficient, but progress has reinforced the initial promise. This aligns to the ABHI Accelerated Transitional Adoption Scheme (ATAS) proposals and work by NICE on contingent reimbursement.

Managed Access Schemes (MAS)

This would constitute an agreement between commissioner and manufacturer of new technologies to enable new interventions that have uncertainty over their cost effectiveness as assessed by NICE, to become available for a limited time period at a discounted price. MAS proposals will include an agreed rationale and duration for the arrangement, populations covered (in particular where they come in the care pathway), clear criteria for starting and stopping the new intervention, definition of outcomes, methods of data collection and frequency of reporting, together with the commercial proposition, financial risk management plans and an understanding of what will happen if reimbursement is eventually withdrawn[14]. This could also support introduction of technologies where there is uncertainty in outcomes given variation in the implementation of the technology in a given pathway, setting or geography.

Per Capita Payments

Many DHTs offer opportunity for prediction/prevention of disease or disease exacerbation. Use of a per capita arrangement offers the opportunity to incentivise the use of such digitally enhanced interventions that can not rely on outcomes as a measure of success, but can reduce overall cost of management of a patient cohort.

Grants and Awards

AI Awards are a good template for this approach, having different awards and approaches based on the maturity of the technology and evidence based. We would recommend that, given the "market ready" nature of the technology, the funding aspects of the phase 4 awards could be transitioned to other mechanisms outlined above, and non-financial elements could remain.

ASSESSMENT

This section addresses schemes associated with DHTs and not the assessment of clinical interventions or service delivery. Current processes in the UK are:

- MDD/UKCA.
- DTAC.
- NICE Medical technologies Evaluation Programme (MTEP) and Diagnostics Assessment Programme (DAP).
- Drug Tariff.
- Procurement.
- Ad-hoc linked to grants and awards.

The first two of these are 'baseline' requirements that are needed by all technologies and are focused on safety and efficacy, making no assessment value.

NICE is the predominant organisation for Health Technology Assessment in the UK. It has successfully completed a first assessment of a DHT under the MTEP programme via a pilot project which paves the way for further reviews of DHTs. Further assessments have been made under the DAP programme. They are focusing on digital technologies with the highest clinical, financial and/or operational risk as defined in Tier C of the Evidence Standards Framework[15].

Whilst positive NICE guidance sends a strong signal to the system about the value of a product, there are few direct links to reimbursement. The Technology Appraisal programme has a legal requirement that approved products are made available, and whilst technically it is open to medical devices, and hence some DHTs, in reality the capacity is fully utilised by drug appraisals.

Assessment methodologies need to be able to address both cost effectiveness and cost saving approaches and be flexible enough cater for a range of appropriate endpoints, for example, prevention.

The MedTech Funding mandate is a further route that directly links positive NICE guidance to a funding decision, however (in its current incarnation) it has a number of further financial barriers[16]:

- **Deliver material savings to the NHS**: the benefits of the innovation are over £1 million over five years for the population of England;
- **Are cost-saving in-year:** NICE modelling demonstrates a net saving in the first 12 months of implementing the technology;
- **Are affordable to the NHS**: the budget impact should not exceed £20 million, in any of the first three years.

Other processes such as those linked to procurement, grants and awards are variable between individual instances and hence not standardised, possibly placing additional administrative and evidential burden on companies. General principles that should apply are:

- Appropriate timelines.
- Early and consistent engagement with the manufacturer.
- Clear feedback.

Whilst different criteria may be required, depending on specific reimbursement mechanisms, we would recommend the following:

- There is alignment and non-duplication of criteria with base processes such as UKCA and DTAC.
- Criteria builds on these base processes as appropriate based on risk profile.
- Criteria and evidence requirements are transparent and specific.
- For 'market-ready products' there should be no cap on numbers eligible/awarded for reimbursement provided they meet criteria.
- Criteria should support innovation and development of a dynamic market.
- Financial criteria should be based on value/cost effectiveness not on affordability (this to be determined at local adoption level).
- The necessary capacity is made available within NICE for DHT assessment.

PRICING AND PROCUREMENT

We recommended that pricing and procurement are seen as two separate, but linked, steps. As previously outlined, the diversity of DHTs make it difficult to adopt a "one size fits all" process. There are several complexities that need to be considered when determining the best procurement route. Implementations of DHTs can be location specific with varying support, components and configurations depending on specific needs, covering areas such as infrastructure, consultancies/data analytics, licences and revenue. This will require at least an element of a localised approach to procurement, conversely, products within some categories of DHTs will be standardised and could lend themselves to national pricing, for example apps via the Drug Tariff.

