World Health Organization
European Region

Data and digital health policy brief series

Building financing pathways for digital health technologies in the WHO European Region

Executive summary

Digital health technologies (DHTs) can bring a variety of benefits in improving access to quality health services, enhancing the efficiency and sustainability of health systems, and empowering individuals to make informed choices about their health and well-being. Although the evidence and implementation experience supporting DHTs have expanded considerably, many Member States in the WHO European Region still encounter significant fiscal challenges that limit their adoption of DHTs. These include a lack of policies to guide the design of DHT financing mechanisms that determine how coverage decisions are made and payment arrangements are effected. This policy brief analyses digital health financing through two interrelated functions: coverage policy and payment arrangements. It examines options for the national financing of DHTs and summarizes recent findings about how countries are approaching the question of payment for DHT use. It also highlights the underlying need to align DHT classification and for evidence standards to facilitate the effective assessment of their value in disease prevention and care delivery. Evidence is presented based on recent findings from scoping reviews and policy analyses of recent peer-reviewed academic literature on the financing pathways of countries in the Region.

Main findings

Robust health financing frameworks for digital health require a clear and common taxonomy, as well as national evidence standards that distinguish between DHTs applied in the health sector and those used within well-being contexts. DHTs in the health sector could be further differentiated based on functionality (e.g. providing administrative or infrastructural support, facilitating communication, or providing disease diagnosis, management or treatment).

Payment arrangements should ensure rate parity, meaning that digital health services with comparable quality, safety and clinical effectiveness are reimbursed at similar rates to their in-person counterparts.

Countries still lack consistent and tailored health technology assessment (HTA) frameworks for DHT, and existing evidence requirements often do not match the specific features of DHTs. As a result, integration into publicly financed benefits packages remains limited, leading to inequitable access across socioeconomic groups. Expanding coverage would require DHT-adjusted assessment approaches that consider safety, clinical effectiveness, cost–effectiveness and budget impact.

Currently, most payment arrangements follow a fee-for-service model that links provider compensation to service volume or to the rate of DHT utilization. However, this risks inducing a demand for services that bring limited clinical value. Over time, digital health tools may also be included in payments for broader service bundles or care pathways.

Outcome-based payment arrangements offer an alternative approach. However, they may entail higher administrative complexity, and current evidence on their cost–effectiveness and impact on clinical outcomes remains limited. Payment arrangements should also consider broader clinical and social outcomes, such as the speed of a patient's return to work or school and the mitigation of financial hardship.

Innovation funds and grants are important instruments that enable the piloting of new DHTs – by helping to demonstrate their value and build trust in their use – while reducing the financial risks for both patients and health professionals.

Financing policies can incentivize the adoption of DHTs through equitable and flexible payment arrangements (including capitation, bundled payments and value-based models) that better align incentives with system objectives such as quality, efficiency, access and population health.

Policy considerations

Drawing on insights from scoping reviews, policy analyses of recent peer-reviewed academic literature and country experiences, this brief presents six strategic policy actions that aim to accelerate the reform of financing for DHT adoption and use.

- **Apply a functional classification to DHTs according to their intended use.** For financing strategies to operate effectively, DHTs must first be categorized based on their role and point of application within the health system and care pathway.
- **Adapt policy and HTA frameworks for DHTs.** Health technologies are evolving rapidly, and HTA processes must reflect the unique characteristics and functions of digital health solutions in operation across diverse care settings. Developing and implementing regulatory and assessment procedures tailored to digital health is essential. HTA frameworks should be updated and refined through co-creation with key stakeholders to ensure that they remain responsive to the specific needs and contexts of digital health innovation while also providing value to patients.
- **Adapt evidence standards for DHTs.** DHTs differ fundamentally from pharmaceuticals and other medical devices. Countries should establish differentiated evidence tiers to reflect these distinctions, while ensuring that evidence requirements are proportionate to the type and intended use of each digital health intervention.
- **Evaluate DHTs and strengthen data collection to assess their impact.** Limited evidence exists on the outcomes and effectiveness of DHTs implemented in health systems in the WHO European Region. Without more evidence, it is not possible to gain a sufficient understanding of which DHTs are fit for purpose and deliver the value expected.
- **Embed digital health into publicly financed benefits packages.** This should occur only after technologies have undergone an appropriate assessment and met the criteria for public coverage, including demonstrated safety, clinical effectiveness, cost–effectiveness, acceptable budget impact and any additional country-specific requirements. Such assessments would enable DHTs to be integrated into prevention and care and, thus, become embedded within standard treatment pathways rather than remaining as optional add-ons.
- **Consider how approved DHTs can be integrated into existing payment arrangements.** Countries should assess how DHTs that meet the criteria for public coverage can be best aligned with the current financing and payment arrangements, while recognizing that no single model fits all contexts. Although outcome-based payment models may represent an important longer-term ambition, they are often difficult to operationalize at scale. Therefore, the immediate priorities should be to ensure that payment arrangements align with current system capacity, policy goals and the national context for health service delivery.