Given the nature of the DHT sector we would recommend that Dynamic Purchasing Systems (DPS) are given wide consideration, as these have several advantages for both suppliers and purchasers[17] that are appropriate to a fast moving, innovative sector. This would build on existing mechanisms such as the Spark Dynamic Purchasing System (DPS), and a number of existing frameworks run by NHSX, as well as initiatives run by regional organisations such as the app framework from the London Procurement Partnership.

Criteria (and evidence) for procurement should not duplicate previous regulatory or assessment processes. If a formal economic assessment has provided a positive recommendation then the pricing utilised within that model should be the basis for procurement.

A voluntary scheme (VPAS)/Pharmaceutical Pricing Regulation Scheme (PPRS) type scheme has been suggested as a national pricing mechanism for DHTs, but due to the characteristics of the technologies described above, as well as different sector dynamics, this may have limited application. Additionally, the current format of the VPAS scheme relies on the existence of two distinct sectors "branded" and "generic", such a distinction does not exist within DHTs. The scheme also relies on all new medicines and significant indications being routinely appraised by NICE[18] which could have significant practical implications if applied to all DHTs, similarly for the commercial negotiations undertaken by NHSE.

APPENDIX 1: INTERNATIONAL BEST PRACTICE

Belgium

The Belgian system has established a reimbursement pathway for "mHealth" applications i.e. mobile software applications (native app or webapp) that are either actively used by the patients for their health monitoring, or that are used for tele-monitoring services where medical devices are connected to patients. The National Institute for Health and Disability Insurance (NIHDI), the responsible authority in Belgium for healthcare reimbursement, has created a three tier (M1 – M3) system for categorising products.

To qualify for reimbursement, the app first needs to pass the M1 (mainly being CE certified as a medical device) and M2 (meet all imposed ICT criteria regarding data privacy, authentication, identification as well as therapeutic relationship and informed consent) levels, and then to achieve M3, and the associated reimbursement, a dossier needs to be submitted showing the clinical and/or socio-economic value. Value is to be considered holistically, including the benefit for society and to healthcare savings in other healthcare settings other than where the cost is generated.

France

In France, the authority for the reimbursement of medical devices is the Haute Autorité de Santé (HAS). HAS maintains a list of products and services qualifying for reimbursement (LPPR, Liste des Produits et Prestations Remboursables), and has recently added "connected medical devices (CMDs)" and Artificial Intelligence[19] in its scope. The process of enlisting a health app in the LPPR is similar to the pathway for implantable devices, invasive non-implantable devices, and medical aids, and requires a very good level of evidence.

Inclusion on the LPPR is based on the available evidence by the Medical Device and Health Technology Evaluation Committee (CNEDiMTS) against the following criteria[20]:

- Actual clinical benefit.
- Clinical added value.
- Intended role in the therapeutic strategy for a given disease.
- Indications and usage (treatment duration, frequency, proper use).
- Target population (estimated number of patients affected by the therapeutic indications).

Severity of the disease, efficacy, adverse effects, intended role in the therapeutic strategy in comparison to other available therapies, as well as public health benefits, are also taken into account. Clinical added value is further assessed considering comparative efficacy and safety data versus alternative solutions. There are five levels of clinical added value which will impact the reimbursement tariff: I major, II important, III moderate, IV minor, V no improvement.

In August 2020, an app for the telemonitoring of recovered lung cancer patients became the first reimbursed health app listed in LPRR, and a specific sub-section, "Web application and software intended for remote monitoring", was created. Eligibility can only be determined by a specialist (oncologist, pulmonologist, or surgeon).

If clinical evidence to justify inclusion in the LPPR is not sufficient, then non-DHT specific programmes (e.g. Hospital Clinical Research Program PHRC, Health Economic Research Program PRME) could be an alternative to obtain reimbursement while developing evidence. After annual national and regional calls for proposals, lump sums are delivered to cover a limited period; funded by an agency dedicated to public interest. There are different examples of projects focusing on the use of health apps, which have been funded in past years.[21]

In addition to the centralised pathway of LPPR listing, some health apps can also be reimbursed via the experimental programme for telemonitoring "ETAPES" (Expérimentation de Télémédecine pour l'Amélioration des Parcours en Santé). The ETAPES programme will end in December 2021 and its continuation is not guaranteed. The programme covers five clinical fields: heart failure, kidney failure, respiratory failure, diabetes, and implantable cardiac devices. The funding provided through ETAPES includes three components:

- Payment for the physician performing tele-monitoring.
- Payment for the healthcare professional providing the therapeutic support to the patient being monitored remotely.
- Payment to the provider of a technical solution for tele-monitoring. The tele-monitoring solution could include a connected medical device, health app, digital platform, or a combination of all the above mentioned.