Introduction

The coronavirus disease (COVID-19) pandemic accelerated digital transformation of the health-care sector by providing an opportunity to leverage digital health solutions to prevent, manage or treat disease *(1)*. WHO recognizes digital health as the field of knowledge and practice associated with the development and use of digital technologies to improve health and strengthen care-delivery systems. Digital health expands the concept of e-health to include digital consumers using a wider range of smart devices and connected equipment. Digital health technologies (DHTs) refer to the use of digital information- and communication-technologies to support health services, health information systems and more broadly health system functions *(2)*. Digital therapeutics are a subcategory of DHTs comprising clinically validated, evidence-informed software interventions that are delivered directly to patients with the explicit aim of preventing, managing, or treating a disease or disorder *(3)*. Beyond digital therapeutics, other DHTs that support care, engagement or decision-making do not constitute therapeutic interventions. The following areas are commonly understood as being part of or related to digital health: machine learning, artificial intelligence, big data, health data, health information systems, digital therapeutics and telemedicine. In practice, digital health encompasses a range of services, including online consultations with medical professionals *(4)*, the use of mobile applications and games *(5)*, real-time updates of algorithms based on patient data, and patient portals (through which patients can engage with their electronic health data *(6)*. Furthermore, recent studies have indicated that combining medication with DHTs for treatment and disease management can lead to improved outcomes for a variety of chronic conditions, such as type 2 diabetes, cardiovascular diseases, and psychiatric and mental health conditions *(7,8)*. DHTs also hold the potential to bring about major improvements in the efficiency of health systems, in terms of both care provision and the administration of the system as a whole *(1,4)*. However, realizing this potential has proven to be a complex process, with mixed and, often, unsustained results *(4,9)*. A key factor influencing the sustained adoption and use of DHTs is the existence of appropriate financing mechanisms.