Germany

In December 2019, the Digital Healthcare Act (Digitale Versorgung Gesetz or DVG) came into force in Germany. This law allows for the reimbursement of various digital healthcare, including apps. It has defined the pathway for the statutory introduction of health apps as medical devices and the process to apply for the reimbursement by manufacturers. The process only applies to lower risk devices class I or IIa (according to the MDR).

Prerequisite for the above is that a DiGA must have successfully completed the assessment of the German Federal Institute for Drugs and Medical Devices (BfArM) leading to a listing in a directory of reimbursable digital health applications (DiGA directory). The essence of this assessment is the examination of the manufacturer's statements about the product qualities - from data protection to interoperability and user friendliness - and an examination of the evidence of the positive healthcare effect of the DiGA provided by the manufacturer.

As well as positive medical benefits DiGAs are required to show improvements in structures and processes that are relevant for the patient. The BfArM guidance lists specifically the areas of:

- Coordination of treatment procedures.
- Alignment of treatment with guidelines and recognised standards.
- Adherence.
- Facilitating access to care.
- Patient safety.
- Health literacy.
- Patient autonomy.
- Coping with illness-related difficulties in everyday life.
- Reduction of therapy-related efforts and strains for patients and their relatives.

BfArM makes a coverage decision within three months after receiving the application. If criteria for inclusion are met, the health app is permanently included in the Directory and can be prescribed and reimbursement by statutory health insurances.

If the manufacturer cannot immediately prove the benefit, but the method seems promising and has the potential to prove the associated benefits, a testing trial for 12 months with a temporary listing in the Directory can be activated on application from the manufacturer (Fast-Track procedure). If the evidence after 12 months is still not sufficient, the manufacturer can prolong the trial period for a maximum of additional 12 months.

If the health app is added to the Directory, the manufacturer sets the price for the first 12 months. After that period, the manufacturer negotiates the reimbursement tariff with the federal association of statutory health insurance funds (GKV SV).

United States

In the U.S., digital health is considered a broad scope of services, defined by the Food and Drug Administration (FDA) in categories such as mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalised medicine.

In light of the COVID-19 crisis, US regulatory agencies and Congress have pulled out a majority, if not all, of the obstacles for covering and reimbursing digital health or telemedicine visits, at least until the end of the declared public health emergency. Industry stakeholders are optimistic that policy makers will keep these flexibilities in place after the pandemic ends.

There are a few digital health reimbursement models in the US today and commercial plans have historically been more nimble in or providing access to digital services. Health plans like Kaiser Permanente have created "Digital Centers of Excellence" to understand how they can standardise the way they evaluate, integrate, and pay for digital services. Some health insurers have rolled-out programmes to support self-insured employers and their own members. Earlier this year, UnitedHealth unveiled Level2, a digital health programme for patients with type 2 diabetes. It uses wearable devices and coaches to help users manage their health. Blue Shield of California developed a Wellvolution program that harnesses digital health tools. The Prescription Digital Therapeutics to Support Recovery Act is a bill to change the Social Security Act to support digital therapeutics. Whilst it focuses on mental health and substance abuse, it could provide a precedent for how to approach reimbursement for digital therapeutics more broadly.[22]

However, in 2018, the Center for Medicare and Medicaid Services (CMS), the agency within the U.S. Department of Health and Human Services (HHS) that administers the nation's major healthcare programmes, created a payment pathway for onboarding and patient education, device supply, patient monitoring and management of the patient condition. This clinical service that uses technology to enable monitoring of patients' physiologic data outside of conventional clinical settings is currently identified as remote physiologic monitoring (RPM).