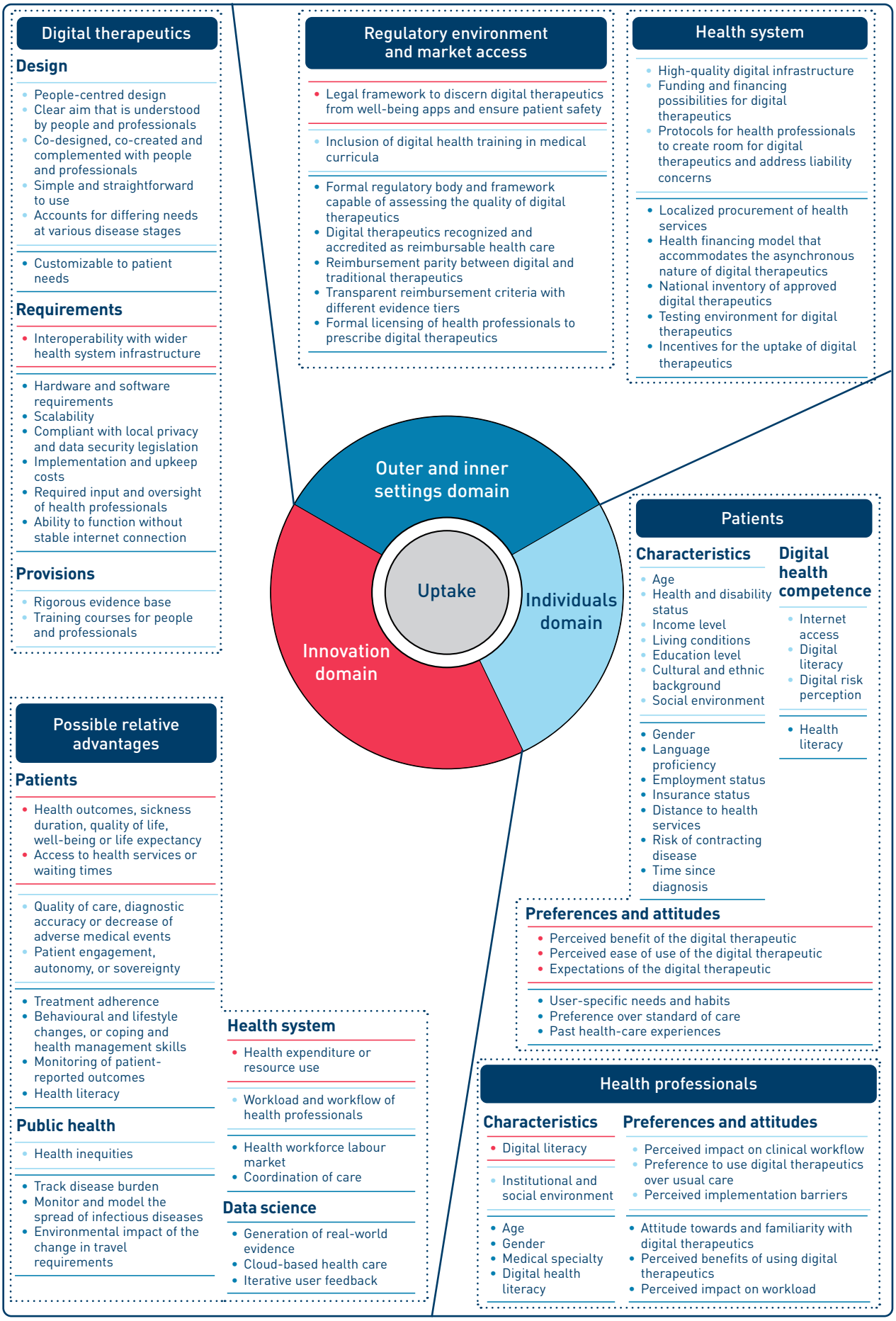
In the context of this policy brief, DHT financing refers to the mechanisms through which public resources are allocated to support the integration of DHTs into health systems. This encompasses two functions of health financing: (i) coverage policy is the process by which decisions are made about whether and how DHTs are included in the publicly financed benefits package; and (ii) payment arrangements are the ways in which funds are transferred to providers or developers, including the choice of payment methods and incentives that influence provider behaviour. Together, these functions determine how DHTs are prioritized, paid for and sustained within health systems.

The following sections explore the interlinked health-financing functions of coverage policy and payment arrangements as they relate to DHTs.

Key factors influencing the sustained adoption and use of DHTs

DHTs need clear pathways to financing so that the incentives for their use are appropriate, equitable and clinically meaningful. The uptake of DHTs within health systems is contingent on addressing a broad spectrum of factors, including health system and policy factors, individual characteristics and preferences, and the design and provision of patient-facing DHTs. Uptake factors for digital technologies were extracted from a scoping review that identified their frequency in the examined literature *(1)*. Fig. 1 offers a comprehensive overview of technical and human-centric perspectives and provides specific digital health-related action points for consideration when implementing DHTs in the health system. One of the key action points involves the development and implementation of payment arrangements for digital health. A recent review of eight countries in the WHO European Region found that these countries have been pursuing heterogeneous approaches to payment for DHTs and called for a clearer understanding of digital health payment and its accompanying incentives *(10)*.

Fig. 1. Factors that can affect the uptake of patient-facing DHTs in health systems



Note: in the articles synthesized in the original review, items in red were very frequently stated, items in light blue were frequently stated and items in dark blue were infrequently stated.

Source: van Kessel et al. *(1)*.

Objectives

This policy brief provides evidence-informed considerations for financing strategies as part of a comprehensive approach to the digital transformation of health systems in the WHO European Region by:

highlighting the importance of financing strategies in enhancing the uptake of DHTs;

synthesizing recent learnings on DHT financing and payment gained from published literature and policy dialogues; and

proposing actions that countries can consider when choosing suitable financing strategies for DHTs to ensure that their use delivers maximum value to health systems and patients in line with the principles of universal health coverage.

Coverage policy for DHTs

Current financing landscape for digital health

DHTs can be funded through various sources, including out-of-pocket payments by individuals, the publicly financed system, private insurance, and donor funds and grants. These funding streams influence the extent to which digital solutions are included in publicly financed benefits packages and, consequently, the level of out-of-pocket payments and equity of access across population groups.

Within publicly financed systems, different payment arrangements may apply. These include fee for service, case-based payments, bundled or pathway-based payments, capitation, and global budgets. All of these payment arrangements can be structured to compensate providers or developers for delivering digital services.

Integration of DHTs into publicly financed benefits packages

It is crucial to integrate appropriate digital health tools into publicly financed benefits packages to ensure accessibility across all socioeconomic layers, preventing exclusivity to those able to pay *(1)*. Without such integration, DHT adoption may be driven by individuals and organizations with greater financial means, thereby widening existing health inequities and limiting the public health impact of DHTs. Embedding digital health into public coverage can help to integrate DHT use into routine care, thus making them part of standard treatment pathways rather than optional add-ons. Funding should also be available from private organizations, patient associations and nongovernmental organizations to serve as a strategy for early implementation phases, supporting pilot projects and enabling access for populations who might otherwise be left out *(10)*.

Classification and regulatory alignment for coverage decisions regarding DHTs

Regulatory procedures must be tailored to the unique characteristics of DHTs, especially when planning to develop robust and sustainable financing for digital health *(11,12)*. A move towards the horizontal integration of services is needed *(13)*. This requires a coordinated regulatory and health technology assessment (HTA) policy response; one example is the Belgian mHealth validation pyramid for assessing whether a digital medical device is eligible for coverage *(14)*. Such a coordinated regulatory and HTA policy response should involve updating and developing policies that foster and encourage technological innovations while providing a common terminology for digital health, establishing evidence standards for assessing DHTs, and developing a framework that recognizes how DHTs can generate value both clinically and outside the clinical context. Regulators need to engage stakeholders to understand and address their concerns during this process *(15)*.

Policy frameworks for digital health are needed to differentiate DHTs from medical devices, pharmaceuticals, or commercial lifestyle and well-being applications *(1,10)*. Similarly, it is important to clarify that DHTs can target different parts of the health system. According to WHO's 2023 *Classification of digital interventions, services and applications in health*, DHTs can be classified into four broad categories *(16)*:

- DHTs for people, i.e. members of the public who are potential or current users of health services, including health prevention and wellness activities – this category broadly corresponds to patient- or client-facing DHTs;
- DHTs for health-care providers, i.e. members of the health workforce who deliver health interventions (also referred to as health workers or health-care workers);
- DHTs for health management and support personnel, i.e. individuals involved in the administration and oversight of health systems, including functions related to supply chain management, health system financial management and human resource management; and

- DHTs for data services, i.e. cross-cutting functions to support a wide range of activities related to data management and use and data governance compliance.

Within each category, DHTs vary widely depending on data, interfaces and integration with the broader health system. The categories are not necessarily mutually exclusive and any DHT can cover more than one category. This classification further divides each of the four categories into between four and 11 subcategories to better capture the diversity of functions and use cases. Some countries have taken an even more granular approach to guide policy and payment decisions. For example, in England (United Kingdom) the National Institute for Health and Care Excellence (NICE) classifies digital health tools according to three evidence tiers: system impact, understanding and communicating, and interventions. Within each tier, a different level of evidence is required to be considered for coverage *(17)*.