The 21st Century Care Act has continued to drive an evolution of CMS in last 1-2 years and continues to see new payment models looking at value[23]. In March 2021, the government broadened the array of services and codes that are reimbursed and structured them so these services are reimbursed at the same rate as they would be in a face-to-face encounter as opposed to a reduced amount.[24]

Policy makers will need to modernise the statutory and regulatory rules that govern how products and services are made available to Medicare beneficiaries, including coverage and reimbursement policies based upon the functional outcome of the care - and viewing digital components as integral to all modes of care. A renewed and revitalised look at modernising public and private healthcare programmes can inevitably lead to increased access to care, quality, and appropriate cost for beneficiaries with the evolution of digital health coverage.

The rate at which telehealth visits are reimbursed, and the determination of which services count as "telehealth," remain in the combined hands of state legislatures, government agencies, and insurance companies.

APPENDIX 2: EXISTING UK REIMBURSEMENT MECHANISMS

There are a number of existing funding and reimbursement systems. The national tariff payment system is used to fund acute activity and direct funding of a limited number of medical devices and diagnostics. Drug Tariff is used to support payment of prescription drugs and devices for use in the community setting.

In addition to these there are a range of awards, competitions and funding rounds that provide direct funding to certain types, often on a time limited ,and number constrained basis. The following existing UK reimbursement schemes have been investigated to assess their applicability to DHTs:

Scheme	Outline	Positives	Negatives	Possible Application for DHTs
National tariff payment system	Payment system used by commissioners and providers of secondary healthcare. It sets the prices and rules that commissioners use to pay providers for services; in many cases, this is a price paid for each patient seen or treated.	› Best Practice Tariff can incentivise targeted practices. › Covers wide range of activities and spend. › Prices reflect efficient costs, giving providers incentives to reduce unit costs and find ways of working more efficiently. › Flexible system.	› Limited opportunity to directly reimburse technology. › Long refresh cycle so pricing cannot react to new innovations. › Does not cover capital budget. › "Buy and Own' models do not necessarily suit DHTs.	Could be used for a range of digital interventions within the acute setting.
Drug Tariff listing	Defines the terms of reimbursement for contractors, the price of drugs and devices, and determines what medical devices are allowable for reimbursement against NHS prescriptions.	› Relatively fast listing process.	› Currently only for CE marked products (i.e. only those that classify as a medical device or Software as a Medical Device (SaMD).	Could be used for 'Apps" that are used directly by patients under HCP supervision.

ITP products	A competitive process for innovations and technologies that have already proved their clinical effectiveness and are ready to be rolled out nationally.	› Adoption support via AAC and AHSNs.	› Competitive process. › Time limited.	› For "breakthrough" type products.
AI Awards	Tiered approach to support AI innovators and technologies from concept development: through to initial NHS adoption and testing within clinical pathways.	› Different awards to cover range of technology maturity. › "Digital" specific.	› Competitive process. › Time limited.	› For products at pre-market stage with uncertainties in both clinical efficacy and financial risk.
MedTech Funding Mandate	Support affordable medical devices that have positive NICE guidance and deliver material savings with benefits >£1m over 5yrs with in-year cost-saving.	› Strong central "comply or explain" regime. › Regional support via AHSNs.	› Stringent financial constraints. › Resource constrained. › High evidence requirements.	
AAC/RUP	Designed to support adoption and spread of proven innovations with NICE approval and aligned to NHS Long Term Plan's key clinical priorities.	› Specific and tailored product support. › Access to AHSN support.	› No direct link to reimbursement. › Competitive process.	Limited. Possibly for a few high impact interventions that can display uniqueness and meet other standard criteria.
Cancer Drug Fund	Funding, via managed access arrangement, whilst further evidence is collected to address clinical uncertainty.	› Specific for a type of technology and indication.	› Additional NHS cost pressures. › Likely to need high evidence requirements.	› Limited. Possibly for a few high impact interventions where evidence is promising, but needs further validation.

QOF/GP enhanced service specifications	A reward and incentive programme for GP practices for the quality of patient care. Helps standardise improvements in the delivery of primary care.	› Direct impact on GP finances. › Can be highly targeted. › Can be changed annually.	› Assessments of its success are mixed.	› Could be used to incentivise pathway change in primary care.
Companion diagnostics	Regional specialised commissioning hubs pay for any activity costs.	› Local Flexibilities.	› Budget capped.	

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Association of British HealthTech Industries
Suite 2, 4th Floor, 1 Duchess St,
London, W1W 6AN

+44 (0)20 7960 4360
enquiries@abhi.org.uk
www.abhi.org.uk
@UK_ABHI

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