Adapting evidence and HTA frameworks to digital health

Establishing different evidence tiers is considered vital to distinguish digital therapeutics from other types of digital health applications *(1)*. This approach further recognizes that there are a vast range of DHTs and they should not all be considered equal for evaluation purposes. For example, it is obvious that DHTs that address administrative or managerial tasks should not be required to provide evidence of clinical or therapeutic effectiveness. In contrast, patient-facing digital therapeutics must be evaluated by clinical effectiveness *(1,15)*. An operational example of such a distinction can be found in the NICE *Evidence standards framework for digital health technologies (17)*.

Specific consideration of what evidence is appropriate may be needed to meet the necessary standards of evidence, in particular those involving real-world evidence or real-world comparisons *(18)*. For example, the German Digital Health Act sets out the evidence requirements for coverage and payment for patient-facing digital health applications *(19)*. It involves a grouping based on the disease coding (10th revision of the International Classification of Diseases *(20)*), population group targeted by the digital health application, functionalities of the digital health application (e.g. documentation, information, prevention prediction, examination of process, detection, monitoring and treatment) and end user *(21)*. This classification system categorizes the required evidence in terms of study design, control groups and end-point measures. Building on the European network for HTA's core model *(21)*, the system also considers other value dimensions (e.g. organizational, social/ethical, other positive health effects and economic aspects).

Although randomized controlled trials are recognized as the gold standard for research in proving effectiveness, their application to DHTs introduces complexities such as long timelines, difficulties in measuring personalized care delivery, and the development of suitable placebos, which may be difficult or impossible. Widespread data collection, the use of remote monitoring and reliance on real-world evidence pose challenges and emphasize the need to address gaps in the regulatory requirements *(15)*. Software undergoes a continual iteration process that differs from the usual processes designed for medical devices *(13)*. Moreover, there is no clear process for monitoring adverse events. Without a process for defining efficacy and safety, both the public and the providers struggle to navigate the growing landscape of apps and online therapies *(13)*.

When considering DHT inclusion in publicly financed benefits packages, countries must also evaluate the cost–effectiveness and budget impact because such economic considerations are essential components of coverage policy and are highly context specific. These combined facts highlight the need for HTA frameworks to evolve to meet the design and operational contexts in which DHTs are used *(15)*. The absence of specific guidance on evidence assessment for DHTs adds a layer of complexity that hinders innovators' understanding of the evidentiary requirements and impedes the pace of digital innovation.

Establishing a standardized HTA framework for DHTs also necessitates collaboration between state regulatory agencies and clinical stakeholders. Collaborations, especially those between medicine regulators and device bodies, are crucial for establishing joint or parallel advisory bodies. Accordingly, the European Commission's Pharmaceutical Strategy for Europe (2020) *(22)* recognizes the need for increased collaboration between regulatory bodies *(11,15,21)*.

Whereas coverage policy defines which DHTs are included in publicly financed benefits packages, payment arrangements determine how they are compensated and what incentives influence their use. The next section explores how different countries are designing payment arrangements that promote innovation, efficiency and quality of care.

Payment arrangements for DHTs

Current payment arrangements for DHTs

Once a DHT has been approved for public coverage, the primary financing priority is to integrate it into existing payment arrangements in a way that reflects its functional characteristics and supports its appropriate use. Depending on the country context, this may include fee for service, case-based payments, bundled or pathway-based payments, capitation, and global budgets. Well-designed payment arrangements can create incentives that facilitate the appropriate uptake of DHTs and align with system objectives such as quality, efficiency, access and population health. Historically, payment and financing approaches based on activity have been easy to develop and implement and have created incentives for health-care providers to increase the access to and use of a range of health-care services *(23)*. Appropriate integration ensures that digital tools complement care pathways, align incentives with quality and efficiency, and facilitate wider uptake where clinically and socially desirable. Payment parity (i.e. ensuring equal compensation for similar services, regardless of delivery mode) is considered a key component of digital health payment arrangements *(10)*. Examples of countries with parity systems are Belgium, Israel and Italy *(10)*.

Focusing on the technology rather than the outcome risks inducing a demand for services that bring limited clinical value *(24)*. DHTs have the potential to reduce health-care costs relative to in-person services but, equally, can inflate health-care spending if poorly implemented. However, this depends on the payment arrangements applied and whether DHTs serve as a complement or substitute for in-person care *(10)*. An increasing cost for DHTs based on payment by activity could lead to a scenario where the return on investment is negligible. Additionally, there are examples where DHT use is counterproductive in terms of increasing the workload of health-care personnel, thereby exacerbating a critical situation *(25)*.

Outcome-based and value-based payment arrangements

Evidence is limited for outcome-based payment arrangements in terms of clinical outcomes or cost savings *(26)*, partly because there is large variability in how the concept is defined and a common conceptualization of the term is lacking *(27)*. Although formal outcome-based payment arrangements for DHTs remain uncommon, several countries are experimenting with approaches that link funding to demonstrated benefits. These examples illustrate potential adaptations rather than established practice and highlight both the opportunities and implementation challenges that such schemes entail. Evidence is lacking on outcomes in terms of patient-reported outcomes in value-based health care *(28)*. Additionally, outcome-based care adds a level of complexity and administrative overhead for payment agencies because it requires the collection of additional data and evidence that are not intrinsically generated as part of the care process. This aspect needs to be taken into account when designing financing and payment arrangements *(27)*.

Beyond direct health outcomes, other metrics could be taken into account (e.g. patient satisfaction and treatment adherence) when considering financing and payment arrangements *(18)*. Since some DHTs can enable patients to reintegrate into society earlier (e.g. return to education or employment) or reduce socioeconomic inequities, non-clinical outcomes could also be integrated into value-based pricing arrangements *(29)*.

Germany has established a specific value-based pricing and payment arrangement for digital health applications based on health outcome dimensions, other positive health effects and economic benefits *(15)*. Specifically, Germany's Digital Health Care Act proposes a hybrid approach between price anchoring and outcome-based payment *(19,30)*. Similarly, NICE has instituted value assessment

guidelines for local purchasers to aid decision-making on payment within integrated care systems *(1,15)*. However, numerous other countries face uncertainty in this domain; for example, Italy lacks regulations beyond the 2017 European Union Medical Devices Regulation *(31)* and the 2024 Artificial Intelligence Act *(32)*, resulting in the absence of market presence, usage or public coverage for digital health applications *(15,33)*. Germany's Digital Health Care Act programme allows certain certified digital health applications to be included in the publicly financed benefits package if they show either a medical benefit or a patient-relevant improvement in care processes *(34)*. Continued payment is contingent on real-world evidence of these outcomes.

In the United Kingdom, early value assessment pathways for digital and remote technologies have been used to enable provisional national uptake, with continued funding dependent on the generation of further evidence on patient benefit and service impact *(35)*. In several value-based or shared-savings arrangements in the United States of America, remote patient monitoring solutions are financed as part of bundled, capitated or shared-savings contracts in which payment is contingent on achieving targets such as reduced acute care use or improved control of chronic conditions, rather than on the number of digital contacts *(36)*. Similar principles are being explored in Italy, where the national telemedicine platform has introduced central monitoring of service performance to support future performance-related financing of telemedicine services *(37)*.

These approaches demonstrate how outcome-based elements can be integrated incrementally into existing payment systems by initially focusing on digital solutions that generate reliable usage and outcome data. However, the challenges associated with these models mean that outcome-based approaches should be viewed as longer-term aspirations rather than immediate priorities.

Innovation funds and transition mechanisms

Several European countries, including Belgium, Germany, Israel, Italy, Netherlands, Sweden and United Kingdom, provide innovation grants to finance ongoing treatment options not covered by national health insurance frameworks; some also provide clear and predictable regulatory procedures *(10)*. While such grants can help to introduce new solutions, they comprise only one element of a broader approach to ensuring that DHTs are accessible and sustainably financed.

Data infrastructure as an enabler of payment reform

The European Health Data Space, currently under implementation throughout Europe, will enable data sharing for secondary use within Member States of the European Union *(38)*. As solutions develop and mature under the legislation, the European Health Data Space aims to facilitate a more streamlined process for health data across the region. This would enable easier access to relevant health data and bring down the costs of acquiring and assembling meaningful data that can be used for payment purposes, thereby potentially alleviating some of the concerns for outcome-based payment arrangements. Such data infrastructures can also reduce the administrative burden of implementing outcome-based payment schemes.

Policy considerations

Together, the two interlinked pillars of digital health financing are coverage policy and payment arrangements. Countries should consider different payment arrangements for DHTs that incentivize effective and efficient health-care processes and enable the implementation of approaches that support equitable access and delivery. This section summarizes key policy priorities for strengthening both functions in a coherent and sustainable way. Based on the findings of this policy brief, specific policy considerations can be proposed to address how countries can realign their financing and payment arrangements for digital health.

Coverage policy

DHTs must be integrated into existing health-care financing systems to ensure accessibility across all socioeconomic layers. This requires establishing and implementing policies for clear regulatory procedures that reflect the specific characteristics of DHTs, as well as for coordinated HTA that considers clinical, economic and system-level impacts. Together, these policies must enable countries to adopt digital interventions in a way that supports integrated care across heterogeneous health system environments, as follows.

- **National policy needs to classify DHTs:** policy frameworks for digital health should differentiate DHTs from other medical technologies and also distinguish different DHTs in terms of their target applications within the health system. DHTs designed to benefit individuals are fundamentally different from those designed to optimize health system performance and, therefore, need to be assessed and paid for under different conditions. A well-adapted classification for DHTs is necessary for decision-making on their inclusion into the benefits package.
- **Adapt evidence standards to DHTs:** evidence standards for digital health should reflect their diverse purposes and implementation contexts. Countries may adopt tiered frameworks aligned with HTA principles to distinguish between system-oriented, patient-facing and clinically oriented technologies. Specific guidance should set expectations for the use of real-world evidence and other non-traditional data sources appropriate to each category. Member States are also encouraged to apply common terminology for DHTs with evidence standards adapted to each tier in terms of study design, control groups and end-point measures. These evidence standards should include other value dimensions beyond those associated with clinical settings, such as organizational, social/ethical and economic dimensions.
- **Update HTA frameworks:** these frameworks need to evolve to capture the characteristics of digital health compared with traditional HTA objectives so that they can be used to assess DHT-relevant criteria for effectiveness, efficiency and socioeconomic impact. The rapidly evolving nature of digital technologies means that it is necessary to take a cooperative approach between State regulatory agencies, researchers and clinical stakeholders, as well as between regulatory bodies. This cooperative approach enables HTA frameworks to be both comprehensive and adaptive.

Payment arrangements

Implementation, use and financing of DHTs should be informed by evidence about their safety and performance and assessed against health system objectives such as access, quality, efficiency, contribution to population health, and equity. Overall outcomes should include patient satisfaction and non-clinical outcomes in addition to immediate health outcomes. Financing strategies should take into account the value of DHTs in facilitating care delivery, achieving population health goals and delivering socioeconomic benefits to individuals. Financing policies can incentivize the adoption of DHTs through equitable and flexible payment arrangements, such as capitation, bundled payments and value-based models.

Conclusions

While the digital health landscape in the WHO European Region continues to experience remarkable growth, efforts to accelerate the adoption of digital health into health systems are challenged by several barriers, including a lack of appropriate financing and of payment arrangements that encompass both coverage and payment functions for DHTs. This policy brief presents a number of findings and policy recommendations to aid in reducing these barriers. These include the need for appropriate policy and HTA frameworks for DHTs, having agreed national classification and adapted evidence standards, and the need for payment arrangements to consider parity between digital and in-person treatment pathways. The benefits of outcome-based versus cost-based payment arrangements for DHTs were briefly discussed to help countries consider which method might be most suited to their local context. Outcome-based approaches may better align incentives with value but depend on mature data systems and administrative capacity. Further calls were made to embed digital health into publicly financed benefits packages and to evaluate DHTs and collect data for assessing their impact.

This brief provides a foundation for future research and implementation efforts in the field of digital health and offers policy-makers, health insurers and other stakeholders a list of action items to consider to develop effective digital health financing and payment arrangements. As such, it is hoped that this guidance will assist Member States of the Region to develop tailored approaches that will benefit their populations and create more efficient and accessible health systems for all.

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